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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE; STEPHEN ALBRIGHT; AMERICAN KIDNEY FUND, INC.; and DIALYSIS PATIENT CITIZENS, INC.,

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

Case No. 8:19-cv-2105-DOC-ADS

DEFENDANTS' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT

Date:	May 2, 2022
Time:	8:30 a.m.
Courtroom:	9D
Judge:	The Honorable David O. Carter
Trial Date:	July 12, 2022
Action Filed:	November 1, 2019

PLEASE TAKE NOTICE that, on May 2, 2022, at 8:30 a.m., or as soon thereafter as the matter may be heard, before the Honorable David O. Carter, U.S. District Judge, in Courtroom 9D of the Ronald Reagan Federal Building and United States Courthouse, U.S. District Court for the Central District of California, located at 411 West Fourth Street, Santa Ana, California 92701, Defendants Rob Bonta, Ricardo Lara, Shelly Rouillard, and Tomás Aragón, sued in their official capacities, will move this Court for summary judgment on the Complaint of Plaintiffs Jane Doe, Stephen Albright, American Kidney Fund, Inc., and Dialysis Patient Citizens, Inc., under Federal Rule of Civil Procedure 56. This motion is made following the conference of counsel pursuant to L.R. 7-3, which took place on February 18, 2022.

Defendants seek summary judgment on the basis that there is no genuine issue of material fact as to whether Assembly Bill 290, enacted by the California Legislature in 2019, violates the Supremacy Clause of the United States Constitution or the First and Fourteenth Amendments to the United States Constitution. Neither Advisory Opinion 97-1 nor the Medicare Secondary Payer Act preempt AB 290. Nor do AB 290's disclosure requirements, patient steering prohibition, reimbursement cap, and provision allowing financially interested entities a grace period to seek an updated advisory opinion violate Plaintiffs' First Amendment rights. Accordingly, Plaintiffs' case should be dismissed in its entirety.

This motion is based on this notice, the accompanying memorandum of points and authorities, the request for judicial notice and attached exhibits, the declaration of Lisa J. Plank and attached exhibits, the Statement of Uncontroverted Facts and Conclusions of Law, the papers and pleadings already on file in this action, and such matters as may be presented to the Court at the hearing.

Dated: February 25, 2022

Respectfully submitted,

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/s/ R. Matthew Wise

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CERTIFICATE OF SERVICE

Case Name: ***Jane Doe, et al v. Xavier Becerra, et al.***

Case No.: **8:19-cv-02105-DOC-(ADSx)**

I hereby certify that on February 25, 2022, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

1. **DEFENDANTS' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT**
2. **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**
3. **DECLARATION OF LISA J. PLANK IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**
4. **EXHIBITS 1a-3 TO THE DECLARATION OF LISA J. PLANK IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**
5. **EXHIBITS 4a-16 TO THE DECLARATION OF LISA J. PLANK IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**
6. **DEFENDANTS' STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**
7. **REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**
8. **[PROPOSED] ORDER GRANTING DEFENDANTS' REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**
9. **[PROPOSED] JUDGMENT RE MOTION FOR SUMMARY JUDGMENT**

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California and the United States of America the foregoing is true and correct.

Executed on February 25, 2022, at San Francisco, California.

Vanessa Jordan	*Vanessa Jordan*
Declarant	Signature

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Defendants.

Case No. 8:19-cv-2105-DOC-ADS

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

PROVISIONALLY REDACTED PURSUANT TO PENDING APPLICATION FOR LEAVE TO FILE UNDER SEAL

Date: May 2, 2022
Time: 8:30 a.m.
Courtroom: 9D
Judge: The Honorable David O. Carter
Trial Date: July 12, 2022
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INTRODUCTION

Assembly Bill 290, enacted by the California Legislature in 2019, addresses a troubling trend in the dialysis industry—a willingness among large providers to exploit the Affordable Care Act's reforms for their own benefit and to the detriment of their patients and the general public. Professing that their business practices are above reproach, Plaintiffs (and their provider partners) attribute AB 290's enactment to lobbying by "the commercial health insurance industry and its labor union allies," which "seek[] to pressure dialysis providers into unionizing their workforces." ECF No. 1 (Compl.), ¶ 11. But Plaintiffs' attempt at misdirection cannot paper over the overwhelming evidence that, at least since 2014, large providers—in particular, DaVita and Fresenius—have maximized their profits (and distorted the insurance risk pool) by steering end-stage renal disease (ESRD) patients who are eligible for Medicare or Medi-Cal into commercial insurance, and funneling money to Plaintiff American Kidney Fund (AKF) to cover the insurance premiums. This open secret within the industry has been the subject of numerous regulatory efforts at the federal and state level, challenged in lawsuits filed throughout the country, and widely covered in the media. Against this backdrop, AB 290 was enacted to protect patients from higher out-of-pocket costs, mid-year disruptions in coverage, and difficulty in obtaining life-saving kidney transplants and to protect the general public from soaring health care costs—in other words, to "alleviate [] to a material degree" "harms [that] are real." *See Edenfield v. Fane*, 507 U.S. 761, 771 (1993).

Plaintiffs challenge AB 290 on two grounds—that it is preempted by federal law and that it violates the First Amendment. Neither claim has merit.

Plaintiffs first allege that AB 290 is preempted by Advisory Opinion 97-1, an opinion issued by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) over two decades ago. But Advisory Opinion 97-1 cannot preempt AB 290 because it does not impose a mandate with

the force of federal law; it is merely a finding that the AKF's practices with respect to the payment of Medicare Part B and Medigap policies, as described in 1997, complied with the Health Insurance Portability and Accountability Act (HIPAA). Nor does AB 290 conflict with Advisory Opinion 97-1, which does not even address premium payments for commercial health insurance or group health plans.

Plaintiffs also allege that AB 290 is preempted by the Medicare Secondary Payer Act (MSPA). This claim fails as a matter of law because AB 290, which treats all ESRD patients equally, does not conflict with MSPA provisions that prohibit disparate treatment of patients based on their Medicare eligibility or their ESRD status.

Plaintiffs' assortment of First Amendment arguments fares no better. AB 290's steering prohibition is constitutionally sound: it does not restrict AKF from appropriately assisting patients, and it provides fair notice of the prohibited conduct. AB 290's reimbursement cap does not even implicate AKF's right of association because AKF has no First Amendment right to "amass funds" from dialysis providers. *Interpipe Contracting, Inc. v. Becerra*, 898 F.3d 879, 892 (9th Cir. 2018). Nor do AB 290's disclosure provisions unlawfully coerce speech; they require only the truthful disclosure of "purely factual and uncontroversial information" about a patient's coverage options, AKF's compliance with AB 290's provisions, and the identity of patients receiving assistance from AKF. *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). And the provision in AB 290 allowing AKF to request an updated advisory opinion from OIG does not violate AKF's right to petition, or any other First Amendment right, because it does not compel AKF to do anything at all.

This Court should reject Plaintiffs' attempt to upset the careful balance struck by the Legislature to protect vulnerable patients while preserving the ability of Plaintiff American Kidney Fund to provide financial assistance to patients in need. Because there is no genuine issue of material fact as to whether Plaintiffs'

constitutional rights were infringed, Defendants' motion for summary judgment should be granted.

BACKGROUND

I. THE DIALYSIS INDUSTRY'S SELF-FUNDED PRIVATE INSURANCE SCHEME

End-stage renal disease "is irreversible and permanent." Defendants' Statement of Uncontroverted Facts and Conclusions of Law (SUF) 1. ESRD patients require a kidney transplant or regular dialysis to survive. SUF 2. Recognizing the necessity and high costs of treatment, Congress permitted ESRD patients, regardless of age, to obtain Medicare coverage when it enacted the Social Security Amendments of 1972. SUF 3. Medicare covers a range of services to treat kidney failure, including transplant and dialysis services, along with other health care needs. SUF 4. Some patients may qualify for and receive coverage through both Medicare and Medi-Cal, California's Medicaid system. SUF 5.

In 2010, the Patient Protection and Affordable Care Act (ACA) enacted a set of reforms "to make health insurance more affordable and accessible to millions of Americans." SUF 6. One such reform, which took effect on January 1, 2014, "prohibited insurers . . . from imposing pre-existing condition exclusions" and required them "to guarantee the availability and renewability of non-grandfathered health plans to any applicant." *Id*. Under this "guaranteed issue" provision, among other ACA provisions, ESRD patients can no longer be denied coverage or charged higher premiums based on their health status. *See id.*

These provisions, together with the "higher reimbursement rates available through private coverage when compared to Medicare," "in effect created a financial incentive for dialysis facilities to leverage [the higher rates] by providing premium assistance to ESRD patients"—primarily through a third party entity, Plaintiff AKF—"and inappropriately steering them to purchase coverage in the individual market." SUF 7. HHS became concerned that health care providers

were "encouraging individuals to make coverage decisions based on the financial interest of the health care provider, rather than the best interests of the individual patients." SUF 8. Based on this concern, the Centers for Medicare & Medicaid Services (CMS), a subdivision of HHS, issued a Request for Information on August 23, 2016, seeking public comment "about health care providers and provider-affiliated organizations steering people eligible for or receiving Medicare and/or Medicaid benefits to an individual market plan for the purpose of obtaining higher payment rates." SUF 9. In response, CMS received over 800 public comments from patients, providers, and other stakeholders. SUF 10.

These comments "documented a range of concerning practices, with providers and suppliers"—such as DaVita and Fresenius—"influencing enrollment decisions in ways that put the financial interest of the supplier above the needs of patients." *Id.* In particular, commenters noted that patients "are sometimes specifically discouraged from pursuing Medicare or Medicaid" and "are unaware that a dialysis facility is seeking to enroll them in the individual market," and that facilities "retaliate against social workers who attempt to disclose additional information to consumers." SUF 11. Commenters agreed that these practices are fueled by a powerful incentive—the considerably higher rates that commercial coverage reimburses dialysis providers as compared to public coverage. SUF 12. Even more troubling, HHS's own data and the comments "suggest[ed] that this inappropriate steering of patients may be accelerating over time." SUF 13.

The comments also reflected three types of possible harms to patients: "[n]egatively impacting patients' determination of readiness for a kidney transplant, potentially exposing patients to additional costs for health care services, and putting individuals at significant risk of a mid-year disruption in health care coverage." SUF 14. In addition, comments "indicat[ed] that inappropriate steering practices"—which add ESRD patients to the individual market—"could have the effect of skewing the insurance risk pool." SUF 15.

In the face of such harms, "which go to essential patient safety and care in life-threatening circumstances," CMS issued an interim final rule establishing new standards for Medicare-certified dialysis facilities that pay premiums for individual market health plans, whether directly or through another entity. SUF 16. But shortly after that rule was issued, it was enjoined for failure to comply with Administrative Procedures Act requirements. SUF 17. That decision was not appealed.

II. CALIFORNIA'S EFFORTS TO REGULATE THE DIALYSIS INDUSTRY

In the absence of federal regulations addressing inappropriate steering of dialysis patients, states across the country, including California, took action. SUF 18.[1] In 2018, the California Legislature passed Senate Bill 1156, a predecessor to AB 290. SUF 19. But Governor Brown ultimately vetoed SB 1156 because it "would permit health plans and insurers to refuse premium assistance and to choose which patients they will cover." SUF 20.

The following legislative session, the Legislature considered AB 290, which included provisions addressing the reason for Governor Brown's veto. AB 290, § 3(m) (reaffirming obligations of health insurers, including the requirement not to "deny coverage to an insured whose premiums are paid by a third party"). Echoing CMS's concerns, the Legislature observed that "third-party payment arrangements have proliferated in recent years as a result of health care providers that have demonstrated a willingness to exploit the Affordable Care Act's guaranteed issue rules for their own financial benefit," which has the effect of "expos[ing] patients to direct harm." AB 290, §§ 1(b)-(c). The Legislature noted that this trend coincided with a rise in DaVita and Fresenius's "market dominance"—these companies now account for 92 percent of all dialysis industry revenue nationwide. *Id.*, § 1(g). The Legislature also embraced CMS's findings that "patients caught up in these

[1] As detailed in SB 1156's legislative record, these states include Delaware, Idaho, Louisiana, Minnesota, New Mexico, North Carolina, Oregon, and Washington. SUF 18.

schemes may face higher out-of-pocket costs and mid-year disruptions in coverage, and may have a more difficult time obtaining critical care such as kidney transplants." *Id.*, § 1(d). And the Legislature recognized that "[c]onsumers also pay higher health insurance premiums due to the distortion of the insurance risk pool" caused by inappropriate steering. *Id.*, § 1(e).

AB 290 approaches the problem at hand from at least three angles. First, AB 290's anti-steering provisions prohibit chronic dialysis clinics from "steer[ing], direct[ing], or advis[ing] a patient regarding any specific coverage program option or health care service plan contract"; require a "financially interested entity" that is making third-party premium payments to notify patients of alternative coverage options, including Medicare and Medicaid; and provide that financial assistance shall not be conditioned on use of any particular facility, healthcare provider, or coverage type. *Id.*, § 2(a), §§ 3(b)(3) & 3(b)(5).[2] Second, AB 290 caps the dialysis reimbursement rate for those patients receiving third-party premium assistance at the Medicare rate, or through an independent dispute resolution process. *Id.*, § 3(e).[3] Third, AB 290 requires that a financially interested entity providing premium assistance submit an annual statement of compliance with the law and disclose to health insurers the names of each insured patient who will receive premium assistance. *Id.*, § 3(c).[4]

[2] The provisions in Section 3 of AB 290 that were added to the Health and Safety Code were also added to the Insurance Code in Section 5 of the bill.

[3] This provision also prohibits providers from billing or seeking reimbursement from the insured patient for services, except for co-payments according to the patient's insurance plan contract. AB 290, § 3(e). Given that third party entities such as AKF often provide patients with debit cards that patients then use to pay their premiums, SUF 21, prohibiting providers from directly billing enrollees facilitates the identification of patients receiving premium assistance.

[4] Insurance companies are then required to report to the California Department of Managed Health Care or Department of Insurance, as applicable, the number of patients who received premium assistance, the identity of providers subject to the Medicare rate cap, and the identity of providers who failed to comply with the disclosure requirements. AB 290, §§ 3(j) & 5(j).

III. AKF'S PLAN TO LEAVE CALIFORNIA

Plaintiff AKF not only opposed AB 290, but notified the Legislature that it would "be forced to shut down in California if AB 290 is enacted" because, in its view, "AB 290 would take us outside the protection of our Advisory Opinion." RJN, Ex. 1.[5] That opinion, Advisory Opinion 97-1, issued by HHS's OIG in 1997 at AKF's request, concluded that AKF's practice of paying Medicare Part B and Medigap premiums for ESRD patients in financial need did not violate the federal prohibition against providing remuneration to Medicare-eligible individuals if such remuneration is likely to influence the individual's health care choices. SUF 63. OIG found it significant that AKF, rather than dialysis providers, determined which patients would receive AKF's Health Insurance Premium Program (HIPP) assistance and that HIPP assistance was available regardless of the patient's provider. SUF 64. AB 290 would have no impact on these aspects of HIPP. Advisory Opinion 97-1 also specifies that it is "case specific" and "is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope." SUF 65.[6]

While AB 290 does not conflict with Advisory Opinion 97-1, the Legislature nonetheless made a concerted effort to accommodate AKF's concerns that AB 290 and Advisory Opinion 97-1 are incompatible. SUF 22. In particular, the Senate amended AB 290 so that it would not become operative as to financially interested entities covered by Advisory Opinion 97-1 until July 1, 2020—and any entity that

[5] California's Legislative Counsel concluded, in contrast, that based on the available facts, AKF "would remain in compliance with the arrangement approved in Advisory Opinion 97-1" if AB 290 were enacted and AKF "complies with the changes enacted by that bill." SUF 66.

[6] Much has changed since Advisory Opinion 97-1 was issued. Back then, ESRD patients generally lacked access to commercial insurance, and "less than ten percent" of donations to AKF were from companies that owned dialysis providers. SUF 67. But now, reforms under the ACA have made commercial insurance more widely available, and as AKF has expanded HIPP assistance to pay the premiums of commercially-insured patients, the contributions of "[l]arge dialysis companies" have grown to "more than 80 percent" of AKF's revenue. AB 290, § 1(h); *see also* Plank Decl., ¶ 5, Ex. 3.

requested an updated advisory opinion would be exempt until OIG issued an opinion confirming that AB 290 does not conflict with federal law. *Compare* RJN, Ex. 2, *with* AB 290, § 7. The Senate also amended the bill to ensure that AKF could continue to provide premium assistance to patients who were receiving assistance as of October 1, 2019, without complying with AB 290's requirements. *Compare* RJN, Ex. 2, *with* AB 290, §§ 3(d)(1)) & 5(d)(1).[7] Yet AKF maintained its plans to leave California at the end of 2019, despite these amendments largely delaying AB 290's implementation. SUF 71.

Governor Newsom signed AB 290 on October 13, 2019.

PROCEDURAL HISTORY

Plaintiffs filed their complaint on November 5, 2019. Days later, they filed a preliminary injunction motion, ECF No. 28, which Defendants opposed, ECF No. 46. On December 30, 2019, this Court granted Plaintiffs' motion, enjoining AB 290 in its entirety. ECF No. 58 at 17. After a delay due to the COVID-19 pandemic, proceedings restarted last fall. ECF No. 121.

LEGAL STANDARD

Summary judgment is proper where no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). While the Court must draw all reasonable inferences in favor of the nonmoving party, *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), Rule 56(c) "mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

[7] In addition, the Senate amended AB 290 to delay implementation of the Medicare-linked reimbursement cap until January 1, 2022. *Compare* RJN, Ex. 2, *with* AB 290, §§ 3(d)(1)) & 5(d)(1).

ARGUMENT

I. AB 290 IS NOT PREEMPTED BY FEDERAL LAW

Plaintiffs' contention that Advisory Opinion 97-1 preempts AB 290 fails because the Advisory Opinion (1) does not have the force of federal law, and (2) does not conflict with AB 290. Nor is there a conflict between AB 290 and the Medicare Secondary Payer Act.

A. Advisory Opinion 97-1 Does Not Preempt AB 290

1. Advisory Opinion 97-1 Does Not Impose a Requirement with the Force of Federal Law

Advisory Opinion 97-1 examines AKF's practice in 1997 of paying premiums for Medicare Part B and Medigap policies using funds that were donated in part by dialysis companies and concludes that the arrangement as described did *not* fall within the HIPAA remuneration prohibition. SUF 63. Advisory Opinion 97-1 is therefore a finding that AKF's practices with respect to the payment of Medicare Part B and Medigap policies, as described in 1997, complied with HIPAA.[8] It imposes no legal obligations on AKF or any other entity. Nor does it immunize AKF from compliance with state law or purport to preempt state law.

Plaintiffs are thus incorrect to ascribe to Advisory Opinion 97-1 the mandate of federal law. It is black letter law that "[i]nterpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all . . . lack the force of law[.]" *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); *see also Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 643 (2013) (agency memorandum and letter approving of state statutory scheme for Medicaid reimbursement were "opinion letters, not regulations with the force of

[8] At the time the Advisory Opinion was issued, patients with ESRD were usually unable to obtain commercial insurance because ESRD was an expensive pre-existing condition. SUF 68. Thus, AKF paid Medigap and Medicare Part B premiums for patients on dialysis. After the ACA was enacted in 2010, many more patients with ESRD were able to access commercial insurance because the ACA prohibits insurance companies from discriminating against patients with pre-existing conditions. SUF 69.

law"); *United States v. Mead Corp*., 533 U.S. 218, 233 (2001) (federal agency's "classification ruling" letters did not have the force of law when agency did not engage in notice-and-comment, and did not bind third parties).

Although "an agency regulation with the force of law can pre-empt conflicting state requirements," an agency action that was not the product of notice-and-comment rulemaking does not have the force of law and thus cannot, by itself, have preemptive effect. *Wyeth v. Levine*, 555 U.S. 555, 576, 580 (2009) (cleaned up); *see also Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) (Ninth Circuit "declin[es] to afford preemptive effect to agency actions that do not carry the force of law under *Mead* and its progeny"). Accordingly, Advisory Opinion 97-1 does not have the force of federal law or regulation and cannot preempt AB 290.

2. Advisory Opinion 97-1 Does Not Conflict with AB 290

Even if Advisory Opinion 97-1 had the force of a federal statute or regulation, it would not preempt AB 290 because there is no conflict between the Opinion and the statute. First, the Opinion's conclusion that AKF's practice of paying Medicare Part B and Medigap premiums did not violate a federal prohibition does not immunize that practice as it existed in 1997—or AKF's current practices, which differ substantially—from the application of state consumer protection or insurance laws. States routinely prohibit conduct that is not prohibited under federal law, and nothing in the Opinion indicates that AKF *must* be permitted to pay Medicare Part B and Medigap premiums, such that AB 290 conflicts with the Opinion.

Second, by its own express terms, Advisory Opinion 97-1 only considers payments for Medicare Part B or Medigap premiums. SUF 65 (Opinion is "case specific" and "limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope."). It does not discuss premium payments for commercial insurance or group health coverage. Thus, the Opinion's restrictions would apply only to payments for Medicare Part B or Medigap premiums, neither which fall within the

scope of AB 290. *See* AB 290, §§ 3(h)(3) & 5(h)(2) (no application to "coverage of Medicare services pursuant to contracts with the United States government [or] Medicare supplement coverage"). Moreover, the fact that other types of coverage options have been created since 1997 does not shift the scope of the Opinion because Advisory Opinion 97-1 is by its own terms limited to federal health care programs, and thereby expressly excludes programs such as Qualified Health Care Programs, Covered California, employer group plans, or private insurance. SUF 72.

Even if Advisory Opinion 97-1 could be construed to apply to premium payments for commercial health insurance and group health plans—and it cannot—it still would not conflict with AB 290. Nothing in AB 290 prevents AKF from using its funds in accordance with its charitable mission or restricts the kinds of patients AKF may help. AB 290 and Advisory Opinion 97-1 also both require that financial assistance not be conditioned on the use of a specific facility or health care provider. SUF 73; AB 290, §§ 3(b)(2) & 5(b)(2). The Opinion is also silent on disclosure of provider contributions to health plans or health insurance companies, and only requires that AKF not disclose a provider's contributions to other providers. AB 290's requirement that AKF disclose provider contributions to health plans or health insurance companies is thus consistent with the Opinion.

Plaintiffs will likely claim that because AB 290 requires AKF to disclose a HIPP recipient's identity to their insurer, the disclosure will lead the HIPP recipient to determine that their provider is a donor, and the recipient will then feel obligated to stay with their provider—a chain of events which they allege is contrary to Advisory Opinion 97-1. To be clear, a HIPP recipient is highly unlikely to learn of their dialysis providers' donor status because of AKF's disclosure. SUF 74. But even under Plaintiffs' theory, a HIPP recipient would only *potentially* learn that their provider is a donor *after* (1) picking a provider, (2) applying for and receiving HIPP, (3) obtaining dialysis, and (4) receiving a benefits statement. By then, the

HIPP recipient has already picked a provider without undue influence, as required by Advisory Opinion 97-1.

B. The Medicare Secondary Payer Act Does Not Preempt AB 290

Plaintiffs also inaccurately contend that AB 290 conflicts with requirements in the Medicare Secondary Payer Act (MSPA) that insurers treat ESRD and non-ESRD patients equally, such that payments for the same service cannot vary based on a patient's ESRD status. Plaintiffs rely on the "take into account" and "non-differentiation" provisions in the MSPA's ESRD sections. Neither provision preempts AB 290.

The "take into account" provision prohibits group health plans from "tak[ing] into account that an individual [with ESRD] is entitled to or eligible for [Medicare] benefits" for the first thirty months of eligibility. 42 U.S.C. § 1395y(b)(1)(C)(i). Similarly, the "nondifferentiation" requirement provides that group health plans "may not differentiate in the benefits [they] provide[] between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner" during the first thirty months of Medicare eligibility. *Id.* § 1395y(b)(1)(C)(ii). Prohibited "differentiation" includes "[i]mposing on persons who have ESRD, but not on others enrolled in the plan, benefit limitations" and "[p]aying providers and suppliers less for services furnished to individuals who have ESRD than for the same services furnished to those who do not have ESRD . . . ." 42 C.F.R. §§ 411.161(b)(ii), (iv). The "pertinent inquiry' is "whether the plan's provisions 'result' in *different benefits for persons with ESRD*, not whether the plan's provisions disproportionately affect persons with ESRD or otherwise 'discriminate' against persons with ESRD." *DaVita Inc. v. Amy's Kitchen, Inc.*, 981 F.3d 664, 674-75 (9th Cir. 2020).

Plaintiffs argue that AB 290 requires insurers to violate both of these provisions because a financially interested provider as defined by the statute would

receive different reimbursement—one amount for HIPP recipients (who necessarily have ESRD) and another amount for everyone else. But Plaintiffs do not—and cannot—show that AB 290 requires health plans to treat patients differently based on their Medicare eligibility or their ESRD status. Although treatments provided to HIPP recipients may be reimbursed at a lower rate, that is not a result of a patient's eligibility or non-eligibility for Medicare. The statute makes no distinction among patients based on their Medicare eligibility; a plan can "ignore[]" this factor. *Amy's Kitchen*, 981 F.3d at 670. Nor does the statute require differentiation between patients based on their ESRD status; a plan can "provide[] identical benefits to someone with ESRD as to someone without ESRD" and thus "not 'differentiate' between those two classes." *Id.* at 678. AB 290 comports with the MSPA.[9]

II. AB 290 DOES NOT VIOLATE PLAINTIFFS' FIRST AMENDMENT RIGHTS

A. AB 290's Steering Prohibition Neither Restricts Plaintiff AKF's Speech Nor Is Unconstitutionally Vague

AB 290 provides that a chronic dialysis clinic or financially interested entity cannot "steer, direct, or advise" a patient toward a specific coverage option or health care plan. AB 290, §§ 2(a), 3(b)(4). As shown below, this steering prohibition is constitutionally sound.

1. AB 290's Steering Prohibition Permissibly Regulates Commercial Speech

The steering prohibition regulates commercial speech. Under the governing test from *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983), speech may be "characterized as commercial when (1) the speech is admittedly advertising, (2)

[9] On March 1, 2022, the Supreme Court will hear oral argument in *Marietta Memorial Hospital Employee Health Benefit Plan v. DaVita Inc.*, No. 20-1641, which addresses whether a group health plan that provides uniform reimbursement of all dialysis treatments nonetheless violated the MSPA's "take into account" and "nondifferentiation" provisions under a disparate impact theory. Because AB 290 does not require a plan to take any actions that would result in disparate treatment of or disparate impact on patients based on their Medicare eligibility or their ESRD status, Plaintiffs are unlikely to be able to salvage their preemption claim based on the Supreme Court's decision in *Marietta*.

the speech references a specific product, and (3) the speaker has an economic motive for engaging in the speech." *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1106 (9th Cir. 2004) (citing *Bolger*, 463 U.S. at 66-67). While the combination of all of these characteristics strengthens the conclusion that the speech at issue is "properly characterized as commercial speech," it is not necessary for "each of the characteristics" to "be present in order for speech to be commercial." *Bolger*, 463 U.S. at 67 n.14.

The steering prohibition meets the latter two *Bolger* factors. It primarily regulates patient interactions with dialysis social workers and insurance counselors, who are tasked with helping patients "obtain insurance and apply for financial assistance," and who "may face a perceived or actual conflict of interest in doing so, since they may recommend insurance options that help patients remain on dialysis and maximize profits for the dialysis centers in which they work." SUF 23. The economic motive for these staff to promote a specific product—commercial insurance, for which "reimbursement rates [] are many times the cost associated with providing care"—is powerful. AB 290, § 1(g). Documents in the legislative record, including J.P. Morgan research reports, detail how critical commercial patients are to the providers' bottom line. SUF 24 (e.g., report describing the increase in "[i]nvestor concern regarding [DaVita's] commercial mix and earning power" in light of the probability that DaVita was "receiving more than its market share" of HIPP-supported commercial patients). So do the providers' communications with shareholders. SUF 25 (assurance from Fresenius CEO that loss of commercial payers in 2018 was "self-inflicted" and that the company would "sort through what needs to be done and get it fixed"). [redacted]. *See*, *e.g.*, SUF 26. The steering prohibition thus regulates a commercial transaction between patients and providers.

Because commercial speech is at issue, intermediate scrutiny applies: AB 290 must directly advance a substantial governmental interest and do so in a manner that is not more extensive than necessary. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). Put another way, AB 290 must tackle harms that are "real" and must "in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. Indeed, AB 290 is tailored to address a practice with harms so compelling that the law would survive any level of scrutiny.

That practice—"encouraging," or steering "patients to enroll in commercial insurance coverage for the financial benefit of the provider"—is well documented. AB 290, § 1(c). In addition to the CMS record, *ante* Background I, the SB 1156 legislative record refers to a Washington Office of the Insurance Commissioner (OIC) order requiring DaVita "to immediately stop engaging in the business of unauthorized insurance via steering dialysis patients into higher reimbursing plans by offering to pay premiums." SUF 27. Washington OIC took enforcement action after learning that DaVita insurance coordinator Cary Ancheta had attempted "to sign up approximately 30 kidney dialysis patients, most of whom [we]re receiving Medicaid," onto commercial insurance. SUF 28. The order was rescinded by stipulation of the parties on the condition, among other requirements, that DaVita counselors "not ask or urge dialysis patients to enroll in any particular kind of insurance from any particular insurer" for a period of two years. SUF 29.

That investigation also uncovered evidence provided by a former DaVita social worker of a DaVita PowerPoint presentation directing insurance counselors and social workers "to 'target' Medicaid eligible patients to get them to purchase commercial insurance." SUF 30. Known as "Medicaid Opportunity," this program, which began in 2015, was designed to increase the number of Medicaid patients enrolled in an individual market plan (paid for with HIPP assistance) as primary coverage. SUF 31. DaVita set about to discuss this "absolutely amazing opportunity" with "every single" patient on Medicaid. SUF 32. DaVita considered

this program a "true win-win situation" for patients and DaVita. SUF 33. DaVita's efforts to enroll patients in HIPP to facilitate the move to private primary insurance were meticulously tracked, and staff were urged to use "additional hours" to ensure that every patient was "educated" on HIPP availability. SUF 34.

While Plaintiffs are unwilling to publicly admit that they have engaged in patient steering, this practice has achieved notoriety in recent years. It has been the subject not only of federal rulemaking and state regulatory efforts, but of numerous lawsuits. One federal court, observing that DaVita's "own definition of 'steering' [] as legal communications with ESRD patients" was "a weak plausible alternative explanation as to the meaning of the statement that it 'does not steer,'" concluded that there was a "strong inference that [DaVita] made statements about steering and the source of [DaVita's] financial success with the intent to manipulate, deceive, or defraud." SUF 37 (*Peace Officers' Annuity and Benefit Fund of Ga. v. DaVita Inc.*, 372 F. Supp. 3d 1139, 1155 (D. Colo. 2019); *id.* at 1143, 1147 (denying DaVita's motion to dismiss securities fraud class action alleging that DaVita made false and misleading statements about steering patients toward private insurance and the impact on its performance)). Another federal court determined that it was "reasonable to infer . . . that the Medicaid Opportunity initiative was part of a

larger, systematic plan by DaVita's management to drive revenues and profitability through [DaVita's] AKF donations." SUF 38 (*In re DaVita Inc. v. Stockholder Derivative Litig.*, No. 17-152-MPT, 2019 WL 1855445, *14 (D. Del. Apr. 25, 2019); *id.* at *1, *12 (denying DaVita's motion to dismiss stockholder derivative action challenging specific Board decisions related to the Medicaid Opportunity initiative)).[10] This industry scheme has also been the focus of countless news articles and investigative journalism (*see*, e.g., SUF 39)[11] and even the report of a California-based House representative.[12]

As the old adage goes, where there's smoke, there's fire. There is ample evidence that when the Legislature turned its attention to regulating patient steering, it was dealing with a "real" problem. *See Edenfield*, 507 U.S. at 771.

And steering causes real harm. As described in the CMS record and the legislative findings, *ante* Background I and II, steering injures patients in at least three ways. First, patients steered into commercial insurance who would have been eligible for a kidney transplant under Medicare may be unable to demonstrate the financial means to care for a new kidney, given that HIPP assistance ends within months to a year of transplant. SUF 40 (e.g., public comment of Dr. Teri Browne, observing that the expected loss of HIPP assistance post-transplant "results in dialysis patients not being eligible to get listed for a kidney transplant"). This "threat of cessation of health insurance benefits" not only impairs transplant eligibility but "may induce some patients to remain on dialysis and never pursue

[10] Other similar lawsuits include *BlueCross and BlueShield of Fla. v. DaVita*, No. 19-cv-574 (M.D. Fla.), *see* Plank Decl., ¶ 17, Ex. 15, and *United States, ex. rel. Gonzalez v. DaVita Health Care Partners*, No. 166-cv-11840-NMG (D. Mass), *see* Plank Decl., ¶ 18, Ex. 16.

[11] *See also,* Carrie Arnold, *Kidney Dialysis is a Booming Business; Is It also a Rigged One?*, Scientific American, Dec. 14, 2020, available at https://www.scientificamerican.com/article/kidney-dialysis-is-a-booming-business-is-it-also-a-rigged-one1/ (last accessed Feb. 24, 2022); *Is Dialysis a Test Case of Medicare for All?*, Freakonomics Radio (Podcast), Apr. 7, 2021, available at https://freakonomics.com/podcast/dialysis/ (last accessed Feb. 16, 2022).

[12] *See* Plank Decl., ¶ 13, Ex. 11 (*Dying on Dialysis: Inside an Industry Putting Profits Over Patients, a report by the Office of Congresswoman Katie Porter*, July 15, 2021).

transplant." SUF 41. Second, patients steered into commercial insurance are saddled with high out-of-pocket expenses post-transplant when HIPP assistance ends, which may lead them to stop taking their immunosuppressant drugs, causing their transplant to fail. SUF 42 (e.g., observation of Dr. Browne that post-transplant patients who were steered into commercial insurance get "stuck" with "impossibly high premiums" they "cannot afford"). Third, and relatedly, patients who are unable to "make other arrangements" face mid-year disruptions in coverage, leading to similarly bad outcomes. SUF 43.

In addition to the harm to patients, steering raises health insurance premiums for a wide swath of the population because it "distort[s] [] the insurance risk pool." AB 290, § 1(e). Various researchers and other groups have examined the potential scope of the problem. SUF 44 (expert John Bertko projected a 5.3% premium increase in Covered California plans due to increase in ESRD enrollees, and cited Dr. Erin Trish's research letter estimating a 4.1% increase in individual market spending if 10% of non-aged Medicare enrollees with ESRD moved to the individual market); *id*. (Association of Health Insurance Plans provided examples of rise in insurance plan spending on ESRD services, including one plan's increase "from $1.7 million in 2013 to $36.8 million in 2015"); *id*. [redacted]. But the fact that an increase in commercially-insured ESRD patients results in higher insurance premiums for everyone in the market is not in serious dispute.

By placing guardrails on staff communications with patients, the steering prohibition "will in fact alleviate [these harms] to a material degree." *Edenfield*, 507 U.S. at 770. It "would remove a potential conflict of interest" from staff-patient interactions, providing the space for independent advocacy organizations, such as the Health Insurance Counseling and Advocacy Program (HICAP), to step in to "help patients navigate the complexities of their different insurance options."

SUF 45. And together with the disclosure requirements, the steering prohibition "[i]ncrease[]s transparency regarding coverage options and third-party premium payments," which "is important for patients to be able to make informed decisions and minimize their potential exposure to financial liabilities." SUF 46. This incremental, targeted approach directly advances California's substantial interest in protecting ESRD patients and the condition of the insurance risk pool without requiring more of Plaintiffs than is necessary to serve the law's purposes.

2. AB 290's Steering Prohibition Is Sufficiently Clear

AB 290's steering prohibition is also sufficiently definite to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Edge v. City of Everitt*, 929 F.3d 657, 664 (9th Cir. 2019) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)). A statute will generally survive a vagueness challenge so long as the speaker is not "compelled to steer too far clear of any forbidden area" of speech. *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 588 (1998) (internal quotation marks omitted). Indeed, "perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity." *Edge*, 929 F.3d at 664 (quoting *United States v. Williams*, 553 U.S. 285, 304 (2008)).

Here, the terms "steer," "direct," and "advise" are not difficult to understand, particularly "when read in context with the entire provision." *Hunt v. City of Los Angeles*, 638 F.3d 703, 714 (9th Cir. 2011). The steering prohibition addresses the concerning practice of "[e]ncouraging patients to enroll in commercial insurance coverage for the financial benefit of the provider." AB 290, § 1(c). Its purpose is thus to "shield patients from potential harm caused by being steered into coverage options that may not be in their best interest." *Id.*, § 1(i). Taken together, the phrase "steer, direct, or advise" covers, in a comprehensive manner, the forms of encouragement prohibited by the statute. When "used in combination," these terms "provide sufficient clarity." *Edge*, 929 F.3d at 665 (quoting *Gammoh v. City of La*

Habra, 395 F.3d 1114, 1120 (9th Cir. 2005)). Providing factual information or answering questions about plan options is permissible; telling or prompting a patient to choose a certain option is not. In short, these terms are "reasonably ascertainable to a person of ordinary intelligence." *Id*. at 666.

B. AB 290's Reimbursement Cap Does Not Violate Plaintiff AKF's Right of Association

AB 290 caps the reimbursement rate for those patients receiving third-party premium assistance at the higher of the Medicare rate or a rate determined through an independent dispute resolution process. AB 290, § 3(e)(1). Plaintiffs suggest that this reimbursement cap "punishes" providers for donating to AKF, and thus "interferes with AKF's ability to associate freely with its major donors." Compl. ¶ 104. The Supreme Court has recognized that an individual's decision to make certain financial contributions, including political contributions, implicates "protected First Amendment interests." *McCutcheon v. FEC*, 572 U.S. 185, 196 (2014). But the Court has only recognized "the right of an individual to contribute, not the right of a[n] . . . organization to amass funds." *Interpipe*, 898 F.3d at 892 (citing *Buckley v. Valeo*, 424 U.S. 1, 21 (1976) (per curiam)). While AKF appears to assert that "the First Amendment right applies equally to the contributor *and* the recipient," the Court has never "establish[ed] an independent constitutional right of recipients to 'amass' funds." *Id.* AKF's argument, which "ignores this bedrock principle," *id.*, thus fails.

C. AB 290's Disclosure Provisions Do Not Unlawfully Compel Plaintiff AKF's Speech

AB 290 requires a financially interested entity like Plaintiff AKF to inform HIPP recipients of "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and employer plans." AB 290, §§ 3(b)(3) & 5(b)(3). AB 290 similarly prohibits a financially interested entity from making a third-party premium payment unless it provides an annual statement

of compliance with the law and discloses to a health insurer the name of each insured patient who will receive premium assistance. *Id.*, § 3(c). These are some of the key provisions in AB 290 that "support[] transparency for ESRD patients" and "assist [patients] in making informed decisions about how to finance their own care by removing potentially ethically compromising dynamics between AKF, dialysis providers, and private insurance companies." SUF 60. They are also the sort of disclosure requirements long held to be permissible under *Zauderer* and its progeny.

In *Zauderer*, the Supreme Court held that Ohio could require lawyers advertising contingency arrangements to disclose that clients might be liable for litigation costs if their cases were unsuccessful. 471 U.S. at 650-53. Noting the "material differences between disclosure requirements and outright prohibitions on speech," the Court recognized that there is only a "minimal" constitutionally protected interest in not providing "factual and uncontroversial information" to a consumer. *Id.* at 650, 651. The Court concluded that such disclosure requirements do not implicate First Amendment concerns as long as they "are reasonably related to the State's interest in preventing deception of consumers." *Id*. at 651.

Consistent with *Zauderer*, the Court has repeatedly acknowledged the government's authority to require disclosures of factual information that promote transparency. The Court has made clear that a requirement for fundraisers to "disclose unambiguously" their paid status "would withstand First Amendment scrutiny," *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 799 n.11 (1988); has upheld a federal statute requiring attorneys advertising debt relief assistance to disclose that such relief would likely involve filing for bankruptcy, *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010); and has observed that a statutorily mandated disclosure of a film's connection to a federally registered agent of a foreign government would "better enable the public to evaluate the [film's] import," *Meese v. Keene*, 481 U.S. 465, 480 (1987). The

Court has also long recognized that requiring entities—including charitable organizations—to "report certain information" on a routine basis does not offend First Amendment interests. *Village of Schaumburg v. Citizens for a Better Env't*, 444 U.S. 620, 637-38 n.12 (1980); *Riley*, 487 U.S. at 800 (same).

The Court's decision in *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (*NIFLA*) did not undermine this precedent. There, the Court held that the *Zauderer* standard applies only if the compelled disclosure involves "purely factual and uncontroversial" information. *Id.* at 2372. In so holding, the Court "d[id] not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *Id.* at 2376. Thus, "[u]nder *Zauderer*, compelled disclosure of commercial speech complies with the First Amendment if the information in the disclosure is reasonably related to a substantial governmental interest and is purely factual and uncontroversial." *CTIA – The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 845 (9th Cir. 2019).

AB 290's disclosure provisions meet this standard: they implicate commercial speech, are reasonably related to a substantial governmental interest, and are purely factual and uncontroversial. Like the steering prohibition, the disclosure provisions regulate the discussion of a specific commercial product—in particular, commercial insurance products—which Plaintiffs have an economic motive to promote. *Ante* Argument I.A. And like the steering prohibition, the disclosure provisions are reasonably related to California's substantial governmental interest in "shield[ing] patients from potential harm caused by being steered into coverage options that may not be in their best interest," AB 290, § 1(i); these provisions ensure that patients are informed of their coverage options and that health plans and insurers receive the information necessary for the law to be properly implemented.[13]

[13] Recall that third party entities such as AKF have at times provided patients with debit cards that patients then use to pay their premiums. *Ante* Background II,

The disclosed information is also "purely factual and uncontroversial," as that requirement was further defined in NIFLA. There, the Court specified that a purely factual statement was not uncontroversial where the statement "took sides in a heated political controversy." *CTIA*, 928 F.3d at 845 (citing *NIFLA*, 138 S. Ct. at 2372). The Court further required that the statement "relate to the product or service that is provided by an entity subject to the requirement." *Id.* (citing *NIFLA*, 138 S. Ct. at 2372). Here, the disclosure provisions require a financially interested entity to make truthful and neutral statements about a patient's health coverage options and receipt of premium assistance, *see* AB 290, §§ 3(b)(3), 3(c)—subjects that relate directly to the HIPP assistance that AKF provides patients. These "purely factual and uncontroversial" statements meet the *Zauderer* standard, and thus, permissibly regulate speech.

D. AB 290's Provision Allowing AKF to Request an Updated Advisory Opinion Does Not Abridge AKF's Right to Petition

Finally, Plaintiffs allege that Section 7 of AB 290, which allows AKF to request an updated advisory opinion, abridges its freedom to petition "by compelling AKF to file a petition it actually opposes." Compl. ¶ 105. This argument mischaracterizes Section 7. That section is not a "mandate," *see id.*; it merely provides AKF the *option* to request an updated advisory opinion. Without "a coerced nexus between the individual and the specific expressive activity," there is no First Amendment violation. *See Cal-Almond, Inc. v. U.S. Dep't of Agric.*, 14 F.3d 429, 435 (9th Cir. 1993).

CONCLUSION

This Court should grant Defendants' motion for summary judgment.

n.2; SUF 21. The requirement for AKF to identify each patient for which it provides premium assistance ensures that health plans and insurers know when a Medicare-linked reimbursement rate applies—i.e., when section 3(e) is applicable.

Dated: February 25, 2022

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE; STEPHEN ALBRIGHT; AMERICAN KIDNEY FUND, INC.; and DIALYSIS PATIENT CITIZENS, INC.,

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

Case No. 8:19-cv-2105-DOC-ADS

DECLARATION OF LISA J. PLANK IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Date:	May 2, 2022
Time:	8:30 a.m.
Courtroom:	9D
Judge:	The Honorable David O. Carter
Trial Date:	July 12, 2022
Action Filed:	November 1, 2019

DECLARATION OF LISA J. PLANK

I, Lisa J. Plank, declare:

1. I am an attorney admitted to practice before the courts of the State of California and before this Court. I am employed by the California Attorney General's Office as a Deputy Attorney General and I am counsel of record for Defendants ROB BONTA, RICARDO LARA, SHELLY ROUILLARD, and TOMÁS J. ARAGÓN (Defendants) in this action. I make this declaration in support of Defendants' Motion for Summary Judgment. I have personal knowledge of the facts set forth in this declaration and if called as a witness, could and would testify competently to these facts under oath.

2. Attached in Exhibits 1a to 1e are true and correct copies of documents and excerpts from documents produced by Defendants to Plaintiffs and cited in Defendants' Memorandum of Points and Authorities in support of their Motion for Summary Judgment (MPA ISO MSJ). The cited documents and excerpts are listed by Bates number in the table of contents attached to this declaration (see column entitled "Cited Bates or Excerpt Pages").

3. Authorized officials employed at the Washington Office of the Insurance Commissioner, Legal Affairs Division, provided to Defendants certain official records of that office's 2016 investigation of DaVita and its employee Cary Ancheta, Investigation #1340003, for use in the *Fresenius* and *Doe* litigation. The records are kept in the normal course of business at that office. True and correct copies of documents and excerpts from documents among those records are in Exhibit 1e in the table of contents attached to this declaration.

4. Attached in Exhibits 2a to 2f are true and correct copies of documents and excerpts from documents produced by the American Kidney Fund (AKF) to Defendants and cited in Defendants' MPA ISO MSJ. The cited documents and excerpts are listed by Bates number in the table of contents attached to this declaration (see column entitled "Cited Bates or Excerpt Pages"). Some of the

documents (as noted in the attached table of contents) have been designated Confidential or Highly Confidential by AKF and are being filed under seal.

5. Attached as Exhibit 3 is a true and correct copy of AKF's Objections and Responses to Defendants' First Set of Requests for Production of Documents, served on March 5, 2020; Defendants cite AKF's response to RFP No. 11 in their MPA ISO MSJ.

6. Attached in Exhibits 4a to 4d are true and correct copies of documents and excerpts from documents produced by the Fresenius Plaintiffs to Defendants and cited in Defendants' MPA ISO MSJ. The cited documents and excerpts are listed by Bates number in the table of contents attached to this declaration (see column entitled "Cited Bates or Excerpt Pages"). Some of the documents (as noted in the attached table of contents) have been designated Highly Confidential by Fresenius and are being filed under seal.

7. Attached in Exhibits 5a to 5b are true and correct copies of documents, excerpts from documents, and a video recording produced by DaVita to Defendants and cited in Defendants' MPA ISO MSJ. The cited documents and excerpts are listed by Bates number in the table of contents attached to this declaration (see column entitled "Cited Bates or Excerpt Pages").

8. Attached as Exhibit 6 is a true and correct copy of the Expert Report of Randolph Wayne Pate, JD, MPH, dated December 17, 2021 (Pate Report).

9. Attached as Exhibit 7 is a true and correct copy of the Expert Report of Amy D. Waterman, PhD, dated March 10, 2020 (Waterman Report).

10. Attached as Exhibit 8 is a true and correct copy of the Supplemental Expert Report of Amy D. Waterman, PhD, dated November 4, 2021 (Waterman Supp. Report).

11. Attached as Exhibit 9 is a true and correct copy of the Expert Report of John Bertko, F.S.A., M.A.A.A., dated March 10, 2020 (Bertko Report).

12. Attached as Exhibit 10 is a true and correct copy of the Supplemental Expert Report of John Bertko, dated October 26, 2021 (Bertko Supp. Report).

13. Attached as Exhibit 11 is a true and correct copy of *Dying on Dialysis: Inside an Industry Putting Profits Over Patients*, a report by the Office of Congresswoman Katie Porter, dated July 15, 2021. The report is also available at https://porter.house.gov/uploadedfiles/dialysis_staff_report_final.pdf.

14. Attached as Exhibit 12 is a true and correct copy of the article entitled *Kidney Fund Seen Insisting on Donations, Contrary to Government Deal*, by Katie Thomas and Reed Abelson, that was published in the New York Times on December 25, 2016, and referenced in the SB 1156 record from the California State Archives. *See* CA2328-CA2329. The article is also available at https://nyti.ms/3BMrzEH.

15. Attached as Exhibit 13 is a true and correct copy of the article entitled *DaVita encouraged some low-income patients to enroll in commercial plans*, by Samantha Liss, that was published in the St. Louis Post Dispatch on October 23, 2016, and referenced in the SB 1156 record from the California State Archives. *See* CA2328-CA2329. The article may also be available at https://bit.ly/3JOzPqhhttps://www.stltoday.com/business/local/davita-encouraged-some-low-income-patients-to-enroll-in-commercial-plans/article_ec5dc34e-ca4d-52e0-bc26-a3e56e1e2c85.html.

16. Attached as Exhibits 14a to 14c are true and correct copies of excerpts (and one exhibit) from the following deposition transcripts:

- Transcript of deposition of Corey Danko taken on November 11, 2021, and Exhibit 3 to that deposition.
- Transcript of deposition of Steve Dover taken on November 18, 2021.
- Transcript of deposition of John Bertko taken on January 13, 2022.

The page and line numbers of the above deposition transcripts are listed individually in the table of contents attached to this declaration. The transcript of

the Danko deposition has been designated Highly Confidential by DaVita, with the exception of the pages cited in Defendants' MPA. The transcript of the Dover deposition has been designated Confidential by Fresenius, and the excerpts from that deposition are being filed under seal.

17. Attached as Exhibit 15 is a true and correct copy of the complaint filed against DaVita, Inc. and DaVita Healthcare Partners, Inc. in the pending case entitled *Blue Cross and Blue Shield of Fla. v. DaVita, Inc.*, No. 3:19-cv-00574 (M.D. Fla.) on May 14, 2019.

18. Attached as Exhibit 16 is a true and correct copy of the *qui tam* Complaint Filed Under Seal Pursuant to 31 U.S.C. §3730(b)(2) by David Gonzalez against DaVita Health Care Partners and DaVita Kidney Care, Fresenius Medical Care North America, and AKF in the case entitled *United States, ex. rel. Gonzalez v. DaVita Health Care Partners*, No. 1:16-cv-11840-NMG (D. Mass) on September 8, 2016.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 25th day of February, 2022, at Berkeley, California.

/s/ Lisa J. Plank
LISA J. PLANK
Deputy Attorney General

DECLARATION OF LISA J. PLANK

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Exhibit	Document Description	Cited Bates or Excerpt Pages
Documents Produced by Defendants to Plaintiffs		
1a	Excerpts from AB 290 Bill File, produced in Defendants' Production No. 1 Includes: - Office of the Legislative Counsel opinion on AB 290 and HHS OIG Advisory Opinion 97-1 provided to the Honorable Jim Wood, CA34-42 - HHS OIG Advisory Opinion 97-1, CA92-99	CA42 CA92 CA94 CA96 CA97 CA99
1b	Excerpts from AB 290 Bill File, produced in Defendants' Production No. 2 Includes: - AKF documents including AKF Patient Handbook dated Jan. 2, 2019, CA582-603	CA582 CA595
1c	Centers for Medicare & Medicaid Services rulemaking process, including Aug. 23, 2016 Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans and Dec. 14, 2016 Interim Final Rule, produced in Defendants' Production No. 4 Includes: - Request for Information (RFI), CA1753-1757 - Interim Final Rule, CA1758-1775 - Letters received during RFI Notice and Comment Period (Blue Cross, CA1782-1806; Teri Browne, CA1826-1829; AHIP, CA1916-1938; UHC, CA1964-1972)	CA1753 CA1759 CA1760 CA1761 CA1762 CA1765 CA1773 CA1786 (Blue Cross) CA1827 (Browne) CA1917 (AHIP) CA1966-1967 (UHC)

1d	SB 1156 record from California State Archives, produced in Defendants' Production No. 5 Includes: - J.P. Morgan, *DaVita Inc. Commercial Mix at Risk (Part 2)*, CA2091-2100 - J.P. Morgan, *DVA Commercial Mix at Risk; Sensitivity is Material*, CA2101-2114 - Washington OIC order to DaVita, CA2596 - Senate Rules Committee "Veto" document, CA2482 - Veto message, CA2585	CA2091 CA2101 CA2104 CA2109 CA2328-2329 CA2482 CA2585 CA2595-2596
1e	Excerpts from State of Washington Office of the Insurance Commissioner, Legal Affairs Division, Investigation #1340003, produced in Defendants' Production No. 6	CA3072-3074 CA3097-3100 CA3171-3173

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2a	AKF letter about non-contributing renal providers, AKF-DOE-805-806; AKF letter about leaving California, AKF-DOE-807	AKF-DOE-805-807
2b	Excerpts from AKF HIPP Guidelines, May 2014 AKF-DOE-10056, 10059-10063	AKF-DOE-10060
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2e	Premium Impacts of ESRD Patients in the Individual Market (Avalere), AKF-DOE-10130-10135 *Designated Confidential by AKF*	AKF-DOE-10132
2f	Excel Spreadsheet – American Kidney Fund Annual Contributions by Requested Providers *Designated Confidential by AKF*	AKF-DOE-10136

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4a	Excerpts from FMC Earnings Call – 3rd Quarter 2018, on Oct. 30, 2018, FMC3036-3062	FMC3049-3050
4b	FMC Insurance Counselor training program – undated "Day 5" training, FMC4921-4936 *Designated Highly Confidential by Fresenius*	FMC4926 FMC4931
4c	2018 Insurance Coordinator Goals *Designated Highly Confidential by Fresenius*	FMC4940
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Documents Produced by DaVita to Defendants		
5a	DaVita 2018 and 2019 Donation Letters to AKF specifying annual contribution and subsequent increases to same *With redactions by DaVita of Confidential information*	DAV8273-8275
5b	Video of WebEx presentation about Medicaid Opportunity program (and transcription of presentation for the Court's convenience)	DAV14359

Depositions		
14a	Excerpts from transcript of deposition of Corey Danko taken on November 11, 2021, and Exhibit 3 *Danko deposition (other than the above-listed excerpts and Exhibit 3) designated Confidential by DaVita*	111:15-113:15 177:20-178:23 182:24-183:3 207:13-24 214:1-25 Ex. 3 to deposition

14b	Excerpts from transcript of deposition of Steve Dover taken on November 18, 2021 *Deposition designated Confidential by Fresenius*	47:2-8 48:6-18 50:10-51:19 63:6-24 64:5-65:24 66:1-67:4 69:8-25 70:5-14 72:11-23 119:11-120:1 148:5-9
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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE; STEPHEN ALBRIGHT; AMERICAN KIDNEY FUND, INC.; and DIALYSIS PATIENT CITIZENS, INC.,

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

8:19-cv-2105-DOC-(ADSx)

EXHIBITS 1a-3 TO THE DECLARATION OF LISA J. PLANK IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

PROVISIONALLY REDACTED PURSUANT TO PENDING APPLICATION FOR LEAVE TO FILE UNDER SEAL

Date:	May 2, 2022
Time:	8:30 a.m.
Courtroom:	9D
Judge:	The Honorable David O. Carter
Trial Date:	July 12, 2022
Action Filed:	November 1, 2019

EXHIBIT 1a

Excerpts from AB 290 Bill File, produced in Defendants' Production No. 1

LEGISLATIVE COUNSEL BUREAU

A TRADITION OF TRUSTED LEGAL SERVICE TO THE CALIFORNIA LEGISLATURE

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June 28, 2019

Honorable Jim Wood
Room 6005, State Capitol

ASSEMBLY BILL NO. 290: DIALYSIS PROVIDERS: CHARITABLE DONATIONS - #1916414

Dear Mr. Wood:

Under federal law, the Office of Inspector General in the federal Department of Health and Human Services (hereafter OIG) may issue advisory opinions to parties seeking advice about whether a proposed or current business arrangement complies with the Health Insurance Portability and Accountability Act of 1996.[1] In 1997, the OIG issued an advisory opinion generally approving an arrangement between the American Kidney Fund (hereafter AKF) and various dialysis providers.[2]

In this context, you have asked whether AKF would remain in compliance with that approved arrangement if Assembly Bill No. 290 (2019-2020 Reg. Sess.) (hereafter AB 290) is enacted and the AKF complies with the requirements of that bill.

1. Background

1.1 AB 290

AB 290 would limit the reimbursement rate for dialysis providers that are "financially interested." The bill would define "financially interested" to include "An entity that receives the majority of its funding from one or more financially interested providers of health care services, parent companies of providers of health care services, subsidiaries of

[1] Social Security Act, § 1128D(b); see also United States Department of Health and Human Services, OIG internet website, available at <https://oig.hhs.gov/faqs/advisory-opinions-faq.asp> (last accessed June 27, 2019).

[2] OIG, Advisory Opinion No. 97-1, available at <https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/index.asp#1997> (last accessed June 27, 2019) (hereafter Opinion 97-1).

health care service providers, or related entities."[3] Under AB 290, the reimbursement rate for such a financially interested dialysis clinic would be the Medicare reimbursement rate.[4]

Additionally, AB 290 would require a financially interested entity to disclose to the health care service plan or insurer the name of each patient for whom it pays a premium. Specifically, the bill would prohibit such an entity from making a third-party premium payment unless it discloses to the health care service plan or health insurer, as applicable, the name of the enrollee or insured for each health care service plan contract or policy on whose behalf a third-party premium payment will be made.[5]

1.2 Section 1128A(a)(5) of the Social Security Act

Section 1128A(a)(5) of the Social Security Act (hereafter section 1128A(a)(5)), enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), prohibits certain offers or transfers of remuneration to a Medicare or Medicaid beneficiary. Specifically, section 1128A(a)(5) imposes civil penalties against any person who

> "offers or transfers remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid]."

Section 1128A(i)(6) of the Social Security Act defines "remuneration" for these purposes as including "the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value."

As will be discussed in greater detail below, this prohibition has been interpreted by the OIG to prohibit a provider from paying the premiums of patients directly, but does not, under certain circumstances, prohibit a third-party entity (such as a nonprofit organization) from making premium payments on behalf of patients.

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[3] Proposed Health & Saf. Code, § 1367.016, subd. (f)(2)(B) & Ins. Code, § 10176.11, subd. (f)(1)(B). The bill also defines "financially interested" to include "A provider of health care services that receives a direct or indirect financial benefit from a third-party premium payment" and "A chronic dialysis clinic that is operated, owned, or controlled by a parent entity or related entity that meets the definition of a large dialysis clinic organization (LDO) under the federal Centers for Medicare and Medicaid Services Comprehensive ESRD Care Model as of January 1, 2019." (Proposed Health & Saf. Code, § 1367.016, subd. (f)(1)(A) & (C) & Ins. Code, § 10176.11, subd. (f)(1)(A) &(C).)

[4] See proposed Health & Saf. Code, § 1367.016, subd. (d) & Ins. Code, § 10176.11, subd. (d).

[5] Proposed Health & Saf. Code, § 1367.016, subd. (c)(2) & Ins. Code, § 10176.11, subd. (c)(2).

The OIG, which was established in the Department of Health and Human Services to identify and eliminate fraud, abuse, and waste in the department's programs, is responsible for enforcing section 1128A(a)(5).[6] Additionally, Congress has authorized the OIG to create regulatory exceptions to section 1128A(a)(5) and to issue advisory opinions to protect acceptable arrangements.[7] When the OIG issues an advisory opinion, it protects the arrangement described in that particular opinion and is binding only with respect to the parties that requested the opinion. It does not establish any legal precedent upon which other parties may rely.[8] Additionally, advisory opinions rely solely on the facts presented to the OIG by the parties to the letter. "If material facts have not been disclosed, [the] opinion is without force and effect."[9] Moreover, an advisory opinion "is limited in scope to the specific arrangement described in [the opinion] and has no applicability to other arrangements, even those which appear similar in nature or scope."[10]

1.2.1 Patient assistance programs

Patient assistance programs provide financial assistance to patients, which may take the form of assistance with the payment of health insurance premiums. Under federal law, financial assistance given directly by a provider to a patient would likely violate section 1128A(a)(5) because this would constitute "remuneration" to an individual patient that would influence the patient's choice of provider.[11] To avoid violating the law, some health care providers have entered into agreements to provide funding for financial assistance to be administered by independent charitable organizations.[12] The OIG determined, beginning in 1997, that these arrangements were lawful in the context of facts provided by the requesters indicating that certain safeguards relating to the independence and autonomy of the charity were in place.[13] The first advisory opinion analyzing such an arrangement was Opinion 97-1, in which the OIG analyzed a particular patient assistance program involving AKF. AKF, which is a charitable and educational organization organized under section 501(c)(3) of the federal Internal Revenue Code, entered into an arrangement with certain dialysis providers whereby the providers contribute funds to AKF, which in turn

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[6] See OIG Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries, 67 Fed.Reg. 55855 (Aug. 30, 2002) (hereafter 2002 Special Advisory Bulletin).

[7] See § 1128A(i)(6)(B) & 1128D(b)(2)(A) of the Social Security Act.

[8] See § 1128D(b)(4)(A) of the Social Security Act; Opinion 97-1, p. 1.

[9] Opinion 97-1, p. 1.

[10] Opinion 97-1, p. 6.

[11] § 1128A(a)(5); see Medicare and State Health Care Programs: Fraud and Abuse; Civil Money Penalty Exception To Protect Payment of Medicare Supplemental Insurance and Medigap Premiums for ESRD Beneficiaries, 67 Fed.Reg. 72896-01 (Dec. 9, 2002).

[12] See Gosfield, *Beneficiary Inducements: What's New and What's Still True*, 2018 Health L. Handbook 10.

[13] See Opinion 97-1.

independently screens patients for financial need and pays Medicare Part B and Medigap premiums on behalf of qualifying patients. We turn now to a discussion of this arrangement as analyzed by the OIG in Opinion 97-1.

1.3 Opinion No. 97-1

In Opinion 97-1, the OIG analyzed the arrangement between AKF and the donor providers for compliance with section 1128A(a)(5). The OIG noted that the arrangement contains the following elements: (1) AKF pays the premiums for financially needy end-stage renal disease patients, and this financial assistance is available to all eligible patients on an equal basis.[14] (2) Providers that make financial donations to AKF agree not to advertise the availability of possible financial assistance to the public and not to disclose directly or indirectly to individual patients they refer that such members have contributed to AKF to fund the grants.[15] (3) AKF staff involved in awarding patient grants do not take into consideration the amount of any provider's donation when assessing patient applications or making grant determinations.[16] (4) The donating companies certify that they will not track the amount that AKF pays on behalf of patients dialyzing at their facilities in order to calculate future contributions. Furthermore, the companies will not disclose to each other, or other dialysis providers, the amount or method of calculating their respective contributions to AKF, and AKF will not disclose one company's contribution to another company or to dialysis providers.[17] (5) There are no restrictions or conditions put on donations, and AKF's discretion as to the uses of contributions is absolute, independent, and autonomous.[18]

The OIG concluded in Opinion 97-1 that the above-described arrangement is allowable under section 1128A(a)(5) because (1) the donations to AKF do not constitute "remuneration" to an eligible patient; and (2) AKF's purchase of premiums is unlikely to influence patients to receive services from particular providers.[19] We address each element of the OIG's analysis in turn.

1.3.1 Donations to AKF are not remuneration

The OIG found that the contributions in question are not made to or on behalf of an individual. In this regard, the OIG emphasized that under the arrangement, AKF has absolute discretion regarding the use of provider contributions made to AKF. Moreover, eligibility for assistance is available to any financially needy patient regardless of provider; it is not limited to patients of the providers. Last, as an "additional safeguard," the providers

[14] Opinion 97-1, p. 2.
[15] Opinion 97-1, p. 3.
[16] Opinion 97-1, p. 3.
[17] Opinion 97-1, p. 3.
[18] Opinion 97-1, p. 4.
[19] Opinion 97-1, pp. 4-5.

agreed not to track the amounts that AKF pays on behalf of patients dialyzing at their facilities in order to calculate amounts of future contributions.[20] The OIG stated as follows:

> "In sum, the interposition of AKF, a bona fide, independent, charitable organization, and its administration of [the program] provides sufficient insulation so that the premium payments should not be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of [program] assistance their patients receive bears any relationship to the amount of their donations."[21]

Thus, the OIG concluded that the payments made on behalf of patients do not constitute "remuneration" under section 1128A(a)(5).

1.3.2 AKF's purchase of premiums is unlikely to influence patient's choice of provider

With respect to whether the payments are likely to influence patients in their choice of providers, the OIG opinion emphasized that in most circumstances a patient will have already selected a provider before applying to AKF for premium assistance. In addition, under the arrangement, the patient assistance programs will not be advertised to the public, reducing the chance that a beneficiary will choose a provider based on its participation in such a program.[22] And "most importantly," the OIG emphasized that a beneficiary may "select any provider . . . . Simply put, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice."[23] Thus, the OIG determined that the payments made on behalf of a patient were not likely to influence the patient's choice of provider. Because the OIG found that those payments would neither constitute remuneration nor be likely to influence a patient's choice of provider, it concluded that the arrangement would not violate section 1128A(a)(5).

Despite the fact that advisory opinions issued by the OIG are binding only as to the parties involved, it is possible to draw inferences as to what types of arrangements the OIG deems permissible under HIPAA based on the analysis contained in those advisory opinions. We now apply the analysis contained in Opinion 97-1 to the requirements that would be imposed by AB 290.

2. Analysis

You have informed us that AKF receives the majority of its funding from one or more financially interested providers of health care services, parent companies of providers of health care services, subsidiaries of health care service providers, or related entities and would

[20] Opinion 97-1, p. 5.
[21] Opinion 97-1, p. 5.
[22] Opinion 97-1, p. 5.
[23] Opinion 97-1, p. 5.

thus meet this definition of a "financially interested" entity for purposes of the disclosure provisions required by AB 290. Therefore, AKF would be subject to the disclosure requirements specified in that bill.[24] These disclosure requirements would require AKF to provide personally identifiable patient information to the health care service plan or insurer that receives premium payments on behalf of a beneficiary.[25]

Opinion 97-1 states, "The OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion as long as . . . the arrangement in practice comports with the information provided."[26] Because these disclosure requirements were not part of the arrangement considered by the OIG when it issued Opinion 97-1, that opinion would not ensure that the version of the patient assistance program operated by AKF in compliance with AB 290 would be immune from OIG sanctions. In this regard, Opinion 97-1 specifically states that it "is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope."[27]

However, although the changes in the premium assistance program required by AB 290 would remove the legal protection afforded by Opinion 97-1, that fact does not mean that the program would violate section 1128A(a)(5). It is possible that the changes to the program necessitated by the enactment of AB 290 would not change the reasoning underlying the opinion and that the OIG would continue to consider the arrangement, as modified, to be compliant with section 1128A(a)(5). Thus, we must consider whether, based on the reasoning in Opinion 97-1, the patient assistance program described in that opinion would violate section 1128A(a)(5), as construed by the OIG, if the arrangement was altered to comply with the requirements of AB 290.

As discussed previously, one element of the arrangement addressed in Opinion 97-1 that was deemed relevant by the OIG was the fact that the companies that donate to AKF will not track the amounts that AKF pays on behalf of patients receiving treatment at their facilities in order to calculate amounts of future contributions. Additionally, the OIG stated that the donors "will not advertise the availability of possible financial assistance to the public and will not disclose directly or indirectly to individual patients they refer that such members have contributed to AKF to fund the grants."[28] In its conclusion, the OIG noted:

> "[T]he interposition of AKF, a bona fide, independent, charitable organization, and its administration of [the program] provides sufficient

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[24] See proposed Health & Saf. Code, § 1367.016, subd. (c)(2); Ins. Code, § 10176.11, subd. (c)(2).

[25] Proposed Health & Saf. Code, § 1367.016, subd. (c)(2); Ins. Code, § 10176.11, subd. (c)(2).

[26] Opinion 97-1, p. 6.

[27] Opinion 97-1, p. 6.

[28] Opinion 97-1, p. 3.

> insulation so that the premium payments should not be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of . . . assistance their patients receive bears any relationship to the amount of their donations. Indeed, the Companies are not guaranteed that beneficiaries they refer to [the program] will receive any assistance at all. In these circumstances, we do not believe that the donations by the Companies to AKF can reasonably be construed as payments to eligible beneficiaries of a Federal health care program."[29]

Thus, the donors' lack of knowledge regarding the identities of patients receiving financial assistance and the patients' lack of knowledge regarding the sources of donations were important factors in the OIG's approval of the arrangement.

We think that AB 290 raises two relevant concerns with respect to its disclosure requirements: the possibility that a provider may discover the identity of a patient receiving assistance from AKF and the possibility that a patient receiving assistance may discover that the patient's provider donated to AKF. We address each of these concerns separately below.

2.1 Disclosing the identity of patients to donors

The patient data specified in AB 290 is required to be reported to the health plan or insurer. There is no indication in the bill that the information will be reported to the dialysis provider that donated funds to AKF. However, if under certain factual scenarios, the provider becomes aware of the identity of patients who are receiving assistance from AKF (by, for example, receiving a lower reimbursement rate from the insurer once the reimbursement cap imposed by AB 290 took effect), it could be possible for the provider to infer that the reason for the lower reimbursement was the fact that the patient had received assistance from AKF. In this manner, the provider could indirectly be provided with information that leads to the conclusion that the patient had received premium assistance.

However, we note that the bill does not require the identity of patients to be provided directly to donors and that the manner in which a provider may discover the identity of patients receiving assistance in the hypothetical situation described above is indirect. It is possible that the OIG would deem this connection to be too attenuated to create a violation of section 1128A(a)(5). Moreover, even if the donors are indirectly made aware that the reimbursement rates for certain patients changed after the enactment of AB 290, so long as the donor agreed not to take steps to track this information, the arrangement could still be in compliance with the arrangement approved in Opinion 97-1.

2.2 Disclosing the identity of donors to patients

The prohibition specified in section 1128A(a)(5) indicates that it applies only to remuneration that influences a patient's choice of provider. In Opinion 97-1, the OIG discusses

[29] Opinion 97-1, p. 5.

the fact that in most circumstances a patient will have already selected a provider before applying to AKF for premium assistance and that the patient assistance programs will not be advertised to the public, reducing the chance that a beneficiary will choose a provider based on its donations to a patient assistance program.[30] This suggests that if a patient has already selected a provider, the patient would not be influenced if the patient subsequently discovered that a provider had donated funds to AKF. However, in its 2002 Special Advisory Bulletin, the OIG suggests that even patients who have already selected a provider could be unlawfully "induced" to continue receiving services from the provider, stating that "the OIG considers the provision of free goods or services to existing customers who have an ongoing relationship with a provider likely to influence those customers' future purchases."[31]

With respect to whether compliance with AB 290 would result in the unlawful inducement of patients by providers, the bill does not expressly require or authorize a patient to be informed of whether a particular provider has donated to AKF. However, if AB 290 is enacted, it may be possible under certain factual scenarios for a patient to infer that the patient's provider had donated. For example, a patient may receive a billing statement showing that the patient's reimbursement rate had been lowered to the Medicare reimbursement rate. That patient could infer that the reason for the lower rate was the fact that the provider was a "financially interested" entity under AB 290 as a result of donations to AKF.[32] This inference could thus influence the patient to remain with the provider.

Nevertheless, the connection between the disclosure requirements mandated by AB 290 and the patient's discovery that a provider donated to AKF is arguably attenuated, and in any case, it is possible that the OIG would not find it to be a significant enough factor in affecting the patient's choice of provider to make the arrangement inconsistent with the one approved in Opinion 97-1.

We conclude that based on the facts available to us, AKF would remain in compliance with the arrangement approved in Opinion 97-1 if AB 290 is enacted and AKF complies with the changes required by that bill. However, this would be a factual determination made by the OIG and could involve a consideration of facts not available to us.[33]

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[30] Opinion 97-1, p. 5.

[31] 2002 Special Advisory Bulletin, p. 3.

[32] However, we note that AB 290 defines "financially interested" as including "[a] chronic dialysis clinic that is operated, owned, or controlled by a parent entity or related entity that meets the definition of a large dialysis clinic organization (LDO) under the federal Centers for Medicare and Medicaid Services Comprehensive ESRD Care Model as of January 1, 2019." (Proposed Health & Saf. Code, § 1367.016, subd. (f)(1)(C) & Ins. Code, § 10176.11, subd. (f)(1)(C).) Because such a clinic need not have donated to a patient assistance program to be considered "financially interested," the reimbursement rate would not necessarily indicate that the provider had donated to such a program.

[33] Although the analysis in Opinion 97-1 is limited to a discussion of section 1128A(a)(5), subsequent OIG advisory opinions have also discussed the federal (continued . . .)

3. Conclusion

It is our opinion that based on the facts available to us, the American Kidney Fund would remain in compliance with the arrangement approved in Advisory Opinion 97-1 issued by the Office of the Inspector General of the federal Department of Health and Human Services if Assembly Bill No. 290 (2019-2020 Reg. Sess.) is enacted and the American Kidney Fund complies with the changes enacted by that bill. However, this would be a factual determination made by the Office of Inspector General and could involve a consideration of facts not available to us.

Very truly yours,

Diane F. Boyer-Vine
Legislative Counsel

By Amy Schweitzer
Amy E. Schweitzer
Deputy Legislative Counsel

AES:blt

(. . . continued)
prohibition on kickbacks in analyzing patient assistance programs. In this regard, the anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. (OIG, Advisory Opinion No. 06-04, available at <https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/index.asp#2006> (last accessed June 27, 2019).) However, "[a] determination regarding whether a particular arrangement violates the anti-kickback statute requires a case-by-case evaluation of all the relevant facts and circumstances, including the intent of the parties." (OIG Special Advisory Bulletin, Patient Assistance Programs for Medicare Part D Enrollees 70 Fed.Reg. 70623 (Nov. 22, 2005).)

[Names and addresses of Requestors have been redacted]

Re: Advisory Opinion No. 97-1

Dear [Names have been redacted]:

We are writing in response to your request for an advisory opinion, which we accepted pursuant to 42 C.F.R. § 1008.41 on April 11, 1997. Your request asks whether donations by renal dialysis providers to an independent 501(c)(3) charitable organization for the purpose of funding a program to pay for Supplementary Medical Insurance Program ("Medicare Part B") or Medicare Supplementary Health Insurance ("Medigap") premiums for financially needy Medicare beneficiaries with end-stage renal disease where such beneficiaries may be receiving treatment from the donor-dialysis providers (the "Proposed Arrangement") would constitute grounds for the imposition of a civil monetary penalty under Section 231(h) of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

You have certified that all of the information you provided in your request, including all supplementary letters, is true and correct, and constitutes a complete description of the facts and agreements among the parties regarding the Proposed Arrangement. You have also certified that upon our approval of the Proposed Arrangement, you will undertake to effectuate the Proposed Arrangement.

In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed, this opinion is without force and effect.

Based on the information provided and subject to certain conditions described below, we have determined that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under Section 231(h) of HIPAA. This opinion may not be relied on by any person other than the addressees and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The American Kidney Fund and Company A, Company B, Company C, Company D, Company E, and Company F, (collectively the "Companies") have made the following representations with respect to the Proposed Arrangement. The American Kidney Fund and the Companies are collectively the "Requestors".

A. End-Stage Renal Disease and Medicare's Dialysis Benefit

End-stage renal disease ("ESRD") is a chronic disease that requires regular dialysis, as well as monitoring of laboratory values, diet, and medication. In addition to chronic renal failure, ESRD patients also commonly suffer from certain co-morbid conditions, including diabetes, anemia, hypertension, and congestive heart failure.

In 1972, Congress created a special Medicare ESRD benefit. This benefit is for all individuals with ESRD who have earned a certain level of eligibility for Social Security benefits (or are dependents of those who have attained that level). People in this category are entitled to benefits under Medicare Part A and are eligible to enroll in Medicare Part B. Medicare Part B payments on behalf of ESRD patients generally cover eighty percent of the composite rate for Medicare-covered maintenance dialysis services, as well as eighty percent of physician services and certain ancillary services.[1] Medigap insurance can be purchased to cover a patient's annual Medicare coinsurance obligations for Medicare-covered services.

B. Parties to the Proposed Arrangement

1. The Companies

[Material redacted] [The companies have formed an association] to address issues that affect the dialysis industry and to improve the way the renal dialysis industry performs as a whole. While the Companies [as an association] have worked with the American Kidney Fund to develop the proposed arrangement, the individual providers have applied for the advisory opinion in their separate capacities.

2. American Kidney Fund

The American Kidney Fund ("AKF") is a bona fide, 501(c)(3) charitable and educational organization that has been in existence for over twenty-five years. AKF, a public charity, is governed by a board of twenty-five members. The board bylaws provide that membership on the board should be comprised of representatives involved with ESRD issues, including nephrology physicians, nephrology nurses, nephrology social workers, patients or family members of ESRD patients, and community leaders. Vacancies on the board are filled by vote of the remaining board members. Although two members of the current board are employees of subsidiaries of one Company, the AKF board is not directly or indirectly

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[1] We note that Medicare reimbursement for some medical services provided to ESRD patients, such as certain lab services, are not covered under the composite rate.

controlled by any Company or Companies. AKF has established a subcommittee of the board's Program and Grant Committee to have primary oversight authority for the Health Insurance Premium Program; membership on such subcommittee will be restricted to exclude any employees, officers, shareholders, or owners of any dialysis provider.

In addition to its educational efforts on behalf of those suffering from renal failure, AKF provides direct financial support in the form of grants to needy persons with ESRD for items such as transportation, medication, and insurance premiums. In the past, AKF has funded 100 percent of all eligible grant requests from ESRD patients. In 1995, AKF assisted over 12,000 patients with ESRD and received over $5 million in donations. Of that amount, less than ten percent was contributed by the Companies. The largest percentage of AKF's funds was directed towards patient aid. AKF disseminates information about its patient assistance and other programs throughout the national dialysis provider community, especially to social workers who work with ESRD patients.

C. Health Insurance Premium Program

AKF's Health Insurance Premium Program ("HIPP") provides financial assistance to financially needy ESRD patients for the costs of medicine, transportation, and health insurance premiums, including Medicare Part B and Medigap premiums. Assistance is available to all eligible patients on an equal basis. In general, eligibility for participation in AKF's assistance programs requires a physician certification, a referral letter signed by a social worker or administrator at a dialysis provider, and an individual Patient Grant Application. The Patient Grant Application requires patients to provide detailed financial information for their entire household.[2] While a patient can apply directly to AKF for a grant, most applications are submitted on the patient's behalf by dialysis providers or social workers employed by a dialysis provider.

Upon receipt of a patient's application, a member of AKF's staff reviews the application, gathers additional information, if necessary, and makes an initial recommendation as to the disposition of the application based upon AKF's needs assessment and eligibility criteria. A senior staff employee reviews the recommendation and makes a final determination. All

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[2] The information required includes: assets held in checking and savings accounts; the value of a home, stocks and bonds, and automobiles; monthly income (which is made up of take-home pay of the patient and spouse, social security, welfare, retirement income, veterans benefits, etc.); and monthly expenses for rent, mortgage, food, utilities, transportation, medical expenses, insurance, charge accounts, and loans. AKF further requires that the patient disclose all sources of alternative assistance available, such as Medicare, Medicaid, and state renal programs.

determinations are made by AKF employees who have no financial interest in the Companies or other dialysis providers and are based on their good faith assessment that the applicant is in financial need and eligible for assistance. If AKF determines that a patient is eligible for assistance, AKF notifies the dialysis provider's social worker that the insurance premium has been paid in order to ensure that the patient's billing information is accurate.

Because of AKF's limited financial resources, an AKF patient assistance grant is provided for a specific time period. Upon expiration of the period, the patient must submit another grant application. Grant requests are reviewed on a first-come, first-served basis to the extent funding is available.

D. The Proposed Arrangement

AKF proposes to expand significantly its patient assistance grants to financially needy ESRD patients for payment of medical insurance premiums through HIPP. Additional funding will be donated primarily by the Companies. Medical social workers at each Company's dialysis facility will assist patients in identifying all available sources of assistance for which they qualify, which may include assistance from HIPP, and if appropriate, will refer financially needy patients to AKF for such assistance. However, the Companies will not advertise the availability of possible financial assistance to the public and will not disclose directly or indirectly to individual patients they refer that such members have contributed to AKF to fund the grants.

AKF will continue to use its current procedures in assessing the financial need and eligibility of all patients, whether self-referred or referred by the Companies, or other non-donor dialysis providers. Determinations will be made solely on AKF's good faith assessment of a patient's financial need. AKF staff involved in awarding patient grants will not take the identity of the referring facility or the amount of any provider's donation into consideration when assessing patient applications or making grant determinations.

Under the Proposed Arrangement, the Companies will be free to determine whether to make contributions to AKF and, if so, how much to contribute. All the Companies have certified that they will not track the amount that AKF pays on behalf of patients dialyzing at their facilities in order to calculate future contributions. However, in calculating their contributions to AKF, the Companies have indicated that they may consider what they would have otherwise paid on behalf of financially needy patients utilizing their facilities. The Companies will not disclose to each other, or other dialysis providers, the amount or method of calculating their respective contributions to AKF, and AKF will not disclose one Company's contribution to another Company or to other dialysis providers.

Contributions will be made without any restrictions or conditions placed on the donation. The Companies have acknowledged that "contributions . . . will be gifts without any guarantee or promise on the part of AKF that patients referred to AKF for possible financial assistance with their insurance premiums will receive such assistance. AKF's discretion as to the uses of contributions will be absolute, independent, and autonomous."

II. LEGAL ANALYSIS

Section 231(h) of HIPAA, effective January 1, 1997, provides for the imposition of civil monetary penalties against any person who:

> offers or transfers remuneration to any individual eligible for benefits under [Federal health care programs (including Medicare or Medicaid)] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, [by a Federal health care program].

Section 231(h) defines "remuneration", in relevant part, as "transfers of items or services for free or for other than fair market value."[3]

We conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under Section 231(h) of HIPAA. A violation of Section 231(h) requires that something of value be given to a beneficiary, either directly or on his or her behalf. Simply put, the contributions to AKF by the Companies are not made to or on behalf of beneficiaries.[4] Moreover, while the premium payments by AKF may constitute remuneration to beneficiaries, they are not likely to influence patients to order or receive services from particular providers. To the contrary, the insurance coverage purchased by AKF will follow a patient regardless of which provider the patient selects, thereby enhancing patient freedom of choice in health care providers.

A. Donations By The Companies Do Not Constitute

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[3] The statutory definition of remuneration provides an exception, not applicable here, for certain waivers of coinsurance and deductible amounts.

[4] The Proposed Arrangement differs from an arrangement where a renal dialysis provider directly pays premiums for beneficiaries, thus potentially influencing them to continue to use that particular dialysis provider in order to ensure continuing payment of premiums.

Remuneration To An Eligible Beneficiary

The Companies' contributions to AKF would not constitute grounds for the imposition of civil monetary penalties under Section 231(h), because such contributions are not made to or on behalf of an individual eligible for Federal heath care program benefits. AKF is a bona fide, independent, publicly-funded, 501(c)(3) charitable organization whose charitable purposes include aiding ESRD patients and their families and is not subject to control, directly or indirectly, by any Company or Companies. Under the Proposed Arrangement, AKF will have absolute discretion regarding the use of provider contributions made to AKF.

Moreover, eligibility for HIPP assistance is available to any financially needy ESRD patient regardless of provider; it is not limited to patients of the companies. AKF will make all AKF eligibility determinations using its own criteria, and AKF staff will not take into account the identity of the referring provider or the amount of any donation to AKF by such provider.

Finally, as an additional safeguard, the Companies have represented that they will not track the amounts that AKF pays on behalf of patients dialyzing at their facilities in order to calculate amounts of future contributions, although donations may take into account the amounts that the Companies would have otherwise expended on financially needy patients. Contributions will not be earmarked for the use of particular beneficiaries or groups of beneficiaries. The Companies may change the amount of their contributions or discontinue contributing to AKF at any time. The Companies have represented that they will individually determine the amount of their contributions without consulting with the other Companies or other contributing dialysis providers.

In sum, the interposition of AKF, a bona fide, independent, charitable organization, and its administration of HIPP provides sufficient insulation so that the premium payments should not be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of HIPP assistance their patients receive bears any relationship to the amount of their donations. Indeed, the Companies are not guaranteed that beneficiaries they refer to HIPP will receive any assistance at all. In these circumstances, we do not believe that the donations by the Companies to AKF can reasonably be construed as payments to eligible beneficiaries of a Federal health care program.

B. AKF's Purchase of Premiums Is Not Likely to Influence A Beneficiary's Choice of a Particular Provider

Section 231(h) prohibits payments to or on behalf of Federal health care program beneficiaries only if the payments are likely to influence such beneficiaries to use a

particular provider. In the circumstances presented by the Proposed Arrangement, we believe that AKF's payments of premiums on behalf of financially needy beneficiaries is not likely to influence a beneficiary's selection of a particular provider.

As part of the application process for HIPP, AKF requires certain medical and financial certifications from the applicant's physician and social worker. While patients may apply directly to AKF, more commonly, the dialysis provider makes the application on behalf of the patient. Thus, a patient will often have already selected a provider prior to submitting his or her application for assistance or the initial payment of premiums by AKF. As an additional safeguard, HIPP will not be advertised to the public by the Companies; this should reduce the probability that a beneficiary would select a Company based on its participation in HIPP. Most importantly, once in possession of Medicare Part B or Medigap coverage, a beneficiary will be able to select any provider of his or her choice. Simply put, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice.

III. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to AKF, Company A, Company B, Company C, Company D, Company E, and Company F, which are the Requestors of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.

- This advisory opinion does not address any other current or past arrangement for the payment of Part B or Medigap premiums by any dialysis provider or any other charitable or non-profit organization. The U.S. Department of Health and Human Services does not accept or acquiesce in any characterizations of the propriety of such arrangements in the materials submitted by the Requestors.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a Requestor to this opinion.

- This advisory opinion is applicable only to the statutory provision specifically noted above. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including any laws relating to insurance or insurance contracts.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is prospective only. It has no application to conduct which precedes the date of this opinion.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion.

Sincerely,

/S/

D. McCarty Thornton
Chief Counsel to the Inspector General

EXHIBIT 1b

Excerpts from AB 290 Bill File, produced in Defendants' Production No. 2

American Kidney Fund®

PATIENT HANDBOOK

HEALTH INSURANCE PREMIUM PROGRAM

Updated January 2, 2019

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ABOUT THE AMERICAN KIDNEY FUND

The American Kidney Fund, a national nonprofit organization founded in 1971, is working to fight kidney disease and help people live healthier lives. Through our many programs, we support people no matter where they are in the fight against kidney disease—from prevention through treatment and transplant.

For the 1 in 5 U.S. dialysis patients who can't afford the cost of care, AKF provides lifesaving financial assistance, and in 2018 we expanded the scope of that program to continue helping patients with insurance premium support for up to a year post-transplant.

To reach people who are at risk of developing kidney disease, we run the nation's largest free kidney disease screening program, providing prevention services to individuals in more than 20 cities annually. Our programs and services to help people manage and live better with kidney disease include a robust website full of up-to-date health information; free monthly webinars; and professional education programs for those who care for kidney patients. We reach into communities with the Kidney Health Coach program and we advocate for issues that matter to patients through our nationwide AKF Advocacy Network of more than 10,000 patients and loved ones.

Our work is possible thanks to more than 62,000 individuals, corporations and foundations who support our mission through charitable contributions to AKF. We spend those contributions where they will do the most good—on programs, not overhead. Our consistent track record of spending 97 cents of every donated dollar on programs has earned AKF the top "Four Star" rating from Charity Navigator for 17 years in a row, placing AKF on the top 10 list of nonprofits nationwide for fiscal accountability.

For more information about AKF and to learn how you can become involved, visit our website at **KidneyFund.org**, or find us on Facebook, Twitter and Instagram.

INTRODUCTION

This handbook is intended to help you fully understand your role and responsibilities as a patient applying for financial help through AKF's **Health Insurance Premium Program (HIPP)**. It will help you in navigating the eligibility, grant entry and grant approval process. It will also help you understand the benefits, responsibilities, and limits of HIPP.

This handbook is not meant to take the place of the HIPP guidelines. Those guidelines are located on our website at **http://www.kidneyfund.org/assets/pdf/financial-assistance/hipp-guidelines.pdf.**

If you would like to apply for HIPP, please speak with your dialysis team. You have the option to apply through your dialysis team, through a caregiver, or by yourself.

GRANTS MANAGEMENT SYSTEM (GMS)

GMS is AKF's online system for managing your financial grant requests. We suggest that you register to use GMS. By registering, you may:

- Submit/monitor grant requests
- Monitor payments
- Update your profile
- Send messages to AKF
- Download important documents
- Review educational information
- Receive important program updates
- Add a caregiver to assist you

To register in GMS, you must have an email account. Please visit **gms.kidneyfund.org** to register. For information on how to register, please refer to the **Patient Registration Guide** in Appendix 1 of this handbook.

MY RIGHTS AND RESPONSIBILITIES

Since 1971, AKF has helped more than 1.5 million kidney patients like you to afford healthcare expenses.

If you are currently being assisted by AKF's HIPP, or if you are thinking about applying, you should know that you have rights and responsibilities as an AKF grant recipient. The rights and responsibilities below apply to any patient who, following submission of a HIPP application, is approved and remains eligible for HIPP assistance.

Your Rights

1. You have the right to **independently choose** the health care coverage that is best for you.
2. You have the right to **change** your health care coverage to any plan that is available to you and that best suits your health and financial needs.
3. You have the right to **cancel** your HIPP assistance from AKF at any time.
4. You have the right to **reapply** for HIPP assistance from AKF at any time.
5. You have the right to **change dialysis providers** and maintain your HIPP eligibility. When you move to another provider, you are still approved for grant assistance for your current full policy year. Please make sure to update your information in your GMS profile. You may do this yourself or get assistance from your caregiver that has registered to assist you on your behalf. You may also inform your new dialysis center so they can update the profile for you or contact AKF directly if employees at your new dialysis clinic cannot assist you.
6. You have the right to **access AKF's GMS** to track the status of your grant request. (**gms.kidneyfund.org**) If you have questions about registering please contact **patientservice@kidneyfund.org**.
7. You have the right to **receive a copy of your records** in GMS (grant request, supporting documents and grant history).
8. You have the right to **report to AKF any concerns about the application or grant process** without fear of retribution.
9. As a HIPP grant recipient or applicant, you have the right to **get answers to your questions directly from an AKF staff member**. You may contact us at **patientservice@kidneyfund.org** or call 800.795.3226.

Your Responsibilities

1. You have the responsibility to provide complete, accurate, and timely information on your HIPP personal profile and grant request, and inform AKF immediately about any changes to your contact information, financial status, dialysis provider or facility, or any other information that may impact your eligibility for HIPP.

2. If you change dialysis providers, it is your responsibility to inform your new provider or AKF directly that you receive grant assistance from AKF so that we may work with you in submitting future grant requests.

3. You have the responsibility to review your GMS patient profile information and grant request for accuracy and completeness. You should do so on a regular basis to be sure that all changes are captured and up to date.

4. You have the responsibility to share information relevant to an AKF grant (i.e. change in address, financial situation, insurance changes, etc.) in a timely fashion on your own through GMS or with your renal professional1 or caregiver, who will assist you in completing the application and submitting it to AKF. You may currently go to your account in GMS and download the patient profile worksheet and complete that for your renal professional or you may complete your information online through GMS.

5. You have the responsibility to make sure that your current health insurance bills are uploaded into GMS in a timely manner. This will allow AKF to process your grants so that premiums are paid on time.

6. You have the responsibility to read the HIPP Guidelines, Patient Handbook and patient information materials provided to you by AKF through GMS and your renal professional and ask questions about anything that you do not understand. These documents are also available online: **kidneyfund.org/information.**

7. You are ultimately responsible for your own health insurance coverage, including timely payment of premiums. AKF offers no guarantee of an initial grant or renewal of grants. If you qualify for assistance from HIPP, AKF will provide a grant to help cover premiums so long as HIPP funds are available. AKF reserves the right to modify or discontinue HIPP assistance if funding becomes limited or for any other reason.

   If you are planning to have a kidney transplant, it is extremely important that you understand that AKF will provide health insurance premium help through the end of the insurance coverage plan year. To be eligible for this post-transplant assistance you must already have been receiving HIPP assistance for at least three consecutive months immediately preceding the transplant. You must work with your dialysis social worker

[1] Renal professional means your dialysis facility's social worker, financial coordinator, insurance counselor or other staff member responsible for assisting patients with the insurance coverage and other financial aspects of their care.

and transplant center to make sure that they understand your post-transplant coverage and related health insurance premium grants or you may update your patient profile in AKF's GMS to reflect that you have received a transplant.

8. You are responsible for all aspects of your health insurance plan. The receipt of financial assistance from HIPP does not alter the fact that health insurance coverage represents a contractual relationship solely between you and your health insurance plan, not between AKF and the health insurance plan.

9. If there is an overpayment for your insurance and that amount is refunded to you, you must send the refunded amount to AKF so that we may place these funds in the HIPP pool for use for other eligible patients.

10. You have responsibility to promptly inform your provider staff and/or AKF if you believe that any of these rights have been violated. You may reach AKF bycontacting 800.795.3226 or **patientservice@kidneyfund.org**.

WHAT IS HIPP?

HIPP is a charitable program run by AKF that provides grants to financially eligible patients with kidney failure. The grants help pay for medical insurance premiums.

HIPP grants help with premium payments for:

- Medicare Part B
- Medicare Advantage (Part C)
- Medicaid (if your state requires a premium payment)
- Medigap/Medicare Supplemental
- Commercial plans (including Marketplace plans)
- Employer Group Health Plans (EGHP)
- COBRA plans

HIPP grants do not:

- Help with copays, spend-downs or medical device purchases.
- Locate or recommend insurance policies or dialysis facilities or other health care providers.
- Assist with dental and vision insurance.
- Cover union dues.

HIPP ELIGIBILITY

In order to qualify for HIPP, you must:

- Receive dialysis treatment for end-stage renal disease (ESRD).
- Be currently enrolled in or applying for health insurance coverage.
- Live in the U.S. or its territories.
- Show that you cannot afford your health coverage.
  - AKF will review your household income, reasonable expenses and liquid assets (such as savings accounts and investment accounts) before granting help.
  - Monthly household income may not be $600 more than reasonable monthly expenses. If you have no income at the time of application, you will need to provide an explanation.
  - Total liquid assets may not be more than $7,000. (IRAs and other retirement accounts are excluded and are not counted towards this amount.)
- For transplant patients seeking HIPP assistance, you must have been on HIPP for at least three months prior to receiving your kidney transplant.
- Carefully review all forms of health insurance coverage (Medicare, Medicaid, Medigap, COBRA, EGHP, and commercial insurance) and available assistance for paying health insurance premiums (Medicaid, state and local assistance, other charitable organizations), and select the combination that best serves your specific medical and financial needs. The selection of health insurance is your choice. AKF will ask you to acknowledge that you have selected the health insurance for which you are requesting help.

NOTE: If you get a kidney transplant you may be eligible for continued assistance for the remainder of your current health insurance policy year based on the following:

- You must update your GMS profile to show you are a transplant patient.
- You must update your clinic information to your current transplant center.
- You must request a grant for the same insurance AKF assisted with prior to your transplant.
- You must request assistance within three months of your transplant date.

Although you may receive HIPP assistance from AKF, remember that it is your health insurance policy. The contract is between you and the insurance company. You are responsible for understanding all of the terms of your contract and for making sure that your health insurance premium is paid on time.

For more HIPP information and rules, please review the **HIPP Guidelines** available through your dialysis team or on GMS.

HOW DO I APPLY?

You have the ability to create your own eligibility profile on **gms.kidneyfund.org**, or you can allow your renal professional or a caregiver create an eligibility profile on your behalf.

1. HIPP Eligibility Application

AKF uses the **HIPP patient profile** to help determine if you are eligible for financial help from AKF.

If you wish to apply for assistance by yourself, please complete the following steps:

- Read the **HIPP Guidelines**. Make sure you ask AKF or your dialysis team about anything that you do not understand.
- Go to **gms.kidneyfund.org** and click on the **Register** button. Follow the steps on the webpage. A detailed **registration walkthrough** can be found at the end of this Handbook.
- Read, sign, date and date the **HIPP consent form** (and upload it to your profile within the **Agreements** tile.

If you allow your renal professional to create your eligibility profile, please complete the following steps:

- Read the **HIPP Guidelines**. Make sure you ask AKF or your dialysis team about anything that you do not understand.
- Fill out the **HIPP worksheet** with your dialysis team. The application requires financial, medical and other information about you.
- Read, sign, date and date the **HIPP consent form**.
- Give the worksheet and consent form to your renal professional to start the application process.

If you allow your caregiver to create your eligibility profile, please complete the following steps:

- Read the **HIPP Guidelines**. Make sure you ask AKF or your dialysis team about anything that you do not understand.
- Fill out the **HIPP worksheet** with your caregiver. You will need to provide financial, medical and other information about you.
- Read, sign, date and date the **HIPP consent form**.
- Provide your caregiver's name and signature on the consent form.
- Give the worksheet and consent form to your caregiver to start the application process.
- Your caregiver can start the registration and profile creation process at **gms.kidneyfund.org**.

2. HIPP Grant Requests

HIPP grant requests are submitted for assistance in paying insurance premiums.

If you wish to enter your own grant request, please complete the following steps:

- After you have created your profile in GMS, click on **Grant Program Eligibility** from your dashboard.
- Click on **Apply Now** for the grant program that you are requesting assistance from.
- Follow the steps within the grant request process. Please note that you will need to upload your insurance bill, know your requested amount and coverage dates.

If you allow your renal professional to enter your grant request, please complete the following steps:

- Provide your dialysis renal professional with a health insurance bill or statement dated within the last three months.
- Your dialysis team will enter the grant request into GMS.

If you allow your caregiver to enter your grant request, please complete the following steps:

- Provide your caregiver with a health insurance bill or statement dated within the last three months.
- Your caregiver will enter the grant request into GMS.

AKF reviews grant requests within 10-14 business days. If your grant is approved, a payment will usually be issued in two business days.

REQUIRED DOCUMENTATION

As previously noted, AKF requires that you provide an insurance bill in order to process your grant request. If your health insurance does not send a bill or payment coupon, AKF will usually accept the following documents in place of a current bill:

Employer Group Health Plan (EGHP)

A letter from the employer that includes:

- Monthly amount for medical portion
- Name of employee
- Name of patient (if not employee and indicate the relationship to employee)
- Any surcharges (smokers, union, weight, or other fees)

Annuity Plans

- Document that shows an amount taken out of the patient's retirement/annuity fund for health insurance
- Must be current and be from the annuity supplier or employer if the patient is still employed.

COBRA

- If your COBRA administrator does not send bills/coupons, AKF can accept a letter from the COBRA administrator from the current year noting the amount of the monthly or quarterly premium.

Medicare

- CMS-500 (dated within 90 days of the grant request)
- Awards/Entitlement Letter (within 60 days of the letter's issue date)
- Termination Letter (within 30 days of the letter's issue date)

Things to remember:

- All bills/invoices/other accepted documents must reference the insured's name, policy number and coverage period. This information must match the grant payment request.
- If you change insurances, update your profile in GMS or tell your dialysis team or caregiver. Please also enter a new grant request after you update your profile if you have applied by yourself, or provide your dialysis team or caregiver with a new insurance application or bill.
- If your premium increases or decreases, please submit a new grant payment request if you have applied by yourself, or bring a current bill to your renal professional or your caregiver to submit a new grant payment request.

If you have any questions regarding your application or grant request, please contact AKF at 1-800-795-3226, message AKF through **GMS messages**, or email **patientservice@kidneyfund.org**.

GRANT PAYMENTS

Once approved, all grant payments are issued by check, debit card, or direct deposit.

When possible, AKF will send grant payments directly to the insurance company. However, some insurance companies do not accept payments directly from AKF. In such cases, AKF will mail checks or debit cards to either your dialysis/transplant center or to your home address. Please review your GMS profile and make any updates if necessary. If your insurance company accepts AKF grant payments, the only option will be to send it directly to the insurance company.

GRANT PAYMENT: CHECKS

If you receive a check at your dialysis/transplant center or your home address, do not endorse and/or send it to the insurance company as it will not be accepted. Instead, please follow the steps below:

GRANT PAYMENT: DEBIT CARDS

Debit cards are a payment method instituted by AKF for some, but not all, insurance plans. **AKF-issued debit cards will ONLY allow you to pay your insurance premiums. They may not be used for any other purpose.**

How do I use my HIPP debit card?

- You must activate the debit card before using it.
- The PIN number is your date of birth in this form (MM/DD/YYYY). Please press pound (#) after you enter your PIN. If your birthdate has been entered in GMS incorrectly, a new grant request will need to be entered and a new card will need to be issued.

If your insurance company requires a zip code to verify the payment, please use **your home zip code** (as it appears in your GMS patient profile).

4 Easy Steps to Using Your HIPP Debit Card

What will I receive?

- An actual plastic debit card (mailed to your home or dialysis facility) with each new grant payment.
- A letter of explanation and step-by-step instructions in English (as pictured above) and in Spanish.

What else do I need to know?

- Cards are valid for 90 days. Once your card expires, it will not be reissued.
- If you lose your debit card, you, your dialysis/transplant team or caregiver must contact AKF so we can void the card and a new one-time grant request will need to be entered if the payment is still needed. You **cannot** request a new card directly from the debit card provider.
- For security reasons AKF does not have access to the debit card information (card number, etc.) and cannot give it to you if the card is lost or stolen.
- Each debit card is for a specific coverage period and will not be reloaded or reused.
- For any debit card related questions, please message AKF within GMS Messages.

Who do I contact if I have questions?

- Questions sent about a debit card related grant (including lost or cards not received) should be directed to AKF at **patientservice@kidneyfund.org** or by messaging AKF through **GMS Messages** or by calling **1-855-541-0950**.

GRANT PAYMENT: DIRECT DEPOSIT

In those cases where an insurance company does not accept third-party payments or AKF is reimbursing the patient, AKF offers the ability to receive your HIPP grant by ACH/direct deposit to your bank account.

If you have chosen this method of receiving your grant payment, you will be prompted to enter your banking information, including routing and account number. For security reasons, AKF does not store this information within GMS.

ACH/direct deposit will go directly into your bank checking or savings account. A list of insurance companies that do not accept third-party payments directly from AKF is available within GMS.

FREQUENTLY ASKED QUESTIONS ABOUT HIPP

Is my grant considered income?

No. In accordance with Internal Revenue Code Section 102, all AKF grants are charitable gifts, which are not considered gross income. Additionally, you will not receive tax forms from AKF, because AKF's grant to you is a charitable gift, not taxable income.

Can AKF pay for more than two health insurance premiums?

No. AKF only provides premium assistance for maximum of two health insurance policies.

I'm receiving HIPP grants and I just received a transplant; can I still receive HIPP assistance?

Yes—after a transplant, AKF will continue to provide financial assistance to you for your current insurance plan year. For example, if you have a calendar year policy and you get a transplant on April 2 and AKF has paid your insurance premium for the quarter January 1-March 31, your grant assistance will end on December 31. If you are already receiving or are applying for assistance from HIPP, talk to your transplant center to make sure that receiving assistance from AKF will not affect your kidney transplant eligibility. In order to receive HIPP grant assistance after your transplant, you must have been a HIPP recipient for at least three months prior to receiving the transplant.

What if I received a termination/delinquent (past due) payment notice?

If you receive a past due notice, if you are in a grace period, either you, your dialysis/transplant center, or caregiver will need to enter a **one-time** grant request for the past due amount.

With most insurance companies there is a grace period in which a payment can be made before the account is terminated. If you are in the grace period, contact your dialysis team immediately for help submitting a grant request to AKF. If you have applied directly through AKF, please contact your AKF contact or call 1.800.795.3226/ email **patientservice@kidneyfund.org**.

If your insurance is terminated, please contact your insurance company to determine if you can get your insurance reinstated. A reinstatement letter or a new policy will be required to get future help from AKF.

Will AKF pay my family or spouse/domestic partner's portion of the insurance plan?

AKF only pays for the patient's portion of a family plan. Please contact your plan administrator for a breakdown of the insurance coverage. If the premium is being

deducted from your spouse/domestic partner's paycheck, please provide the necessary documentation that details your portion of the insurance premium.

My insurance company hasn't received my payment, what should I do?

You should check your grant payment status in GMS. If you do not have access to the internet, please contact your caregiver or your dialysis/transplant center to check your grant payment status in GMS.

You may then need to contact your insurance company directly to find out why the payment has not yet been credited.

For more information on how to register to GMS, please refer to the **Patient Registration Guide** attached to this Handbook.

What if I receive a refund check from my insurance company?

Any premium refund in connection with any health insurance plan paid by AKF is the property of AKF and must be promptly returned. These refunds are deposited into the HIPP funding pool to support others in the program. If you do not return the refund to AKF, you may be ineligible for future HIPP assistance.

What if I require a loved one or caregiver to speak to AKF on my behalf?

AKF requires that your caregiver information be provided through your consent/acknowledgement form and stored within your GMS account profile.

I've switched dialysis centers. Can I still get help from AKF?

Yes, regardless of where you dialyze, AKF will provide assistance to you. Please update your facility information on your GMS profile. You may also ask your new dialysis/transplant center to put in your grant requests. If your new center is not registered in AKF's GMS, please have them contact AKF at 1-800-795-3226 or at **patientservice@kidneyfund.org**. The registration process for a new center is quick and simple. If your new center declines to help you with the HIPP application process, please contact AKF at **1-800-795-3226**, through **GMS messages**, or by emailing **patientservice@kidneyfund.org**.

How do I edit my profile or grant request?

Please refer to the **Resources** tab in GMS for detailed instructions on how to edit any information within your GMS profile.

What if I am experiencing technical issues?

Please contact AKF via GMS chat or please call 800-795-3226.

What if I cannot cash a check?

If you are unable to cash your check, log on to GMS and send a **GMS chat message** explaining the situation. An AKF representative will assist you.

What is a plan year?

Your policy plan year is determined based upon your policy effective date and the amount of time your premium is effective. Please contact your insurance company if you need to know what your plan year is.

Can you accept screenshots?

Yes. Please be sure the screenshot is legible and clear. All necessary information needs to be visible within the screenshot.

What information needs to be on a bill?

The patient name, requested amount and coverage dates, date the bill was created, policy ID number and the remittance address for the insurance company need to be printed on the bill. If the amount requested is not clearly shown on the bill, a breakdown of the requested amount will be needed as well.

What to do if my insurance has termed?

- In the case that your insurance has termed, contact your insurance company for information on whether or not the policy can be reinstated and cancel any future payments for the terminated insurance within GMS.
- If the policy can be reinstated enter a grant request with a document from the insurance company showing the owed amount for reinstatement.
- If the policy cannot be reinstated, you will need to enroll in a new insurance plan in order to continue receiving Health Insurance Premium Assistance from AKF.

My bill is due today. What do I do?

It's important to submit grant requests to AKF in a timely manner, because it takes 10-14 business days for AKF to process a grant request. In the case that you have a payment due, it is your responsibility to maintain your health insurance coverage. AKF will not process grant requests out of order.

Where is my check?

We send our checks via USPS. You may log onto GMS to check the status and the address of the check.

What type of insurance do I have?

Please contact your insurance company to inquire about your insurance type or please look for the insurance type on your premium bill.

How do I upload documents from my computer?

Please refer to the document titled **How to Upload Documents** in the **Resources** tab on GMS.

How long will it take my grant to be processed?

Please allow 10-14 business days for pending grant requests to be processed.

What other expenses does AKF assist with?

AKF assists with health insurance premiums, reimbursement costs for transportation to and from dialysis, over-the-counter medicines, co-payments; and other needs, for example, dentures.

Do you help international patients?

AKF assists all people who reside within the United States and its territories.

Do you help undocumented patients?

AKF assists all people who reside within the United States and its territories.

How do I remove a caregiver or renal professional from my account?

Please update your profile in GMS in the **Contacts** section. You may add or remove renal professionals and caregivers in this section.

How often do I need to apply?

You will need to update your profile once a year. You will also need to request a new grant request if you are in a new policy year or if your policy has changed. Please remember that you can create "one-time" grant requests that can be used to pay for balance due requests.

How do I upload documents from my phone?

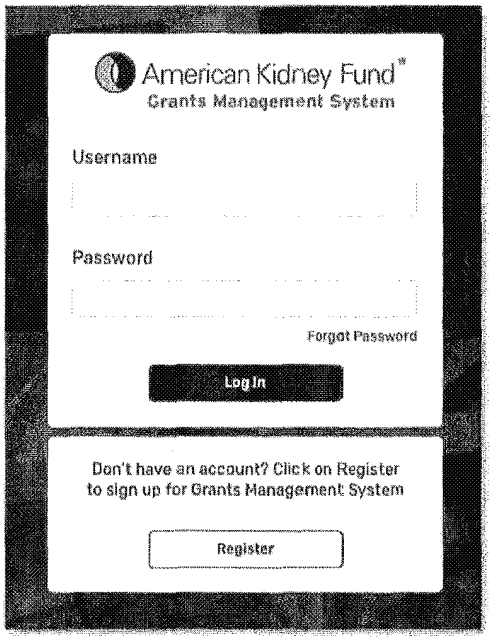
You can upload documents by emailing them as images on your cellphone:

1. Take the photo using the photo app and save it on your phone.
2. Tap the **Share** icon and choose your desired email.
3. **Select** the photo(s) you want to email.
4. Tap the **Next** button to attach the photos to the email.
5. Compose your email and send.

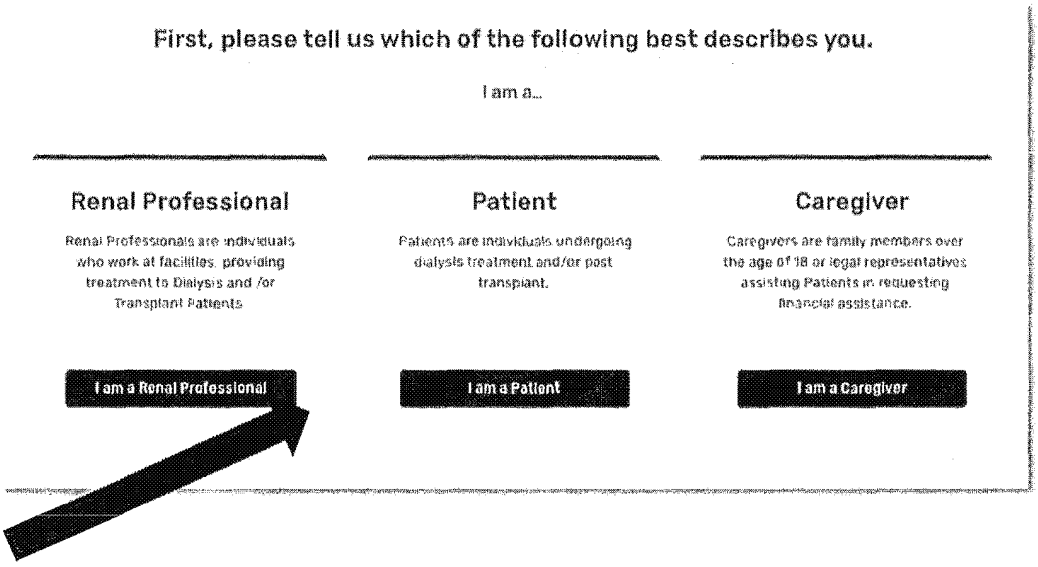
APPENDIX 1: GMS PATIENT PROFILE REGISTRATION GUIDE

The following Patient profile registration guide provides step-by-step instructions for the profile registration process. If you have questions, please contact AKF at **patientservice@kidneyfund.org** or call 1-800-795-3226.

Step One: To start the registration process, please click the **Register** button:



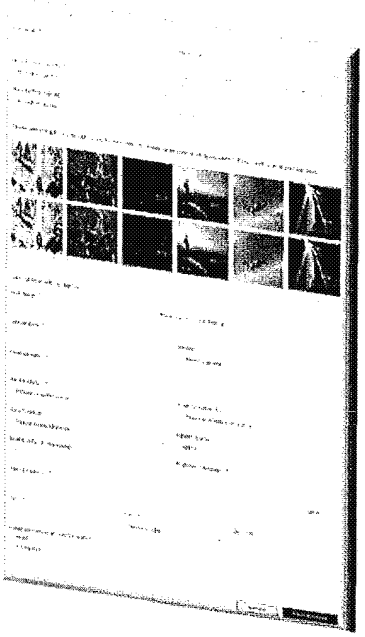
Step Two: Click **I am a Patient** to start the registration process:



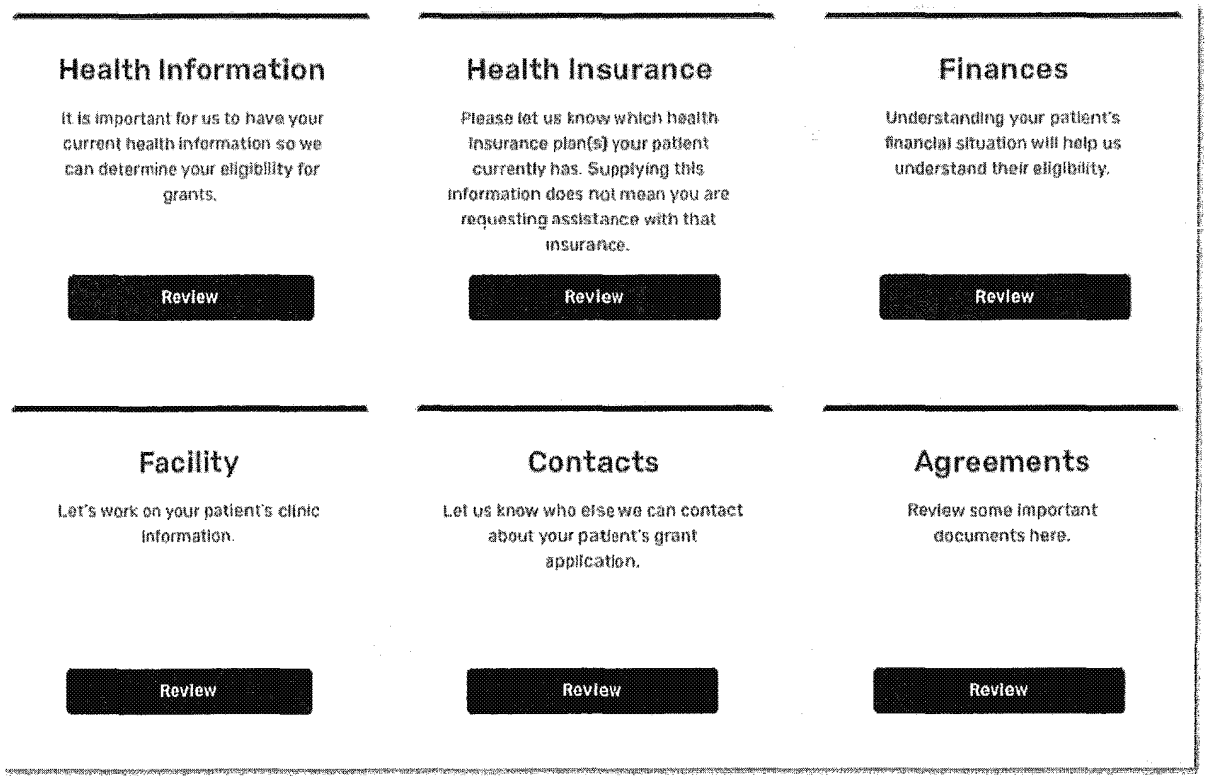
Step Three:

- Please fill out every information box on this page. Please also select an image by clicking on it. This image will be used to verify your identity if you need to reset your password. When finished, click **Create My Account**.

- You will receive a verification email at the address you provided. Remember to verify your profile by following the instructions within the verification email.



Step Four: Please follow the step-by-step instructions for each of the sections shown in the screenshot below. Each section asks specific questions on your health history, insurance information, personal finances, dialysis facility information, contact information, and important/relevant documents.



Have questions? Need assistance?

Call 1-800-795-3226
or email:
patientservice@kidneyfund.org

11921 Rockville Pike, Suite 300 | Rockville, MD 20852
Phone: 800-638-8299

KidneyFund.org

EXHIBIT 1c

Centers for Medicare & Medicaid Services rulemaking process, produced in Defendants' Production No. 4

V. Proposed Action

With the exception of interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance in other states and visibility protection requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4), EPA is proposing to approve Georgia's December 14, 2015, SIP submission, for the 2012 Annual $PM_{2.5}$ NAAQS for the above described infrastructure SIP requirements. EPA is proposing to approve Georgia's infrastructure SIP submission for the 2012 Annual $PM_{2.5}$ NAAQS because the submission is consistent with section 110 of the CAA.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 9, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2016–20139 Filed 8–22–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 402, 420, and, 455

[CMS–6074–NC]

RIN 0938–ZB31

Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for information.

SUMMARY: This request for information seeks public comment regarding concerns about health care providers and provider-affiliated organizations steering people eligible for or receiving Medicare and/or Medicaid benefits to an individual market plan for the purpose of obtaining higher payment rates. CMS is concerned about reports of this practice and is requesting comments on the frequency and impact of this issue from the public. We believe this practice not only could raise overall health system costs, but could potentially be harmful to patient care and service coordination because of changes to provider networks and drug formularies, result in higher out-of-pocket costs for enrollees, and have a negative impact on the individual market single risk pool (or the combined risk pool in states that have chosen to merge their risk pools). We are seeking input from stakeholders and the public regarding the frequency and impact of this practice, and options to limit this practice.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 22, 2016.

ADDRESSES: In commenting, refer to file code CMS–6074–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the "Submit a comment" instructions.
2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–*6074*–NC, P.O. Box 8010, Baltimore, MD 21244–*8010*.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–*6074*–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.
4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots

located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Morgan Burns, 301–492–4493.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

This is a request for information only. Respondents are encouraged to provide complete but concise responses to the questions listed in the sections outlined below. Please note that a response to every question is not required. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals.

Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that CMS will not respond to questions about the policy issues raised in this RFI. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

I. Background

The Centers for Medicare & Medicaid Services (CMS) believes that when health care providers or provider-affiliated organizations steer or influence people eligible for or receiving Medicare and/or Medicaid benefits, it may not be in the best interests of the individual, it may have deleterious effects on the insurance market, including disruptions to the individual market risk pool, and it is likely to raise overall healthcare costs. Individuals eligible for Medicare and/or Medicaid benefits are not required to enroll in these programs.[1] However, individuals eligible for Medicaid or Medicare Part A benefits are generally ineligible for the premium tax credit (PTC), including advance payments thereof (APTC), and for cost-sharing reductions (CSR) for their Qualified Health Plan (QHP) coverage for the months they have access to minimum essential coverage (MEC) through the Medicare or Medicaid programs.[2]

We have heard anecdotal reports that individuals who are eligible for Medicare and/or Medicaid benefits are receiving premium and other cost-sharing assistance from a third party so that the individual can enroll in individual market plans for the provider's financial benefit. In some cases, a health care provider may estimate that the higher payment rate from an individual market plan compared to Medicare or Medicaid is sufficient to allow it to pay a patient's premiums and still financially gain from the higher reimbursement rates. Issuers are not required to accept such payments from health care providers or provider-affiliated organizations, as described below. Enrollment decisions should be made, without influence, by the individual based on their specific circumstances, and health and financial needs. CMS has established standards for enrollment assisters, including navigators, which prohibit gifts of any value as an inducement for enrollment, and require information and services to be provided in a fair, accurate, and impartial manner.[3] Additionally, CMS has established standards for insurance agents and brokers that register with the Federal Marketplace, including training about the interaction of Medicare and Medicaid eligibility with eligibility for individual market plans and financial assistance, and has remedies for insurance agents that provide inaccurate or incorrect information to consumers, such as misinformation about the impact of not enrolling in Medicare when an individual first becomes eligible, including termination of the Marketplace agreement, civil monetary penalties, and denial of right to enter agreements in future years.[4]

We believe there is potential for financial harm to a consumer when a health care provider or provider-affiliated organization (including a non-profit organization affiliated with the provider) steers people who could receive or are receiving benefits under Medicare and/or Medicaid to enroll in an individual market plan. The potential harm is particularly acute when the steering occurs for the financial gain of the health care provider through higher payment rates

[1] Individuals eligible to receive premium free Medicare Part A benefits may not decline Medicare Part A entitlement if they accept Social Security benefits.

[2] See 26 U.S.C. 36B. In general, an individual who is eligible for minimum essential coverage (other than coverage in the individual market) for a month is ineligible for the premium tax credit for that month. Medicare part A and most Medicaid programs are minimum essential coverage. See 26 U.S.C. 5000A(f) and 26 CFR 1.5000A–2(b).

[3] 45 CFR 155.210.

[4] 45 CFR 155.220.

without taking into account the needs of these beneficiaries. People who are steered from Medicare and Medicaid to the individual market may also experience a disruption in the continuity and coordination of their care as a result of changes in access to their network of providers, changes in prescription drug benefits, and loss of dental care for certain Medicaid beneficiaries. If an individual receives the benefit of APTC for a month he or she is eligible for minimum essential coverage, the individual (or the person who claims the individual as a tax dependent) may be required to repay some or all of the APTC at the time such person files his or her federal income tax return. Moreover, it is unlawful to enroll an individual in individual market coverage if they are known to be entitled to benefits under Medicare Part A, enrolled in Medicare Part B, or receiving Medicaid benefits. Importantly, those eligible for Medicare may be subject to late enrollment penalties if they do not enroll in Medicare when first eligible to do so—a monthly premium for Part B may go up 10 percent for each full 12-month period an individual could have had Part B, but did not sign up for it.[5] Individuals who become eligible for Medicare based on receipt of Social Security benefits based on age or Social Security Disability Insurance (SSDI) must forgo and if received repay their Social Security cash benefits if they wish to decline Medicare Part A benefits.[6] Additionally, individuals who are steered into an individual market plan for renal dialysis services and then have a kidney transplant while enrolled in the individual market plan will not be eligible for Medicare Part B coverage of their immunosuppressant drugs if they enroll in Medicare at a later date.[7]

Federal regulations at 45 CFR 156.1250 require that issuers offering Qualified Health Plans (QHPs), including stand-alone dental plans, and their downstream entities, accept premium and cost-sharing payments on behalf of QHP enrollees from the following third-party entities (in the case of a downstream entity, to the extent the entity routinely collects premiums or cost sharing): (a) A Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act; (b) an Indian tribe, tribal organization, or urban Indian organization; and (c) a local, state, or Federal government program, including a grantee directed by a government program to make payments on its behalf.[8] Issuers are not required to accept such payments from other entities. These regulations were finalized in the 2017 HHS Notice of Benefit and Payment Parameters Final Rule, which made several amendments to the regulations previously codified through a March 19, 2014, HHS Interim final rule (IFR) with comment period titled, Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums (79 FR 15240).

Prior to publishing the IFR, HHS issued two ''Frequently Asked Questions'' (FAQ) documents regarding premium and cost-sharing payments made by third parties on behalf of individual market plan enrollees. In an FAQ issued on November 4, 2013 (the November FAQ), HHS discouraged QHP issuers from accepting third-party payments made on behalf of enrollees by hospitals, other health care providers, and other commercial entities due to concerns that such practices could skew the insurance risk pool and create an unlevel field in the Exchanges. The FAQ also noted that HHS intended to monitor this practice and to take appropriate action, if necessary.

On February 7, 2014, HHS issued another FAQ (the February FAQ) clarifying that the November FAQ did not apply to third party premium and cost-sharing payments made on behalf of enrollees by Indian tribes, tribal organizations, and urban Indian organizations; state and Federal government programs (such as the Ryan White HIV/AIDS Program); or private, not-for-profit foundations that base eligibility on financial status, do not consider enrollees' health status, and provide assistance for an entire year. In the February FAQ, HHS affirmatively encouraged QHP issuers to accept payments from Indian tribes, tribal organizations, and urban Indian organizations; and state and Federal government programs (such as the Ryan White HIV/AIDS Program) given that Federal or state law or policy specifically envisions third party payment of premium and cost-sharing amounts by these entities.

CMS seeks to clarify that offering premium and cost-sharing assistance in order to steer people eligible for or receiving Medicare and/or Medicaid benefits to individual market plans for a provider's financial gain is an inappropriate action that may have negative impacts on patients. CMS is strongly encouraging any provider or provider-affiliated organization that may be currently engaged in such a practice to end the practice. As noted above, enrollment decisions should be made based on an individual's particular financial and health needs.

As we assess the extent of potential steering activities, its impact on beneficiaries and enrollees and the individual market single risk pool, CMS reminds healthcare providers and other entities that may be engaged in such behavior that we have several regulatory and operational tools that we may use to discourage premium payments and routine waiver of cost-sharing for individual market plans by health care providers, including, but not limited to, revisions to Medicare and Medicaid provider conditions of participation and enrollment rules, and imposition of civil monetary penalties for individuals who failed to provide correct information to the Exchange when enrolling consumers into QHPs.[9] CMS is also working closely with federal, state and local law enforcement to investigate instances of potential fraud and abuse, as well as collaborating with private and public health plans on provider fraud in the Healthcare Fraud Prevention Partnership.[10] We are exploring ways to use our existing authorities to impose civil monetary penalties on health care providers when their actions result in late enrollment penalties for Medicare eligible individuals who were steered to an individual market plan and delayed Medicare enrollment.

II. Solicitation of Comments

We are seeking information from the public about circumstances in which steering into individual market plans may be taking place and the extent of such practices. We are particularly interested in transparency around the current practices providers may be using to enroll consumers in coverage. Our goal is to protect consumers from inappropriate health care provider behavior. People eligible for or receiving Medicare and/or Medicaid benefits should not be unduly influenced in their decisions about their health coverage options. We also seek to maintain continuity of care for these beneficiaries and ensure patient choice is the primary reason for any change in health coverage. We also want to ensure healthcare is being provided efficiently

[5] *https://www.medicare.gov/your-medicare-costs/part-b-costs/penalty/part-b-late-enrollment-penalty.html.*

[6] *https://www.cms.gov/Outreach-and-Education/Find-Your-Provider-Type/Employers-and-Unions/Top-5-things-you-need-to-know-about-Medicare-Enrollment.html.*

[7] *https://www.medicare.gov/coverage/prescription-drugs-outpatient.html.*

[8] 2017 HHS Payment Notice Final Rule.

[9] 45 CFR 155.285 Bases and process for imposing civil penalties for provision of false or fraudulent information to an Exchange or improper use or disclosure of information.

[10] See *https://hfpp.cms.gov/* for more information.

and affordably. Accordingly, to more fully understand the types of situations in which steering may occur as we develop regulatory or operational changes to address these problems, we request comments on the following:

- In what types of circumstances are healthcare providers or provider-affiliated organizations in a position to steer people to individual market plans? How, and to what extent, are health care providers actively engaged in such steering?
- What impact is there to the single risk pool and to rates when people enter the single risk pool who might not otherwise have been in the pool because they would normally be covered under another government program? Are issuers accounting for this uncertainty when they are setting rates?
- Are there examples of steering practices that specifically target people eligible for or receiving Medicare and/or Medicaid benefits to enroll in individual market plans? In what ways are people eligible for or receiving Medicare and/or Medicaid benefits particularly vulnerable to steering? To what extent, if any, are providers steering people eligible for or receiving Medicare and/or Medicaid to individual market plans because they are prohibited from billing the Medicare and Medicaid programs, through exclusion by the HHS Office of Inspector General, termination from State Medicaid plans or the revocation of Medicare billing privileges?
- Is the payment of premiums and cost-sharing commonly used to steer individuals to individual market plans, or are other methods leading to Medicare and Medicaid eligible individuals being enrolled in individual market plans? Specifically, how often are issuers receiving payments directly from health care providers and/or provider affiliated organizations? Are issuers capable of determining when third party payments are made directly to a beneficiary and then transferred to the issuer? What actions could CMS consider to add transparency to third party payments?
- How are enrollees impacted by the practice of a health care provider or provider-affiliated organizations enrolling an individual into an individual market plan and paying premiums for that individual market plan, when the individual was previously or concurrently receiving Medicare and/or Medicaid benefits? We are concerned about instances where individuals eligible for Medicare and/or Medicaid benefits may have been disadvantaged by unscrupulous practices aimed at increasing provider payments, including impacts to the enrollee's continuity of care. We would be interested in knowing more about these practices and the extent to which they may be more widespread or varied than we have identified.
- How are enrollees impacted by the practice of a health care provider enrolling an individual into an individual market plan and paying premiums for individual market plans, when the individual was eligible for Medicare and/or Medicaid, but not enrolled? We are particularly interested in information about how to measure negative impacts on beneficiaries and enrollees, and what data sources and measurement methodologies are available to assess the impact of this behavior described in this request for information on beneficiaries and enrollees. We are seeking information on any financial impacts that are in addition to Medicare late enrollment penalties. For example, differentials in copayments and deductibles paid by enrollees in individual market plans, Medicare or Medicaid, and the impact of individual market plan network limitations on the financial obligations of enrollees, such as increased copayments and deductibles where the enrollee's chosen provider is out-of-network to the individual market plan.
- What remedies could effectively deter health care providers or provider-affiliated organizations from steering people eligible for or enrolled in Medicare and/or Medicaid to individual market plans and paying premiums for the provider's financial gain? CMS is considering modifying regulations regarding civil monetary penalties and authority related to individual market plans.
- What steps do third party payers take to effectively screen for Medicare and/or Medicaid eligibility before offering premium assistance? What steps do these entities take to make sure that any such individuals understand the impact of signing up for an individual market plan if they are already eligible for or receiving Medicare and/or Medicaid benefits?
- For providers that offer premium assistance, who is interacting with beneficiaries to determine proper enrollment? What questions are asked of the consumer to determine eligibility pathways? How are consumers connected to foundations or others who are in the position to provide premium assistance? How are premiums paid by providers or foundations for consumers?
- We seek comment on policies prohibiting providers from making offers of premium assistance and routine cost-sharing waivers for individual market plans when a beneficiary is currently enrolled or could become enrolled in Medicare Part A and other adjustments to federal policy on premium assistance programs in the individual market to prevent negative impact to beneficiaries and the single risk pool.
- We seek comments on changes to Medicare and Medicaid provider enrollment requirements and conditions of participation that would potentially restrict the ability of health care providers to manipulate patient enrollment in various health plans for their own benefit. We are also interested in information on the extent steering is associated with other inappropriate behavior, such as billing for services not provided, or quality of care concerns. We seek comment on the advisability of such restrictions, as well as considerations of how such restrictions would affect health care providers and beneficiaries.
- We seek comment on policies to require Medicare and Medicaid-enrolled providers to report premium assistance and cost-sharing waivers for individual market enrollees to CMS or issuers.
- We seek comments on whether individual market plans considered limiting their payment to health care providers to Medicare-based amounts for particular services and items of care and on potential approaches that would allow individual market plans to limit their payment to health care providers to Medicare-based amounts for particular services and items of care.
- We seek comment on policies that would allow individual market plans to make retroactive payment adjustments to providers, when health care providers are found to have steered Medicare or Medicaid beneficiaries and enrollees to enroll in an individual market plan for the provider's financial gain.

III. Collection of Information Requirements

This request for information constitutes a general solicitation of public comments as stated in the implementing regulations of the Paperwork Reduction Act at 5 CFR 1320.3(h)(4). Therefore, this request for information does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: August 16, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–20034 Filed 8–18–16; 4:15 pm]

BILLING CODE 4120–01–P

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This action merely determines that the HGB area failed to meet an ozone NAAQS attainment deadline, reclassifies the area, and sets the date when a revised SIP is due to EPA.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 13, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 8, 2016.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 81 is amended as follows:

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart SS—Texas

■ 2. In § 81.344, the table titled "Texas—2008 8-Hour Ozone NAAQS (Primary and secondary)" is amended by revising the entry for "Houston-Galveston-Brazoria, TX" to read as follows.

§ 81.344 Texas.

* * * * *

TEXAS—2008 OZONE NAAQS
[Primary and secondary][2]

Designated area	Designation		Classification	
	Date[1]	Type	Date[1]	Type
* * * * * * *				
Houston-Galveston-Brazoria, TX:[2]		Nonattainment	1/13/17	Moderate.
Brazoria County				
Chambers County				
Fort Bend County				
Galveston County				
Harris County				
Liberty County				
Montgomery County				
Waller County				
* * * * * * *				

[1] This date is July 20, 2012, unless otherwise noted.
[2] Excludes Indian country located in each area, unless otherwise noted.

* * * * *

[FR Doc. 2016–29999 Filed 12–13–16; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 494

[CMS–3337–IFC]

RIN 0938–AT11

Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements new requirements for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans. These requirements apply to dialysis facilities that make such payments directly, through a parent organization, or through a third party. These requirements are intended to protect patient health and safety; improve patient disclosure and transparency; ensure that health insurance coverage decisions are not

inappropriately influenced by the financial interests of dialysis facilities rather than the health and financial interests of patients; and protect patients from mid-year interruptions in coverage.

DATES: *Effective date:* These regulations are effective on January 13, 2017.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 11, 2017.

ADDRESSES: In commenting, please refer to file code CMS–3337–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3337–IFC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3337–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lauren Oviatt, (410) 786–4683, for issues related to the ESRD Conditions for Coverage.

Lina Rashid, (301) 492–4103, for issues related to individual market health plans.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Statutory and Regulatory Background

1. End-Stage Renal Disease, Medicare, and Medicaid

End-Stage Renal Disease (ESRD) is a kidney impairment that is irreversible and permanent. Dialysis is a process for cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. People with ESRD require either a regular course of dialysis or kidney transplantation in order to live.

Given the high costs and absolute necessity of transplantation or dialysis for people with failed kidneys, Medicare provides health care coverage to qualifying individuals diagnosed with ESRD, regardless of age, including coverage for kidney transplantation, maintenance dialysis, and other health care needs. The ESRD benefit was established by the Social Security Amendments of 1972 (Pub. L. 92–603). This benefit is not a separate program, but allows qualifying individuals of any age to become Medicare beneficiaries and receive coverage. Under the statute, individuals under 65 who are entitled to Medicare through the ESRD program, or individuals over age 65 who are diagnosed with ESRD while in Original Medicare, generally cannot enroll in Medicare Advantage. Additionally, as access to Medigap policies is generally governed by state law, individuals under age 65 who are entitled to Medicare through the ESRD program cannot sign up for a Medigap policy in many States.[1]

The ESRD Amendments of 1978 (Pub. L. 95–292), amended title XVIII of the Social Security Act (the Act) by adding section 1881 of the Act. Section 1881(b)(1) of the Act further authorizes the Secretary of the Department of Health and Human Services (the Secretary) to prescribe additional requirements (known as conditions for coverage or CfCs) that a facility providing dialysis and transplantation services to dialysis patients must meet to qualify for Medicare payment.

Medicare pays for routine maintenance dialysis provided by Medicare-certified ESRD facilities, also known as dialysis facilities. To gain certification, the State survey agency performs an on-site survey of the facility to determine if it meets the ESRD CfCs at 42 CFR part 494. If a survey indicates that a facility is in compliance with the conditions, and all other Federal requirements are met, CMS then certifies the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis is limited to facilities meeting these conditions. The ESRD CfCs were first adopted in 1976 and comprehensively revised in 2008 (73 FR 20369). There are approximately 6,737 Medicare-certified dialysis facilities in the United States, providing dialysis services and specialized care to people with ESRD.

In addition to Medicare, Medicaid provides coverage for some people with ESRD. Many individuals enrolled in

[1] Medigap policies are available to people under age 65 with ESRD only in the following states: Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Oklahoma, and Wisconsin.

Medicare may also qualify for full benefits under the Medicaid program on the basis of their income, receipt of Supplemental Security Income, being determined medically-needy, or other eligibility categories under the State Plan. In addition, low income individuals enrolled in Medicare may qualify for the Medicare Savings Program under which the state's Medicaid program covers some or all of the individual's Medicare premiums and, for some individuals, Medicare cost-sharing. Finally, some individuals who are not eligible for enrollment in Medicare may qualify for Medicaid.

According to data published by the United States Renal Data System (USRDS), Medicare is the predominant payer of ESRD services in the United States, covering (as primary or secondary payer) about 88 percent of the United States ESRD patients receiving hemodialysis in 2014. Among those enrolled in Medicare on the basis of ESRD and receiving hemodialysis in 2015, CMS has determined 41 percent were enrolled in both Medicare and Medicaid (including full and partial duals). Among those enrolled in Medicare on the basis of ESRD under age 65, 51 percent were dual enrollees.

2. The Affordable Care Act and Health Insurance Exchanges

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and the Affordable Care Act, was enacted on March 30, 2010. In this interim final rule with comment, we refer to the two statutes collectively as the ''Affordable Care Act.''

The Affordable Care Act reorganizes and amends the provisions of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act enacted a set of reforms to make health insurance coverage more affordable and accessible to millions of Americans. These reforms include the creation of competitive marketplaces called Affordable Insurance Exchanges, or ''Exchanges'' through which qualified individuals and qualified employers can purchase health insurance coverage.

In addition, many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible for advance payments of the premium tax credit (APTC) to make health insurance premiums more affordable, and cost-sharing reduction (CSR) payments to reduce out-of-pocket expenses for health care services. Individuals enrolled in Medicare or Medicaid are not eligible for APTC or CSRs. The Affordable Care Act also established a risk adjustment program and other measures that are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets.

The Public Health Service Act, as amended by the Affordable Care Act, generally prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from imposing any preexisting condition exclusions. Health insurers can no longer charge different cost sharing or deny coverage to an individual because of a pre-existing health condition. Health insurance issuers also cannot limit benefits for that condition. The pre-existing condition provision does not apply to ''grandfathered'' individual health insurance policies.

Beginning January 1, 2014, the Affordable Care Act prohibited insurers in the individual and group markets (with the exception of grandfathered individual plans) from imposing pre-existing condition exclusions. The Affordable Care Act's prohibition on pre-existing condition exclusions enables consumers to access necessary benefits and services, beginning from their first day of coverage. The law also requires insurance companies to guarantee the availability and renewability of non-grandfathered health plans to any applicant regardless of his or her health status, subject to certain exceptions. It imposes rating restrictions on issuers prohibiting non-grandfathered individual and small group market insurance plans from varying premiums based on an individual's health status. Issuers of such plans are now only allowed to vary premiums based on age, family size, geography, or tobacco use.

In previous rulemaking, CMS outlined major provisions and parameters related to many Affordable Care Act programs. This includes regulations at 45 CFR 156.1250, which require, among other things, that issuers offering individual market QHPs, including stand-alone dental plans, and their downstream entities, accept premium payments made on behalf of QHP enrollees from the following third party entities (in the case of a downstream entity, to the extent the entity routinely collects premiums or cost sharing): (1) A Ryan White HIV/AIDS Program under title XXVI of the PHS Act; (2) an Indian tribe, tribal organization, or urban Indian organization; and (3) a local, state, or Federal government program, including a grantee directed by a government program to make payments on its behalf. This regulation made clear that it did not prevent issuers from contractually prohibiting other third party payments. The regulation also reiterated that CMS discouraged premium payments and cost sharing assistance by certain other entities, including hospitals and other health care providers, and discouraged issuers from accepting premium payments from such providers.[2] Regulations at 45 CFR 156.1240 require issuers offering individual market QHPs to accept payment from individuals in the form of paper checks, cashier's checks, money orders, EFT, and all general-purpose pre-paid debit cards. Regulations at 45 CFR 147.104 and 156.805 prohibit issuers from discriminating against or employing marketing practices that discriminate against individuals with significant health care needs.

3. Anti-Duplication

Individuals who are already covered by Medicare generally cannot become concurrently enrolled in coverage in the individual market. Section 1882(d)(3) of the Act makes it unlawful to sell or issue a health insurance policy (including policies issued on and off Exchanges) to an individual entitled to benefits under Medicare Part A or enrolled under Medicare part B with the knowledge that the policy duplicates the health benefits to which the individual is entitled. Therefore, while an individual with ESRD is not required to apply for and enroll in Medicare, once they become covered by Medicare it is unlawful for them to be sold a commercial health insurance policy in the individual market if the seller knows the individual market policy would duplicate benefits to which the individual is entitled.[3] CMS has, moreover, solicited comments in a recent proposed rulemaking about whether it is unlawful in most or all cases to knowingly renew coverage under the same circumstances.[4]

[2] Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums; Final Rule, 79 FR 15240 (March 14, 2014).

[3] As discussed below, these anti-duplication standards—which govern the conduct of insurance companies, not health care providers—have not prevented inappropriate steering of individuals eligible for Medicare to individual market plans.

[4] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Proposed Rule, 81 FR 61455 (September 6, 2016).

4. HHS Request for Information on Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans

HHS has recently become concerned about the inappropriate ''steering'' of individuals eligible for or entitled to Medicare or Medicaid into individual market plans. In particular, HHS is concerned that because individual market health plans typically provide significantly greater reimbursement to health care providers than public coverage like Medicare or Medicaid, providers and suppliers may be engaged in practices designed to encourage individual patients to forego public coverage for which they are eligible and instead enroll in an individual market plan.[5] In other words, health care providers may be encouraging individual patients to make coverage decisions based on the financial interest of the health care provider, rather than the best interests of the individual patient. Further, as one tool to influence these coverage decisions, health care providers may be offering to pay for, or arrange payment for, the premium for the individual market plan.

Based on these concerns, in August 2016, CMS issued a request for information (RFI), titled ''Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans'', which published in the **Federal Register** on August 23, 2016, seeking comment from the public regarding concerns about health care providers and provider-affiliated organizations steering people into coverage that was of financial benefit to the provider, without regard to the impact on the patient (81 FR 57554). In response to this RFI, we received over 800 public comments by the comment closing date of September 22, 2016. Commenters included: Patients; providers and provider-affiliated organizations involved in the financing of care for patients; health insurance companies; social workers who are involved in counseling patients about potential health care coverage options; and other stakeholders. While commenters discussed patients with a variety of health care needs, the overwhelming majority of comments focused on patients with ESRD.

Comments indicated that dialysis facilities are involving themselves in ESRD patients' coverage decisions and that this practice is widespread. In addition, all commenters on the topic—including insurance companies, dialysis facilities, patients, and non-profit organizations—stated that they believe many dialysis facilities are paying for or arranging payments for individual market health care premiums for patients they serve.

Comments show that some ESRD patients are satisfied with their current premium arrangements. In particular, more than 600 individuals currently receiving assistance for premiums participated in a letter writing campaign in response to the RFI and stated that charitable premium assistance supports patient choice and is valuable to avoid relying on ''taxpayer dollars.''

However, comments also documented a range of concerning practices, with providers and suppliers influencing enrollment decisions in ways that put the financial interest of the supplier above the needs of patients. As explained further below, commenters detailed that dialysis facilities benefit financially when individuals enroll in individual market health care coverage. Comments also described that, even though it is financially beneficial to suppliers, enrollment in individual market coverage paid for by dialysis facilities or organizations affiliated with dialysis facilities can lead to three types of harm to patients: Negatively impacting their determination of readiness for a kidney transplant, potentially exposing patients to additional costs for health care services, and putting them at significant risk of a mid-year disruption in health care coverage. Based on these comments, HHS has concluded that the differences between providers' and suppliers' financial interests and patients' interests may result in providers and suppliers taking actions that put patients' lives and wellbeing at risk.

B. Individual Market Coverage Is in the Financial Interest of Dialysis Facilities

All commenters who addressed the issue made clear that enrolling a patient in commercial coverage (including coverage in the individual market) rather than public coverage like Medicare and/or Medicaid is of significant financial benefit to dialysis facilities. For example, one comment cited reports from financial analysts estimating that commercial coverage generally pays dialysis facilities an average of four times more per treatment ($1,000 per treatment in commercial coverage, compared to $260 per treatment under public coverage). For a specific subset of individual market health plans—QHPs—the analysts estimated that the differential could be somewhat smaller, but that QHPs would still provide an average of an additional $600 per treatment when compared to public coverage. Based on these reports, dialysis facilities would be estimated to be paid at least $100,000 more per year per patient if a typical patient enrolled in commercial coverage rather than public coverage, despite providing the exact same services to patients. Another commenter estimated that a dialysis facility would earn an additional $234,000 per year per patient by enrolling a patient in commercial coverage rather than Medicaid ($312,000 per year rather than $78,000 per year). A number of other commenters explained that commercial coverage reimburses dialysis facilities at significantly higher rates overall. These figures are consistent with other sources of data. For example, USRDS data show that for individuals with ESRD enrolled in Medicare receiving hemodialysis, health care spending averaged $91,000 per individual in 2014, including dialysis and non-dialysis services. By contrast, using the Truven MarketScan database, a widely-used database of health care claims, we estimate that average total spending for individuals with ESRD who are enrolled in commercial coverage was $187,000 in 2014. In addition, recent filings with a federal court by one insurance company concluded that commercial coverage could pay more than ten times more per treatment than public coverage ($4,000 per treatment rather than $300 per treatment).[6]

As described, the comments in response to the RFI, data related to CMS's administration of the risk adjustment program, and registry data from the USRDS demonstrate that dialysis facilities can be paid tens or even hundreds of thousands of dollars more per patient when patients enroll in individual market coverage rather than public coverage. On the other hand, the premiums for enrollment in individual market coverage average $4,200 per year according to data related to CMS's administration of the risk adjustment program. Dialysis facilities therefore have much to gain financially (on the order of tens or even hundreds of thousands of dollars per patient) by making a relatively small outlay to pay

[5] Throughout this Interim Final Rule with Comment, the term ''public coverage'' is intended to refer to Medicare and Medicaid, not to a group health plan or health insurance purchased in the individual market in a state. A qualified health plan (QHP) purchased through an Exchange is individual market coverage, not public coverage.

[6] Davita encouraged some low-income patients to enroll in commercial plans; (Oct 23, 2016). *http://www.stltoday.com/business/local/davita-encouraged-some-low-income-patients-to-enroll-in-commercial/article_ec5dc34e-ca4d-52e0-bc26-a3e56e1e2c85.html.*

an individual's premium to enroll in commercial coverage so as to receive a much larger payment for providing an identical set of health care services. This asymmetry creates a strong financial incentive for such providers to use premium payments to steer as many patients as possible to commercial plans.

Commercial coverage pays at higher rates than public coverage for many health care services, and therefore this pattern could theoretically appear in a variety of contexts. Dialysis patients are, however, particularly vulnerable to harmful steering practices for a number of reasons. First, ESRD is the only health condition for which nearly all patients are eligible to apply for and enroll in Medicare coverage and with eligibility linked specifically to the diagnosis. Thus, individuals with ESRD face a unique situation where they have alternative public coverage options, but these coverage options may be less profitable from the perspective of the facilities providing their treatment due to lower reimbursement rates. Second, as described above, patients with ESRD must receive services from a dialysis facility several times per week for the remainder of their lives (unless and until they obtain a kidney transplant). This sort of ongoing receipt of specialized care from a particular facility is not typical of most health conditions and it creates especially strong incentives and opportunities for dialysis facilities to influence the coverage arrangements of the patients under their care.

C. Individual Market Coverage Supported by Third Parties Places Patients at Risk of Harm

Supporting premium payments to facilitate enrollment of their patients in individual market coverage is, as illustrated above, in the financial interest of the dialysis facilities. It is often not, however, in the best interests of individual patients. The comments in response to the RFI illustrated three types of potential harm to patients that these arrangements create for ESRD patients: Negatively impacting patients' determination of readiness for a kidney transplant, potentially exposing patients to additional costs for health care services, and putting individuals at significant risk of a mid-year disruption in health care coverage.

While each of these potential harms is itself cause for concern, they collectively underscore the complexity of the decision for a patient with ESRD of choosing between coverage options, decisions that have very significant consequences for these patients in particular. The involvement of their providers in incentivizing, and steering them to enroll in, individual market coverage is highly problematic absent safeguards to ensure both that the individual is making a decision fully informed of these complex tradeoffs and that the risk of a mid-year disruption in health care coverage is eliminated. Each of these specific potential harms to the patient is discussed further below.

1. Interference With Transplant Readiness

Access to kidney transplantation is a major and immediate concern for many patients with ESRD; transplantation is the recommended course of treatment for individuals with severe kidney disease, and is a life-saving treatment, as the risk of death for transplant recipients is less than half of that for dialysis patients. In addition to improving health outcomes, receipt of a transplant can dramatically improve patients' quality of life; instead of being required to undergo dialysis several times per week, individuals who have received transplants are able to resume a more typical pattern of daily life, travel, and employment. Of the approximately 700,000 people with ESRD in the United States, more than 100,000 are on formal waiting lists to receive a kidney transplant. Further, in 2015 more than 80 percent of kidney transplants went to patients under age 65, suggesting that transplantation is of special concern to nonelderly patients, who are most likely to be targeted by dialysis facilities for enrollment in individual market coverage because they may not already be enrolled in Medicare.

Therefore, any practice that interferes with patients' ability to pursue a kidney transplant is of significant concern. Even a small reduction in the likelihood of a patient receiving a transplant would be detrimental to a patient's health and wellbeing. The comments in response to the RFI support the conclusion that, today, enrollment in individual market coverage for which there are third party premium payments is hampering patients' ability to be determined ready for a kidney transplant. Comments make clear that, consistent with clinical guidelines, in order for a transplant center to determine that a patient is ready for a transplant, they must conclude that the individual will have access to continuous health care coverage. (This is necessary to ensure that the patient will have ongoing access to necessary monitoring and follow-up care, and to immunosuppressant medications, which must typically be taken for the lifetime of a transplanted organ to prevent rejection.) However, when individuals with ESRD are enrolled in individual market coverage supported by third parties, they may have difficulty demonstrating continued access to care due to loss of premium support after transplantation. Documents in the comment record indicate that major non-profits that receive significant financial support from dialysis facilities will support payment of health insurance premiums only for patients currently receiving dialysis. Documents in the record show that these non-profits will not continue to provide financial assistance once a patient receives a successful kidney transplant, nor will the non-profit cover any costs of the transplant itself, living donor care, post-surgical care, post-transplant immunosuppressive therapy, or long-term monitoring, which can cause significant issues for patients that cannot afford their coverage without financial support. This policy is consistent with the conclusion that these third party payments are being targeted based on the financial interest of the dialysis facilities who contribute to these non-profits, rather than the patients' interests. Once a patient has received a transplant, it is no longer in the dialysis facility's financial interest to continue to support premium payments, although there are severe consequences to individuals when that support ceases. If this occurs after transplantation, individuals enrolled in individual market coverage could be required to pay the full amount of the premium, which may be unaffordable for many patients who previously relied on third party premium assistance.

Theoretically, individuals could arrange for Medicare coverage to begin at the time of transplantation, thereby demonstrating continued access to care. In practice, however, patients struggle to understand their coverage options and rapidly navigate the Medicare sign-up process during a period where they are particularly sick and preparing for major surgery. Some commenters to the RFI emphasized that this is an extremely vulnerable group of patients who have difficulty navigating their health insurance options. As evidenced by the rate of dually eligible individuals discussed above, many ESRD patients are low income and have limited access to the resources necessary to navigate these sorts of coverage transitions, and patients are particularly vulnerable during the short window when they are preparing for transplants. Consistent with this, a number of comments describe how these arrangements and patients' vulnerability and confusion

about alternative coverage both pre- and post-transplant have in fact interfered with patients' care. For example, one comment describes a family that was trying to obtain a transplant for a young child that had to arrange other coverage on an emergency basis to obtain their child's transplant. The family had allegedly been given inaccurate information by a dialysis facility about their coverage options and how private health insurance and Medicare would affect their child's transplant. Another commenter employed by a transplant facility described that "many" patients in individual market plans had "their transplant evaluations discontinued or delayed while they worked to obtain appropriate and affordable insurance coverage." A number of other social workers who submitted comments in response to the RFI also identified these transplant access issues as a major concern.

2. Exposure to Additional Costs for Health Care Services

In addition to impeding access to transplants, enrollment in individual market coverage, even when third parties cover costs, is financially disadvantageous for some patients with ESRD. That is, while it is in dialysis facilities' financial interest to support enrollment in the individual market, those arrangements may cause financial harms to patients that would have been avoided had the patients instead enrolled in public coverage.

People with ESRD often have complex needs and receive care from a wide variety of health care providers and suppliers. Data from USRDS show that total health care spending per Medicare ESRD enrollee receiving hemodialysis averaged more than $91,000 in 2014, but spending on hemodialysis is only 32 percent of that amount, meaning that a typical patient may incur thousands of dollars in costs for other services. While some of the non-dialysis services these patients receive may also be provided by their dialysis facilities, half or more of Medicare spending on this population is for care that is likely delivered by other providers and suppliers, including creation and maintenance of vascular access, inpatient hospital care, skilled nursing facility services, home health services, palliative services, ambulance services, treatment for primary care and comorbid conditions, and prescription drugs. Thus, when considering the financial impact of coverage decisions, it is important to consider costs that a patient will incur for services received that go beyond dialysis.

a. Eligibility for Medicaid

As described above, many people with ESRD are eligible for Medicaid. Indeed, more than half of ESRD Medicare enrollees under age 65 are also enrolled in Medicaid.[7] For many Medicaid enrollees, the health care costs for which they are financially responsible are negligible—and many face no cost-sharing or premiums at all. By contrast, consumers in the individual market were responsible for out-of-pocket costs up to $7,150 in 2017.[8] As described above, much of that out-of-pocket exposure is likely to be incurred outside of the dialysis facility so, even if a provider or non-profit covers out-of-pocket costs related to dialysis, enrolling in an individual market plan rather than Medicaid exposes very-low income patients to thousands of dollars in out-of-pocket costs.[9] Indeed, given the Medicaid income limits, this cost-sharing is likely to be an extraordinarily large fraction of their income. Further, Medicaid includes coverage for services not likely to be covered by individual market plans, such as non-emergency medical transportation (which can vary based on the state or type of Medicaid coverage), and patients will forego these benefits if they instead enroll in the individual market. It is possible for an individual to be enrolled in both Medicaid and individual market coverage,[10] and Medicaid would, in theory, wrap around the individual market plan. Such an arrangement would be of great financial benefit to the dialysis facility, but would be unlikely to provide financial benefits to the individual (because the individual's cost sharing and benefits would often be the same as if they had enrolled only in Medicaid). Moreover, in practice, this arrangement creates a significant financial risk for low-income individuals, who will need to coordinate multiple types of coverage or else could find themselves receiving large bills from health care providers and suppliers not aware of their Medicaid coverage. Thus, it is very unlikely that it would be in such individual's financial interest to elect individual market coverage.

b. Eligible for Medicare But Not Medicaid

For individuals with ESRD not eligible for Medicaid, enrolling in the individual market rather than Medicare may also pose significant financial risks. As noted above, these patients generally require access to a wide variety of services received outside of a dialysis facility. Patients with ESRD are generally enrolled in Original Medicare (including Part A and Part B) and can therefore receive services from any Medicare-participating provider or supplier. However, unlike Original Medicare, which provides access to a wide range of eligible providers and suppliers, and which has standard cost-sharing requirements for all Medicare-eligible providers and suppliers, individual market plans generally limit access to a set network of providers that is more restrictive than what is available to an Original Medicare beneficiary. If the individual sees providers or suppliers outside of that network, they will incur higher cost-sharing for necessary out-of-network services, and may have very limited coverage for non-emergency out-of-network health care.

There may be other personal circumstances that lead to financial burden caused by enrolling in an individual market plan rather than Medicare. For example, individuals who are entitled to Part A and do not enroll in Part B generally will incur a Part B late enrollment penalty when they do ultimately enroll in Medicare Part B. Accordingly, an individual who enrolls in Part A based on ESRD but does not enroll in or drops Part B will generally be subject to a late enrollment penalty should they decide to enroll in Part B later while still entitled to Part A on the basis of ESRD. Individuals who receive a kidney transplant may also face higher cost-sharing for immunosuppressant drugs if they delay Medicare enrollment as immunosuppressive drugs are covered under Part B only if the transplant recipient established Part A effective with the month of the transplant.

As noted above, for some members of this group, there is potentially an offsetting financial benefit from individual market coverage if total premiums and cost sharing are lower in an individual market plan with third party premium assistance than in Medicare. In particular, non-grandfathered individual markets plans are required to cap total annual out-of-pocket expenditures for essential health benefits at a fixed amount, the

[7] This figure includes both individuals who are fully enrolled in Medicare and Medicaid, and individuals enrolled in Medicare and the Medicare Saving Program.

[8] Patient Protection and Affordable Care Act; HHS Notice of Payment and Benefit Parameters for 2017, (March 8, 2016); *https://www.gpo.gov/fdsys/pkg/FR-2016-09-06/pdf/2016-20896.pdf.*

[9] Because these individuals are eligible for Medicaid, they are generally prohibited from receiving cost-sharing reductions for enrolling in coverage through an Exchange.

[10] No APTC or CSR would be available to support enrollment in the individual market in this circumstance.

maximum out-of-pocket limit, which is $7,150 in 2017. The individual may not be able to cap their annual out-of-pocket expenses in Medicare; while individuals over age 65 are eligible to enroll in Medicare Advantage or Medigap supplemental plans, which do cap annual expenses, individuals under age 65 with ESRD generally do not have such options in many states.[11] However, third party assistance is also frequently available to offset out-of-pocket costs for Medicare enrollees. Moreover, if dialysis facilities were not providing assistance for individual market coverage on such a widespread basis, they might use these resources to make assistance for out-of-pocket Medicare costs even more widely available.

3. Risks of Mid-Year Disruption in Coverage

Finally, the comments in response to the RFI demonstrate that there is a significant risk of mid-year disruptions in coverage for patients/individuals who have individual market coverage for which third parties make premium payments. It is critically important that patients on dialysis have continuous access to health care coverage. Prior to transplantation this population requires an expensive health care service several times per week in order to live; any interruption in their access to care is serious and life-threatening. Moreover, as noted, this group generally has health care needs beyond dialysis that require care from a variety of medical professionals.

However, the comments reveal that patients/individuals who have individual market coverage for which third parties make premium payments are presently at risk of having their coverage disrupted at any point during the year. CMS does not require that issuers accept premium payments made by third parties except in certain circumstances consistent with applicable legal requirements,[12] and CMS has consistently discouraged issuers from accepting payments directly from health care providers.[13] Many issuers have provisions in their contracts with enrollees that are intended to void the contract if payment is made by someone other than the enrollee. Issuers that provided comments in response to the RFI confirmed that they do not accept certain third party payments. One comment included a list of ten states where major issuers are known to reject these payments when identified. Comments from health care providers and non-profits described that entities that make third party payments to issuers have attempted to disguise their payments to circumvent detection by issuers. These comments also described how issuers are increasingly monitoring for and seeking to identify third party payments, and when issuers discover those payments, they are rejected. The lack of transparency around third party payments has therefore resulted in a situation in which patients are at significant and ongoing risk of losing access to coverage based on their issuer detecting payment of their premiums by parties other than the enrollee.

When payments are rejected, commenters noted that individuals are typically unable to continue their coverage because of the increased financial burden. Indeed, patients may not even realize for some period that their premiums, which are being paid by third parties, are being rejected and that their coverage will be terminated if they do not have an ability to pay themselves. HHS received 600 comments from ESRD patients participating in a letter-writing campaign that describe the adverse impact on patients receiving third party payment premium assistance if those funds were no longer available. Other patients who commented described significant and unexpected disruptions in coverage such as no longer being able to afford the high cost of prescriptions and office visit copays, delays receiving dialysis treatments, or no longer being able to receive treatments. Due to the life-sustaining nature of dialysis, dialysis facilities are not permitted to involuntarily discharge patients, except in very limited circumstances. However, one of those circumstances is lack of payment (42 CFR 494.180 (f)(1)). While we believe that such discharges are rare, and that dialysis facilities try to avoid them, they are permitted. Moreover, even when patients are able to enroll in other public coverage (which may have retroactive effective dates) disruptions in coverage still force patients to navigate a complicated set of coverage options. They may face gaps in care or be forced to appeal health care claims. Comments emphasized that many ESRD patients are low-income and do not have a great deal of familiarity with the health care system, leaving them more vulnerable to gaps in coverage. Therefore, any disruption in coverage is problematic and can interrupt patient care.

In sum, the lack of transparency in how these payments are made and whether or not they are accepted means that patients are at risk of sudden gaps in coverage which may be dangerous to patients' health.

D. Conflict Between Dialysis Facilities' Financial Interest and Patients' Interest Has Led to Problematic Steering

As described above, dialysis facilities have very meaningful financial incentives to have their patients enroll in individual market coverage rather than public coverage programs. However, enrollments in individual market coverage are often not in patients' best interest: It can complicate and potentially delay the process for obtaining a kidney transplant; is often financially costly for patients, especially when they are eligible for Medicaid; and places consumers at risk of a mid-year coverage disruption. These risks make the task of deciding among coverage options complex for ESRD patients. Furthermore, the asymmetry between facilities' and patients' interests and information with respect to enrollment decisions creates a high likelihood that a conflict of interest will develop. Comments submitted in response to the RFI support the conclusion that this conflict of interest is harming patients, with dialysis facility patients being steered toward enrollment in individual market coverage with third party premium payments, rather than enrollment in the public coverage for which they are likely eligible and which is frequently the better coverage option for them.

Many comments were submitted by social workers or other professionals who work or have worked with ESRD patients. Those comments describe a variety of ways in which dialysis facilities have attempted to influence coverage decisions made by patients or have failed to disclose information that is relevant to determining consumers' best interest. Specific practices described in comments include:

- Facilities engaging in systematic efforts to enroll people in the individual market, often targeting Medicaid enrollees, without assessing any personal needs. One commenter explained, "My experience was that the provider wanted anyone [who] was Medicaid only to be educated about the opportunity to apply for an individual plan. . . . The goal was 100%

[11] Congress recently passed legislation that would allow people enrolled in Medicare on the basis of ESRD to select a Medicare Advantage plan beginning in 2021.

[12] 45 CFR 156.1250 requires issuers to accept third party payment from federal, state and local government programs, Ryan White/HIV Aids Programs and Indian Tribes, Tribal Organizations, and Urban Indian Organizations.

[13] Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces, November 4, 2013, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf.*

education, whether there was an assessed need or not. . . . Valuable hours of professional interventions were taken from direct patient care concerns and diverted to this.'' Another explained, ''There was a list of all Medicaid patients and the insurance management team was responsible for documenting why the patient did not switch to an individual market plan.'' Comments also described cases in which social worker compensation was linked to enrolling patients in individual market coverage.

- Patients are not always informed about eligibility for Medicare or Medicaid, or the benefits of those programs. For example, one social worker explained, ''The patient is frequently not educated about the benefits that are available with Medicaid (that is, transportation, dental, and other home support services).'' Another former social worker said that facility employees ''may not tell patients that they could be subject to premium penalties and potentially higher out-of-pocket costs than they would have with traditional Medicare.'' Another commenter said, ''Enrollment counselors offer no information about Medicare eligibility to members. In several cases members were not aware that they were Medicare eligible.''
- Patients are sometimes specifically discouraged from pursuing Medicare or Medicaid. One commenter said: ''In the transplant setting I have seen patients advised to delay in securing Medicare.'' Another employee at a dialysis facility relayed the story of a mother seeking a transplant for her daughter but being told by a dialysis facility not to enroll in Medicare. A transplant facility employee explained ''In some circumstances, the patient has been encouraged to drop their MediCal (Medicaid) coverage in favor of the individual market plan, without having a full understanding of the personal financial impact of doing so.''
- Patients are unaware that a dialysis facility is seeking to enroll them in the individual market and are not informed of this fact by their health care providers. As one commenter said, ''In numerous instances, these patients were already admitted at these facilities, and interviews have found that many were unaware they had insurance, let alone who was providing it.''
- Patients are not informed about how their third party premium support is linked to continued receipt of dialysis. For example, one comment explained, ''People receiving assistance don't realize that if they want a transplant the premiums will no longer get paid.''
- Facilities retaliate against social workers who attempt to disclose additional information to consumers. One commenter explained that they were ''reported to upper management of [dialysis corporations] for voicing my concerns of the impact this [enrollment in the individual market] will have on patients after transplant.''
- Social workers are concerned that patients' trust in health care providers is being manipulated to facilitate individual market enrollment. For example, comments explained that insurance counselors ''meet often with the patients establishing a relationship of trust'' before pursuing individual market enrollment. A commenter said, ''Most of us, who have some sophistication in health care coverage, are aware of how confusing it is to negotiate the information and reach the best decisions. Dialysis patients who may be less sophisticated and already highly stressed are vulnerable to being steered.'' Another commenter vividly explained, ''Patients . . . are in a vulnerable position when they come to a dialysis facility. I hope those of you reviewing these comments realize the power disequilibrium which exists when a patient is hooked up with needles in their arm, lifeblood running through their arms attached to a machine.''

In addition, HHS's own data and information submitted in response to the RFI suggest that this inappropriate steering of patients may be accelerating over time. Insurance industry commenters stated that the number of enrollees in individual market plans receiving dialysis increased 2 to 5 fold in recent years. Based on concerns raised in the public comments in response to the RFI, we have reviewed administrative data on enrollment of patients with ESRD. Information available from the risk adjustment program in the individual market show that between 2014 and 2015, the number of individual market enrollees with an ESRD diagnosis more than doubled.[14] In some states increases were more rapid, with some states seeing more than five times as many patients with ESRD in the individual market in 2015 as in 2014. While increased enrollment in the individual market among individuals who have ESRD is not in itself evidence of inappropriate provider or supplier behavior, these changes in enrollment patterns raise concerns that the steering behavior commenters described may be becoming increasingly common over time.

[14] Risk adjustment applies to the entire individual market, including plans offered on and off an Exchange.

E. HHS Is Taking Immediate Regulatory Action To Protect Patients

In the face of harms like those above, which go to essential patient safety and care in life-threatening circumstances, HHS is taking immediate regulatory action to prevent harms to patients. As described in more detail below, we are establishing new Conditions for Coverage standards (CfCs) for dialysis facilities. This standard applies to any dialysis facility that makes payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments). Dialysis facilities subject to the new standard will be required to make patients aware of potential coverage options and educate them about the benefits of each to improve transparency for consumers. Further, in order to ensure that patients' coverage is not disrupted mid-year, facilities must ensure that issuers are informed of and have agreed to accept the payments.[15]

This action is consistent with comments from dialysis facilities, non-profits, social workers, and issuers that generally emphasized disclosure and transparency as important components of a potential rulemaking. By focusing on transparency, we believe we can promote patients' best interests. CMS remains concerned, however, about the extent of the abuses reported. We are considering whether it would be appropriate to prohibit third party premium payments for individual market coverage completely for people with alternative public coverage. Given the magnitude of the potential financial conflict of interest and the abusive practices described above, we are unsure if disclosure standards will be sufficient to protect patients. We seek comments from stakeholders on whether patients would be better off if premium payments in this context were more strictly limited. We also seek comment on alternative options where

[15] There are two potential ways to prevent mid-year disruptions in coverage—either requiring issuers to accept these payments or requiring facilities to disclose them and assure acceptance. Both would equally promote continuity of coverage for consumers. However, requiring issuers to accept payments in these circumstances would destabilize the individual market risk pool, a position CMS has consistently articulated since 2013, when we expressly discouraged issuers from accepting these third party payments from providers. The underlying policy considerations have not changed and therefore CMS is seeking to prevent mid-year disruption by requiring facilities to disclose payments and assure acceptance.

payments would be prohibited absent a showing that a third party payment was in the individual's best interest, and we seek comment on what such a showing would require and how it could prevent mid-year disruptions in coverage.

II. Provisions of the Interim Final Rule

Through this Interim Final Rule with comment (IFC) we are implementing a number of disclosure requirements for dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, to ensure proper protections for those patients. These requirements are intended to ensure that patients are able to make insurance coverage decisions based on full and accurate information.

As described in more detail below, we are establishing new CfC standards for dialysis facilities. New standards apply to any dialysis facility that makes payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments). While we remain concerned about any type of financial assistance that could be used to influence patients' coverage decisions, we believe these individual market premium payments are particularly prone to abuse because they are so closely tied to the type of coverage an individual selects. Further, as described above, such third party payments in the individual market uniquely put patients at risk of mid-year coverage disruption if their issuer discovers and rejects such payments. Dialysis facilities subject to the new standards will be required to make patients aware of potential coverage options and educate them about certain benefits and risks of each. Further, in order to ensure that patients' coverage is not disrupted mid-year, dialysis facilities must ensure that issuers are informed of and have agreed to accept such payments for the duration of the plan year.

A. Disclosures to Consumers: Patients' Right To Be Informed of Coverage Options and Third Party Premium Payments (42 CFR 494.70(c))

In order to increase awareness of health coverage options for individuals receiving maintenance dialysis in Medicare-certified dialysis facilities, we are establishing a new patient rights standard under the CfCs at 42 CFR 494.70(c). This new standard applies only to those facilities that make payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments).

Dialysis facilities that do not make premium payments, and do not make financial contributions to other entities that make such payments, are not subject to the new requirements.[16] We recognize that dialysis facilities make charitable contributions to a variety of groups and causes. This rule applies only to those dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity.

At § 494.70(c)(1), we detail the health insurance information that must be provided to all patients served by applicable facilities. These requirements establish that such information must cover how plans in the individual market will affect the patient's access to and costs for the providers and suppliers, services, and prescription drugs that are currently within the individual's care plan, as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange). This information must reflect local, current plans, and thus would need to be updated at least annually to reflect changes to individual market plans. We expect that applicable dialysis facilities will meet this requirement by providing the required information upon an individual's admittance to the facility, and annually thereafter, on a timely basis for each plan year.

While current costs to the patient are important, information about potential future costs related to the current health plan selection must also be addressed. In particular, we are requiring that coverage of transplantation and associated transplant costs must be included in information provided to patients. For example, some plans may not cover all costs typically covered by Medicare, such as necessary medical expenses for living donors. Kidney transplant patients who want Medicare to cover immunosuppressive drugs must have Part A at the time of the kidney transplant. Upon enrolling in Part B, Medicare will generally cover the immunosuppressive drugs. Therefore, the beneficiary must file for Part A no later than the 12th month after the month of the kidney transplant. Entitlement to Part A and Part B based on a kidney transplant terminates 36 months after the transplant. However, a beneficiary who establishes Part A entitlement effective with the month of the transplant is eligible for immunosuppressive drug coverage when subsequent entitlement to Part B is based on age or disability. Facilities must provide information regarding enrollment in Medicare, and clearly explain Medicare's benefits to the patient. Facilities must also provide individuals with information about Medicaid, including State eligibility requirements, and if there is any reason to believe the patient may be eligible, clearly explain the State's Medicaid benefits, including the Medicare Savings Programs.

For other potential future effects, the facilities must provide information about penalties associated with late enrollment (or re-enrollment) in Medicare Part B or Part D for those that have Medicare Part A as well as potential delays or gaps in coverage. Section 1839(b) of the Act outlines the Medicare premium—Part A (for those who are not eligible for premium-free Part A) and Part B late enrollment penalty. Individuals who do not enroll in Medicare premium—Part A or Medicare Part B when first eligible (that is, during their Initial Enrollment Period) will have to pay a late enrollment penalty should they decide to enroll at a later time. There are certain circumstances in which individuals are exempt from the late enrollment penalty, such as those who are eligible for Medicare based on Age or Disability, and did not enroll when first eligible because they had or have group health plan coverage based on their own or spouse's (or a family

[16] A facility that makes payments of premiums for individual market coverage of its patients must comply with this standard. Similarly, a facility that makes a financial contribution to another organization, that is able to use the funds to make payments of premiums for individual market coverage of some dialysis patients must also comply, even when the contributions from the facility are not directly linked to the premium payments; we note, moreover, that mere recitation on a check that a contribution cannot be used for premium payments would not establish that an organization is unable to use the contribution for such payments. Further, an entity that makes contributions through a third party that in turn contributes to an entity that is able to use the contribution to make third party premium payments will still be subject to these standards. In contrast, a facility that does not make payments of premiums for individual market coverage and does not contribute to any organization that makes such payments, but does contribute to an organization that supports premiums for Medicare enrollment, would not be required to comply with this standard.

member if Medicare is based on disability) current employment.

Although an ESRD diagnosis may establish eligibility for Medicare regardless of age, it does not make individuals eligible for a Medicare Special Enrollment Period or provide relief from the late enrollment penalty. Thus, if an individual enrolls in Medicare Part A but does not enroll in Part B, or later drops Part B coverage, that individual will pay a Part B (and Part D) late enrollment penalty when ultimately enrolling, or reenrolling, in Medicare Part B (and Part D). Additionally, that individual will need to wait until the Medicare General Enrollment Period to apply for Medicare Part B. The General Enrollment Period runs from January 1 to March 31 each year, and Part B coverage becomes effective July 1 of the same year. Thus, individuals could face significant gaps in coverage while waiting for their Medicare Part B coverage to become effective. We note that late enrollment penalties and statutory enrollment periods do not apply to premium-free Part A.

Information about potential costs to the patient is vitally important for patients considering individual market coverage. An individual may benefit in the short term by selecting a private health plan instead of enrolling in Medicare, but patients must be informed that those plans, or the particular costs and benefits of those plans, may only exist for a given plan year, and that the individual may be at a disadvantage (that is, late enrollment penalties for those that are enrolled in Medicare Part A) should they choose to enroll in Medicare Part B (or Part D) at a later date.

At § 494.70(c)(2) and (3), we require that applicable facilities provide information to all patients about available premium payments for individual market plans and the nature of the facility's or parent organization's contributions to such efforts and programs. This information must include, but is not limited to, limits on financial assistance and other information important for the patient to make an informed decision, including the reimbursements for services rendered that the facility would receive from each coverage option. For example, if premium payments are not guaranteed for an entire plan year, or funding is capped at a certain dollar amount, patients must be informed of such limits. Facilities also must inform patients if the premium payments are contingent on continued use of dialysis services or use of a particular facility, and would therefore be terminated in the event that the patient receives a successful kidney transplant or transfers to a different dialysis facility. Further, facilities must disclose to patients all aggregate amounts that support enrollment in individual market health plans provided to patients directly, to issuers directly, through the facility's parent organization, or through third parties.

As with all patient rights standards for dialysis facilities, the information and disclosures required in § 494.70(c) must be provided to all patients of applicable facilities, not just those new to a facility who have not yet enrolled in Medicare or Medicaid. This ensures that all patients are treated fairly and appropriately, and not treated differently based on their health care payer, as required by CMS regulations at 42 CFR 489.53(a)(2).

B. Disclosures to Issuers (42 CFR 494.180(k))

In conjunction with these requirements for patient information and disclosures, we establish at § 494.180(k), a new standard that requires facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity to ensure that issuers are informed of and have agreed to accept the third party payments. Facilities should develop reasonable procedures for communicating with health insurance issuers in the individual market, and for obtaining and documenting that the issuer has agreed to accept such payments. If an issuer does not agree to accept the payments for the duration of the plan year, the facility shall not make payments of premiums and shall take reasonable steps to ensure that such payments are not made by any third parties to which the facility contributes.

These requirements are intended to protect ESRD patients from avoidable interruptions in health insurance coverage mid-year by ensuring that they have access to full, accurate information about health coverage options. We intend to outline expectations for compliance in subsequent guidance. This rule does not alter the legal obligations or requirements placed on issuers, including with respect to the guaranteed availability and renewability requirements of the Public Health Service Act and non-discrimination-related regulations issued pursuant to the Affordable Care Act.[17]

[17] See 45 CFR 147.104, 156.225, 156.805.

C. Effective Date

Because we are concerned that patients face risks that are not disclosed to them, and that they may be at risk of disruptions in coverage on an ongoing basis, we are taking action to ensure greater disclosure to consumers and to provide for smooth and continuous access to stable coverage when these rules are fully implemented. At the same time, we are mindful of the need for dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, to develop new procedures to comply with the standards established in this rule. Therefore, the requirements in this rule will become effective beginning January 13, 2017.

We note that, in specific circumstances, individuals may not be eligible to enroll in Medicare Part A or Part B except during the General Enrollment Period, which runs from January 1 to March 31 and after which coverage becomes effective on July 1. These individuals may experience a temporary disruption in coverage between the effective date of the rule and the time when Medicare Part A and/or Part B coverage becomes effective. In light of these circumstances, while the standards under § 494.180(k) will be effective beginning January 13, 2017, if a facility is aware of a patient who is not eligible for Medicaid and is not eligible to enroll in Medicare Part A and/or Part B except during the General Enrollment Period, and the facility is aware that the patient intends to enroll in Medicare Part A and/or Part B during that period, the standards under § 494.180(k) will not apply until July 1, 2017, with respect to payments made for that patient.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule in accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA) and section 1871(b)(1) of the Social Security Act. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a

statement of the finding and its reasons in the rule issued.

HHS has determined that issuing this regulation as a proposed rulemaking, such that it would not become effective until after public comments are submitted, considered and responded to in a final rule, would be contrary to the public interest and would cause harm to patients. Based on the newly available evidence discussed in section I of this rule, that is, the responses to the August 2016 RFI, HHS has determined that the widespread practice of third parties making payments of premiums for individual market coverage places dialysis patients at significant risk of three kinds of harms: Having their ability to be determined ready for a kidney transplant negatively affected, being exposed to additional costs for health care services, and being exposed to a significant risk of a mid-year disruption in health care coverage. We believe these are unacceptable risks to patient health that will be greatly mitigated by this rulemaking, and that the delay caused by notice and comment rulemaking would continue to put patient health at risk. Given the risk of patient harm, notice and comment rulemaking would be contrary to the public interest. Therefore, we find good cause to waive notice and comment rulemaking and to issue this interim final rule with comment. We are providing a 30-day public comment period.

In addition, we ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the APA (5 U.S.C. 553(d)), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 553(d)(3).

In addition, the Congressional Review Act (5 U.S.C. 801(a)(3)) requires a 60-day delayed effective date for major rules. However, we can determine the effective date of the rule if the Secretary finds, for good cause, that notice and public procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 808(2)).

As noted above, for good cause, we have found that notice and public procedure is contrary to the public interest. Accordingly, we have determined that it is appropriate to issue this regulation with an effective date 30 days from the date of publication. As described above, we believe patients are currently at risk of harm. Health-related and financial risks are not fully disclosed to them, and they may have their transplant readiness delayed or face additional financial consequences because of coverage decisions that are not fully explained. Further, consumers are at risk of mid-year coverage disruptions. This is the time of year when patients often make enrollment decisions, with Open Enrollment in the individual market ongoing and General Enrollment Period for certain new enrollees in Medicare about to begin on January 1. We have therefore determined that the rule will become effective on January 13, 2017 to best protect consumers.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This interim final rule with comment contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 1. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of the interim final rule with comment that contain ICRs. We generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[18]

1. ICRs Regarding Patient Rights (§ 494.70(c))

Under § 494.70(c), HHS implements a number of requirements and establishes a new patient rights standard for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, to ensure proper protections for those patients. Those applicable facilities will be required, on an annual basis, to inform patients of health coverage options available to them, including Medicare and Medicaid and locally available individual market plans; enrollment periods for both Medicare and the individual market; the effects each option will have on the patients access to, and costs for the providers and suppliers, services, and prescription drugs that are currently within the individual's ESRD plan of care and other documented health care needs; coverage and anticipated costs for transplant services, including pre- and post-transplant care; any funds available to the patient for enrollment in an individual market health plan, including but not limited to limitations and any associated risks of such assistance; and current information about the facility's, or its parent organization's premium payments for patients, or to other third parties that make such premium payments to individual market health plans for individuals on dialysis.

We assume that each applicable facility will develop a system to educate and inform each ESRD patient of their options and the effects of these options. For our purposes, we assume that each facility will develop a pamphlet containing information that compares the benefits and costs for each locally available individual market plan, Medicare, and Medicaid, and display it prominently in their facility. In addition, it is assumed that a facility staff such as a health care social worker will review the required information with the patient and answer any questions.

There are 6,737 Medicare-certified dialysis facilities. As explained later in the regulatory impact analysis section, we estimate that approximately 90 percent, or 6,064, facilities make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, and therefore, will need to comply with these disclosure requirements. We estimate

[18] See May 2015 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at *http://www.bls.gov/oes/current/oes_stru.htm.*

that approximately 491,500 patients receive services at Medicare-certified facilities. Therefore, on average, each facility provides dialysis services to approximately 73 patients annually. While we expect to detail in forthcoming guidance how dialysis facilities may comply with these requirements, we are providing an example of one type of disclosure, an informational pamphlet, to illustrate potential costs. We note, that we expect dialysis facilities will use various tools for disclosure including but not limited to informational pamphlets, handouts, etc. It is estimated that each facility will prepare, on average, a 6-page pamphlet that includes all required information. We estimate that an administrative assistant will spend approximately 40 hours (at an hourly rate of $37.86) on average to research the required information and develop a pamphlet. We estimate it will take an administrative manager (at an hourly rate of $91.20) 4 hours to review the pamphlet. The total annual burden for each facility will be 44 hours with an equivalent cost of $1,879.20 ((40 hours × $37.86 hourly rate) + (4 hours × $91.20 hourly rate)). In order to print the pamphlet, we estimate that it will cost each facility $3.00 (for a 6-page pamphlet at $0.50 per page). For all 6,064 facilities, the total annual burden will be 266,816 hours (44 hours × 6,064 facilities) with an equivalent cost of approximately $11,395,469 ($1,879.20 annual burden cost × 6,064 facilities) and a total materials and printing cost of $1,328,016. It is anticipated that the burden to prepare the pamphlet will be lower in subsequent years since all that will be needed is to review and update plan information. We estimate that an administrative assistant will spend approximately 32 hours (at an hourly rate of $37.86) on average to update the information in the pamphlet, and it will take an administrative manager (at an hourly rate of $91.20) 3 hours to review it. The total annual burden for each facility will be 35 hours with an equivalent cost of approximately $1,485 ((32 hours × $37.86 hourly rate) + (3 hours × $91.20 hourly rate)). The total burden for all facilities will be 212,240 hours (35 hours × 6,064 facilities) with an equivalent cost of approximately $9,005,768 ($1,485.12 annual burden cost × 6,064 facilities).

In addition to providing a copy of the pamphlet to the patients, it is assumed that a health care social worker or other patient assistance personnel at each facility will review the information with the patients and obtain a signed acknowledgement form stating that the patient has received this information. We estimate that a lawyer (at an hourly rate of $131.02) will take 30 minutes to develop an acknowledgement form confirming that the required information was provided to be signed by the ESRD patient. The total burden for all 6,064 facilities to develop the acknowledgement form in the initial year only will be 3,032 hours (0.5 hours × 6,064 facilities) with an equivalent cost of approximately $397,253 (($131.02 hourly rate × 0.5 hours) × 6,064 facilities).

We estimate that a health care social worker (at an hourly rate of $51.94) will take an average of 45 minutes to further educate each patient about their coverage options. The social worker will also obtain the patient's signature on the acknowledgement form and save a copy of the signed form for recordkeeping, incurring a materials and printing cost of $0.05 per form. The total annual burden for each facility will be 54.75 hours (0.75 hours × 73 patients) with an equivalent cost of approximately $2,844 ($51.94 hourly rate × 54.75 hours), and approximately $4 in printing and materials cost. The total annual burden for all 6,064 facilities will be 332,004 hours 54.75 hours × 6,064 facilities) with an equivalent cost of approximately $17,244,288 ($2,843.72 annual burden cost × 6,064 facilities), and approximately $22,134 in printing and materials cost.

We will revise the information collection currently approved under OMB Control Number 0938–0386 to account for this additional burden.

2. ICRs Regarding Disclosure of Third Party Premium Payments, or Contributions to Such Payments, to Issuers (§ 494.180(k))

Under § 494.180(k), HHS is implementing a requirement for those dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, must ensure issuers are informed of and have agreed to accept the payments for the duration of the plan year.

Based on comments received in response to the RFI, it is assumed that approximately 7,000 patients that receive such payments are enrolled in individual market plans. Therefore, we estimate that 6,064 facilities will be required to send approximately 7,000 notices. It is assumed that these notices will be sent and returned electronically at minimal cost. We estimate that, for each facility during the initial year, it will take a lawyer one hour (at an hourly rate of $131.02) to draft a letter template notifying the issuer of third party payments and requesting assurance of acceptance for such payments. The total annual burden for all facilities during the initial year will be 6,064 hours with an equivalent cost of approximately $794,505 ($131.02 × 6,064 facilities). This is likely to be an overestimation since parent organizations will probably develop a single template for all individual facilities they own. We further estimate that it will require an administrative assistant approximately 30 minutes (at an hourly rate of $37.86) to insert customized information and email the notification to the issuer, send any follow-up communication, and then save copies of the responses for recordkeeping. The total annual burden for all facilities for sending the notifications will be 3,500 hours (7,000 notifications x 0.5 hours) with an equivalent cost of $132,510 ($37.86 hourly rate × 3,500 hours).

There are an estimated 468 issuers in the individual market. It is assumed that the approximately 7,000 patients are uniformly distributed between these issuers. Issuers will incur a burden if they respond to the notifications from dialysis facilities and inform them whether or not they will accept third party payments. It is estimated that it will take a lawyer 30 minutes (at an hourly rate of $131.02) to review the notification and an administrative manager 30 minutes (at an hourly rate of $91.20) to approve or deny the request and respond to any follow-up communication. It will further take an administrative assistant approximately 30 minutes (at an hourly rate of $37.86) to respond electronically to the initial notification and any follow-up communications. The total annual burden for all issuers to respond to 7,000 notifications will be 10,500 hours (1.5 hours × 7,000 notifications) with an equivalent cost of $910,280 (10,500 hours × $86.69 average hourly rate per notification per issuer).

We will revise the information collection currently approved under OMB Control Number 0938–0386 to account for this additional burden.

TABLE 1—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN: FIRST YEAR

Regulation section(s)	OMB control No.	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
Patient Rights (§494.70 (c)) 0 Pamphlets	0938–0386	6,064	442,672	44	266,816	$42.71	$11,395,468.80	$1,328,016.00	$12,723,484.80
Patient Rights (§494.70 (c))—Patient Education and Recordkeeping	0938–0386	6,064	442,672	0.75	332,004	51.94	17,244,287.76	22,133.60	17,266,421.36
Patient Rights (§494.70 (c))—acknowledgement form	0938–0386	6,064	6,064	0.5	3,032	131.02	397,252.64	0.00	397,252.64
Disclosure of Third Party Premium Assistance to Issuers (§494.180(k))—letter template	0938–0386	6,064	6,064	1	6,064	131.02	794,505.28	0.00	794,505.28
Disclosure of Third Party Premium Assistance to Issuers (§494.180(k))—notification from facility	0938–0386	6,064	7,000	0.5	3,500	37.86	132,510	0.00	132,510
Disclosure of Third Party Premium Assistance to Issuers (§494.180(k))—issuer response	0938–0386	468	7,000	1.5	10,500	86.69	910,280	0.00	910,280
Total		6,532	911,472	48.25	621,916	481.24	30,874,304.48	1,350,149.60	32,224,454.08

TABLE 2—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN: SUBSEQUENT YEARS

Regulation section(s)	OMB control No.	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
Patient Rights (§494.70 (c)) 0 Pamphlets	0938–0386	6,064	442,672	35	212,240	$42.43	$9,005,767.68	$1,328,016.00	$10,333,783.68
Patient Rights (§494.70 (c))—Patient Education and Recordkeeping	0938–0386	6,064	442,672	0.75	332,004	51.94	17,244,287.76	22,133.60	17,266,421.36
Disclosure of Third Party Premium Assistance to Issuers (§494.180(k))—notification from facility	0938–0386	6,064	7,000	0.5	3,500	37.86	132,510.00	0.00	132,510.00
Disclosure of Third Party Premium Assistance to Issuers (§494.180(k))—issuer response	0938–0386	468	7,000	1.5	10,500	86.69	910,280.00	0.00	910,280.00
Total		6,532	899,344	37.75	558,244	218.93	27,292,845.44	1,350,149.60	28,642,995.04

If you comment on these information collection requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this interim final rule with comment; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–3337–IFC. Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

V. Regulatory Impact Analysis

A. Introduction

This interim final rule with comment implements a number of requirements for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity. It establishes a new patient rights standard applicable only to such facilities that they must provide patients with information on available health insurance options, including locally available individual market plans, Medicare, Medicaid, and CHIP coverage. This information must include the effects each option will have on the patient's access to, and costs for the providers and suppliers, services, and prescription drugs that are currently within the individual's ESRD plan of care as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange). Patients must also receive information about all available financial assistance for enrollment in an individual market health plan and the limitations and associated risks of such assistance; including any and all current information about the facility's, or its parent organization's contributions to patients or third parties that subsidize enrollment in individual market health plans for individuals on dialysis.

In addition, the interim final rule with comment establishes a new standard requiring dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, to disclose these payments to applicable issuers and requiring the contributing facility to obtain assurance from the issuer that the issuer will accept such payments for the duration of the plan year.

These requirements are intended to ensure that patients are able to make coverage decisions based on full, accurate information, and are not inappropriately influenced by financial interests of dialysis facilities and suppliers, and to minimize the likelihood that coverage is interrupted midyear for these vulnerable patients.

B. Statement of Need

This interim final rule with comment addresses concerns raised by commenters and by HHS regarding the inappropriate steering of patients with ESRD, especially those eligible for Medicare and Medicaid, into individual market health plans that offer significantly higher reimbursement rates compared to Medicare and Medicaid, without regard to the potential risks incurred by the patient. As discussed previously in the preamble, public comments received in response to the August 2016 RFI indicated that dialysis facilities may be encouraging patients to move from one type of coverage into another based solely on the financial benefit to the dialysis facility, and without transparency about the potential consequences for the patient, in circumstances where these actions may result in harm to the individual.[19] Further, enrollment trends indicate that the number of individual market enrollees with ESRD more than doubled between 2014 and 2015, which is not itself evidence of inappropriate behavior but does raise concerns that the steering behavior described by commenters may be becoming increasingly common, and without immediate rulemaking patients are at considerable risk of harm.

This interim final rule with comment addresses these issues by implementing a number of requirements that will provide patients with the information they need to make informed decisions about their coverage and will help to ensure that their care is not at risk of disruptions, gaps in coverage, limited access to necessary treatment, or undermined by the providers' or suppliers' financial interests.

C. Overall Impact

We have examined the effects of this rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule—(1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year. We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking.

D. Impact Estimates and Accounting Table

In accordance with OMB Circular A–4, Table 3 below depicts an accounting statement summarizing HHS' assessment of the benefits, costs, and transfers associated with this regulatory action. The period covered by the RIA is 2017 through 2026.

HHS anticipates that the provisions of this interim final rule with comment will enhance patient protections and enable patients with ESRD to choose health insurance coverage that best suits their needs and improve their health outcomes. Providing patients with accurate information will help to ensure that patients are able to obtain necessary health care, reduce the likelihood of coverage gaps, as well as provide financial protection. Dialysis facilities and issuers will incur costs to comply with these requirements. If patients covered through individual market plans opt to move to (or return to) Medicare and Medicaid, then there will be a transfer of patient care costs to the Medicare and Medicaid programs. For those patients covered through individual market plans who chose to apply for and enroll in Medicare, there would be a transfer of premium payments from individual market issuers to the Medicare program. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

TABLE 3—ACCOUNTING TABLE

Benefits:
Qualitative:
* Provide patient protections and ensure that patients are able to make coverage decisions based on complete and accurate information, and are not inappropriately influenced by the financial interests of dialysis facilities.

[19] Individuals who are already covered by Medicare generally cannot become enrolled in coverage in the individual market. Section 1882(d)(3) of the Social Security Act makes it unlawful to sell or issue a health insurance policy (including policies issued on and off Exchanges) to an individual entitled to benefits under Medicare Part A or enrolled under Medicare part B with the knowledge that the policy duplicates the health benefits to which the individual is entitled. Therefore, while an individual with ESRD is not required to apply for and enroll in Medicare, once they become enrolled, it is unlawful for them to be sold a commercial health insurance policy in the individual market if the seller knows the individual market policy would duplicate benefits to which the individual is entitled. The financial consequences for patients moving from Medicare to private insurance—including late enrollment penalties for individuals in Medicare Part A but not Part B if they return to Medicare, and lack of coverage for certain drugs following a kidney transplant—are routinely not disclosed and may be unknown to patients. These financial consequences can have significant impact on patient care.

TABLE 3—ACCOUNTING TABLE—Continued

* Improve health outcomes for patients by ensuring that patients have coverage that best fits both current and future needs, including transplantation services.
* Ensure that issuers will accept any premium assistance payments for the duration of the plan year and patients' coverage is not interrupted midyear.

Costs:	Estimate (millions)	Year dollar	Discount rate percent	Period covered
Annualized Monetized	$29.1	2016	7	2017–2026
	29.1	2016	3	2017–2026
Costs reflect administrative costs incurred by dialysis facilities and issuers to comply with ICRs.				
Transfers:				
Annualized Monetized	$688.4	2016	7	2017–2026
	688.4	2016	3	2017–2016
Transfers reflect transfer of patient care costs from individual market issuers to Medicare and Medicaid; out-of-pocket costs from dual eligible patients to Medicare and Medicaid; transfer of premium dollars from individual market issuers to Medicare; and transfer of reimbursements from dialysis facilities to individual market issuers if patients move from individual market plans to Medicare and Medicaid.				

a. Number of Affected Entities

There are 6,737 dialysis facilities across the country that are certified by Medicare, and an estimated 495,000 patients on dialysis. Based on USRDS data for recent years, we estimated that approximately 99.3 percent or 491,500 patients receive services at Medicare-certified facilities. Therefore, each Medicare-certified facility is providing services to approximately 73 patients on average annually. As mentioned previously, data indicates that about 88 percent of ESRD patients receiving hemodialysis were covered by Medicare (as primary or secondary payer) in 2014. Data from the CMS risk adjustment program in the individual market (both on and off exchange) suggest that the number of enrollees with an ESRD diagnosis in the individual market more than doubled between 2014 and 2015. Although some of the increase could be due to increases in coding intensity and cross-year claims, the gross number is still significant and concerning. Comments received in response to the RFI suggest that the inappropriate steering of patients may be accelerating over time. Insurance industry commenters stated that the number of patients in individual market plans receiving dialysis increased 2 to 5 fold in recent years. We will continue to analyze these data to better understand trends in ESRD diagnoses as well as the extent to which individuals may be enrolled in both Medicare and individual market plans and implications for the anti-duplication provision outlined in section 1882(d)(3) of the Act.

There is no data on how many dialysis facilities make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity. We believe that these practices are likely concentrated within large dialysis chains that together operate approximately 90 percent of dialysis facilities, and therefore estimate that approximately 6,064 facilities make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity.

b. Anticipated Benefits, Costs and Transfers

This interim final rule with comment implements a number of requirements for Medicare-certified dialysis facilities (as defined in 42 CFR 494.10) that make payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments). Such facilities must provide patients with information on available health coverage options, including local, current individual market plans, Medicare, Medicaid, and CHIP coverage. This information must include; the effects each coverage option will have on the patient's access to, and costs for, the providers and suppliers, services, and prescription drugs that are currently within the individual's ESRD plan of care as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange). Information on coverage of transplant-associated costs must also be provided to patients, including pre- and post-transplant care. In addition, facilities must provide information about penalties associated with late enrollment in Medicare. Patients must also receive information about available financial assistance for enrollment in an individual market health plan and limitations and associated risks of such assistance; the financial benefit to the facility of enrolling the individual in an individual market plan as opposed to public plans; and current information about the facility's, or its parent organization's contributions to patients or third parties that make payments of premiums for individual market plans for individuals on dialysis.

These requirements are intended to ensure that patients are able to make insurance coverage decisions based on full, accurate information, and not based on misleading, inaccurate, or incomplete information that prioritizes providers and suppliers' financial interests. It is likely that some patients will elect to apply for and enroll in Medicare and Medicaid (if eligible) instead of individual market plans once they are provided all the information as required. As previously discussed, Medicare (and Medicaid) enrollment will provide health benefits by reducing the likelihood of disruption of care, gaps in coverage, limited access to necessary treatment, denial of access to kidney transplants or delay in transplant readiness, and denial of post-surgical care. By enrolling in Medicare (and Medicaid), many individuals can avoid potential financial loss due to Medicare late enrollment penalties; higher cost-sharing, especially for out-of-network services; higher deductibles; and coverage limits in individual market plans. This is particularly true for the individuals eligible for Medicare based on ESRD who are also eligible for

Medicaid. While a patient with individual market coverage could be liable for out-of pocket costs of up to $7,150 in 2017, a patient dually enrolled in Medicare and Medicaid will have very limited, and in many cases no, out-of-pocket costs in addition to a wider range of eligible providers and suppliers.

In addition, this interim final rule with comment establishes a new standard, applicable only to facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments), requiring that the facility disclose such payments to applicable issuers and obtain assurance from the issuer that they will accept such payments for the duration of the plan year. This will lead to improved health outcomes for patients by ensuring that coverage is not interrupted midyear for these vulnerable patients, leaving them in medical or financial jeopardy.

Dialysis facilities that make premium payments for patients as discussed above will incur costs to comply with the provisions of this rule. The administrative costs related to the disclosure requirements have been estimated in the previous section.

If patients elect to apply for and enroll in Medicare and Medicaid (if eligible) instead of individual market plans, the cost of their coverage will be transferred from the patients and the individual market issuers to the Medicare and Medicaid programs (if the patient is eligible for both). This will lead to increased spending for these programs. For the purpose of this analysis, we assume that approximately 50 percent of patients enrolled in individual market plans that receive third party premium payments will elect to apply for and enroll in Medicare. USRDS data show that for individuals with ESRD enrolled in Medicare receiving hemodialysis, total health care spending averaged $91,000 per person in 2014, including dialysis and non-dialysis services. Therefore, if 3,500 patients switch to Medicare, the total transfer from individual market issuers to the Medicare program will be approximately $318,500,000. We assume that about 50 percent of patients that opt to enroll in Medicare will also be eligible for Medicaid and will have negligible or zero cost-sharing, rather than the maximum out-of-pocket cost of $7,150, which will be a transfer from the patients to the Medicare and Medicaid programs. Therefore, for 1,750 dual eligible patients, the total transfer is estimated to be $12,512,500. For those patients covered through individual market plans who choose to enroll in Medicare there will also be a transfer of premium payments from the individual market issuers to the Medicare program. Assuming that patients will pay the standard Part B premium amount, which will be $134 in 2017, and an average Part D premium of $42.17,[20] the total transfer for 3,500 patients is estimated to be $7,399,140. In addition, if patients move from individual market plans to Medicare, then reimbursements to dialysis facilities will be reduced, since individual market plans currently have higher reimbursement rates for dialysis services compared to Medicare, resulting in a transfer from dialysis facilities to issuers. As discussed previously, based on comments received, dialysis facilities are estimated to be paid at least $100,000 more per year per patient for a typical patient enrolled in commercial coverage rather than public coverage. For 3,500 patients, the total transfer from dialysis facilities to issuers is estimated to be at least $350,000,000.

E. Alternatives Considered

Under the Executive Order, HHS is required to consider alternatives to issuing rules and alternative regulatory approaches. HHS considered not requiring any additional disclosures to patients. Providing complex information regarding available coverage options may not always help patients make the best decisions. In addition, disclosure requirements may not be as effective where financial conflicts of interest remain for the dialysis facilities. We also considered prohibiting outright contributions from dialysis suppliers to patients or third parties for individual market plan premiums, but determined that we wanted to have additional data before implementing additional restrictions. A ban could potentially cause financial hardship for some patients. On the other hand, dialysis facilities would not be able to use these contributions to steer patients towards individual market plans that are more in the financial interests of dialysis facilities rather than those of the patient. In the absence of additional data, it is not possible to estimate the costs, benefits and transfers associated with such a ban, whether the benefits would outweigh the costs, and whether it would be more effective in ending the practice of steering.

HHS believes, however, that patients will benefit from having complete and accurate information regarding their options, especially information on Medicare and Medicaid and the financial and medical/coverage consequences of each option. In addition, CMS can ensure compliance with the disclosure requirements through the survey and certification process. CMS plans to issue interpretive guidance and a survey protocol for the enforcement of the new standards by state surveyors to ensure that the facilities share appropriate information with patients.

We also considered requiring issuers to accept all third party premium payments. However, requiring issuers to accept such payments could skew the individual market risk pool, a position CMS has consistently articulated since 2013, when we expressly discouraged issuers from accepting these premium payments from providers. We also received comments from issuers, social workers, and others in response to the RFI indicating that inappropriate steering practices could have the effect of skewing the insurance risk pool. The underlying policy considerations have not changed and therefore CMS is seeking to prevent mid-year disruption by requiring facilities to disclose payments and assure acceptance. In light of the comments received regarding dialysis facilities' practices in particular, and the unique health needs and coverage options available to this population, we are at this time imposing disclosure-related obligations only on the ESRD facilities themselves. This rule does not change the legal obligations or requirements placed on issuers.

In addition, to determine whether further action is warranted, we seek comments from stakeholders on whether patients would be better off on balance if premium assistance originating from health care providers and suppliers were more strictly limited and disclosed. We also seek comment on alternative options where payments would be limited absent a showing that the individual market coverage was in the individual's best interest, and we seek comment on what such a showing would require and how it could prevent mid-year disruptions in coverage.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative

[20] Source: Jack Hoadley et al., Medicare Part D: A First Look at Prescription Drug Plans in 2017, Kaiser Family Foundation, October 2016, *http://kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2017/.*

Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a rule is not likely to have a significant economic impact on a substantial number of small entities, section 604 of RFA requires that the agency present a final regulatory flexibility analysis describing the impact of the rule on small entities and seeking public comment on such impact.

The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA) (13 CFR 121.201); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of "small entity.") HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

Because this provision is issued as a final rule without being preceded by a general notice of proposed rulemaking, a final regulatory analysis under section 604 of the Regulatory Flexibility Act (94 Stat. 1167) is not required. Nevertheless, HHS estimates that approximately 10 percent of Medicare-certified dialysis facilities are not part of a large chain and may qualify as small entities. It is not clear how many of these facilities make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity. To the extent that they do so, these facilities will incur costs to comply with the provisions of this interim final rule with comment and experience a reduction in reimbursements if patients transfer from individual market coverage to Medicare. However, HHS believes that very few small entities, if any, make such payments. Therefore, HHS expects that this interim final rule with comment will not affect a substantial number of small entities. Accordingly, the Secretary certifies that a regulatory flexibility analysis is not required.

In addition, section 1102(b) of the Social Security Act requires agencies to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This interim final rule with comment will not affect small rural hospitals. Therefore, HHS has determined that this regulation will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by state, local or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately $146 million.

UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This interim final rule with comment includes no mandates on state, local, or tribal governments. Thus, this rule does not impose an unfunded mandate on state, local or tribal governments. As discussed previously, dialysis facilities that wish to make payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments), will incur administrative costs in order to comply with the provisions of this interim final rule with comment. Issuers will incur some administrative costs as well. However, consistent with policy embodied in UMRA, this interim final rule with comment has been designed to be the least burdensome alternative for state, local and tribal governments, and the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by Federal agencies in formulating and implementing policies that have "substantial direct effects" on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government.

This rule does not have direct effects on the states, the relationship between the Federal government and states, or on the distribution of power and responsibilities among various levels of government.

I. Congressional Review Act

This interim final rule with comment is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 494

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 1. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 494.70 is amended by redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c) to read as follows:

§ 494.70 Condition: Patients' rights.

* * * * *

(c) Standard: Right to be informed of health coverage options. For patients of dialysis facilities that make payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments), the patient has the right to—

(1) Be informed annually, on a timely basis for each plan year, of all available health coverage options, including but not limited to Medicare, Medicaid, CHIP and individual market plans. This must include information on:

(i) How plans in the individual market will affect the patient's access to, and costs for the providers and suppliers, services, and prescription

drugs that are currently within the individual's ESRD plan of care as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange).

(ii) Medicare and Medicaid/Children's Health Insurance Coverage (CHIP) coverage, including Medicare Savings Programs, and how enrollment in those programs will affect the patient's access to and costs for health care providers, services, and prescription drugs that are currently within the individual's plan of care.

(iii) Each option's coverage and anticipated costs associated with transplantation, including patient and living donor costs for pre- and post-transplant care.

(2) Receive current information from the facility about premium assistance for enrollment in an individual market health plan that may be available to the patient from the facility, its parent organization, or third parties, including but not limited to limitations and any associated risks of such assistance.

(3) Receive current information about the facility's, or its parent organization's, contributions to patients or third parties that subsidize the individual's enrollment in individual market health plans for individuals on dialysis, including the reimbursements for services rendered that the facility receives as a result of subsidizing such enrollment.

* * * * *

■ 3. Section 494.180 is amended by adding a new paragraph (k) to read as follows:

§ 494.180 Condition: Governance.

* * * * *

(k) *Standard: Disclosure to Insurers of Payments of Premiums.* (1) Facilities that make payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments) must—

(i) Disclose to the applicable issuer each policy for which a third party payment described in this paragraph (k) will be made, and

(ii) Obtain assurance from the issuer that the issuer will accept such payments for the duration of the plan year. If such assurances are not provided, the facility shall not make payments of premiums and shall take reasonable steps to ensure such payments are not made by the facility or by third parties to which the facility contributes as described in this paragraph (k).

(2) If a facility is aware that a patient is not eligible for Medicaid and is not eligible to enroll in Medicare Part A and/or Part B except during the General Enrollment Period, and the facility is aware that the patient intends to enroll in Medicare Part A and/or Part B during that period, the standards under this paragraph (k) will not apply with respect to payments for that patient until July 1, 2017.

Dated: November 28, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 29, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–30016 Filed 12–12–16; 4:15 pm]

BILLING CODE 4120–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1816, 1832, 1842, and 1852

RIN 2700–AE34

NASA Federal Acquisition Regulation Supplement: Revised Voucher Submission & Payment Process (NFS Case 2016–N025)

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: NASA has adopted as final, without change, an interim rule amending the NASA Federal Acquisition Regulation Supplement (NFS) to implement revisions to the voucher submittal and payment process.

DATES: *Effective:* December 14, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. John J. Lopez, telephone 202–358–3740.

SUPPLEMENTARY INFORMATION:

I. Background:

NASA published an interim rule in the **Federal Register** at 81 FR 63143 on September 14, 2016, to amend the NASA Federal Acquisition Regulation Supplement (NFS) to implement revisions to the voucher submittal and payment process.

II. Discussion and Analysis

There were no public comments submitted in response to the interim rule. The interim rule has been converted to a final rule, without change.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

NASA does not expect this final rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* A final regulatory flexibility analysis has been performed and is summarized as follows:

The purpose of this rule is to implement revisions to the NASA voucher submittal and payment process. These revisions are necessary due to section 893 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92) prohibiting DCAA from performing audit work for non-Defense Agencies. This rule removes an outdated NFS payment clause and its associated prescription relative to the NASA voucher submittal and payment process and replaces it with a new clause that revises NASA's current cost voucher submission and payment process to ensure the continued prompt payment to its suppliers.

No comments were received in response to the initial regulatory flexibility analysis.

This rule applies to contractors requesting payment under cost reimbursement contracts. An analysis of data in the Federal Procurement Data System (FPDS) revealed that cost reimbursement contracts are primarily awarded to large businesses. FPDS data compiled over the past three fiscal years (FY 2013 through FY 2015) showed an average of 311 active cost reimbursement NASA contracts, of which 141 (approximately 45%) were awarded to small businesses. However, there is no significant economic or administrative cost impact to small or

Blue Cross of Idaho

September 22, 2016

Submitted electronically to www.regulations.gov

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6074-NC
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: **CMS-6074-NC—Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans**

Dear CMS:

Blue Cross of Idaho Health Service, Inc. ("Blue Cross of Idaho" or "BCI") appreciates the opportunity to submit these comments in response to the questions posed in CMS-6074-NC—Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans.

Blue Cross of Idaho Overview

Blue Cross of Idaho is a not-for-profit mutual insurance corporation licensed as a health insurance issuer by the State of Idaho Department of Insurance. BCI is Idaho's oldest and leading health insurance issuer, with more than 800,000 members enrolled in our commercial, Medicare Advantage, Medicare-Medicaid dual eligible, self-insured and ancillary lines of business.

Blue Cross of Idaho is dedicated to being the best choice for healthcare coverage, ensuring our members have access to high quality healthcare services and financial peace of mind. BCI focuses on giving members exceptional customer service while engaging them throughout their healthcare journey.

Blue Cross of Idaho offers members the most extensive provider networks in Idaho. BCI strives to maintain close relationships with the healthcare provider community and works with providers to achieve outcomes-based, cost-effective care for all our members.

Blue Cross of Idaho offers commercial health insurance and managed care products in the large group, small group and individual markets throughout Idaho. BCI has offered qualified health

plans ("QHPs") in the individual market both on and off Your Health Idaho since the inception of that State-based exchange.

Blue Cross of Idaho is an independent licensee of the Blue Cross Blue Shield Association. BCI submits these comments on behalf of itself and its affiliate, Blue Cross of Idaho Care Plus, Inc. ("ICP"). ICP contracts with the Centers for Medicare and Medicaid Services ("CMS") to offer Medicare Advantage plans in Idaho; ICP contracts with the Idaho Department of Health and Welfare and CMS to offer Medicaid managed care plans to dually-eligible Medicare-Medicaid beneficiaries in Idaho.

Blue Cross of Idaho's Interests in Preventing Inappropriate Steering

Blue Cross of Idaho has experienced first-hand the negative effects on the affordability and availability of its individual market plans, including exchange QHPs, of third party payment of premiums and cost-sharing for individuals in Idaho eligible for Medicare and/or Medicaid. Because of those negative effects, the Idaho Department of Insurance recently issued guidance that clarifies that commercial health insurance issuers in Idaho are required to accept third party premium and cost-sharing payments only from governmental programs and other qualifying organizations, none of which has commercial interests in health plan benefit payments. *See* State of Idaho Department of Insurance Bulletin No. 16-34, "Third Party Payments of Premiums or Cost-Sharing Expenses for Health Benefit Plans and Medicare Supplement Plans" (June 28, 2016) (attached as Exhibit A). The concerns that underlay the issuance of that Bulletin reflect the concerns of BCI that, without CMS action and enforcement, inappropriate steering of Medicare and/or Medicaid beneficiaries to individual market plans will continue and persist in skewing the individual market risk pool. That will leave issuers and the individuals and families purchasing exchange QHPs and other individual market plans exposed to escalating costs and diminishing coverage options.

BCI has seen how third party premium and cost-sharing payment tactics by healthcare providers, pharmaceutical and device manufacturers and other organizations, which receive the majority of their funding from or are subject to direct or indirect control of providers or manufacturers ("financially interested organizations"), influence Medicare and Medicaid beneficiaries to enroll in BCI's exchange QHPs and other individual market plans. These steering tactics are particularly insidious when conducted by financially interested organizations that are ostensibly "independent" public charities predominantly funded by tax-deductible "donations" from providers or manufacturers. These tactics have been especially evident with respect to dialysis providers treating individuals with end-stage renal disease ("ESRD"). The purportedly "charitable" payment programs that enable these steering tactics also enable their provider "donors" to obtain commercial payments for their healthcare services substantially higher than Medicare or Medicaid payments for the same services.

These steering tactics are undertaken with little apparent regard for the health and financial interests of the Medicare and Medicaid beneficiaries who are diverted away from available—and usually more suitable—Medicare and Medicaid coverage. The Medicare and Medicaid beneficiaries subject to these steering tactics are seldom provided meaningful explanations from the providers or their co-opted public charities that the beneficiaries may face substantial financial harm by foregoing available Medicare or Medicaid enrollment. That harm can include lifetime Medicare late enrollment penalties, higher commercial premium and cost-sharing obligations, and disruptions in the beneficiary's care patterns and in-network provider access.

These steering tactics are undertaken with no regard for the health and financial interests of individuals and families purchasing individual market plans who must bear the cost inflation of these tactics. Moreover, Medicare and Medicaid, like individual market plans, qualify as minimum essential coverage for purposes of the Affordable Care Act's ("ACA") individual mandate. That means Medicare and Medicaid beneficiaries steered to exchange QHPs are disqualified from receipt of premium tax credits and cost-sharing reduction subsidies otherwise available for exchange QHPs.

BCI welcomes CMS's interest in examining the steering tactics that are detrimental both to Medicare and Medicaid beneficiaries *and* to individuals and families purchasing exchange QHPs and other individual market plans. The steering tactics shift the cost of providers' revenue gains from higher commercial payment rates onto those individuals and families. That negatively skews the individual market risk pool and improperly inflates the cost of individual market plans. BCI encourages CMS to take action to halt these steering tactics and protect the interests of Medicare and Medicaid beneficiaries *and* individuals and families purchasing individual market plans. Below BCI provides various options for CMS to do just that.

Comments Responding to RFI Questions

1. **In what types of circumstances are healthcare providers or provider-affiliated organizations in a position to steer people to individual market plans? How, and to what extent, are health care providers actively engaged in such steering?**

   a. Providers steer Medicare and Medicaid beneficiaries to individual market plans when it is to the providers' financial advantage.

   Healthcare providers steer Medicare and/or Medicaid beneficiaries to individual market plans with offers to arrange for premium and/or cost-sharing assistance whenever commercial coverage can financially benefit these providers. The providers are in strong positions to steer Medicare and Medicaid beneficiaries to individual market plans because of the way these providers and the public charities they fund cooperate to arrange premium and/or cost-sharing assistance. In short, these steerage schemes require that *providers*

must approve patients' applications for financial assistance from the charities predominantly funded by the providers' tax-deductible "donations."

As the "assisted" Medicare and/or Medicaid beneficiaries are already patients of the "assisting" providers, these beneficiaries are already subject to the care and influence of those providers. These beneficiaries are unlikely either to change providers or to question why the providers steer them into individual market plans instead of Medicare and/or Medicaid.

The fundamental assumptions that underlay Advisory Opinion 97-1, issued by the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") nearly 20 years ago, do not reflect the structure and operation of the third party payment programs that have evolved since the ACA's individual market reforms were implemented in 2014. Those fundamental assumptions—based on the representations made by the advisory opinion applicants—include, among other things:

a) that the public charities receive minimal amounts of their donations (for example, less than 10 percent) from providers that have financial interests in the health benefits coverage these charities fund;

b) that patients can apply directly for financial assistance; and

c) that providers will not track the amounts the charities expend to assist the providers' patients as a means for the providers to calculate their contributions to the charities. *See* OIG Ad. Op. 97-1, pp. 3, 4.

Importantly, Advisory Opinion 97-1 involved financial assistance for individuals enrolled in Medicare to help with Medicare Part B and Medicare supplement premiums. The providers funding these charitable third party payment programs were, thus, receiving Medicare payment rates. With the advent of the ACA individual market reforms, those providers are now steering Medicare and Medicaid beneficiaries *away* from available Medicare and Medicaid coverage to individual market plans to reap the increased revenue of higher commercial payment rates. The charities these providers fund furnish the financial assistance to pay the individual market plan premiums using the providers' tax deductible "donations." Put simply, the ACA individual market reforms have created strong financial incentives for providers to co-opt the public charities they fund to furnish the financial means that support the diversion of Medicare and Medicaid beneficiaries to commercial coverage paying much higher rates. These diversions pay no heed that Medicare or Medicaid coverage may be substantially more beneficial for the beneficiaries' health and finances.

BCI has experienced the negative financial impact of these steering tactics since the inception of the ACA, especially by dialysis providers and the public charity, the American

Kidney Fund ("AKF"). AKF's Financial Statements for 2014 and 2015 report that AKF's Health Insurance Premium Program ("HIPP"), which makes premium payments on behalf of ESRD patients receiving dialysis services, receives nearly 80% of its annual donations—which exceeded $260 million in 2015—from "two corporations" [1]; disclosures made during 2012 public hearings of the Oregon Medical Insurance Pool identify those "two corporations" as the nation's largest dialysis providers—DaVita Healthcare Partners, Inc. ("DaVita") and Fresenius Medical Care Holdings, Inc. ("Fresenius").[2] These two dialysis providers' "donations" are 8 times more than the "less than 10%" represented to OIG as the funding level AKF received from dialysis providers in obtaining Advisory Opinion 97-1.

DaVita and Fresenius together control over 80% of Idaho's dialysis facilities. That has enabled them to extract robust commercial payment rates from BCI and other Idaho health insurance issuers substantially in excess of Medicare and Medicaid payment rates. The financial incentives for DaVita and Fresenius to drive their patients into individual market plans and away from Medicare and Medicaid are substantial, and their funding of AKF furnishes the vehicle to assist with the commercial coverage premium costs of those patients.[3]

BCI understands that dialysis providers, including DaVita and Fresenius, employ insurance counselors who guide their ESRD patients to individual market plans with the premium assistance of AKF's HIPP. *See*, *e.g.*, Declaration of Dialysis Clinic Social Worker (attached as Exhibit B). Indeed, AKF's May 2014 HIPP Guidelines *mandate* that "eligibility for participation in HIPP requires a signed grant application by a social worker employed by or an administrator of a dialysis provider."[4] That mandate is at odds with the representations

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[1] *See* American Kidney Fund, Inc., Financial Statements Dec. 31, 2014 & 2015, p. 19 Note 9 ("AKF received public support from two corporations in the amount of $206,822,500 and $189,415,000 for 2015 and 2014, respectively, These contributions represented 78% and 79% of the total support and revenue for 2015 and 2014, respectively."), available at http://www.kidneyfund.org/assets/pdf/about-us/2015-akf-audit-report.pdf.

[2] *See* Budnick, "Oregon Officials Grill Dialysis Companies and the American Kidney Fund about High Costs, Transplants," *The Oregonian* (Jan. 4, 2012), available at http://www.oregonlive.com/health/index.ssf/2012/01/oregon_officials_grill_dialysi.html.

[3] DaVita discloses in its Form 10-K for fiscal year ended 2015 that "payments we receive from commercial payors generate nearly all of our profits" and, consequently, if its patients "are unable to obtain or continue to receive financial assistance" from AKF, DaVita's "revenues, earnings, and cash flow could be substantially reduced." DaVita Form 10-K for Fiscal Year Ended 2015, p. 6 (Mar. 8, 2016), available at https://www.sec.gov/Archives/edgar/data/927066/000156459016013587/dva-10k_20151231.htm.

[4] AKF HIPP Guidelines p. 4 (May 2014). AKF revised its HIPP Guidelines in August 2016 to say only that each premium assistance "application must be verified and submitted to AKF by a renal professional." AKF HIPP Guidelines p. 6 (Aug. 2016), available at http://www.kidneyfund.org/assets/pdf/financial-assistance/hipp-guidelines.pdf.

that AKF and its funding providers made in applying for Advisory Opinion 97-1 that patients "can apply directly to AKF." OIG Ad. Op. 97-1, p. 3.

By mandating the involvement of dialysis social workers and renal professionals in the HIPP application process, AKF enables dialysis providers to influence their patients' health coverage choices. That supports the financial incentives of dialysis providers to divert their patients away from Medicare and Medicaid into individual market plans. These patients, often emotionally vulnerable and lacking the time and resources to effectively evaluate their coverage options, put their trust in their providers. They are not likely to question the advice of their dialysis providers' insurance counselors on insurance coverage, let alone *change* dialysis providers who *appear* to be assisting in obtaining financial support for the commercial coverage to which they are being diverted.

BCI has learned that dialysis providers track the premium assistance that AKF provides on behalf of the providers' patients. *See* Exhibit B ¶ 5. AKF's May 2014 HIPP Guidelines essentially admits this fact by directing that each dialysis provider needs to "make equitable contributions to the HIPP pool" and to determine its "'fair share' contribution to the pool by considering the number of patients it refers to HIPP."[5]

These tracking activities are also at odds with the representations that AKF and its funding dialysis providers made in applying for Advisory Opinion 97-1. Clearly, Advisory Opinion 97-1 provides neither legal insulation nor justification for schemes that involve or enable provider steerage *away* from available Medicare and Medicaid coverage to individual market plans to increase provider revenue.

b. Health insurance issuers generally lack tools to determine when providers are engaged in steering and to know the full extent of the steering occurring in the marketplace for health benefits coverage.

BCI believes that schemes to steer Medicare and Medicaid beneficiaries to individual market plans for providers' financial benefit have increased significantly since implementation of the ACA individual market reforms. But, health insurance issuers like BCI have limited access to information that identifies when third party payments are funding premiums or cost-sharing. For example, issuers are particularly unable to identify third

[5] *See* AKF May 2014 HIPP Guidelines p. 5 at *supra* note 1. AKF's May 2014 HIPP Guidelines set as one of its "provider utilization rules" that each dialysis provider "assign a corporate Finance Administrator . . . to be the financial contact with AKF [who] must have the financial authority from the Provider to make contributions to AKF's HIPP program." *Id.* at 6.

party funding when the financially interested organization issues payment directly to the covered individual, who then makes the payment to the issuer from a personal account.

There have been occasions in which the third party payment is identified as coming from a financially interest organization, such as AKF. An example is the "AKF virtual credit card" (attached as Exhibit C), which instructs the BCI member to "[u]se this virtual credit card number to pay for your health insurance premium." Because the member provided BCI with the AKF letter and embedded "virtual credit card," rather than giving BCI only the virtual credit card number, BCI was able to determine that AKF was attempting to fund the premium. Had the member only furnished the virtual credit card number, BCI may never have known that AKF, not the member, was the funding source.

In light of recent guidance from the Idaho Department of Insurance Bulletin clarifying that Idaho health insurance issuers need not accept third party premium payments from financially interested organizations (*see* Exhibit A), BCI believes financially interested organizations have turned to sending vouchers and similar payment instruments, like the AKF "virtual credit card," directly to health plan enrollees with instructions on how the enrollees can use these instruments to appear to be personally paying their premium obligations. Issuers, including BCI, have very limited means to uncover that these payments are, in fact, coming from financially interested organizations.

2. **What impact is there to the single risk pool and to rates when people enter the single risk pool who might not otherwise have been in the pool because they would normally be covered under another government program? Are issuers accounting for this uncertainty when they are setting rates?**

The steerage of individuals eligible for Medicare or Medicaid to exchange QHPs and other individual market plans has a substantial negative impact on the individual market risk pool. The steerage has impaired, and unless stopped, will continue to impair the affordability and availability of exchange QHPs and other individual market plans for the individuals and families in that risk pool.

Issuers cannot effectively anticipate the number of seriously ill individuals eligible for Medicare or Medicaid who may be diverted to the individual market risk pool by third party payment schemes. Since enactment of the ACA requirements for guaranteed issue and modified community rating and the ACA prohibition on pre-existing condition exclusions, no one can be denied individual market coverage. Issuers like BCI must have the ability to reasonably identify the risk profile of those expected to be in the individual market risk pool to be able to set premiums to cover that risk. Improper third party premium payments undermine the ability of issuers to predict the risk profile of individual market plan enrollees. Issuers also face challenges obtaining the premium increases needed to offset the

cost inflation caused by third party payment schemes. Accordingly, continued improper funding of individual market coverage will substantially undermine the financial viability of the individual market.

3. **Are there examples of steering practices that specifically target people eligible for or receiving Medicare and/or Medicaid benefits to enroll in individual market plans? In what ways are people eligible for or receiving Medicare and/or Medicaid particularly vulnerable to steering? To what extent, if any, are providers steering people eligible for or receiving Medicare and/or Medicaid to individual market plans because they are prohibited from billing the Medicare or Medicaid programs, through exclusion by the HHS Office of Inspector General, termination from State Medicaid plans or revocation of Medicare billing privileges?**

As discussed in section (a) of our responses to the Questions numbered 1, above, BCI has seen steering practices specifically targeted to individuals with ESRD who are eligible for Medicare and/or Medicaid benefits. BCI has determined that ESRD patients have been and are being diverted from Medicare and/or Medicaid coverage to BCI's exchange QHPs and other individual market plans by dialysis providers' insurance counselors. These counselors identify the providers' ESRD patients appropriate for financial assistance, then complete the patients' application to obtain premium support from AKF HIPP. AKF arranges premium payments for coverage of these otherwise Medicare or Medicaid-eligible beneficiaries by BCI individual market plans, including QHPs.

ESRD patients suffer from a severe, chronic disease and commonly have other co-morbidities, such as diabetes, anemia, hypertension or congestive heart failure. *See* OIG Ad. Op. 97-1, p. 2. Their conditions and, often their income levels, impact their abilities to make informed, dispassionate and independent decisions regarding their health care and health benefits coverage options. They of necessity must trust their healthcare providers, including their dialysis providers, to put their health and financial interests above the providers' pecuniary interests. Their providers' health benefits coverage recommendations, especially those involving potential financial assistance, are substantially, if not unduly, influential.

BCI believes it unlikely that the dialysis providers' insurance counselors disclose the providers' pecuniary interest in the patients' coverage decisions. BCI also believes it unlikely that these patients are informed that enrolling in commercial coverage over Medicare or Medicaid will substantially increase the providers' revenue.

BCI does not believe these patients are told that commercial coverage generally has higher premiums and cost-sharing obligations than Medicare or Medicaid, or that, if they receive a kidney transplant, the public charity will stop paying the premium for commercial coverage

because dialysis services will no longer be needed. Nor does BCI believe these patients are told that, if they later elect or need to enroll in Medicare, they may pay a lifetime late enrollment penalty. *See* Exhibit B ¶¶ 11-12.

These and more adverse consequences for Medicare and Medicaid beneficiaries diverted to commercial coverage by these steerage schemes urge that CMS implement policies and procedures to prohibit them. BCI proposes several options for CMS to do that in our responses to the Questions numbered 7, below.

4. **Is the payment of premiums and cost-sharing commonly used to steer individuals to individual market plans, or are other methods leading to Medicare and Medicaid eligible individuals being enrolled in individual market plans? Specifically, how often are issuers receiving payments directly from health care providers and/or provider affiliated organizations? Are issuers capable of determining when third party payments are made directly to a beneficiary and then transferred to the issuer? What actions could CMS consider to add transparency to third party payments?**

Please see our responses to the Questions numbered 3, above. BCI further observes in response to these Questions as follows.

a. Steerage affects health benefits markets besides the individual market.

BCI has identified numerous situations in which Medicare-eligible individuals who have ESRD and are eligible for or enrolled in COBRA are directed to individual market plans, rather than applying for Medicare. *See* Exhibit B ¶ 12. Based on what BCI has learned about the steerage tactics of dialysis providers, BCI believes these Medicare beneficiaries' decisions to enter the individual market, rather than enroll in Medicare, are driven by the dialysis providers who treat these beneficiaries. *See* Ex. B ¶ 11.

b. Steerage involves prescription drug benefits as well as medical benefits.

Another way in which individuals may be steered to individual market plans is through pharmaceutical manufacturers' provision of coupons or other discount devices to enrollees that enables them to purchase covered specialty or other prescription drugs with little or no out-of-pocket expense. When those enrollees' deductibles or out-of-pocket maximums are unknowingly credited by the issuer for the cost of the prescription drug without adjustment for the coupon or other discount device, the enrollee gets deductible or cost-sharing credit for paying out-of-pocket expense amounts that the enrollee did not, in fact, pay.

In these situations, enrollees artificially meet their deductibles and/or out-of-pocket maximums. That is particularly troubling for health insurance issuers, like BCI, which have a

single deductible and/or out-of-pocket maximum for their medical and pharmacy benefits. The reason is that the enrollee may satisfy the single deductible or out-of-pocket maximum with coupon-paid (rather than personally paid) out-of-pocket expenses for high cost prescription drugs, undermining the utilization control effects of deductibles and out-of-pocket maximums.

Even worse, health insurance issuers like BCI may send a refund check to an enrollee in the mistaken belief that the enrollee has overpaid out-of-pocket expenses for a medical service or procedure after the enrollee's deductible or out-of-pocket maximum had been satisfied by the enrollee's supposed out-of-pocket expenses for prescription drugs. In some of these instances, BCI has been notified by honest enrollees that BCI refunded them thousands of dollars that were not due and owing to them. But, it is difficult to know how many of these inappropriate refunds go unreported and unreturned.

c. Steerage supported by third party payments is very difficult for issuers to detect.

As explained in section (b) to our responses to the Questions numbered 1, above, issuers like BCI have few means to identify up-front the source of funds used to pay premium for an enrollee's individual market coverage. Investigations and audits by BCI's special investigation unit may sometimes reveal after-the-fact inappropriate third party payments; but, by then, it is often too late for BCI to reverse application of the inappropriate third party payment.

d. CMS should implement transparency requirements for public disclosure of third party payment programs.

BCI proposes that, to ensure transparency of third party payments and enable enforcement when those payments are prohibited or may be declined by health insurance issuers, CMS require Medicare and Medicaid participating providers to publicly disclose their contributions to organizations that provide funding for third party premium and cost-sharing programs, such as AKF's HIPP. These disclosures would help inform issuers, Medicare and Medicaid beneficiaries, and individuals and families purchasing individual market plans when public charities are subject to the influence of contributing providers. Public transparency should assist consumers, issuers, beneficiaries, CMS and State insurance departments to determine and evaluate when those contributions are improperly influencing consumers in their choice of health benefits coverage.

5. **How are enrollees impacted by the practice of a health care provider or provider-affiliated organizations enrolling an individual into an individual market plan, when the individual was previously or concurrently receiving Medicare and/or Medicaid benefits? We are concerned about instances where individuals eligible for Medicare and/or Medicaid**

benefits may have been disadvantaged by unscrupulous practices aimed at increasing provider payments, including impacts to the enrollee's continuity of care. We would be interested in knowing more about these practices and the extent to which they may be more widespread or varied than we have identified.

Please see our responses to the Questions numbered 3, above.

6. **How are enrollees impacted by the practice of a health care provider enrolling an individual into an individual market plan and paying premiums for individual market plans, when the individual was eligible for Medicare and/or Medicaid, but not enrolled? We are particularly interested in information about how to measure negative impacts on beneficiaries and enrollees, and what data sources and measurement methodologies are available to assess the impact of this behavior described in this request for information on beneficiaries and enrollees. We are seeking information on any financial impacts that are in addition to Medicare late enrollment penalties. For example, differentials in copayments and deductibles paid by enrollees in individual market plans, Medicare or Medicaid, and the impact of individual market plan network limitations on the financial obligations of enrollees, such as increased copayments and deductibles where the enrollee's chosen provider is out-of-network to the individual market plan.**

Please see our responses to the Questions numbered 2 through 4, above.

7. **What remedies could effectively deter health care providers or provider-affiliated organizations from steering people eligible for or enrolled in Medicare and/or Medicaid to individual market plans and paying premiums for the provider's financial gain? CMS is considering modifying regulations regarding civil monetary penalties and authority related to individual market plans.**

   a. <u>CMS should reinforce and reemphasize its support and encouragement for individual market issuers to decline to accept third party payments from healthcare providers, pharmaceutical and device manufacturers and other financially interested organizations.</u>

Minimally CMS should reinforce and reemphasize its support and encouragement that individual market issuers decline to accept third party payments for individual market plan enrollees made directly or indirectly by healthcare providers, pharmaceutical or device manufacturers, and other financially interested organizations, including public charities financially aligned and dependent on these providers or manufacturers. *See* CMS FAQ, "Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces" (Nov. 14, 2013) ("CMS 11/4/13 FAQ") ("HHS discourages" "hospitals, other healthcare providers, and other commercial entities . . . supporting premium payments and cost-sharing

obligations" and "encourages issuers to reject such third party payments"); CMS, Interim Final Rule, "Patient Protection and Affordable Care Act: Third Party Payment of Qualified Health Plan Premiums," 79 *Fed. Reg.* 15240, 15242 (Mar. 19, 2014) (CMS "does not prevent QHPs . . . from having contractual prohibitions on accepting payments of premiums and cost-sharing from" providers, pharmaceutical and device manufacturers and financially interested organizations).

Altruistic assertions cannot alter that healthcare providers and pharmaceutical and device manufacturers have commercial interests in enrollees' benefit payments They have financial incentives to steer enrollees needing their services to coverage that pays the most, without regard for the enrollees' health or financial needs or interests. For health care providers and pharmaceutical and device manufacturers, their "donations" for public charities, to use for the premium and cost-sharing payments that enable steerage of Medicare and Medicaid beneficiaries to individual market coverage, are investments to increase revenue. *See, e.g.*, Elgin & Langreth, "How Big Pharma Uses Charity Programs to Cover for Drug Price Hikes," Bloomberg.com (May 19, 2016), available at http://www.bloomberg.com/news/articles/2016-05-19/the-real-reason-big-pharma-wants-to-help-pay-for-your-prescription; O'Donnell, "Drug Co-Pay Assistance Programs Facing Increasing State, Federal Scrutiny," USA Today (June 6, 2016), available at http://www.usatoday.com/story/news/politics/2016/06/08/drug-co-pay-assistance-programs-facing-increasing-state-federal-scrutiny/85547788/.

To prevent the commercial exploitation of individuals with health needs, many State laws require a third party payer—whether charitable or commercial—to have an identifiable, *non-commercial* "insurable interest" in the individual for whom the third party payments are made or those payments can be rejected by issuers. *See, e.g.*, Idaho Insurance Code § 41-1804; Arkansas Insurance Code § 23-79-103. These "insurable interest" laws provide authoritative support for CMS to adopt similar protections for both enrollees in and issuers of individual market plans. So, too, does the federal Anti-Influencing Statute (Social Security Act § 1128A(a)(5)), which makes illegal "remuneration"—such as paying or waiving cost-sharing—to influence a Medicare or Medicaid beneficiary "to order or receive from a particular provider, practitioner, or supplier any item or service for which" Medicare or Medicaid may pay in whole or part. These precise concerns about payments that put the commercial interests of the "provider, practitioner, or supplier" paying the "remuneration" above the health and financial needs of the Medicare or Medicaid beneficiary are why the same prohibitions need to be applied for individual market plans.

CMS should build on its support and encouragement for individual market issuers to decline third party payments from those with commercial interest in enrollees' benefits payments by issuing affirmative regulatory standards that (1) authorize individual market issuers, not just to decline to accept these third party payments, but also to decline to issue and to

cancel or terminate individual market plans obtained or funded by these third party payments without exposure to claims of violating guaranteed availability or renewability or engaging in unlawful discrimination, and (2) require providers to write off their claims for benefits payments until the issuer can effectively cancel or terminate the coverage.

b. CMS should acknowledge that exchange QHPs are a "federal health care program" protected by the federal fraud and abuse laws.

CMS can and should acknowledge that exchange QHPs are a "federal health care program" protected by the federal fraud and abuse laws. Protecting exchange QHPs by application of the Anti-Kickback Statute (Social Security Act § 1128B(b)) and other federal fraud and abuse laws will instantly stem the expansion of the third party payment schemes that are skewing individual market risk pools and jeopardizing the affordability and availability of exchange QHPs. All of the extensive case law, CMS and OIG enforcement actions (including imposition of civil monetary penalties and program exclusions), and OIG guidance applying the Anti-Kickback Statute and other federal health care program anti-fraud provisions would immediately become applicable to third party payments for exchange QHPs. Exchange QHPs would then have the same protections as Medicare and Medicaid.

Healthcare providers, pharmaceutical and device manufacturers and financially interested organizations, including the public charities the providers and manufacturers fund, will immediately have to reassess the legal and regulatory risk created by the structure and nature of their third party payment tactics. They will have to ensure that their third party payment programs conform to the rigorous strictures and program protections of the applicable OIG advisory opinions and published guidance that protect Medicare and Medicaid beneficiaries from undue influence and exploitation in selecting health benefits coverage and providers to serve their health care needs.

CMS has acknowledged that it has "broad authority to regulate the Federal and State Marketplaces." CMS 11/4/13 FAQ. That broad authority includes the ACA mandate that CMS "implement any measure or procedure . . . determine[d] . . . appropriate to reduce fraud and abuse in the administration" of ACA Title I that HHS "has authority to implement under [ACA Title I] or any other Act," which includes the Anti-Kickback Statute and other federal fraud and abuse laws. ACA § 1313(a)(5). Further evidencing the need for fraud and abuse protections of the individual insurance market reformed by ACA Title I is that "[p]ayments made by, through, or in connection with an Exchange are subject to the False Claims Act (31 U.S.C. § 3729 *et seq.*) if those payments include any Federal funds." ACA § 1313(a)(6)(A).

Federal funds do flow through and in connection with ACA exchanges. Exchange QHPs are supported by federal funds in the form of cost-sharing reduction subsidies that the federal

government pays to issuers; federal funds also finance the advance premium tax credits for exchange QHPs that the federal government pays to issuers. Hence, exchange QHPs involve federal funding, just as do Medicare and Medicaid.

A "federal health care program" is defined as "any plan or program that provides health benefits, whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by the United States Government." Social Security Act § 1128B(f)(1). Exchange QHPs are plainly funded directly and in part by the United States Government. The ACA provisions empowering CMS to implement anti-fraud provisions to protect the individual insurance market reformed by ACA Title I strongly show Congressional intention that exchange QHPs be considered a "federal health care program" subject to existing federal anti-fraud protection. There is, thus, ample authority and logic for deeming exchange QHPs a "federal health care program"; CMS should so decree.

Moreover, deeming exchange QHPs a "federal health care program" will mean that third party payment schemes of commercially-motivated providers, pharmaceutical and device manufacturers and financially interested organizations found to violate the Anti-Kickback Statute will bring exposure to the substantial civil monetary penalties of the False Claims Act. The reason is that ACA § 6402(f) amended the Anti-Kickback Statute (Social Security Act § 1128B(g)) to make a "claim that includes items or services resulting from a violation of" the Anti-Kickback Statute a "false or fraudulent claim" under the False Claims Act.

Neither CMS nor OIG has published official regulations, guidance or analysis whether exchange QHPs are a "federal health care program." The only public position to date has been the letter exchanges with members of Congress and Congressional testimony by former HHS Secretary Kathleen Sebelius. Former Secretary Sebelius asserted in these Congressional exchanges that HHS "does not consider" QHPs "federal health care programs." HHS Sec. K. Sebelius Ltr. to U.S. Rep. J. McDermott (Oct. 30, 2013). But, apart from stating that determination was based on "careful review" and "consultation with the Department of Justice," no authority or analysis was then nor has since been disclosed to explain why QHPs are not a "federal health care program." U.S. Senator Charles Grassley at least expressed repeated disagreement with Secretary Sebelius's position, and pressed for further explanation, none of which has been provided. *See* U.S. Sen. C. Grassley Ltr. to HHS Sec. K. Sebelius (Nov. 7, 2013); U.S. Sen. C. Grassley Ltr. to HHS Sec. K. Sebelius (Feb. 12, 2014).

There is no apparent reason that the federal funds supporting exchange QHPs ought not to be protected by the federal fraud and abuse laws, just as those laws protect the federal funds supporting the Medicare and Medicaid programs. Quite the contrary, there is every reason to protect the affordability and availability of exchange QHPs and the federal funds that pay cost-sharing reduction subsidies and advance premium tax credits by deeming

exchange QHPs to be a "federal health care program." Doing so will immediately and effectively stem the growth of commercially-motivated third party payment schemes that are unsettling the market for exchange QHPs.

c. Alternatively, CMS should establish prohibitions to protect individual market plans that are similar to, but separate from, the Anti-Kickback Statute under the authority of ACA § 1313(a).

CMS has the authority to protect individual market plans, including exchange QHPs (whether or not deemed a "federal health care program"), under the mandate of ACA § 1313(a)(5). That ACA provision empowers CMS to "implement any measure or procedure . . . determine[d] . . . appropriate to reduce fraud and abuse in the administration" of ACA Title I programs (which include exchange QHPs and other individual market plans) that HHS "has authority to implement under [ACA Title I] or any other Act." Additional authority for CMS to implement Anti-Kickback Statute-like fraud protections for exchange QHPs, independent of whether they are a "federal health care program," is ACA § 1321(a). That ACA provision empowers CMS to issue regulations setting standards for the "operation of Exchanges," including the "offering of [QHPs] through such Exchanges."

These authorities enable CMS to implement effective enforcement of prohibitions against abusive third party payment schemes by providers, pharmaceutical and device manufacturers and financially interested organizations. A particular advantage of implementing fraud and abuse protections for individual market plans, including exchange QHPs, under these ACA provisions is that various OIG Advisory Opinions—used by public charities to shield their third party payment programs, notwithstanding questionable compliance with the rigorous conditions set by these Advisory Opinions—will have no application. Hence, these public charities will face anew obligations to establish *true* independence from their commercially-motivated funding sources and *true* focus on the needs of the individuals they purport to support, rather than the financial interests of those who fund them.

8. **What steps do third party payers take to effectively screen for Medicare and/or Medicaid eligibility before offering premium assistance? What steps do these entities take to make sure that any such individuals understand the impact of signing up for an individual market plan if they are already eligible for or receiving Medicare and/or Medicaid benefits?**

Please see our responses to the Questions numbered 1 through 4, above. BCI believes that providers affirmatively identify Medicare and Medicaid beneficiaries to divert *from* Medicare or Medicaid coverage *into* individual market plans for the providers' financial

benefit. BCI further believes that the Medicare and Medicaid beneficiaries so diverted are *not* informed of the adverse consequences to their health and finances of that diversion.

Among the options for CMS to effect transparency for Medicare and Medicaid beneficiaries whose healthcare providers are seeking to steer them to individual market plans is to strengthen the laws and the penalties enforced by CMS that require providers, including those providing dialysis services, to fully and accurately explain to their Medicare- and/or Medicaid-eligible or enrolled patients those patients' Medicare or Medicaid benefits and rights.

9. **For providers that offer premium assistance, who is interacting with beneficiaries to determine proper enrollment? What questions are asked of the consumer to determine eligibility pathways? How are consumers connected to foundations or others who are in the position to provide premium assistance? How are premiums paid by providers or foundations for consumers?**

   Please see our responses to the Questions numbered 1 and 3, above.

10. **We seek comment on policies prohibiting providers from making offers of premium assistance and routine cost-sharing waivers for individual market plans when a beneficiary is currently enrolled or could become enrolled in Medicare Part A and other adjustments to federal policy on premium assistance programs in the individual market to prevent negative impact to beneficiaries and the single risk pool.**

    Please see our responses to the Questions numbered 7, above.

11. **We seek comments on changes to Medicare and Medicaid provider enrollment requirements and conditions of participation that would potentially restrict the ability of health care providers to manipulate patient enrollment in various health plans for their own benefit. We are also interested in information on the extent steering is associated with other inappropriate behavior, such as billing for services not provided, or quality of care concerns. We seek comment on the advisability of such restrictions, as well as considerations of how such restrictions would affect health care providers and beneficiaries.**

    In addition to the protections against abusive third party payment schemes set out in our responses to Questions numbered 7, above, we propose that CMS consider establishing, as a condition for provider participation in Medicare or Medicaid, that healthcare providers be prohibited from steering, or cooperating or coordinating with or funding directly or indirectly the activities of third parties, including public charities, to facilitate steering, or

from attempting to influence Medicare or Medicaid beneficiaries to leave or decline their Medicare or Medicaid coverage for individual market coverage.

12. **We seek comment on policies to require Medicare and Medicaid-enrolled providers to report premium assistance and cost-sharing waivers for individual market enrollees to CMS or issuers.**

Please see section (d) to our responses to the Questions numbered 4, above. We there propose that, "to ensure transparency of third party payments and enable enforcement when those payments are prohibited or may be declined by health insurance issuers, CMS [should] require Medicare and Medicaid participating providers to publicly disclose their contributions to organizations that provide funding for third party premium and cost-sharing programs, such as AKF's HIPP."

CMS should, accordingly, implement information collection that will require Medicare- and Medicaid-enrolled providers to report to CMS their payments—whether directly or through "donations" to financially interested organizations—for premium and cost-sharing assistance for individual market plan enrollees. That reporting will enable CMS to establish a searchable public online national registry of these Medicare- and Medicaid-enrolled providers.

CMS is in a better position than issuers to efficiently and effectively establish and maintain that national registry. The national registry would be a resource for CMS and States for screening healthcare providers for satisfaction of conditions of participation in the Medicare and Medicaid programs. The national registry would also be a resource for health insurance issuers, which now have few tools to identify third party payment tactics, as explained in section (b) of our responses to the Questions numbered 1 and section (c) of our responses to the Questions numbered 4, above. But issuer consultation of the registry should *not* become an issuer obligation before issuers may decline to accept third party payments for individual market coverage.

13. **We seek comments on whether individual market plans considered limiting their payment to health care providers to Medicare-based amounts for particular services and items of care and on potential approaches that would allow individual market plans to limit their payment to health care providers to Medicare-based amounts for particular services and items of care.**

Health insurance issuers generally seek the lowest reasonable payment rates they can negotiate with their network providers. Those rates are rarely as low as the rates that Medicare can and does set by regulation. Indeed, issuers are rarely, if ever, in a sufficient market position to obtain Medicare rates and still comply with applicable network adequacy

obligations under State and federal standards for exchange QHPs and other individual market plans.

Because of the virtual duopoly of dialysis facilities controlled by DaVita and Fresenius in Idaho, BCI is significantly challenged in negotiating appropriate payment rates with these and other Idaho dialysis providers. Rather than seeking Medicare rates, BCI faces dialysis payment demands that are multiples of Medicare, yet has little choice but to accept grossly inflated payment terms to be able to provide sufficient access to satisfy network adequacy requirements.

BCI urges that CMS not institute network adequacy requirements for exchange QHPs and other individual market plans that exacerbate the substantial market power of many providers, including especially dialysis providers DaVita and Fresenius. Although CMS generally has declined to become involved in the private contract negotiations between issuers and their network providers, should CMS determine it has the authority, it may consider—as one effective means of countering these third party payment schemes that divert Medicare and Medicaid beneficiaries to individual market plans for the providers' financial benefit–requiring as a condition of participation in Medicare and Medicaid that healthcare providers must accept Medicare and Medicaid payment rates for treatment of Medicare- or Medicaid-eligible beneficiaries enrolled in exchange QHPs and other individual market plans.

14. **We seek comment on policies that would allow individual market plans to make retroactive payment adjustments to providers, when health care providers are found to have steered Medicare or Medicaid beneficiaries and enrollees to enroll in an individual market plan for the provider's financial gain.**

Please see responses to the Questions numbered 13, above.

Respectfully submitted,

Blue Cross of Idaho Health Service, Inc.

By: Steve Fidler

Its: General Counsel

EXHIBIT A

State of Idaho

DEPARTMENT OF INSURANCE

C.L. "BUTCH" OTTER
Governor

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DEAN L. CAMERON
Director

BULLETIN NO. 16-04

DATE: June 28, 2016

TO: Disability/Health Insurance Carriers in Group or Individual Markets

FROM: Dean L. Cameron, Director

SUBJECT: Third Party Payments of Premiums or Cost-sharing Expenses for Health Benefit Plans and Medicare Supplement Plans

Carriers in the group and individual health insurance markets may accept payments of premiums and out-of-pocket expenses from any third party.

This bulletin provides guidance regarding the circumstances under which carriers **must** accept third party payments toward a policyholder's or certificate holder's (the insured's) insurance premium or out-of-pocket expenses, including deductibles, copayments and coinsurance. This bulletin also addresses the issue of whether out-of-pocket expenses paid by a third party must be counted toward the insured's deductibles or out-of-pocket maximums.

Third party payments made by service providers are addressed at Idaho Code § 41-348(2), which prohibits the practice of providers "waiving, rebating, giving, paying, or offering to waive, rebate, give or pay all or part of a claimant's deductible or claim for casualty, disability insurance, worker's compensation insurance, health insurance or property insurance."

Federal regulation addresses third party payments at 45 CFR § 156.1250, requiring carriers offering Qualified Health Plans (QHPs) to accept and apply third party payments of premiums or cost-sharing from the following entities:

- a Ryan White HIV/AIDS Program;
- an Indian tribe, tribal organization, or urban Indian organization; and
- local, state or federal government programs, including grantees directed by a government program to make payments on its behalf.

The Department of Insurance (Department) extends the federal requirement at 45 CFR § 156.1250 to all carriers offering health benefit plans, as defined at Idaho Code § 41-4703(15) and §41-5203(12) in Idaho's group and individual markets, because policies that fail to do so would be unfairly prejudicial to the policyholder under Idaho Code § 41-1813.

Inasmuch as Medicare supplement insurance policies are not included in the definition of health benefit plans, carriers must accept payments from third parties toward Medicare supplement policies as long as such payments do not violate the anti-kickback provisions of the Social Security Act (§1128B codified at 42 USC § 1320a-7b).

In addition to the federal requirement at 45 CFR § 156.1250, and for the same reason, carriers offering health benefit plans in the group and individual markets are required to accept payment on behalf of an insured from the third parties described in the next paragraph.

Carriers must accept third party payments from individuals such as family and friends. Carriers must also accept third party payments made by religious institutions and other not-for-profit organizations when each of the following three criteria is met:

- the assistance is provided on the basis of the insured's financial need;
- the institution/organization is not a healthcare provider; and
- the institution/organization is not financially interested. Financially interested institutions/organizations include institutions/organizations that receive the majority of their funding from entities with a pecuniary interest in the payment of health insurance claims, or institutions/organizations that are subject to direct or indirect control of entities with a pecuniary interest in the payment of health insurance claims.

The above language defines the minimum set of third parties from which carriers must accept third party payments. Carriers must apply cost-sharing contributions from such third parties toward deductibles and out-of-pocket maximums as if the insured made the payment directly.

Payments made directly by the insured to the carrier must be accepted, and carriers must not require certification or verification of the source of the funds.

Health benefit plans issued or renewed on or after January 1, 2017, that include a third party payer prohibition must have the prohibition as part of the insured's contract, and the language must be no more restrictive than the minimum standard of this bulletin. The carrier's third party payer policy language must not include a discretionary clause, as defined and prohibited by IDAPA 18.01.29.

The requirement that carriers, at a minimum, accept third party payments as set forth in this bulletin is effective immediately for health insurance policies regulated under Title 41, including policies currently in force that contain a third party payer prohibition, and the Department will interpret any third party payer prohibition included in any such health insurance policies consistent with this bulletin. The Department encourages carriers to proactively contact the Department at 208-334-4300 to discuss any third parties from which the carrier will not be allowing payments. Upon rejecting or otherwise refusing to treat a third party payment as a payment from the insured, carriers must inform the insured in writing of the reason for doing so and of the insured's right to file a complaint with the Department.

EXHIBIT B

DECLARATION OF ANONYMOUS DIALYSIS CLINIC SOCIAL WORKER*

I state the following under penalty of perjury:

1. I have been employed by Blue Cross of Idaho Health Service, Inc. ("BCI") since October 2014. I am a licensed master social worker and a certified case manager.

2. I have worked for 25 years as a dialysis social worker. I previously worked in the dialysis clinic of an Idaho hospital. In 2006, that clinic was sold to a company that owns and operates many dialysis clinics throughout the United States. I was employed by that company as a dialysis social worker and worked in several of its Idaho dialysis clinics through October 2014. Once that company assumed ownership and management of the dialysis clinic at which I worked, the clinic's referrals of its patients to the American Kidney Fund ("AKF") Health Insurance Premium Program ("HIPP") increased.

3. I learned that each clinic of the company, including those at which I worked, has an insurance counselor who interacts with social workers to assist in directing patients to the AKF HIPP. These insurance counselors were highly experienced in completing the necessary paperwork to obtain the premium assistance from AKF HIPP. The company's dialysis social workers and insurance counselors have direct access to an online application system in which they are able to track the status of applications and, after approval, review the status of AKF's premium payments for the patients' insurance policies.

4. There is very little involvement by the patient in seeking the premium assistance from AKF. The social workers and insurance counselors obtain the necessary information from the patients and do all remaining tasks necessary to obtain the AKF premium assistance.

* The name and signature of this anonymous dialysis clinic social worker are on file with Blue Cross of Idaho Health Service, Inc.

5. I understood that the AKF HIPP was funded by the dialysis company reimbursing AKF for the funds spent on premiums for insurance for the company's dialysis patients. I learned that the dialysis provider I worked for received letters from AKF explaining funds to pay premiums for the clinic's patients were low. These letters included how many clinic patients received AKF premium assistance and how much AKF spent on behalf of those patients.

6. In one instance, I was working with an individual who was seeking dialysis treatment. The patient had insurance through a high risk pool that would only cover dialysis after the first year of coverage. When I consulted with the clinic's insurance counselor, I was told not to seek premium assistance from AKF until insurance would pay for dialysis.

7. In my experience as a dialysis clinic social worker and working with patients, I never encountered a situation in which the clinic balance billed a patient because the clinic was an out-of-network provider with respect to the patient's commercial insurance.

8. Beginning in late December 2015, I had several telephone calls with dialysis clinic social workers and patients to notify them that BCI no longer accepted premium payments from AKF, and had and would continue to return or refund payments made by AKF received by BCI on or after January 1, 2016.

9. Based on my telephone calls with dialysis clinic social workers and BCI members, I have no reason to believe that my former employer has changed its practices with regard to how it handles financial assistance for patients since the time I worked for that company.

10. Based on similar interaction with the dialysis clinic social workers for the other major dialysis providers in Idaho, upon personal knowledge and belief, all three of the major dialysis providers in Idaho employ social workers and insurance counselors who interact with AKF in similar ways to obtain financial assistance through AKF for their patients.

11. As a social worker for a dialysis clinic and now a social worker and case manager for BCI, I witness ongoing situations in which dialysis patients trust in the information provided to them by the dialysis clinic, and where they do not fully understand the impact of the decision to obtain financial assistance from AKF and delay signing up for Medicare. In some instances, they do not even know they may qualify for Medicare.

12. I often encounter situations in which members with end stage renal disease have not been fully informed of all their dialysis treatment options, including home dialysis. This lack of information is present not only with members in the individual market, but also with members I assist through case management who are on a group plan receiving dialysis and who have not been referred to Medicare by their dialysis provider. These members often continue with more expensive COBRA coverage, likely with premium assistance from AKF.

DATED this 22 day of September, 2016.

[Signature on File]

EXHIBIT C

American Kidney Fund®

March 21, 2016

Patient HAP# XXXXX

BCI Member
c/o: YYYYY Dialysis
Attention: YYYYYYYYYY
YYYYYYYYYYYYYYYY
Boise, ID YYYYY-YYYY

Dear BCI Member :

This virtual credit card has been given to you through a Health Insurance Premium Program (HIPP) grant from the American Kidney Fund. The virtual credit card number can only be used to pay your Blue Cross Blue Shield of ID health insurance premium in the exact amount noted below. It can only be used one time, for the exact amount and cannot be used for anything else besides your health insurance premium.

Use this virtual credit card number to pay for your health insurance premium as soon as possible. Your virtual credit card number will expire 60 days from the date of this letter. You can find the phone number or website of your health insurance company on the back of your health insurance card.

Instructions on how to use this virtual credit card number are on the included sheet.

Below is your virtual credit card number. You must use it to pay for your health insurance premium. **You will not receive a physical credit card.**

RECEIVED
APR 0 8 2016
BY:

Security Code (CVV code): 481
Billing zip code: 20852*

*Make sure to use 20852 as the billing zip code if asked. Do not use your personal zip code as this will cause the card to be denied.

If you have any questions about using this card, please contact the American Kidney Fund directly at 855.541.0950 or email HIPPVCCPayments@kidneyfund.org.

3 Easy Steps to Using Your HIPP Virtual Credit Card

1

Gather the paperwork you will need

- ☑ The enclosed letter
- ☐ Your health insurance company's phone number or website
- ☐ Your health insurance ID#

2

Contact your health insurance company via phone or web

Follow the prompts to make a payment

3

Pay using the credit card information in this letter

Remember to use **billing zip code 20852** and the **exact $ amount** printed on the enclosed letter

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CA0001806

Teri Browne, PhD, MSW, NSW-C, LSW
Response to Docket ID: CMS-2016-0145
September 22, 2016

Dear Centers for Medicare Medicaid Services:

Thank you for the opportunity to comment on the "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans." I have worked in the nephrology community for 21 years, and am a certified nephrology social worker. I worked as a dialysis social worker for 13 years including at Gambro (now Davita) and Fresenius. I currently am an associate professor of social work and focus my research on psychosocial barriers to kidney disease outcomes, and kidney transplant disparities. I have spent decades serving and continuing to serve in local, national and international kidney organizations including several ESRD networks, kidney patient organizations, and was the national chairperson of the Council of Nephrology Social Workers. I am considered an international nephrology social work expert, and have presented across the country and around the world on kidney disease and nephrology social work issues (as well as published numerous book chapters and peer-reviewed articles on these topics).

Based on my personal experience as a dialysis social worker, and information I receive from dialysis and transplant patients and professionals from across the country, I know that there is indeed "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans." The greatest focus of my work for Fresenius was to track and promote commercial insurance for our patients- they had a special form for this to track all patients with commercial insurance, and this was heavily promoted at a local and regional level as one of all social workers' primary tasks. The expectation was that all commercially insured patients keep their commercial insurance (using American Kidney Fund to pay the premiums), and not pursue Medicare or Medicaid if that meant the commercial insurance would not be the primary payor. Also, Fresenius prioritized efforts to procure commercial insurance for all patients without such insurance. The % of commercially insured patients was a metric used by all dialysis units as an important quality indicator, and constantly monitored.

In my capacity as a kidney disease scholar, I have the opportunities to speak with patients with ESRD, their care partners and nephrology professionals from across the country. I have heard from countless patients and professionals that for-profit dialysis companies continue to steer patients into commercial market insurance plans, despite their eligibility for Medicare and Medicaid. This is done by the companies billing departments, as well as by social workers directed by their company to do so. Tragically, this is done with no regard for the patients' existing coverage gaps (many times there are none) with Medicare and/or Medicaid, and no regard for the consequences of this efforts. I have heard from and about many patients who end up with large copayments, significantly reduced benefits, and drastically limited provider access and continuity of care because they are steered into commercial insurance plans despite their eligibility for Medicaid and/or Medicare.

For me, the most alarming phenomenon related to these practices is the barriers these practices create for patients to get kidney transplants and have successful transplant outcomes. What has happened is that patients are steered into these commercial insurance plans (or persuaded to keep their commercial insurance despite their eligibility for Medicare or Medicaid- this may be happening even more frequently than the "steering") with impossibly high premiums, which are paid by the American Kidney Fund. This allows the dialysis unit to charge commercial insurance rates for services. However, as soon as the patient receives a transplant, the patient cannot keep their insurance, because this "charity" premium funding from American Kidney Fund disappears (as the American Kidney Fund only helps those who receive dialysis because their funds for this program comes from dialysis companies). Patients are then stuck with this market plan, which is most definitely not in their best interest as a transplant patient as they cannot afford the premiums that American Kidney Fund once paid. In worst case scenarios, they also are stuck with penalties because they did not enroll in Medicare when they were eligible.

This results in dialysis patients not being eligible to get listed for a kidney transplant, or have serious consequences related to having no/inadequate insurance once they are transplanted. Horrifically, this impacts the country's most underserved patients the most (who cannot afford these commercial insurance premiums), further contributing to the kidney transplant disparity that already exists in this country and is a public health crisis. Kidney transplant is the best and most cost-effective treatment modality for ESRD- and these practices are seriously limiting access to this modality because patients are steered into insurance decisions (entering into market place plans or keeping commercial insurance when eligible for Medicare and/or Medicaid) that are **only best for dialysis companies' profits, not patients' transplant pursuit.** I have personally heard both Fresenius and Davita representatives talk about helping patients get commercial insurance as a priority (with American Kidney Fund paying the premiums), and have questioned them about the negative consequences for patients related to getting kidney transplants (to no avail). I have heard as recently as this week (and for many many years) horror stories from transplant social workers trying to work with dialysis patients who have insurance paid for by the American Kidney Fund, and how this is a serious barrier to getting patients transplants. This is absolutely unacceptable and unconscionable.

I know that the narrative from American Kidney Fund, the dialysis companies, and Dialysis Patient Citizens (which is **not an independent patient organization**- it was started by a for-profit dialysis company, the majority of its funding comes from Davita and Fresenius, and its CEO is not a patient) is that looking into this practice of steering is somehow taking away dialysis patients' "choices." One look at American Kidney Fund's Facebook page and other social media (https://www.facebook.com/AmericanKidneyFund/?fref=ts) demonstrates how they are terrifying patients and making the narrative about how this request for information is taking away patient choice: "We believe all dialysis patients should be educated about their insurance options, and deserve to freely choose the insurance that best fits their personal needs." Dialysis Patient Citizens' newsletter stated: "Insurers are trying to kick ESRD patients off their plans in the health exchanges by refusing to accept charitable assistance for insurance premiums from

organizations like the American Kidney Fund. Tell CMS they shouldn't cave into insurers demands. Help us protect patient choice for insurance coverage by submitting your comments on the next page. You will be provided with talking points to formulate your comments, and they will be submitted to DPC."

As a social worker, I am fiercely protective of and an advocate for patient choice. However, currently, **patients are not given the FULL information needed to actually make a choice**- they are not informed about how their commercial insurance compares to Medicare or Medicaid as it relates to access to providers, continuity of care, copayments and deductibles for all providers (dialysis companies may waive these for patients, but certainly their other medical providers do not); how these plans will specifically impact their candidacy for transplant; exactly what happens if they do get a transplant but are dependent on the American Kidney Fund for premium assistance, etc. Patients also need to know how much more their dialysis companies can bill if they have commercial insurance (i.e. how their dialysis companies profit from this "choice"); how much their dialysis company contributes to the American Kidney Fund; how the vast majority of the funding for the American Kidney Fund and Dialysis Patient Citizens comes from for-profit dialysis companies (patients can make a choice to determine if that influences any information provided); how the CEO of the American Kidney Fund made over $515,000/year in reportable and other compensation last year and received more than a $40,000 raise in each of the last few years (patients can make a choice to determine if they think that the American Kidney Fund has no vested interest in this matter); and how the American Kidney Fund refused to help patients in dialysis units that did not pay into their fund (this has been the case in practice for years, this past year with all this scrutiny they do seem to be backing away from this). They also can be informed that the OIG opinion that allowed dialysis companies to make "donations" to the American Kidney Fund so that the American Kidney Fund's CEO can make more than $500,000/year and they can pay patients' premiums**, only mentioned Medicare and Medigap policies in their opinion**, so it is unclear that any other assistance is even allowed.

If patients can get full information about all these things that are truly necessary to make insurance decisions, I am totally fine with patients choosing to pursue market insurance plans even if they are eligible for Medicaid and/or Medicare. Given that these decisions are very confusing and insurance plan benefits are constantly changing, perhaps requiring that patients be counseled by an independent insurance advocate that is not beholden to the for-profit dialysis company? (like the independent donor advocate we require for kidney transplants).

In regards to the specific questions for this request for information, the only people interacting with beneficiaries to determine proper enrollment may be dialysis company staff and insurance companies. We have no idea what questions are asked of the consumer to determine eligibility pathways, and this is the greatest problem. If this is only done by dialysis unit staff, they have a vested interest in promoting the dialysis unit's best interest, not the patient's best interest (and certainly not their interest outside of dialysis). Consumers are

connected to foundations or others who are in the position to provide premium assistance by their dialysis units! This is an extreme example of conflict of interest.

I strongly believe that if dialysis providers are allowed to continue to pay their patients' insurance premiums through donations to the American Kidney Fund, they must publically report premium assistance and cost-sharing waivers for individual market enrollees.

Thank you for soliciting comments on this very important issue.

Sincerely,

Teri Browne

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September 22, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-6074-NC
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via: http://www.regulations.gov

RE: Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans (CMS-6074-NC) – AHIP Comments

Dear Mr. Slavitt:

America's Health Insurance Plans (AHIP) appreciates this opportunity to offer comments and recommendations in response to the Centers for Medicare & Medicaid Services' (CMS') August 23, 2016 request for information (RFI): Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans (81 Fed. Reg. 57554) and accompanying letter to end-stage renal disease (ESRD) providers.

AHIP and our members support access by all consumers to affordable health coverage without regard to health status and through the coverage program that best meets their needs based on their specific circumstances and eligibility. We also recognize the important role that many entities, such as Ryan White HIV/AIDS Programs and other third-party entities recognized in CMS guidance, play in providing financial assistance for consumers. Our comments are related to the specific and widespread abuse of third-party payments by certain providers, institutions, and non-profit entities that are steering patients eligible for or receiving Medicare and/or Medicaid benefits into individual market plans (both on-and-off the Marketplace) for the primary purpose of obtaining higher reimbursement.

We commend CMS for addressing this serious problem. Over the last three years our member health plans have seen a significant increase in the types of activities outlined in the RFI, including inappropriate third-party premium payments and copay assistance programs such as prescription drug coupons. Many arrangements involve ESRD providers and related foundations, but they also extend to a range of other providers and entities. They mirror practices that are prohibited in Federal health care programs under the anti-kickback and civil

monetary penalty (CMP) laws as a result of the adverse consequences for vulnerable beneficiaries and market stability.

In many cases, these practices are harming patients and undermining the individual market by skewing the risk pool and driving up overall health care costs and premiums. While such activity has not been limited to ESRD, our members' experiences have shown that individuals with ESRD are particularly vulnerable. In many cases, third-party organizations (who receive provider funding) directly steer ESRD patients to individual market coverage without any discussion of the options available to them (including Medicare and Medicaid). Moreover, third-party groups often stop paying premiums after the patient has received a kidney transplant and no longer needs dialysis, leaving patients financially exposed and subject to significant penalties in cases where they are receiving premium tax credits under the Affordable Care Act (ACA) for which they are not eligible.

In the Appendix to our detailed comments, we provide examples of inappropriate steering that is taking place today. We also provide data from plans that illustrate the significant growth in the number of individual market enrollees who are receiving dialysis and the impact of this growth on health care spending. For example, some plans have seen claims for dialysis services more than double in one year. In fact, one plan saw its spending on ESRD services increase more than twenty-fold, from ***$1.7 million in 2013 to $36.8 million in 2015.*** Similarly, for other plans, enrollment of individuals with ESRD has increased by 200-500% over a period of only one to three years.

These trends demonstrate the serious and significant nature of the problem. CMS must take immediate action before the start of the 2017 open enrollment period to address these abuses. Given the potential for continued harm to patients and to the stability of the individual marketplace, CMS has "good cause" to find that the notice-and- comment rulemaking process would be "impracticable, unnecessary, or contrary to the public interest" and should adopt an interim final rule (IFR) to curtail these harmful practices. See 5 U.S.C. § 553(b).

In our detailed comments below, we discuss a variety of legal authorities pursuant to which CMS can take the steps necessary to prohibit these activities and impose sanctions on those who engage in such tactics. In summary, we recommend that CMS immediately issue an IFR effective for 2017 that:

1. Prohibits direct and indirect premium payments by providers to entities in which the provider has a financial interest by using CMS' broad rulemaking authority under Medicare and Medicaid;
2. Confirms that certain third-party payments are prohibited under the Civil Monetary Penalties (CMP) law;

3. Considers health care providers out of compliance with Conditions of Coverage if they fail to provide information to consumers on their full range of coverage options;
4. Interprets Medicare private contracting requirements in ways that discourage intentional steerage between markets;
5. Clarifies plan authority to reject certain third-party payments and establishes that federal rules supersede state guidance;
6. Revises guaranteed availability and renewability requirements for Medicare-eligible individuals;
7. Modifies individual market rules to prevent inappropriate steering of Medicaid enrollees to marketplace coverage;
8. Increases transparency of third-party payments; and
9. Utilizes additional regulatory and operational tools to address third-party payments.

Finally, we recommend that CMS issue a new RFI on another concerning area that falls under third-party payments: the growing use of pharmaceutical manufacturer drug coupons, co-pay cards, and related charity programs.

Again, thank you for the opportunity to provide comments, data and other information in support of this RFI.

Sincerely,

Matthew Eyles

Matthew Eyles
Executive Vice President
Policy and Regulatory Affairs

Julie Miller

Julie Miller
General Counsel

AHIP Detailed Comments & Recommendations

1. ***Prohibit Direct and Indirect Premium Payments by Providers to Entities in which the Provider has a Financial Interest by Using CMS' Broad Rulemaking Authority under Medicare and Medicaid***

We strongly recommend that CMS utilize its broad rulemaking authority to prohibit providers from funding premiums directly or indirectly through contributions to third-party entities. It is critical to address, as the Department of Health and Human Services Office of the Inspector General (OIG) has done in advisory opinions, indirect premium payments made via third parties. It is an inherent conflict of interest for providers to make payments that incentivize individuals to obtain and maintain coverage that will ultimately benefit the provider. CMS should take action to prevent such activity from occurring.[1] Failure to do so gives providers that otherwise "agree" to Medicare or Medicaid reimbursement rates an optional higher payment amount based on subsidizing the premium in the private market.

We believe CMS has the clear authority through its general rulemaking authority as well as through its Conditions of Participation (CoP) requirements for Medicare and its provider enrollment rules for Medicare and Medicaid to prohibit such direct or indirect payments by providers. The threat of discontinuing Medicare and Medicaid payments could be an effective means to curtail activities that undermine the quality and safety of care for individuals entitled to or eligible for Medicare or Medicaid. The statutory bases for CMS' authority to take action are described below.

First, Sections 1102 and 1871 of the Social Security Act ("SSA"), which are codified at 42 U.S.C. §§ 1302 and 1395hh, provide general authority for the Secretary to prescribe regulations as necessary for the efficient administration of the Medicare program. CMS relied upon these authorities to promulgate the Patients' Rights Condition of Participation, which is applicable to all Medicare and Medicaid participating hospitals and contains standards that ensure minimum protections of each patient's physical and emotional health and safety. See 71 Fed. Reg. 71378 (Dec. 8, 2006).

Second, Section 1866(j) of the SSA, codified at 42 U.S.C. § 1395cc(j), provides specific authority with respect to the enrollment process for providers and suppliers. The Secretary could, under this authority, include a requirement in 42 CFR Part 424, Subpart P (Requirements for

[1] In the context of the Medicare Advantage and Medicare Prescription Drug Benefit Programs, CMS has recognized the potential conflict of interest that a provider may have and requires "that any assistance provided to a beneficiary by a contractual, co-branded, or otherwise affiliated provider, results in a plan selection that is always in the best interest of the beneficiary." Medicare Marketing Guidelines at § 70.11.1. In the individual market context where providers are giving direct or indirect premium support to influence coverage decisions, the conflict of interest is real as is the concern that the individual's coverage selection may not be in their best interest.

Establishing and Maintaining Medicare Billing Privileges), to prohibit, as a condition of enrollment and payment, third-party payment of premiums (either directly or indirectly) to a qualified health plan on behalf of a person who is entitled to or eligible for Medicare.

Third, Section 1881(b) of the SSA, codified at 42 U.S.C. § 1395rr(b), provides that the "Secretary shall by regulation prescribe" requirements "for institutional dialysis services and suppliers" to be eligible for Medicare payment. Pursuant to this and other authorities, CMS promulgated Conditions for Coverage for End-Stage Renal Disease Facilities establishing "conditions for coverage that dialysis facilities must meet to be certified under the Medicare program." 73 Fed. Reg. 20370 (April 15, 2008). The purpose of such conditions "is to protect dialysis patients' health and safety and to ensure that quality care is furnished to all patients in Medicare-approved dialysis facilities." Id. at 20372 (emphasis added). In addition, the Conditions of Coverage include a focus on patient's rights, including the right to "be informed about and participate, if desired, in all aspects of his or her care." 42 C.F.R. § 494.70. Such rights of information and participation are meaningless if the facility at which the patient is receiving care is using its trusted position to cause the patient to make health care coverage decisions in the provider's financial interests without complete information regarding all available coverage options.

The Secretary could, under this authority, include a requirement in 42 C.F.R. Part 424, Subpart C (Claims for Payment), to prohibit, as a Condition of Payment, third-party payment of premiums (either directly or indirectly) to a qualified health plan (QHP) on behalf of a person who is entitled to or eligible for Medicare. Such an approach would also impact activities directed at individuals eligible for or enrolled in Medicaid since CMS regulations at 42 C.F.R. § 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in Medicaid.[2]

Fourth, Section 1902(a)(27) of the SSA, codified at 42 U.S.C. § 1396a(a)(27), provides general authority for the Secretary to require provider agreements under Medicaid State Plans with every person or institution providing services under the State Plan. This broad authority would permit the Secretary to revise 42 C.F.R. § 431.107 (required provider agreement) to ensure that that Medicaid providers and institutions do not inappropriately steer Medicaid recipients away from the Medicaid program for purposes of obtaining higher reimbursement.

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[2] Such concerns are not, of course, limited to the ESRD context. Section 1861(e)(9) of the SSA, which requires hospitals to "meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individual," provides the basis for including a similar requirement in the hospital conditions of participation. See also 77 Fed. Reg. 29037 (May 16, 2012) (Noting, with respect to hospital conditions of participation that the "purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals." Id..

This provision would not run afoul of 1902(a)(25)(G)[3] insofar as a Medicaid enrollee may be dual enrolled in a QHP. The restriction would be on the Medicaid-enrolled provider directly or indirectly paying the premium or cost sharing of such an enrollee.

2. Confirm that Certain Third-Party Payments are Prohibited under the CMP Law

Under section 1128A(a)(5) of the SSA, codified at 42 U.S.C. § 132a-7a(a)(5), "any person" who offers or transfers to an individual eligible for Medicare or Medicaid any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier any item for which payment **may** be made under Medicare or Medicaid, is subject to CMPs. In an August 2002 Special Advisory Bulletin, the OIG noted the "broad language of the prohibition and the number of marketing practices potentially affected". 65 Fed. Reg. 55844 (Aug. 30, 2002).

We believe that the CMP statute is sufficiently broad to prohibit third-party premium payments for individuals eligible for Medicare or Medicaid to enroll in an individual market plan. First, the statute broadly applies to "any person." Second, premium payments are clearly remuneration within the meaning of the statute. Third, where the services at issue are eligible for payment under Medicare or Medicaid, the "may be made" requirement is satisfied where the individual is entitled to benefits under Medicare or Medicaid.

The limited situations where the OIG has concluded that such payments pose a low risk for fraud and abuse (e.g., independent charity assistance programs) are not present here. See e.g., OIG Advisory Opinion Nos. 06-04 and 06-04A. We note that, on May 2, 2000, the OIG proposed a new safe harbor that would have protected Medigap premium payments for beneficiaries with ESRD. See 65 Fed. Reg. 25460 67 Fed. Reg. 72896 (December 9, 2002). The OIG ultimately withdrew the proposed safe harbor noting:[4]

- The CMP statute targets corruption of the provider selection process. Since any exception would be permissive, any ESRD facility that did not pay premiums for financially needy patients would likely lose business. In short, the exception would promote the very conduct the statute prohibits: the offering of remuneration to influence the selection of a provider.

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[3] Under this section, the State Plan must provide that the State prohibits any health insurer (including a group health plan, as defined in section 607(1) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1167(1)], a self-insured plan, a service benefit plan, a managed care organization, a pharmacy benefit manager, or other party that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service), in enrolling an individual or in making any payments for benefits to the individual or on the individual's behalf, from taking into account that the individual is eligible for or is provided medical assistance under a plan under this subchapter for such State, or any other State.

- Patients would not only be influenced to select ESRD facilities that buy them supplemental health insurance, but would be "locked in" to those facilities, since changing facilities would jeopardize their supplemental insurance for all services, including substantial non-ESRD services.
- Creating an exception for direct premium payments by ESRD providers would create demands for additional exceptions for comparable payments by other health care providers and would potentially increase federal expenditures and Medigap premiums.
- It is to a provider's financial advantage to pay the Medigap premium whenever the premium is less than the expected copayments. Thus, the insurer will always lose money on these policies, as the amount paid out to the provider will always exceed the premiums received. This phenomenon—adverse selection— will likely cause insurers to raise premiums for all other enrollees to cover the losses.

The OIG's rationale is equally applicable in this context where the third-party premium payments benefit the providers who make them, directly or indirectly, but no one else. Not the enrollee, the issuer or providers that do not engage in such activity.

3. Consider Health Care Providers Out of Compliance with Conditions of Coverage if They Fail to Provide Information to Consumers on their Full Range of Coverage Options

We fully support efforts to ensure patients are enrolled in health care coverage that best meets their needs. For some individuals, this may be Medicare's ESRD benefit. For others, it may be Medicaid. For those who do not meet the eligibility requirements for Medicare or Medicaid, health plans are available in the individual market that offer the range of essential health benefits (EHBs) required under the ACA, including coverage for dialysis treatment. We are very concerned that the steering practices that are the subject of the RFI have significant, negative impact on consumers, including: late enrollment penalties under Part B; lack of immunosuppressant coverage under Part B if the kidney transplant is provided outside the Medicare benefit; and implications for other care needed outside dialysis treatment due to lack of health insurance coverage.

It is important to note that the health care providers who stand to benefit most from private insurance coverage are uniquely positioned to steer patients towards both individual market plans and the charitable organizations that pay the premiums for those plans. Under the Conditions of Coverage for ESRD facilities, CMS requires every dialysis facility to employ a renal social worker, 42 C.F.R. § 494.140(d), who works with patients to address their psychosocial needs and often assists them with issues related to their health insurance coverage. 42 C.F.R. § 494.80(a)(7); see also 73 Fed. Reg. 20370, 20424 (noting that commenters to the proposed rule on Conditions of Coverage for ESRD facilities indicated that renal social workers are often used

to perform activities related to insurance coverage). The charitable organization that provides premium support for ESRD members explicitly relies on this social worker[5] as the conduit for patient access to its support programs. Indeed, this organization will not accept applications from individuals directly and, instead, requires every individual seeking premium support to go through the social worker or other qualified staff at their dialysis facility.[6] Because every dialysis facility maintains staff who work with patients to address insurance coverage issues and serve as the sole conduit for certain premium support programs, these providers are in a clear position to steer patients towards the health plans that are known to provide higher reimbursement and to the charitable programs that will allow providers to maximize their reimbursement by paying for private health insurance coverage.

CMS requires providers or health plans to provide clear and accurate written information to Medicare beneficiaries in a variety of matters related to coverage and payment. Thus, Medicare Advantage plans "are responsible for ensuring that beneficiaries are fully informed of the benefits covered under the contract as part of their marketing material, evidence of coverage, and summary of benefits," and all marketing materials are subject to review and approval. 70 Fed. Reg. 4588, at 4690 (Jan. 28, 2005) (promulgating 42 C.F.R. § 422.80). Likewise, before any private agreement can be entered into between a physician and a beneficiary under Section 1802(b) of the Act (42 U.S.C. § 1395a(b)(2)), the physician must obtain a signed consent from the beneficiary that they understand that Medicare will not cover or pay for services provided by the physician.[7] Providers are required to obtain a signed advance beneficiary notice (ABN) that fully informs the beneficiary of their financial liability for non-covered services, before the beneficiary incurs liability for the service. All of these requirements protect individuals from making coverage decisions or incurring significant financial liability without the benefit of clear and accurate information from parties that may have a financial interest in the outcome of the beneficiary's decision.

In this context, a provider is either agreeing to pay premiums in a specific plan or making a referral with the expectation that another party will agree to pay a premium for an individual market plan. In many cases, individual patients being referred for such coverage would clearly be eligible for Medicare or Medicaid and the coverage decision thus has significant consequences regarding the suitability of coverage or the possibility of forgoing greater financial assistance or benefits from the Medicare or Medicaid program. However, there is no specific obligation that providers or their employed social workers have to provide clear and accurate

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[5] The organization indicates that other qualified staff at a dialysis facility can perform this function.
[6] Appendix, Example 2
[7] Among other requirements, the contract must be in writing and signed by the beneficiary "before any item or service is provided pursuant to the contract," may not be "entered into at a time when the Medicare beneficiary is facing an emergency or urgent health care situation," and must inform the beneficiary of "the right to have such items or services provided by other physicians or practitioners for whom payment would be made under this title." 42 U.S.C. §1395a(b)(2).

information about the individual's options or alternatives when they recommend or make such referrals for coverage.

We recommend CMS consider health care providers out of compliance with Conditions of Coverage if they fail to provide information to consumers on their full range of coverage options. In addition, CMS should require these social workers to provide consumers with an overview of all health insurance coverage options including any negative consequences of diferent options for consumers. We recommend CMS develop a model notice that provides individuals with information on how to contact the Medicare program directly by phone or via Internet access, and clearly indicates the consequences of not enrolling in the Medicare ESRD benefit.

4. Interpret Private Contract Requirements in Ways that Discourage Intentional Steerage between Markets

The offer to fund health care coverage premiums in exchange for forgoing Medicare coverage appears to be, in effect, a private contract. We therefore urge CMS to consider its authority to impose the private contract requirements at 42 C.F.R. Part 405, Subpart D, on physicians and practitioners who directly or indirectly make premium payments for individual market plan coverage on behalf of Medicare beneficiaries.

Under Section 1802 of the SSA, codified at 42 U.S.C. § 1395a, a physician or practitioner may enter into a private contract with a Medicare beneficiary for a service that would otherwise be covered under Medicare. Any such private contract must be in writing, signed by the beneficiary, and include that the beneficiary:

(i) agrees not to submit a claim (or to request that the physician submit a claim) under Medicare for the services;
(ii) agrees to be responsible, whether through insurance or otherwise, for payment of the services and understands that no reimbursement will be provided under Medicare;
(iii) acknowledges that the Medicare payment limits do not apply to amounts that may be charged for the services;
(iv) acknowledges that Medigap plans do not, and other supplemental insurance plans may elect not to, make payments for such items and services because payment is not made under Medicare; and
(v) acknowledges that the Medicare beneficiary has the right to have such services provided by other physicians or practitioners for whom payment would be made under Medicare.

Notably, a private contract is null and void if it is entered into at a time when the beneficiary is facing an emergency or urgent health care situation. Section 1802(b)(2)(A)(iii). See also 42 C.F.R. § 405.415(k). Moreover, a physician or practitioner entering into at least one private

contract must opt out of Medicare for at least a two-year period, and continue the opt-out for successive two-year periods unless the opt-out is cancelled. 42 C.F.R. § 405.405(b).

5. *Clarify Plan Authority to Reject Certain Third-Party Payments and Establishes that Federal Rules Supersede State Guidance*

Under 45 C.F.R. § 156.1250, health plans are required to accept third-party premium and cost-sharing payments from the following third-party entities: Ryan White HIV/AIDS programs; Indian tribes, tribal organizations, or urban Indian organizations; and a local, State, or Federal government program, including a grantee directed by a government program to make payments on its behalf. CMS has also issued related guidance in the form of Frequently Asked Questions (FAQs) and official letters to Members of Congress and others.[8]

We urge CMS to clarify these regulations and related guidance documents by making clear that health plans may deny any third-party payments that are outside the federal requirements and that these requirements supersede any state guidance to the contrary. At a minimum, we recommend that CMS revise its existing FAQ from 2/7/14[9] by providing further clarification of acceptable and unacceptable foundation entities as well as examples of allowed and disallowed payments. Guidance on the following key areas would also support the appropriate application of these payments moving forward:

- Outline clear guidelines for how a foundation must "market" its assistance to ensure that individuals are meeting financial criteria as opposed to targeting enrollees based on health status.
- Require proportional enrollment across health plans to prevent risk pool issues.
- Allow health plans to reject premium payments if an individual is not enrolled for the entire year.

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[8] See, for example: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf; https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf

[9] See FAQ (2/7/14) available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf. Q2. Does the November 4, 2013 FAQ apply to QHP premium and cost sharing payments on behalf of QHP enrollees from private, not-for-profit foundations? A2. No. The concerns addressed in the November 4, 2013 FAQ would not apply to payments from private, not-for-profit foundations if: (a) they are described in Question 1, or (b) if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status. In situation (b), CMS would expect that premium and any cost sharing payments cover the entire policy year.

6. Revise Guaranteed Availability and Renewability Requirements for Medicare-Eligible Individuals

A significant number of individuals steered into individual market coverage are also entitled to, eligible for, or enrolled in Medicare. Unlawful steering of Medicare-eligible beneficiaries into the individual market results in higher premiums for all individuals enrolled in the individual market and in turn increases the amount of subsides for Marketplace plans. Further, such unlawful practices expose consumers and health plans to Medicare penalties. Medicare beneficiaries face penalties for receiving subsidies (i.e., premium tax credits) to which they were not entitled. Health plans also face Medicare anti-duplication penalties.

CMS' current interpretation of the guaranteed availability and renewability provisions of the Public Health Service Act (PHSA) (as modified by the ACA) has created an unnecessary and untenable conflict between an issuer's PHSA obligations and its obligations under Medicare.[10] To resolve this conflict, CMS should revise its interpretation of the guaranteed availability and renewability requirements to recognize that issuers are not required to issue or renew individual health insurance coverage to individuals entitled to, eligible for or enrolled in Medicare because doing so conflicts with Medicare's anti-duplication requirements. See SSA Section 1882(d), codified at 42 U.S.C. § 1395ss(d).

The ACA market reforms are specifically designed to provide coverage for those consumers outside of the qualifications for the Medicare and Medicaid programs. For example, the 3-1 age rating bands do not encompass ages greater than 65, and individuals who are enrolled in Medicare are not eligible for advance premium tax credits (APTC). Because Congress made a specific policy judgment to afford individuals with ESRD access to coverage under the Medicare program, the program did not contemplate shifts from Medicare to individual market coverage. Even CMS' own messaging to on www.healthcare.gov provides "advice" to Medicare beneficiaries that they need not purchase an individual market QHP on an Exchange and goes on to state that "it is against the law" for someone with Medicare to purchase a QHP on an Exchange.

We strongly support a revision to the existing guaranteed renewability requirements as discussed in the proposed 2018 Notice of Benefit and Payment Parameters[11] that would prohibit the renewal of a Medicare eligible individual or Medicare beneficiary at the end of the plan year. For the Marketplace population, we recommend that the Marketplace provide these Medicare-eligible enrollees with information about their Medicare eligibility and support a transition to their enrollment in the Medicare program. For the population off the Marketplace, health plans

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[10] See FAQs A.1-A.4 and B.1. and B.2., at https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf

[11] 81 Fed. Reg. 61456 (Sep. 6, 2016).

would request information from their enrollees regarding their eligibility for Medicare coverage. We recommend that CMS clarify that, during any plan year in which an enrollee becomes Medicare-eligible, their individual market coverage is secondary to their Medicare coverage. We believe this approach would remove the incentive for providers and others to inappropriately steer these individuals into commercial insurance coverage in order to obtain higher reimbursement. We will discuss this issue further in our forthcoming comments on the 2018 Payment Notice.

In addition, we strongly support a change in the interpretation of guaranteed availability as it relates to Medicare. CMS' regulation already provides that guaranteed issue is not required when it is otherwise prohibited under federal law. We recommend that CMS interpret its own rule to include the Medicare anti-duplication requirement as "federal law." Because issuers are prohibited from marketing this coverage to individuals with Medicare Part A or B, issuers should not be required to enroll individuals without the opportunity for screening individuals for Medicare Parts A or B (or having the Marketplaces carry out such screening and recommend enrollment in the appropriate federal program).

We recommend that opportunities to identify and educate Medicare and Medicaid eligible individuals prior to their enrollment continue to be explored. It would be better for individuals (and issuers) if individuals enrolled in Medicare or Medicaid when initially eligible – and the penalty structure underscores the fact that this was the intent of the program. We discuss potential changes to the Marketplace application later in our comments.

We also urge CMS, for individuals inappropriately steered to Marketplace plans, to take steps to ensure continuity of coverage in transitioning these individuals to Medicare and Medicaid. For example, CMS should consider allowing such individuals to enroll in Medicare without late enrollment penalties on the basis that these persons were not fully informed of the ramifications of their decision. This could be done as a one-time exception for 2017.

7. *Modify Individual Market Rules to Prevent Inappropriate Steering of Medicaid Enrollees to Marketplace Coverage*

Our members report a growing number of third-party payments for enrollees who are dually enrolled in Medicaid and Marketplace coverage. This scenario is contrary to the intent of the ACA, which established a central Marketplace to determine eligibility for Medicaid, CHIP and Marketplace coverage and enroll the individual in the applicable program.[12] Dual enrollment was

[12] Section 1413(a) of the Affordable Care Act. (a) …residents of each State may apply for enrollment in, receive a determination of eligibility for participation in, and continue participation in, applicable State health subsidy programs. Such system shall ensure that if an individual applying to an Exchange is found through screening to be eligible for medical assistance under the State Medicaid plan under title XIX, or eligible for enrollment under a State

not contemplated, except in the limited scenario where a consumer enrolls in coverage and is eligible for APTC while their Medicaid eligibility is being determined.[13]

We appreciate that the existing Marketplace application screens for Medicaid eligibility and recent periodic data matching processes check state Medicaid systems for consumers who are potentially dually enrolled in Medicaid and Marketplace coverage and receiving APTC and/or cost-sharing reductions. We understand that CMS will soon take action to end their APTC, however, we recommend that CMS go further by terminating coverage for these individuals to avoid duplicate coverage and reduce incentives for improper steering.

As an alternate approach, to eliminate the incentive for providers to steer Medicaid enrollees into individual market coverage, we recommend that CMS permit health plans to modify the reimbursement rate to the provider to match Medicaid if the member is dually enrolled. We recommend CMS revisit existing FAQs on third-party liability and coordination of benefits in relation to Medicaid which currently prohibits issuers from taking this approach. FAQ #2 indicates that the Social Security Act as amended[14] "prohibits health insurers from taking an individual's Medicaid status into account in enrollment or payment decisions."[15] However, such action is critical given the impact on state Medicaid funding as well as the negative impact on consumers who would potentially owe premium tax credit once determined eligible for Medicaid and on issuers that cannot rely on Medicaid payments for these dual enrollees.

8. Increase Transparency of Third-Party Payments

CMS seeks input on how premium payments are made by third parties and how to increase transparency of such payments.[16] Per the recommendations we outlined above, we believe CMS'

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children's health insurance program (CHIP) under title XXI of such Act, the **individual is enrolled for assistance under such plan or program** *(emphasis added)*.

[13] 45 C.F.R. 155.345(e) requires Exchanges to treat someone eligible for APTC while their Medicaid eligibility is being determined.

[14] A State plan for medical assistance must—…provide…that the State prohibits any health insurer (including a group health plan, as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, a self-insured plan, a service benefit plan, a managed care organization, a pharmacy benefit manager, or other party that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service), in enrolling an individual or in making any payments for benefits to the individual or on the individual's behalf, from taking into account that the individual is eligible for or is provided medical assistance under a plan under this title for such State, or any other State;

[15] See "Medicaid and CHIP FAQs: Identification of Medicaid Beneficiaries' Third Party Resources and Coordination of Benefits with Medicaid" Available at https://www.medicaid.gov/federal-policy-guidance/downloads/faq-09-04-2014.pdf. Updated September 11, 2014.

[16] See 81 Fed. Reg. 57554, 57557 (Aug. 23, 2016): "Is the payment of premiums and cost-sharing commonly used to steer individuals to individual market plans, or are other methods leading to Medicare and Medicaid eligible individuals being enrolled in individual market plans? Specifically, how often are issuers receiving payments directly from health care providers and/or provider affiliated organizations? Are issuers capable of determining

focus should be on finalizing regulations that will ***prevent*** inappropriate third-party payments and steering. We also believe increased transparency is critically important to assure visibility and proper oversight of such payments. Unfortunately, today, there is no systematic way of capturing this information. Rather, these activities are often identified "after-the-fact" when health plans see unusual spikes in enrollment trends or claims costs in certain geographic areas (see Appendix for examples). Such a post hoc approach is insufficient for identifying issues that have the potential to greatly harm consumers. Instead, greater transparency is needed to ensure that individuals are not being steered inappropriately into coverage that may not be in their best interest. Such an approach is also necessary to prevent disruption to the individual market risk pool and an increase in overall health care spending.

Specifically, we urge CMS to:

- Require third-party organizations that are making premium or cost sharing payments on behalf of individual market enrollees to report certain information to CMS and attest that they meet the requirements as specified by CMS guidance and FAQs. Specifically, we recommend CMS collect the following information:
    - Number of consumers for whom the entity makes payments (by state or rating area);
    - Volume of payments over a specified time period;
    - Contact information;
    - Tax ID and filing status;
    - Governance (e.g., leadership, members of Board of Directors, principal shareholders, etc.);
    - Funding sources;
    - Information on relationships with provider organizations (financial or other); and
    - Information on relationships with pharmaceutical companies (financial or other).

- Impose new transparency requirements on providers. In instances where providers donate to third-party organizations and where there is a potential downstream reimbursement interest, providers should be required to report such payments to CMS. CMS could implement these requirements through revisions to its existing rules regarding conditions of participation and provider enrollment (discussed above).

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when third party payments are made directly to a beneficiary and then transferred to the issuer? What actions could CMS consider to add transparency to third-party payments?"

9. Utilize Additional Regulatory and Operational Tools to Address Third-Party Payments

We believe CMS' primary focus should be on *preventing* inappropriate third-party payments. We also recommend the following actions:

CMS should Engage the Healthcare Fraud Prevention Partnership (HFPP):
We strongly support CMS' efforts to investigate instances of potential fraud and abuse and agree that collaboration through the HFPP should be a key element of such efforts. Another egregious example of fraud and abuse by third-party sources of health insurance premiums has come to AHIP's attention through conversations within the HFPP. Briefly, recruiters (also known as "body brokers") are paid to identify and recruit individuals with alcohol or drug problems to receive services in facilities known as "sober homes." These recruited individuals are transported, often across the country, to the sober homes and fraudulently enrolled in health plans. Enrollees typically are not aware of their enrollment. The providers in some cases arrange to keep relevant information, such as Explanation of Benefit statements, from the enrollees. Once a consumer is enrolled, the providers charge the targeted health plans for frequent unnecessary and inappropriate urine screening tests and other inappropriate services.

The HFPP has become an important venue for sharing information regarding health care fraud and abuse schemes involving drug abuse, sober homes, and urine screening tests. We suggest that the HFPP could and should deepen its focus on these issues, including cooperation with HFPP members to address the questions raised in the RFI and to identify and combat health insurance premium payment by third parties that are a part of health care fraud and abuse schemes.

CMS should revise the Marketplace application to collect information on providers and screen for Medicare and Supplemental Security Income (SSI) eligibility:
To address inappropriate third-party payments, we recommend that CMS add the following questions to the "Single Streamlined Application" for use by both the Federal and State Marketplaces. In addition, state marketplaces should be required to include the following questions if they have developed their own state-specific application.[17] In addition to the changes below, we recommend that when consumers report a life change to the Marketplace, the applicant should be prompted to update their eligibility information for Medicare, Medicaid, and ESRD status.

- Under "Help Applying for Coverage" (p. 11)– Revise question to ask if the consumer was referred by a Medical Provider and capture the provider's name and related

[17] CMS-10400 Attachment A: Electronic Application: List of Items in the Electronic Application to Support Eligibility Determinations for Enrollment through the Health Insurance Marketplace and for Medicaid and the Children's Health Insurance Program, March 7, 2016. Accessed at http://www.reginfo.gov/public/do/PRAMain.

information. The existing categories of Navigator, Certified Application Counselor, Non-Navigator assistance personal, agent and broker may miss other types of individuals who are assisting consumers.

- Under "Help Paying for Coverage" (p. 12) – New question could be added, e.g., "Has any organization offered to pay your premium or cost-sharing?" In addition to this or alternatively, the question regarding income (p. 32) could ask about premium or cost sharing assistance (under "O. Other income").

- Regarding Medicare and SSI (p. 51), the application only asks if an individual currently has Medicare. This question could be expanded to inquire about Medicare and SSI eligibility. An alternative would be to permit plans to request this information.

- Regarding potential eligibility for Medicare due to ESRD, the application could ask whether the individual is currently undergoing treatment for ESRD.

CMS should enhance consumer education regarding third-party payments:
We urge CMS to consider approaches that would help consumers better understand issues around third-party payments, including the type of third-party payments that are allowed and not allowed in the individual market. This could include a model notice that issuers could have the option to provide to enrollees regarding acceptable third-party payments.

10. Issue an RFI on the Impact of Pharmaceutical Manufacturer Coupons, Co-Pay Cards and Charity Programs

We also believe CMS should outline a strategy for ongoing assessment and monitoring of another concerning area of third-party payments – the growing use of prescription drug coupons, co-pay assistance cards, and charity programs. An important first step in that regard is issuing a separate RFI aimed at understanding the scope and impact of these programs.

On the issue of drug coupons, academics have concluded that such programs – while portrayed as a consumer-friendly benefit – actually increase overall costs and drive up premiums:

> "Drug coupons have long-term financial consequences, particularly when generic or other lower-cost therapeutic options are available. They lead to unnecessary spending by insurers which is passed on to all patients in the form of

> increased premiums and reduced coverage of other potentially useful health care interventions."[18]

Similar concerns have been raised by the OIG:[19]

> "Cost-sharing requirements for Federal health care program drugs serve an important role in protecting both Federal health care programs and their beneficiaries. These cost-sharing requirements promote: (1) prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs and (2) price competition in the pharmaceutical market. While copayment coupons provide an immediate financial benefit to beneficiaries, they ultimately can harm both Federal health care programs and their beneficiaries.[5] The availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices. Excessive costs to Federal programs are among the harms that the anti-kickback statute is intended to prevent."

Of further concern, the use of coupon programs continues to grow. According to the IMS Institute for Healthcare Informatics, copay cards are used for 8% of all branded prescriptions with use in some expensive specialty drug classes much higher – as high as 70% for multiple sclerosis and rheumatoid arthritis drugs.[20]

As part of a new RFI that examines the use of coupons, we recommend that CMS include an examination of the practice of pharmaceutical companies donating product to charitable organizations. Such an examination is critical to ensure that these charities are operating as intended and that pharmaceutical companies are not exerting influence over how the charities allocate their funding. A recent analysis[21] highlights the potential for concern, with the

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[18] Alfred Engelberg, October 29, 2015, http://healthaffairs.org/blog/2015/10/29/how-government-policy-promotes-high-drug-prices/; The Short-Term And Long-Term Outlook Of Drug Coupons; Lara Maggs and Aaron Kesselheim. November 12, 2014 http://healthaffairs.org/blog/2014/11/12/the-short-term-and-long-term-outlook-of-drug-coupons/.

[19] Office of Inspector General, Special Advisory Bulletin September 2014. https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf

[20] IMS Institute for Healthcare Informatics. April 2015. Medicines Use and Spending Shifts. https://www.imshealth.com/files/web/IMSH%20Institute/Reports/Medicines_Use_and_Spending_Shifts/Medicine-Spending-and-Growth_1995-2014.pdf.

[21] "How Big Pharma Uses Charity Programs to Cover for Drug Price Hikes," May 19, 2016, available at http://www.bloomberg.com/news/articles/2016-05-19/the-real-reason-big-pharma-wants-to-help-pay-for-your-prescription

significant growth in such charities and the fact that the vast majority of their funding comes from pharmaceutical companies:

> "…[P]SI's revenue grew rapidly, from $16 million in 2003 to $128 million last year. In 2014 the charity said just over half its funds came from a single drug company, though it didn't name the donor. Former employees say it was Novartis; Novartis confirmed it's given to PSI, but declined to say how much.
>
> The largest copay charity, the PAN Foundation, grew even faster, soaring from about $36 million in contributions in 2010 to more than $800 million last year. About 95 percent of PAN's contributions come from the pharma industry, the charity says; in 2014, five unnamed drug companies kicked in more than $70 million apiece, according to PAN's tax filing. With this eager stable of donors, PAN spent just $597,000 on fundraising in 2014. That's less than 1 percent of the fundraising expense for similar-sized charities, like the American Cancer Society and the American Heart Association."

Appendix
Examples of Steering into Individual Market Plans and Individual Market Impacts

CMS seeks information about circumstances in which steering into individual market plans may be taking place as well as the impact on the individual market.[22]

AHIP has aggregated and de-identified information from our member health insurance plans with the understanding that it would be included in our comments to CMS. Information on the financial impact was provided through an analysis of certain health insurance claims in the individual market from 2013 to the present. In certain examples information on the increase of per member per month (PMPM) spending is included. Information on steering of potential Medicare and Medicaid eligible or enrolled individuals to individual market coverage (both on and off the Marketplace) was obtained through a series of health plan interviews conducted by health plan staff during investigation of improper payments throughout 2015 and 2016.

It is clear from our examples the significant financial impact these third-party payments have had as well as evidence that consumers are being enrolled without understanding the negative financial impact of enrolling in private coverage (late Part B enrollment penalties, lack of overage for certain drugs post Kidney transplant). Below, we also outline examples of other third-party activity outside ESRD.

The impact of the addition of any single individual to a risk pool ultimately depends on the relationship between the amount of premiums that the member pays to the health plan (or that are paid on the member's behalf) and the amount of covered medical expenses incurred by the member. When an individual incurs medical expenses that substantially exceed the premiums paid, the resources available in the risk pool become depleted at a much faster rate than they otherwise would. Although there are a number of activities that health plans can take to control the medical expenses incurred by such individuals (e.g., care management, value-based provider arrangements), the addition of such individuals to a risk pool will inevitably lead to increased rates for everyone individual who is covered by the same risk pool. The potential impacts of such activity on the individual market can be very significant, especially when activity is focused on a vulnerable, high-cost population such as those with ESRD and when there is a concerted effort to move all such individuals into a single plan in the individual market.[23]

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[22] 81 CFR 57557. "In what types of circumstances are healthcare providers or provider-affiliated organizations in a position to steer people to individual market plans? What impact is there to the single risk pool and to rates when people enter the single risk pool who might not otherwise have been in the pool because they would normally be covered under another government program? Are issuers accounting for this uncertainty when they are setting rates?"

[23] According to MedPAC, in 2014, about 383,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare representing spending that totaled $11.2 billion a 1% increase over 2013. MedPAC, Report to the Congress: Medicare Payment Policy, March 2016.

Typically, health plans will see unusual spikes in claims for services such as dialysis services. In investigating this activity and talking with their members, concerning information has been discovered regarding the circumstances under which individuals have been enrolled. Several examples are provided below.

Example One: This plan had $8 million in paid claims for dialysis services in 2014. ***In 2015, this figure more than doubled to $19.3 million. Projected paid claims for 2016 will be $29.5 million.*** In investigating these trends, the plan was able to identify numerous individuals whose premiums had been paid for by the American Kidney Fund (AKF). In discussing the circumstances of their enrollment process with these members, a strikingly similar pattern was identified:

- Members who are approached for financial assistance usually are receiving services from a dialysis center owned by contributors to the AKF.
- "Enrollment Counselors" or "social workers" at these dialysis facilities approach patients about financial assistance with their health care premiums. These "enrollment counselors" offer no information about Medicare eligibility to members. In several cases members were not aware that they were Medicare eligible until they were later told by the health plan.
- The AKF would pay premiums for these Medicare-eligible enrollees with a check. However, more recent information indicates that the AKF is now giving members a pre-paid debit card to pay their premium. Such payments cannot be tracked by health insurance plans, making it difficult to assess the extent of these arrangements.
- When asked about bills for cost-sharing or other out of pockets cost, members are advised to ask the dialysis provider to bill them. In most cases the members never receive bills or they are waived.
- If members receive a kidney transplant—and are no longer in need of dialysis services—the AKF will no longer pay their premiums. One member who became eligible for a kidney transplant at a major California hospital system was told by the social worker at the hospital that many of her clients have been on the AKF premium support program and were later surprised to find out they lost the premium support once they had the transplant. This social worker now routinely advises members receiving AKF payments that they will lose their premium payments after a transplant—when these enrollees will be in critical need of health coverage to ensure a successful recovery.

Example Two: The following information is based on a health plan's interviews with individual members diagnosed with ESRD and were enrolled in Marketplace coverage through the assistance of provider facilities. It is difficult to identify the specifics of the third-party payment process other than to speak with members directly, as the payments are rarely provided directly by the facilities to the insurance carrier. It is not possible to quantify exact damages without

identifying every individual member subjected to this experience; however, the estimated exposure based on investigations done to date is significant. ***For every 100 members that were subject to the scheme described below, estimated costs incurred are approximately $20 million. The plan has seen its number of enrollees with ESRD increase by 200% from 2015 to 2016.***

- Many members arrive at the facilities directly from the nephrologist or hospital and are met by individuals representing themselves as "social workers." These "social workers" guide the member and assist in signing them up for the "best" policy. The member is either coached or the social worker completes the application. Other names used for the "social worker" are Benefit Coordinator and Financial Advisor.
- Based on member experiences discussed during these interviews, there is no discussion of the various insurance options or of Medicare coverage. Individuals are immediately guided to specific commercial insurance plans.
- Some members have been instructed to open a checking account in their name. The sole purpose of this account is to receive third-party payer checks. Premium payments are drafted electronically or bank checks are written using the checking account and sent to the insurance carrier. To facilitate this, the member is summoned to the facility's office to endorse the check. The check is deposited by a representative of the provider. Other members pay directly at the provider's office. Most members appear to have no understanding as to what is paid on their behalf, or how payment is made.
- Many believe the individual market policy they receive is a supplement to Medicare, and this coverage takes care of any cost-sharing amounts not covered by Medicare. Investigation continues on this issue, but it appears that some individuals are in fact covered by both Medicare and an individual market plan while others are only covered by the individual market plan but believe they have purchased a plan that is "better" than Medicare and includes coverage for all cost-share amounts associated with their ESRD.

Example Three: Another health plan experienced a significant increase in the number of individual market members receiving treatment for ESRD. Comparing June 2015 to June 2016, the percentage of the plan's individual members receiving dialysis treatments was ***69% higher in 2016*** (based on member months). This trend is expected to result ***in $10 million more in paid claims by the end of 2016, compared to 2015.***

- This increase was primarily driven by members new this health plan. Specifically, of the 208 plan members who received at least one dialysis treatment as of May 2016, 142 were new members in 2016.
- Of the 142 new individual members, over half (87) were actively enrolled in a Medicaid plan, either offered by the same plan or another managed care organization.
- The AKF paid most/all of the individual premiums for 86 of the 87 active Medicaid members; the exception was a member who had a $0 premium.

- In addition to the increased population receiving dialysis treatments, the average paid claim per visit has also increased, from $2,250 per dialysis visit in 2015 to approximately $2,500 for 2016.

Example Four: A plan saw its spending on ESRD increase dramatically from ***$1.7 million in 2013 to $36.8 million in 2015. Spending to date for 2016 is $28 million. ESRD spend per patient has increased three-fold: from $59,626 to $150,599.*** Over this time period, the number of patients with ESRD who are enrolled in the plan has ***increased by 564% --*** from 28 individuals in 2013 to 186 currently.

Example Five: A large health plan has seen a significant spike of ESRD active members in the individual Marketplace between 2014 and 2016. For example, the percentage of members with ESRD among exchange enrollees is ***five times higher in 2016 than in 2014.*** Similarly, the percentage of ESRD members enrolled off the Marketplace in 2016 was ***more than three times the percentage in 2014.***

Example Six: Another plan conducted an analysis of individuals enrolled in its individual plans who had been diagnosed with end-stage renal disease (ESRD). Through its review, the plan ***identified 30 individuals with ESRD who reported Medicaid as their sole payer source when beginning dialysis treatment, but who subsequently enrolled in an individual plan and whose premiums are being paid for by a charitable organization funded primarily by dialysis providers.*** Notably, the majority of these Medicaid beneficiaries (25 of 30) also reported being either unemployed or retired due to disability at the start of their dialysis. Nevertheless, the vast ***majority (25 of 30) enrolled in the most-expensive level the company's individual plans (Platinum), agreeing to pay premiums averaging over $900 per month***. Because the financial ability to pay monthly premiums at such levels would disqualify most, if not all, individuals from Medicaid benefits in the state, it is highly unlikely that any of these members would have sought out and enrolled in Platinum plans of their own accord and without some form of steering or promise for premium support. Indeed, even if a Medicaid beneficiary who developed ESRD had the resources to pay such premiums, it is unclear why he or she would opt for the most expensive private health insurance option when comprehensive coverage could be obtained at a far lower premium cost and with far lower exposure to out-of-pocket costs through enrollment in original Medicare and pairing that coverage with a Medicare Supplement plan that covered the Part B deductible and excess charges. For the healthcare provider supplying dialysis, however, the benefit of having that individual covered under a Platinum-level individual plan is manifest given the higher reimbursement rates paid by private health plans.

Example Seven: A health plan discovered that a local Medicaid plan was enrolling members into individual coverage off the Marketplace. Premium payments for the individual market coverage were being made by the Medicaid plan's chief financial officer. As of March 31, 2016, the plan had identified a total of forty members enrolled in its individual market plan through this

scheme. Thirty-nine of the Medicaid members had been diagnosed with end-stage renal disease, some subsequently required transplants. By June 1, 2016, the plan had paid more than $11.5 million in claims for just these forty members. The Medicaid plan openly described its strategy in its FY2015-2016 budget as follows: "This program pays existing private or group health insurance premiums for members with existing high-cost medical conditions. Purchasing health coverage for these members helps shift the cost of their medical care to the other insurance carrier..." The Medicaid plan also advertised its program to providers as a way to obtain higher reimbursement for covered services.

Example Eight: Above we highlight fraudulent activity related to "sober homes." Similarly, a plan has seen widespread fraud and third-party payments by residential treatment facilities providing substance abuse treatment. Many of the individuals enrolled through these programs would be eligible for Medicaid, but they are enrolled in individual coverage off the Marketplace to avoid any eligibility screening. These facilities advertise to out-of-state or homeless people, and then enroll the individuals through the SEP for a "permanent move" even though they do not qualify. The premiums are frequently paid by the residential treatment facility on behalf of the enrollees.

One facility billed this plan $60 million in claims, most of which were denied after investigation. These facilities often pay premiums and offer financial incentives including rent reductions and waiver of patient responsibilities as long as patients agrees to reside at the facility. Investigations consistently show excessive lab fees and falsified billing from these facilities. Recently these residential treatment facilities have started claiming to be "non-profits" to shield themselves from the allegation of financial gain. Any regulation in this area must therefore not rely on an organization's status as a "non-profit" because that status can be readily manipulated.

September 22, 2016

Submitted via http://www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–6074–NC
P.O. Box 8010
Baltimore, MD 21244–8010

RE: Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans

Dear Sir or Madam:

UnitedHealthcare appreciates the opportunity to provide the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services ("HHS") with comments to the above-referenced Request for Information.

UnitedHealthcare, a division of UnitedHealth Group, is dedicated to helping people live healthier lives. As a recognized leader in the health and well-being industry, UnitedHealthcare strives to improve the quality and effectiveness of health care for all Americans, enhance access to health benefits, create products and services that make health care more affordable, and use technology to make the health care system easier to navigate. UnitedHealthcare serves many of the country's most respected employers, and UnitedHealthcare is also the nation's largest Medicare health plan – serving nearly one in five seniors nationwide – and one of the largest Medicaid health plans, supporting underserved communities in 24 states and the District of Columbia.

Below please find our comments and recommendations.

I. What are the circumstances in which providers and provider-affiliated organizations are positioned to steer people to individual market plans and what are the means providers and provider-affiliated organizations are using to steer people into those plans? In particular, what steering practices specifically target people eligible for or receiving Medicare and/or Medicaid benefits to enroll in individual market plans, and how are those people particularly vulnerable to being steered?

Providers are positioned to steer people into individual market plans where the services they render are reimbursed at materially higher rates by commercial plans than under the Medicare or Medicaid fee schedules. For example, in public disclosures, publicly traded providers of dialysis services have acknowledged that their profits are driven almost entirely by providing services to patients that are insured commercially. There are, therefore, built-in incentives for certain providers to steer patients into the higher-reimbursing commercial plans.

Steering tends to target patients who are the most vulnerable to provider influence: those who are indigent, who suffer from significant health issues, and who are inexperienced in health insurance. Indeed, in addition to the dialysis patients referenced above, UnitedHealthcare has observed a very high rate of steering activity involving patients undergoing substance use disorder treatments.

Based on UnitedHealthcare's recent experience, providers appear to be deploying the following techniques in order to steer these vulnerable patients into individual market plans in order to increase the providers' "commercial mix" – *i.e.*, the percentage of patients insured under commercial plans.

First, providers identify commercial insurance plans offered by private insurers (both on and off exchange) that offer attractive reimbursement rates.

Second, based on conversations with some members UnitedHealthcare has learned that the targeted patients are "counseled" by providers that the higher-reimbursing plans are the patients' best option, irrespective of the needs of the patient. Many patients may not understand the differences among their various options – including Medicare and Medicaid – or the additional financial obligations they might incur when they agree to enroll in the commercial plans their providers recommend.

Third, because the commercial plans generally require patients to pay some form of cost-sharing obligation (such as copay, coinsurance or deductible), providers agree to waive these obligations. Since the patients being steered onto individual market plans tend to have *multiple* health issues, and the steering provider almost certainly does not explain to the patients that their other providers cannot waive cost-sharing obligations, patients experience higher than expected out-of-pocket expenses.

Fourth, for targeted patients who cannot afford to pay the premiums associated with the commercial plans to which providers have steered them, providers may secure payments from a third party to cover that expense. In the dialysis industry, for example, providers routinely use the American Kidney Fund ("AKF") to pay patients' commercial plan premiums. AKF, in turn, receives the vast majority of its funding from these same providers and, until recently, informed the providers that they had an "ethical obligation" to make donations to AKF in an amount equivalent to what the providers' respective patient populations required for premium assistance.

Finally, in some extreme cases within the substance use treatment area, members have informed UnitedHealthcare that providers are employing additional financial incentives (e.g., airfare to treatment centers or programs, expensive gift cards, etc.) to steer patients to commercial insurance plans.

II. What impact is there to the single risk pool and to rates when people enter the single risk pool who might not otherwise have been in the pool because they would normally be covered under another government program? Are issuers accounting for this uncertainty when they are setting rates?

There is a significant impact to the risk pool and rates resulting from steering. Issuer pricing assumes that consumers who are eligible for Medicare and/or Medicaid are appropriately enrolled in those programs. Historically, issuer pricing did not anticipate that providers would engage in activity that would steer individuals with significant health issues into individual market plans. These individuals have health care costs that are usually higher that the average costs within the single risk pool. Thus, the increased costs associated with their claims negatively impacts affordability throughout the entire marketplace. Issuers must account for the unanticipated costs by raising rates for the single risk pool; the higher rates in turn dissuade young, healthy individuals from purchasing coverage; and the absence of young, healthy individuals from the single risk pool creates additional challenges to affordability that inevitably necessitate additional rate increases.

III. To what extent, if any, are providers steering people eligible for or receiving Medicare and/or Medicaid to individual market plans because they are prohibited from billing the Medicare and Medicaid programs, through exclusion by the HHS Office of Inspector General, termination from State Medicaid plans or the revocation of Medicare billing privileges?

UnitedHealthcare is not directly aware of the extent to which providers that are prohibited from billing the Medicare and Medicaid programs are steering consumers into individual market plans. However, UnitedHealthcare acknowledges that this could pose a significant risk and, as such, recommends that CMS extend existing provider participation prohibitions applicable to the Medicare and Medicaid programs to all Individual Marketplaces.

IV. Is the payment of premiums and cost-sharing commonly used to steer individuals to individual market plans, or are other methods leading to Medicare and Medicaid eligible individuals being enrolled in individual market plans? Specifically, how often are issuers receiving payments directly from health care providers and/or provider affiliated organizations? Are issuers capable of determining when third party payments are made directly to a beneficiary and then transferred to the issuer? What actions could CMS consider to add transparency to third party payments?

UnitedHealthcare believes that the payment of premiums and cost-sharing is commonly used to steer individuals to individual market plans. In some cases, other methods are also leading to Medicare and Medicaid eligible individuals being enrolled in individual market plans.

As noted above, many of the targeted Medicare and Medicaid eligible individuals cannot afford the premiums or cost-sharing obligations associated with the individual market plans to which they have been steered. Thus, the steering providers must find a way to cover these payments.

In the dialysis industry, providers routinely pay patient premiums using AKF to hide the true source of the funds. Specifically, AKF administers a Health Insurance Premium Payment ("HIPP") program designed to cover dialysis patient insurance premiums. Until August 16,

2016, AKF publicly maintained a "HIPP Honor System" and instructed that "each referring dialysis provider should make equitable contributions to the HIPP pool," and each provider should "reasonably determine its 'fair share' contribution to the pool by considering the number of patients it refers to HIPP." AKF emphasized that all dialysis providers had an "ethical obligation to contribute their respective 'fair share' to ensure that the HIPP pool is adequately funded." Finally, AKF told providers that "[i]f your company cannot make fair and equitable contributions, we respectfully request that your organization *not refer patients to the HIPP program*… ." Thus, AKF required – and UnitedHealthcare believes still requires – each dialysis provider to make "donations" that were commensurate with the amount AKF would pay for commercial insurance premiums for that provider's patient population.

Based on feedback received from dozens of UnitedHealthcare members, it is also apparent that dialysis providers frequently waive their patients' cost-sharing obligations under individual market plans.

In the substance use treatment field, providers frequently pay member premiums. They also pay, or routinely waive, member cost-sharing obligations, such as copayments, coinsurance and deductibles. In addition, providers offer free transportation, gift cards, housing and other financial incentives to further induce individuals to enroll in commercial plans that provide benefits exceeding those available under Medicare and Medicaid.

Based on UnitedHealthcare's experience, premiums paid with third party funds for the individual exchanges are typically paid on a quarterly basis, whereas off exchange plan premiums are generally paid on a monthly basis.

Many commercial plans prohibit third party payment of premiums through language contained in the Conditions of Coverage filed with and approved by state regulators. As a result, providers and third party payers have developed a process to hide the true source of premium payments. For example, dialysis providers employ "insurance counselors," "social workers" and "financial consultants" who assist patients with individual market plan applications and enrollments. These individuals also submit applications for premium assistance to AKF on behalf of the patients.

The dialysis providers then make "donations" to AKF that are intended to cover the patients' individual market plan premiums. Using these "donations," AKF then either pays patient premiums directly to the issuer via check, or (as is more often the case) it routes payment to the dialysis provider so that "social workers" can give the payments to the patients who, pursuant to instructions from AKF and the dialysis providers, cash the AKF checks and obtain money orders that are used to pay the individual market plan premiums in a way that is intended to look like the patient paid the premium with his or her own funds. Additionally, in the substance use treatment field, providers frequently arrange for phony "charitable organizations" to provide "scholarships" for patients' premiums and/or out-of-pocket costs (e.g. scholarships in the exact amount of patient deductibles).

Rarely, but on occasion, members inform us that they have used third party funds to pay their premiums and/or cost-sharing obligations. This typically occurs after the fact during member

interviews conducted by UnitedHealthcare's Special Investigations Unit. Absent member admissions, it is virtually impossible to determine if premiums have been paid with third party assistance.

To add transparency to the process, UnitedHealthcare recommends that member applications be amended to require the consumer to identify any party that is providing direct or indirect financial assistance in connection with the consumer's individual market plan premiums or cost-sharing obligations. Any failure to disclose third party assistance would constitute grounds for immediate rescission of insurance coverage.

V. How are enrollees impacted by the practice of a health care provider or provider-affiliated organizations enrolling an individual into an individual market plan and paying premiums for that individual market plan, when the individual was previously or concurrently receiving Medicare and/or Medicaid benefits?

Using the aforementioned methods to steer (and enroll) patients who were previously receiving Medicare or Medicaid benefits raises the risk that the patients will be negatively impacted in several ways.

First, patients become financially responsible for complying with the premium payment and cost-sharing requirements of the commercial plan into which they have been steered. As many of these individuals are indigent, patients are effectively put into a situation by their providers wherein they are unable to satisfy their contractual financial obligations. And while some providers (including the providers doing the steering), might systemically waive the patients' cost-sharing obligations, other providers that the patient sees might not agree to take that unlawful step. Additionally, while balance billing is prohibited in the Medicare and Medicaid plans, it is permitted for commercial plans in some states. Thus, steering patients into individual market plans may expose them to greater financial risks.

This is particularly true with respect to the cost of medications. UnitedHealthcare believes many of the patients who providers target for steering are barely able to afford their medications under the generous terms of their Medicare or Medicaid coverage, which require the patients to make minimal payments to obtain needed medications. Under the terms of individual market plans, patients are often required to make much greater contributions to the cost of medications – contributions they cannot afford to make.

Second, and relatedly, patients are put at risk of breaching the terms of their individual market plans and, thus, losing their insurance coverage. Providers know that many of the individual market plans into which they are steering their patients require patients to fulfill their cost-sharing obligations to their providers and expressly prohibit them from accepting premium payment assistance from third parties. Thus, by systematically failing to collect cost-sharing obligations from these patients, and by routing money through third parties to pay premiums, providers effectively cause patients to breach the terms of the very plans in which the providers have caused them to enroll. This puts the steered patients at risk of having their primary insurance coverage terminated.

Third, it is possible that the checks indigent patients receive indirectly from their providers (through "charities") to pay their premiums constitute "income" for tax purposes. It is therefore also possible that by funneling these payments to patients, providers and provider-affiliated "charities" cause these patients to acquire income which, if properly reported, could affect or compromise those patients' eligibility for Medicaid, which could have widespread negative ramifications for these patients. It is unlikely that providers or provider-affiliated "charities" are advising the patients whose premiums they are paying of the reporting requirements and tax consequences associated with the checks received by the patients.

Fourth, though not true in all cases, in the substance use disorder treatment field UnitedHealthcare has observed a significant correlation between the steering of patients and lack of effective, quality treatment and positive clinical outcomes for patients. The providers using these steering approaches are in many cases providing no evidence-based or effective treatment.

Fifth, networks in the individual market may be narrower than the Medicare and Medicaid networks. This can cause patients to select different providers, disrupting well-established patient-doctor relationships and in some cases causing interruptions in care.

VI. How are enrollees impacted by the practice of a health care provider enrolling an individual into an individual market plan and paying premiums for individual market plans, when the individual was eligible for Medicare and/or Medicaid, but not enrolled?

In addition to the adverse impacts noted throughout these comments (e.g., the fact that some individuals receiving premium assistance may lose eligibility for Medicaid because of the associated income tax consequences), consumers steered to commercial coverage rather than enrolling in Medicare may be responsible for late enrollment penalties if they later elect to enroll in Medicare.

VII. What remedies and/or policies could deter health care providers or provider-affiliated organizations from steering people eligible for or enrolled in Medicare and/or Medicaid to individual market plans and paying premiums for the providers' financial gain.

There are a number of remedies and/or policies that could be adopted that would make it more difficult for providers and provider-affiliated organizations (like "charities" that take money from providers and use it to pay the premiums of those providers' patients) to inappropriately steer patients into individual market plans. These remedies and/or policies include:

(a) CMS could adopt rules formalizing its position that "offering premium and cost-sharing assistance in order to steer people eligible for or receiving Medicare and/or Medicaid benefits to individual market plans for a provider's financial gain is an inappropriate action[.]"

(b) CMS could adopt rules prohibiting providers (and their employees or agents) from counseling their patients who are eligible for or enrolled in Medicare or Medicaid about commercial insurance products offered through the ACA exchanges.

(c) CMS could adopt rules requiring that, in order to do business as a Medicare and Medicaid provider, a provider must certify that they are not engaged and will not engage in any

inappropriate steering of Medicare and Medicaid patients into individual market plans. The rules might subject providers who are found to have engaged in inappropriate steering to civil monetary penalties or the loss of their status as an enrolled Medicare and Medicaid provider.

(d) CMS could adopt rules giving insurance companies who have Medicare and Medicaid eligible members enrolled in the companies' individual market plans the right to (i) limit payments to providers for services billed to those plans to Medicare-based rates, or, where applicable, a lower rate set forth in the issuer's contract with the provider; (ii) audit, and/or (iii) retroactively recoup the full amount of any payments made to providers for patients who have been inappropriately steered onto those individual market plans by their providers.

(e) Where there is substantiated evidence of a violation of the prohibitions on third party payments, CMS could allow issuers to dis-enroll consumers without sending them back to the Marketplace and regardless of whether the policy at issue independently supports disenrollment.

VIII. What steps do third party payers take to effectively screen for Medicare and/or Medicaid eligibility before offering premium assistance? What steps do these entities take to make sure that any such individuals understand the impact of signing up for an individual market plan if they are already eligible for or receiving Medicare and/or Medicaid benefits?

UnitedHealthcare does not have direct knowledge about the steps, if any, taken by third party payers to screen for Medicare and/or Medicaid eligibility before offering premium assistance. However, based on certain third parties' failures to adhere to their own published eligibility criteria, UnitedHealthcare has reason to doubt that any such steps are being taken. For instance, AKF characterizes its HIPP program as a last resort for patients who cannot otherwise obtain insurance. Thus, Medicare and Medicaid eligible patients are, by definition, ineligible for the HIPP program. Nevertheless, UnitedHealthcare is aware that AKF utilized its HIPP program to pay individual market plan premiums for hundreds of Medicare and Medicaid eligible patients.

Pursuant to 42 U.S.C. § 1395, it is unlawful for a person to sell or issue to an individual entitled to benefits under Medicare Part A or enrolled under Part B, a health insurance policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled. UnitedHealthcare recommends that CMS consider extending the penalties available under 42 U.S.C. § 1395(d)(3) to providers and provider-affiliated organizations and their respective agents, employees and representatives.

IX. For providers that offer premium assistance, who is interacting with beneficiaries to determine proper enrollment? What questions are asked of the consumer to determine eligibility pathways? How are consumers connected to foundations or others who are in the position to provide premium assistance? How are premiums paid by providers or foundations for consumers?

As noted in response to Topic IV above, dialysis providers employ "insurance counselors," "social workers" and "financial consultants" to assist beneficiaries with individual market plan applications, enrollments and financial assistance.

In other cases, particularly within the substance use treatment field, third party "brokers" assist with the enrollment process and then refer beneficiaries to providers pursuant to "marketing arrangements" that include referral fees for commercially insured patients. In other words, providers "buy" commercially insured patients from "independent" third party sources. UnitedHealthcare does not have direct knowledge about how these third party brokers connect beneficiaries to foundations or others who are in a position to provide premium assistance.

X. We seek comment on policies prohibiting providers from making offers of premium assistance and routine cost-sharing waivers for individual market plans when a beneficiary is currently enrolled or could become enrolled in Medicare Part A and other adjustments to federal policy on premium assistance programs in the individual market to prevent negative impact to beneficiaries and the single risk pool.

In addition to the numerous proposed measures set forth above, attention should be given to how existing laws and regulations, including but not limited to the Federal Anti-Kickback Statute, the Federal Tax Code and various State Consumer Protection Statutes, could be employed to curtail improper steering of patients to individual market plans.

XI. We seek comments on changes to Medicare and Medicaid provider enrollment requirements and conditions of participation that would potentially restrict the ability of health care providers to manipulate patient enrollment in various health plans for their own benefit. We are also interested in information on the extent steering is associated with other inappropriate behavior, such as billing for services not provided, or quality of care concerns. We seek comment on the advisability of such restrictions, as well as considerations of how such restrictions would affect health care providers and beneficiaries.

UnitedHealthcare recommends that controls are put in place to tighten the Medicare and Medicaid provider enrollment requirements and conditions of participation. As mentioned above in item VII, UnitedHealthcare recommends that a provider, including any agent, representative, or third party associated with that provider, must certify that they are not engaged in and will not engage in any inappropriate steering of Medicare and Medicaid patients into individual market plans. It would be prudent to ensure the provider attestation/certification becomes part of the screening/application process to become part of the network. Sanctions would apply should a provider violate the certification.

XII. We seek comment on policies to require Medicare- and Medicaid-enrolled providers to report premium assistance and cost-sharing waivers for individual market enrollees to CMS or issuers.

UnitedHealthcare recommends that CMS adopt rules requiring Medicare- and Medicaid-enrolled providers, including any agent, representative, or third party associated with that providers to track and report to CMS, and the applicable commercial insurer, on a quarterly basis, (i) the names of patients enrolled in individual market plans for whom the provider has waived any cost-sharing obligation(s), (ii) the names of patients enrolled in individual market plans that the provider knows are receiving third-party premium or cost-sharing assistance, and (iii) if the provider is aware of patients who are receiving third-party premium or cost-sharing

assistance, the amount of money the provider, including any agent, representative, or third party associated with that provider, has "donated" or otherwise paid to the third party payer during the applicable quarter and the amount the provider expects its patients to receive from that third party for premium or cost-sharing assistance.

Providers who are found to have engaged in inappropriate steering should be subject to civil monetary penalties and/or the loss of their status as enrolled Medicare and Medicaid providers.

XIII. Whether individual market plans considered limiting their payment to health care providers to Medicare-based amounts for particular services and items of care and on potential approaches that would allow individual market plans to limit their payment to health care providers to Medicare-based amounts for particular services and items of care.

CMS should adopt rules giving issuers who have Medicare- and Medicaid-eligible members enrolled in individual market plans the right to limit provider payments to Medicare-based rates or, where applicable, a lower rate set forth in the issuer's contract with the provider.

XIV. We seek comment on policies that would allow individual market plans to make retroactive payment adjustments to providers, when health care providers are found to have steered Medicare or Medicaid beneficiaries and enrollees to enroll in an individual market plan for the provider's financial gain.

CMS should adopt rules memorializing issuers' ability to audit and retroactively recoup the full amount of any claim payments made for Medicare- or Medicaid-eligible members who have been inappropriately steered onto individual market plans.

Thank you for taking time to review these comments. UnitedHealthcare appreciates your consideration and welcomes the opportunity to discuss these issues further.

Sincerely,

Heather Kane

Heather Kane
CEO, Public Exchange Marketplace
UnitedHealthcare Employer & Individual

EXHIBIT 1d

SB 1156 record from California State Archives, produced in Defendants' Production No. 5

Disseminated 26 Oct 2016 05:20 AM EDT
North America Equity Research
26 October 2016

J.P.Morgan

DaVita Inc

Commercial Mix at Risk (Part 2)

Neutral

DVA, DVA US
Price: $58.29

▼ **Price Target: $54.00**
Previous: $65.00

Investor concern regarding DVA's commercial mix and earnings power has increased since our 8/19/16 note "Commercial Mix at Risk, Sensitivity is Material". In that note, we cited "at least" 100bp of commercial mix risk for 2017 (10-15% of EPS) if DVA was receiving its market share of the American Kidney Fund's (AKF) subsidized exchange (HIX) patients. Since that note, we have developed increased conviction that DVA is probably receiving more than its market share of such patients. While much of this HIX risk is now discounted in the stock price (DVA -24% since its 8/8/16 earnings call vs -1% SPX), we remain on the sidelines due to the tail-risk that 1) DVA's broader relationship & benefits from AKF come under scrutiny (this broader relationship still carries additional plausible headline and fundamental risk) & 2) DVA could possibly incur legal liability if the CMS legal position prevails.

- **DVA Appears to Have Pursued AKF HIX Aggressively** – DVA and FMC both enjoy ~38% market share of the U.S. dialysis population. Accordingly, one might expect both to have ~2,400 of the 6,400 AKF-subsidized HIX patients. In its response to the CMS RFI, FMC cites only 700 such patients (and no "program" to steer such patients). By comparison, DVA has made no such disclosure, but several employee comments to the CMS RFI and a recent newspaper article suggest DVA operated a very purposeful, targeted "steerage" program to enroll MDCD patients and "pre-MDCR" patients into HIX policies subsidized by AKF. These two sources of information suggest DVA could face >100bp of commercial mix decline in 2017 if CMS requires disclosure of AKF subsidies (or health plans successfully identify such patients) or regulates against certain third party premium assistance. Whether deemed illegal or not, DVA could at least face serious reputational risk from playing any role in moving zero cost-share MDCD patients into high-deductible/copay HIX plans. We are lowering our 2017 EPS by an additional 10% to account for another 100bp of commercial mix deterioration.

- **Could DVA Face Legal Consequences?** The August 18, 2016 RFI from CMS explicitly states "it is unlawful to enroll an individual in individual market coverage if they are known to be entitled to benefits under Medicare Part A, enrolled in Medicare Part B, or receiving Medicaid benefits". In its RFI response, DVA takes the complete opposite view of its regulator, stating "Contrary to the letter written to dialysis facilities in connection with the RFI,

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	YTD	1m	3m	12m
Abs	-15.1%	-12.3%	-25.2%	-23.7%
Rel	-21.6%	-11.3%	-24.0%	-27.2%

DaVita Inc (DVA;DVA US)

FYE Dec	2015A	2016E (Prev)	2016E (Curr)	2017E (Prev)	2017E (Curr)	2018E (Prev)	2018E (Curr)
EPS - Recurring ($)							
Q1 (Mar)	0.82	0.92A	0.92A	-	-	-	-
Q2 (Jun)	0.94	0.97A	0.97A	-	-	-	-
Q3 (Sep)	1.00	0.97	0.98	-	-	-	-
Q4 (Dec)	0.94	0.94	0.93	-	-	-	-
FY	3.71	3.80	3.80	3.75	3.35	4.28	3.73
Bloomberg EPS FY ($)	3.77	-	3.77	-	4.12	-	4.59

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data	
Price ($)	58.29
Date Of Price	25 Oct 16
52-week Range ($)	78.94-57.58
Market Cap ($ mn)	12,120.13
Fiscal Year End	Dec
Shares O/S (mn)	208
Price Target ($)	54.00
Price Target End Date	31-Dec-17

See page 7 for analyst certification and important disclosures.

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Medicaid patients have the right under the current regulations to enroll in an individual market plan." This may be an implicit acknowledgement that DVA has played a role in enrolling such patients into HIX plans. Further, numerous RFI comments and a recent news article suggest DVA "educated" not just MDCD-eligibles, but current MDCD enrollees. DVA states that it "educates" patients but does not steer "patients".

- **HIX Is Only One Part of the Benefits DVA Derives from Its Relationship with AKF** – We have previously written that DVA's contributions to AKF also funds premium subsidization/adverse selection in the COBRA, Medigap & Part B markets (which seemed to be a revelation to most health insurance plans that we've talked to), but we were hesitant to size this exposure given the range & difficulty of estimates required. We now feel compelled to quantify this earnings contribution as a basis for our continued unwillingness to recommend the stock at these lower levels. While we're not yet willing to suggest it is probable that DVA's broader relationship (beyond HIX) with the AKF is threatened, we do suggest it is possible. Including the aforementioned HIX benefits, we estimate DVA contributes ~$100m annually to AKF and receives as much as $500-700m (30-45% net) of annual pretax income benefit from this unique relationship with what is described as an independent 501(c)3 charity. At minimum, we believe health insurers will increasingly scrutinize dialysis payment rates and third party premium support throughout their enrollment, pressuring net commercial rate growth in 2017-2018.

- **Lowering Estimates & Price Target** – We are lowering 2016/17/18 cash EPS from $4.30/4.21/4.75 to $4.30/3.80/4.20. We are lowering our 2017YE price target from $65 to $54 using a risk-adjusted 2018 cash EPS target multiple of 13x.

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J.P.Morgan

Figure 1: Plausible AKF-Subsidies Contribution to DVA Earnings

HIX EPS Benefit from AKF Premium Assistance			
DVA market Share	38%	38%	% of DVA
DVA Share of AKF-Disclosed Subsidized Patients	2,458	2,458	1.3%
Annual Treatments in question	383,386	383,386	
$/Tx Medicare	$250	$250	
Revenue as Medicare Patients	$96m	$96m	
Delta com'l vs MDCR	$600	$800	
$/tx Com'l	$850	$1,050	
Revenue as Com'l Patients	$326m	$403m	
Revenue/OpIncome Pickup	$230m	$307m	
EPS Impact	$0.67	$0.91	
% of 2016 EPS	**16%**	**21%**	
COBRA Benefit from AKF Premium Assistance			
% of DVA Patients	1,923	1,923	**1%**
Annual Treatments in question	299,931	299,931	
$/Tx Medicare	$250	$250	
Revenue as Medicare Patients	$75m	$75m	
Delta com'l vs MDCR	$600	$800	
$/tx Com'l	$850	$1,050	
Revenue as Com'l Patients	$255m	$315m	
Revenue/OpIncome Pickup	$180m	$240m	
EPS Impact	$0.52	$0.71	
% of 2016 EPS	**12%**	**17%**	
Medigap Benefit from AKF Premium Assistance			
% of Medicare Patients	23,072	23,072	**15%**
Annual MDCR Dialysis Copay	7,800	7,800	
Annual Medigap Premiums	$2,400	$4,800	
Estimated Copay Collection	$1,560	$1,560	
			Bad Debt %
Revenue/OpIncome Pickup	$89m	$33m	80%
EPS Impact	$0.26	$0.10	
% of 2016 EPS	**6%**	**2%**	
Subtotal Adverse Selection Markets	**34%**	**40%**	
Part B Premium Assistance			
% of Medicare Patients	7,691	7,691	**5%**
Annual CMS-Sourced MDCR Dialysis Revenue	$31,200	$31,200	
Total CMS-Sourced Revenue Supported	$240m	$240m	
Annual PartB Premiums	$1,464	$1,464	
Total Annual PartB Premiums	$11m	$11m	
Delta CMS Revenue vs Premium	$29,736	$29,736	
Contribution Margin	10%	50%	
Revenue/OpIncome Pickup	$23m	$114m	
EPS Impact	$0.07	$0.34	
% of 2016 EPS	**2%**	**8%**	
Total Gross Benefit	$521m	$694m	
Less: Annual Contribution to AKF	-$100m	-$100m	
TOTAL NET EPS FROM AKF	**32%**	**45%**	

Source: Company reports and J.P. Morgan estimates.

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Figure 2: DVA Model

	FY2010	FY2011	FY2012	FY2013	FY2014	1Q15	2Q15	3Q15	4Q15	FY2015	1Q16	2Q16	3Q16E	1Q16E	FY2016E	FY2017E	FY2018E
Dialysis Gross Revenue	6,072	6,491	7,316	8,032	8,516	2,166	2,252	2,301	2,316	9,035	2,328	2,367	2,406	2,408	9,509	9,515	10,036
Yr/Yr Change	5%	7%	13%	10%	6%	6%	7%	6%	5%	6%	7%	5%	5%	4%	5%	0%	5%
PPM Gross Revenue			453	3,155	3,424	914	934	969	930	3,747	978	1,034	1,076	1,036	4,125	4,401	4,665
Yr/Yr Change			na	596%	9%	10%	11%	9%	8%	9%	7%	11%	11%	11%	10%	7%	6%
Other Revenue	375	497	704	871	1,173	307	359	365	401	1,432	384	428	430	444	1,686	1,854	2,010
	18%	32%	42%	24%	35%	16%	26%	21%	24%	22%	25%	19%	18%	11%	18%	10%	8%
Total Revenue	6,447.4	6,987.7	8,472.5	12,057.6	13,113.0	3,387.1	3,544.6	3,635.1	3,646.9	14,213.7	3,690.3	3,829.1	3,912.4	3,887.5	15,319.4	15,770.6	16,711.6
Yr/Yr Change	6%	8%	21%	42%	9%	8%	10%	8%	7%	8%	9%	8%	8%	7%	8%	3%	6%
Provision for Doubtful Accounts	171.3	198.0	235.2	293.5	366.9	99.2	106.0	109.5	113.3	427.9	109.2	111.4	114.9	115.4	450.9	472.7	519.9
% of Revenue	2.7%	2.8%	2.8%	2.4%	2.8%	2.9%	3.0%	3.0%	3.1%	3.0%	3.0%	2.9%	2.9%	3.0%	2.9%	3.0%	3.1%
NET REVENUE	6,276.1	6,789.7	8,237.4	11,764.1	12,746.1	3,288.0	3,434.6	3,525.7	3,533.6	13,785.8	3,581.1	3,717.7	3,797.5	3,772.2	14,868.5	15,298.0	16,191.7
Yr/Yr Change	6%	8%	21%	43%	8%	8%	9%	8%	7%	8%	9%	8%	8%	7%	8%	3%	6%
Sequential Change	NM	NM	NM	NM	NM	(0%)	4%	3%	0%	NM	1%	4%	2%	(1%)	NM	NM	NM
Patient Care Costs	4,474.7	4,684.8	5,619.1	8,190.2	9,119.3	2,362.6	2,446.1	2,501.0	2,515.1	9,824.8	2,566.3	2,671.0	2,725.4	2,677.5	10,640.2	11,211.7	11,908.3
% of Revenue	71.3%	69.0%	68.2%	69.6%	71.5%	71.9%	71.2%	70.9%	71.2%	71.3%	71.7%	71.8%	71.8%	71.0%	71.6%	73.3%	73.5%
General & Administrative	579.0	691.2	895.8	1,163.1	1,280.6	343.6	354.2	356.0	389.1	1,442.9	388.9	391.1	420.6	464.3	1,664.9	1,758.4	1,841.6
% of Revenue	9.2%	10.2%	10.9%	9.9%	10.0%	10.5%	10.3%	10.1%	11.0%	10.5%	10.9%	10.5%	11.1%	12.3%	11.2%	11.5%	11.4%
Equity Income	(9.0)	(8.8)	(16.4)	(34.6)	(23.2)	(2.9)	(5.0)	(2.8)	(7.6)	(18.3)	(1.4)	(0.1)	(2.8)	(4.0)	(8.3)	(12.0)	(12.0)
EBITDA	1,231.4	1,422.5	1,738.9	2,445.3	2,369.4	584.6	639.4	671.4	637.0	2,536.4	627.2	655.7	654.4	634.3	2,571.6	2,339.8	2,453.8
EBITDA Margin	19.6%	21.0%	21.1%	20.8%	18.6%	17.8%	18.6%	19.0%	18.0%	18.4%	17.5%	17.6%	17.2%	16.8%	17.3%	15.3%	15.2%
EBITDA Yr/Yr	6%	16%	22%	41%	(3%)	(1%)	6%	11%	11%	7%	7%	3%	(3%)	0%	1%	-9%	5%
Depreciation & Amortization	234.4	267.1	343.6	528.7	590.9	153.8	158.8	162.1	163.3	638.0	169.4	180.4	174.4	177.2	701.3	684.1	708.8
% of Revenue	3.7%	3.9%	4.2%	4.5%	4.6%	4.7%	4.6%	4.6%	4.6%	4.6%	4.7%	4.9%	4.6%	4.7%	4.7%	4.5%	4.4%
OPERATING INCOME	997.0	1,155.4	1,395.2	1,916.6	1,778.5	430.8	480.5	509.4	473.6	1,898.4	457.9	475.3	480.0	457.2	1,870.3	1,655.7	1,745.0
Operating Margin	15.9%	17.0%	16.9%	16.3%	14.0%	13.1%	14.0%	14.4%	13.4%	13.8%	12.8%	12.8%	12.6%	12.1%	12.6%	10.8%	10.8%
Operating Income Yr/Yr	6%	16%	21%	37%	(7%)	(4%)	5%	12%	13%	7%	6%	(1%)	(6%)	(3%)	(1%)	(11%)	5%
Minority Interest	78.5	95.4	102.2	123.8	140.2	34.5	37.3	45.4	40.5	157.7	40.7	41.1	44.1	40.1	166.0	151.4	159.0
Interest Expense and Other Income, Net	178.2	238.1	277.9	425.2	407.9	96.9	101.9	101.0	98.6	398.4	99.9	99.7	99.4	99.1	398.1	396.5	396.4
% of Revenue	2.8%	3.5%	3.4%	3.6%	3.2%	2.9%	3.0%	2.9%	2.8%	2.9%	2.8%	2.7%	2.6%	2.6%	2.7%	2.6%	2.4%
PRE TAX INCOME (ex. non-recurring)	740.3	821.9	1,015.2	1,367.7	1,230.4	299.5	341.3	362.9	334.5	1,338.3	317.3	334.5	336.6	317.9	1,306.2	1,107.8	1,189.6
Pre-Tax Margin	11.8%	12.1%	12.3%	11.6%	9.7%	9.1%	9.9%	10.3%	9.5%	9.7%	8.9%	9.0%	8.9%	8.4%	8.8%	7.2%	7.3%
Pre-Tax Income Yr/Yr	6%	11%	24%	35%	(10%)	(5%)	7%	14%	20%	9%	6%	(2%)	(7%)	(5%)	(2%)	(15%)	7%
Provision for Taxes	296.1	328.8	411.2	550.8	488.2	119.8	136.5	145.2	133.8	535.3	126.9	132.1	134.6	127.2	520.8	443.1	475.9
Tax Rate	40.0%	40.0%	40.5%	40.3%	39.7%	40.0%	40.0%	40.0%	40.0%	40.0%	40.0%	39.5%	40.0%	40.0%	39.9%	40.0%	40.0%
NET INCOME (ex. non-recurring)	444.2	493.2	604.0	816.8	742.2	179.7	204.8	217.8	200.7	803.0	190.4	202.4	201.9	190.7	785.4	664.7	713.8
Net Margin	7.1%	7.3%	7.3%	6.9%	5.8%	5.5%	6.0%	6.2%	5.7%	5.8%	5.3%	5.4%	5.3%	5.1%	5.3%	4.3%	4.4%
Net Income Yr/Yr	6.0%	11.0%	22.5%	35.2%	(9.1%)	(5.1%)	6.6%	12.3%	20.2%	8.2%	5.9%	(1.2%)	(7.3%)	(5.0%)	(2.2%)	(15.4%)	7.4%
EPS (ex. non-recurring charges)	$1.97	$2.33	$2.86	$3.80	$3.42	$0.82	$0.94	$1.00	$0.94	$3.71	$0.92	$0.97	$0.98	$0.93	$3.80	$3.35	$3.73
EPS Yr/Yr Change	7%	18%	23%	33%	(10%)	(6%)	6%	13%	23%	9%	11%	3%	(3%)	(1%)	2%	(12%)	11%
EPS Sequential Change	NM	NM	NM	NM	NM	7%	14%	7%	(6%)	NM	(3%)	6%	0%	(4%)	NM	NM	NM
EPS ex-NonCash Amortization	$1.97	$2.33	$2.93	$4.20	$3.86	$0.94	$1.06	$1.12	$1.06	$4.18	$1.03	$1.10	$1.10	$1.06	$4.30	$3.80	$4.20
EPS Yr/Yr Change	7%	18%	26%	44%	(8%)	(4%)	7%	11%	20%	8%	9%	4%	(2%)	1%	3%	(12%)	10%
Diluted Shares Outstanding	224.95	211.89	211.28	214.76	216.92	217.99	217.61	216.69	212.78	216.27	207.93	208.05	207.05	204.30	206.83	198.55	191.55
Share Count Yr/Yr	(1.0%)	(5.8%)	(0.3%)	1.6%	1.0%	0.9%	0.4%	(0.3%)	(2.2%)	(0.3%)	(4.6%)	(4.4%)	(4.5%)	(4.0%)	(4.4%)	(4.0%)	(3.5%)

Source: Company reports and J.P. Morgan estimates.

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Investment Thesis, Valuation and Risks

DaVita Inc *(Neutral; Price Target: $54.00)*

Investment Thesis

Although we believe both of DVA's segments are well positioned even within a long-term industry thesis that favors payors over providers, we still see near-term growth as challenged in DVA's key dialysis segment. DVA still enjoys solid FCF characteristics (approaching $1b annually) and a fairly conservative balance sheet (~3.4x net leverage) and is essentially tied for top U.S. market share (~35%) in the provision of dialysis services. Dialysis services constitute ~70% of DVA's total revenues and ~85% of total operating income. In addition, DVA is a large operator of capitated medical groups via its $4.4b acquisition of privately-held Healthcare Partners (HCP) in 2012. We view HCP as an important strategic asset that will remain a limited contributor to DVA's earnings growth over the near term.

Valuation

Our risk-adjusted, relative value model comps DVA vs. the S&P 500 on the basis of EPS growth, earnings quality, reimbursement risk, UFCF ROAA, and B/S leverage, deriving a target P/E of 12.9x (implied ~8.8 x 2018 EV/EBITDA-MI), which applied to our 2018E cash EPS yields a Dec-17 price target of $54.

Risks to Rating and Price Target

Upside risks include 1) thematic opportunity for HCP as a larger portion of FFS revenues moves into alternative risk-based payment models, 2) continued capital deployment given strong annual FCF, 3) competing ESAs given entry of Roche's Mircera in 2015 and the anticipated launch of Hospira's ESA in 2016, 4) ESCO—we think there is a possibly material long-term opportunity.

Downside risks include 1) margin pressures in dialysis as ~80% of DVA's patients are funded by MDCR, 2) HCP growth pains as its annual operating income has been nearly cut in half since DVA's 2012 acquisition, 3) government reimbursement risk, and 4) commercial reimbursement risk as DVA's large local market share position has historically supported commercial rates ~4-5x prevailing MDCR rates.

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DaVita Inc: Summary of Financials

Income Statement - Annual	FY14A	FY15A	FY16E	FY17E	FY18E
Revenue	**12,746**	**13,782**	**14,868**	**15,298**	**16,192**
COGS	(9,119)	(9,825)	(10,640)	(11,212)	(11,908)
Gross profit			**4,251**	-	-
SG&A	(1,211)	(1,377)	(1,606)	(1,697)	(1,776)
Adj. EBITDA	**2,369**	**2,532**	**2,572**	**2,340**	**2,454**
D&A	(591)	(638)	(701)	(684)	(709)
Adj. EBIT	**1,778**	**1,894**	**1,870**	**1,656**	**1,745**
Net Interest	2	10	12	12	12
Adj. PBT	**1,230**	**1,338**	**1,306**	**1,108**	**1,190**
Tax	(488)	(535)	(521)	(443)	(476)
Minority Interest				-	-
Adj. Net Income	**742**	**803**	**785**	**665**	**714**
Reported EPS	3.42	3.71	3.80	3.35	3.73
Adj. EPS	**3.42**	**3.71**	**3.80**	**3.35**	**3.73**
DPS	-	-	-	-	-
Payout ratio	-	-	-	-	-
Shares outstanding	212	212	203	195	188

Income Statement - Quarterly	1Q16A	2Q16A	3Q16E	4Q16E
Revenue	**3,581A**	**3,718A**	**3,798**	**3,772**
COGS	(2,566)A	(2,671)A	(2,725)	(2,677)
Gross profit	-	-	-	-
SG&A	(373)A	(377)A	(406)	(450)
Adj. EBITDA	**627A**	**656A**	**654**	**634**
D&A	(169)A	(180)A	(174)	(177)
Adj. EBIT	**458A**	**475A**	**480**	**457**
Net Interest	3A	3A	3	3
Adj. PBT	**317A**	**334A**	**337**	**318**
Tax	(127)A	(132)A	(135)	(127)
Minority Interest	-	-	-	-
Adj. Net Income	**190A**	**202A**	**202**	**191**
Reported EPS	0.92A	0.97A	0.98	0.93
Adj. EPS	**0.92A**	**0.97A**	**0.98**	**0.93**
DPS	-	-	-	-
Payout ratio	-	-	-	-
Shares outstanding	204A	204A	203	201

Balance Sheet & Cash Flow Statement	FY14A	FY15A	FY16E	FY17E	FY18E
Cash and cash equivalents	965	1,499	1,586	1,615	1,658
Accounts receivable	1,526	1,724	1,623	1,620	1,723
Inventories	136	186	200	205	218
Other current assets	912	663	748	788	837
Current assets	**3,877**	**4,480**	**4,551**	**4,623**	**4,830**
PP&E	2,469	2,780	3,060	3,235	3,429
LT investments	-	-	-	-	-
Other non current assets	11,597	11,223	11,273	11,373	11,473
Total assets	**17,943**	**18,482**	**18,884**	**19,231**	**19,731**
Short term borrowings	120	129	144	144	144
Payables	445	505	559	589	626
Other short term liabilities	1,523	1,733	1,997	1,997	1,997
Current liabilities	**2,089**	**2,367**	**2,700**	**2,730**	**2,767**
Long-term debt	8,383	9,001	8,941	8,941	8,941
Other long term liabilities	1,281	1,166	1,193	1,193	1,193
Total liabilities	**11,752**	**12,534**	**12,835**	**12,864**	**12,901**
Shareholders' equity	5,360	5,084	5,113	5,430	5,893
Minority interests	830	864	937	937	937
Total liabilities & equity	**17,943**	**18,482**	**18,884**	**19,231**	**19,731**
BVPS	**25.25**	**24.00**	**25.15**	**27.84**	**31.35**
y/y Growth	*15.1%*	*(5.0%)*	*4.8%*	*10.7%*	*12.6%*
Net debt/(cash)	7,538	7,631	7,500	7,470	7,427
Cash flow from operating activities	**1,459**	**1,557**	**2,098**	**1,535**	**1,504**
o/w Depreciation & amortization	591	638	701	684	709
o/w Changes in working capital	39	(403)	(81)	(43)	(128)
Cash flow from investing activities	**(1,278)**	**(882)**	**(1,159)**	**(810)**	**(852)**
o/w Capital expenditure	(641)	(708)	(710)	(710)	(752)
as % of sales	*5.0%*	*5.1%*	*4.8%*	*4.6%*	*4.6%*
Cash flow from financing activities	**(163)**	**(142)**	**(852)**	**(696)**	**(609)**
o/w Dividends paid	-	-	-	-	-
o/w Net debt issued/(repaid)	(8)	620	(77)	0	0
Net change in cash	**965**	**1,499**	**1,586**	**1,615**	**1,658**
Free cash flow to firm	**817**	**843**	**1,381**	**818**	**745**
y/y Growth	*(29.2%)*	*3.3%*	*63.8%*	*(40.8%)*	*(8.9%)*

Ratio Analysis	FY14A	FY15A	FY16E	FY17E	FY18E
Gross margin	-	-	28.6%	-	-
EBITDA margin	18.6%	18.4%	17.3%	15.3%	15.2%
EBIT margin	14.0%	13.7%	12.6%	10.8%	10.8%
Net profit margin	5.8%	5.8%	5.3%	4.3%	4.4%
ROE	14.9%	15.4%	15.4%	12.6%	12.6%
ROA	4.2%	4.4%	4.2%	3.5%	3.7%
ROCE	8.0%	8.1%	7.9%	6.9%	7.1%
SG&A/Sales	9.5%	10.0%	10.8%	11.1%	11.0%
Net debt/equity	121.8%	128.3%	124.0%	117.3%	108.7%
P/E (x)	17.0	15.7	15.4	17.4	15.6
P/BV (x)	2.3	2.4	2.3	2.1	1.9
EV/EBITDA (x)	8.6	8.1	8.0	8.8	8.3
Dividend Yield	-	-	-	-	-
Sales/Assets (x)	0.7	0.8	0.8	0.8	0.8
Interest cover (x)	NM	NM	NM	NM	NM
Operating leverage	(86.3%)	80.2%	(16.1%)	(397.2%)	92.3%
Revenue y/y Growth	8.3%	8.1%	7.9%	2.9%	5.8%
EBITDA y/y Growth	(3.1%)	6.9%	1.5%	(9.0%)	4.9%
Tax rate	39.7%	40.0%	39.9%	40.0%	40.0%
Adj. Net Income y/y Growth	(9.1%)	8.2%	(2.2%)	(15.4%)	7.4%
EPS y/y Growth	(10.0%)	8.5%	2.3%	(11.8%)	11.3%
DPS y/y Growth	-	-	-	-	-

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data). Fiscal year ends Dec. o/w - out of which

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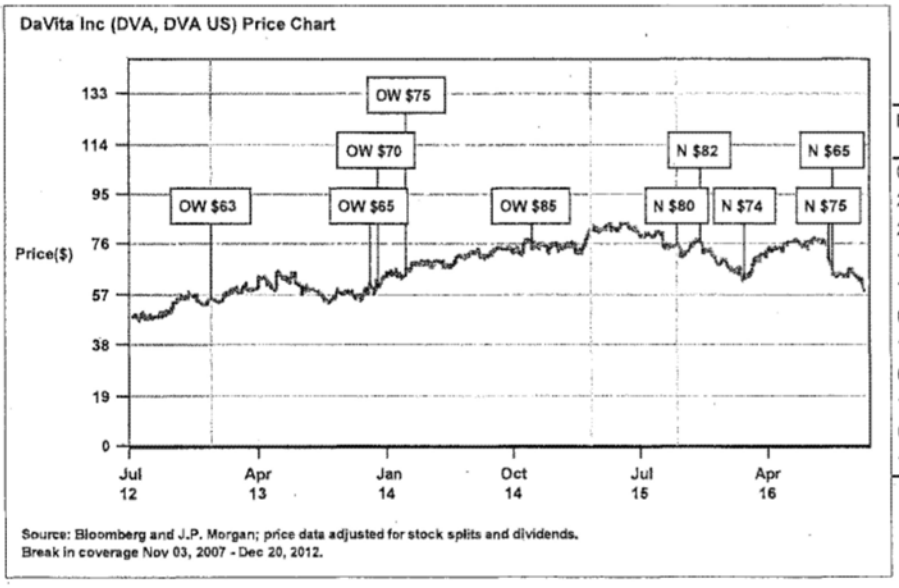

Date	Rating	Share Price ($)	Price Target ($)
03-Nov-07	OW	48.68	--
20-Dec-12	OW	55.44	63.00
25-Nov-13	OW	61.55	65.00
10-Dec-13	OW	62.17	70.00
12-Feb-14	OW	66.35	75.00
07-Nov-14	OW	78.03	85.00
16-Sep-15	N	75.82	80.00
04-Nov-15	N	77.45	82.00
12-Feb-16	N	62.56	74.00
08-Aug-16	N	72.31	75.00
18-Aug-16	N	67.65	65.00

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	Overweight (buy)	Neutral (hold)	Underweight (sell)
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IB clients*	51%	48%	34%
JPMS Equity Research Coverage	42%	50%	8%
IB clients*	68%	61%	43%

*Percentage of investment banking clients in each rating category.
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North America Equity Research
18 August 2016

DaVita HealthCare Partners

DVA Commercial Mix at Risk, Sensitivity is Material

Neutral

DVA, DVA US
Price: $67.65

▼ **Price Target: $65.00**
Previous: $75.00

We believe exchange health plans may reject the majority of American Kidney Fund (AKF) dialysis third party premium assistance payments during 2017 open enrollment this Fall. We believe this threatens at least 1% of DVA's patient mix (10-15% of EPS). During the last month since the UNH lawsuit vs ARA, we've compiled an extensive analysis of the relevant regulatory, legislative and payor policies. To be clear, this issue is not one of whether ESRD patients are eligible for QHP (they are if they have not yet accepted MDCR eligibility), the issue is whether providers and financially interested third parties can pay the premiums for ESRD patients in order to benefit from higher commercial reimbursement rates. CMS has previously cautioned that such assistance could drive adverse selection and negatively impact the exchange risk pool. Given that the health insurance industry collectively lost over $2b underwriting exchange policies in 2015 and UNH/HUM/AET are exiting for 2017, CMS has been prompted to address the issue. Following DVA's 2Q16 call we wrote "management did not do a great job of explaining the primary recent investor concern regarding the sustainability of the AKF patient subsidy program". Follow up conversations with DVA heightened our concerns. Before we could complete our analysis, CMS pre-empted our work on Thursday by issuing a request for public information; "CMS examines inappropriate steering of people eligible for Medicare or Medicaid into Marketplace plans". Today, we are lowering our forward earnings estimates for DVA and reducing our 2017YE PT from $75 to $65. To the extent that our insurance coverage universe maintains any material forward HIX presence, this possible CMS regulatory action could provide a material HIX margin benefit of 400+bp (and possibly lift Medigap margins as well).

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	YTD	1m	3m	12m
Abs	-1.5%	-12.7%	-12.0%	-15.4%
Rel	-10.2%	-13.6%	-18.8%	-19.7%

DaVita HealthCare Partners, Inc. (DVA;DVA US)

FYE Dec	2015A	2016E (Prev)	2016E (Curr)	2017E (Prev)	2017E (Curr)	2018E (Prev)	2018E (Curr)
EPS - Recurring ($)							
Q1 (Mar)	0.82	0.92A	0.92A	-	-	-	-
Q2 (Jun)	0.94	0.97A	0.97A	-	-	-	-
Q3 (Sep)	1.00	0.95	0.97	-	-	-	-
Q4 (Dec)	0.94	0.97	0.94	-	-	-	-
FY	3.71	3.81	3.80	4.27	3.75	4.87	4.28
Bloomberg EPS FY ($)	3.77	-	3.78	-	4.19	-	4.79

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data	
Price ($)	67.65
Date Of Price	18 Aug 16
52-week Range ($)	80.63-61.36
Market Cap ($ mn)	14,066.34
Fiscal Year End	Dec
Shares O/S (mn)	208
Price Target ($)	65.00
Price Target End Date	31-Dec-17

See page 11 for analyst certification and important disclosures.

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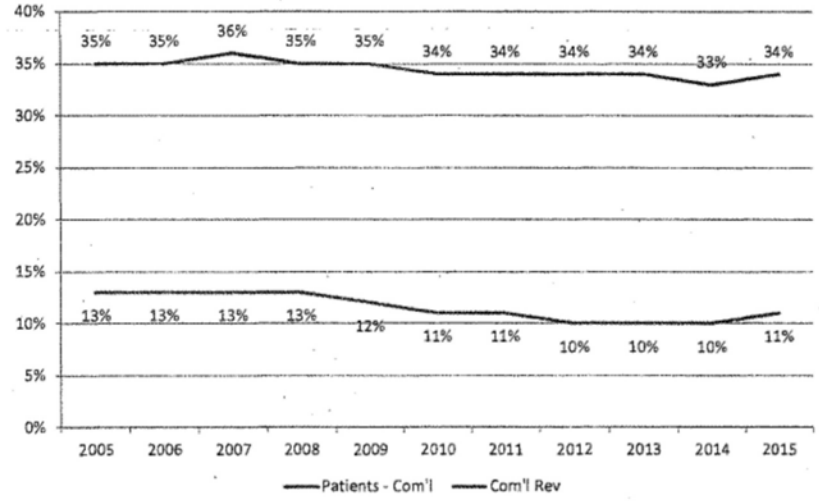
- **Background** – Medicare has provided universal coverage for dialysis patients since 1972 (currently following a 90-day wait period for those uninsured or on Medicaid and after a further 30-month coordination period for those with group commercial coverage). In-network commercial payments for dialysis average $1,000-1,000/tx, MDCR and MDCD payments average $260/tx. Thus, dialysis providers have a large financial incentive for patients to acquire or maintain commercial coverage. Over the last decade, DVA's commercial patient mix has consistently and slowly declined as total U.S. commercial coverage declined and MDCD/uninsured populations increased. Prior to the 2014 ACA health insurance exchanges, insurers would generally not underwrite individual commercial policies for ESRD patients. But with the establishment of community rating in the ACA exchanges, insurers now must underwrite individual policies for ESRD patients. The ACA subsidies make such coverage affordable for lower income populations and should have legitimately slowed the rate of DVA's commercial mix decline but by only ~20bp (our estimate based on industry coverage data). Instead, DVA reported stable mix in 2014 and a 100bp increase in 2015, reversing a long trend.

Figure 1: DVA Dialysis Commercial Mix (% of Revenue, % of Patients)



Source: Company reports and J.P. Morgan estimates.

- DVA has conceded that a portion of this improvement in mix is attributable to the AKF premium assistance program. The AKF is a nfp 501(c)3 organization that accepts donations (per 2015 IRS form 990, 80% of AKF's total $265m donations came from two redacted donors, it is logical to believe that DVA is one of the donors contributing ~$100m annually) to provide financial assistance for ESRD patients to pay commercial premiums (whether COBRA or QHP), Medigap premiums and commercial/MDCR cost-sharing.

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- AKF current reports subsidizing 6,400 QHP policies (0.057% of total 11.1m QHP enrollment at 6/30/16), a miniscule percentage that we estimate drives nearly $1.7 billion of adverse selection (given most previously uninsured dialysis patients would be MDCD eligible on day 1 and most newly uninsured dialysis patients would be MDCR-eligible on day 91) on a run-rate basis, a remarkable 400bp of HIX MLR alone (with further unrelated adverse selection potentially larger from premium assistance programs for patients prescribed orphan/specialty drugs).

Figure 2: Impact of Cost Shifting from Medicare to Exchange Plans

	MDCR	Commercial
Revenue/Treatment	$250	$1,000
Treatments/Year	$156	$156
Annual TX Costs per patient	$39,000	$156,000
Other Annual Medical Costs	$71,000	$106,500
Total Annual Medical Costs, per patient	$110,000	$262,500
HIX Annual Premium		$3,600
Annual UW Loss/Patient		-$258,900
HIPP HIX Patients	6,400	6,400
Total Annual Premiums		$23m
Total Annual Costs ($m)	-$704m	-$1,680m
Total Annual UW Loss ($m)		-$1,657m

Source: Company report, AKF and J.P. Morgan estimates.

- **Concurrent Payor & State Activity** – We are aware that the largest NFP Blue (TX, OK, IL, MT, NM) has begun rejecting AKF premium assistance, as well as (at minimum) insurers in ID, IA, MN, NC & OR. On the other hand, in 2014, the LA legislature passed a law requiring insurers to accept AKF premium assistance and a similar bill in NC has been stuck in committee for over a year. We presume a new Federal regulation or clarification from CMS would curtail most state DOI or legislative activity favoring third party premium assistance.

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- **Estimates & Target** – 1% of DVA's total 192k patients is 1,900. DVA's ~40% market share of AKF's disclosed 6,400 subsidized QHP patients would be 2,560. We calculate an average $800 difference between DVA's average commercial and MDCR payment/tx, but believe the QHP differential could be as low as $600/tx producing a range of revenue risk of $178-240m (54-72c or 11-15% of our previous 2017 cash EPS excluding possible risk related to AKF premium assistance for Medigap policies). We don't know if AKF is paying the entire HIX premium for 6,400 patients or paying only the unsubsidized portion of the HIX premium, which means a portion of the 6,400 may be able to maintain their HIX coverage on their own (the stated purpose of AKF is to provide financial assistance for those unable to afford coverage). We are therefore reducing our 2016/17/18 cash EPS by our low-end AKF estimate from $4.31/4.72/5.34 to $4.30/4.21/4.75 (current consensus is still on a GAAP basis, adding ~50c amortization yields equivalent consensus cash EPS of $4.28/4.70/5.29). We are reducing our 2017YE PT from $75 to $65 (risk-adjusted target 2018 P/E of 14.3x, implied 2018 EV/EBITDA 8.7x). What levers could DVA pull to offset any potential loss of commercial revenue? 1) curtail estimated $100m (30c) AKF contributions at the risk of higher bad debt expense, 2) press for higher commercial reimbursement rates, which will be difficult with 20% dialysis EBITDA margins solely attributed to current commercial payments, 3) accelerate share repurchase, we currently model $1.8b ratably over 2016-2018 vs DVA's current $1.5b authorization, 4) press for a renewed EPO contract with AMGN prior to 12/31/18 expiration, DVA has been unsuccessful despite pushing publicly over the last year.

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Background:

In implementing the Affordable Care Act (ACA) various regulatory entities have provided guidance surrounding third party premium assistance payments. Below we summarize the key provisions.

IRS Notice 2013-41 – June 2013

Summary: ESRD patients who are under 65 years old are eligible for enrollment in subsidized exchange plans despite their eligibility for Medicare coverage.

Add'l Detail: In June of 2013 the IRS issued guidance on individual eligibility for enrollment in exchange plans and premium tax credit (subsidies) to purchase such coverage. Generally under the Affordable Care Act (ACA) an individual is only eligible to enroll in a qualified health plan (QHP) through the exchange if they are not otherwise eligible for other insurance coverage.

The IRS guidance however clarifies that when the individual's Medicare eligibility is based on disability or illness (i.e., ESRD), then an individual is considered eligible for Medicare (and therefore not eligible for exchange enrollment) only upon the affirmative determination by the government agency responsible. The IRS reasons that since a patient qualifying based on illness or disability may not be able to easily determine whether they are eligible for Medicare, (because unlike the traditional eligibility criteria of simply turning 65 years old, a determination of disability or specific diagnosis of disease must be made by a third party), a patient will not be considered Medicare eligible until the patient applies for and receives approval from the Medicare program. Put another way, the IRS isn't willing to rule that a patient is definitively eligible for Medicare based on illness or disability unless they have gone through the process of applying and being approved for Medicare coverage. Therefore, ***if a patient under the age of 65 does not apply for or enroll in Medicare upon being diagnosed with ESRD, they are not considered "Medicare eligible" in the eyes of the IRS, and therefore are permitted to enroll in subsidized exchange coverage.***

CMS FAQs on Third Party Premium Payments in Exchanges – November 4, 2013 & February 7, 2014

Summary: Non-profit foundations are permitted to make premium assistance payments on behalf of exchange enrollees provided such payments are made on the basis of financial status and do not consider an enrollees' health status.

Add'l Details: In November of 2013 CMS issued a brief response to the question *"Are third party payors permitted to make premium payments to health insurance issuers for qualified health plans on behalf of enrolled individuals?"*

CMS responded, *it has been suggested that hospitals, other healthcare providers, and other commercial entities may be considering supporting premium payments and cost-sharing obligations with respect to qualified health plans purchased by patients in the Marketplaces.* ***HHS has significant concerns with this practice because it could skew the insurance risk pool and create an unlevel field in the Marketplaces. HHS discourages this practice and encourages issuers to reject such third party payments. HHS intends to monitor this practice and to take appropriate action, if necessary"***

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Three months later, on February 7, 2014, CMS posted further clarifications in response to additional questions. In that response, CMS clarified that

The November 2013 guidance does not apply to the three groups that are specifically permitted by law to make premium support payments (Indian tribes, urban Indian organizations, and state and federal government programs (such as the Ryan White HIV/AIDS Program). CMS "encouraged" insurance issuers to continue to accept third party payments from these organizations.

The November 2013 guidance does not apply to payments from private non-profit foundations if ***"if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status".***

Final Interim Rule - March 2014

In CMS's final rule entitled "Third Party Payment and Qualified Health Plan Premiums, effective March 14, 2014, CMS codifies that exchange plans must accept third party payments from the three entities required under law – Indian tribes, tribal organizations, and state & federal government programs. CMS also specifically reiterated their view on other third party payments from commercial entities that could skew the risk pool;

"as stated in our November FAQ, we remain concerned that third party payments of premium and cost sharing provided by hospitals, other healthcare providers, and other commercial entities could skew the insurance risk pool and create an unlevel competitive field in the insurance market. We continue to discourage such third party payments of premiums and cost sharing, and we encourage QHPs and SADPs to reject these payments"

OIG Advisory Opinions 15-16 & 15-17 – Issued December 28, 2015

Summary: In 2015 the OIG issued two narrow opinions related to patient assistance programs, neither of which applied to the ESRD population or specifically to premium assistance programs for the purchase of insurance plans in the healthcare exchange. The OIG opinion was limited to opining on whether these two specific arrangements were likely to violate the anti-kickback statute.

Add'l Details: In response to requests for an opinion from a third party (name redacted), the OIG issued two advisory opinions in December of 2015 surrounding third party assistance with premiums & out-of-pocket expenses.

In the first opinion (15-16), a charitable organization proposed to establish a patient assistance program for assistance with out-of-pocket expense for outpatient prescription drugs. Two separate disease funds would be set up – one for assistance to patients with various types of cancer, and one for patients with chronic kidney disease not on dialysis. The requesting organization inquired whether the proposed arrangement would violate the Federal anti-kickback statute (the anti-kickback statute prohibits the acceptance of any remuneration in exchange for referrals for federal healthcare program business). The OIG found that the arrangement would entail minimal risk or influencing direct or indirect referrals on the grounds that (1)

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no donor or affiliate of any donor or provider would exert control over the program (2) each patient was required to select a provider prior to applying for assistance (3) no data would be provided to donors that would enable a donor to determine the influence of its donations over the use of its drugs or services. In short, the OIG determined that arrangement presented "a low risk of fraud and abuse" and is not likely to influence any beneficiary's selection of particular provider.

In the second opinion (15-17) a charitable organization proposed to establish a patient assistance program for assistance with premiums, copayments & deductibles for patients with a specific disease state (the actual disease is redacted, although references to "stage 3 or stage 4" suggest the disease fund was for patients with pre-dialysis chronic kidney disease, and the majority of donations were received from drug manufacturers). As in the first opinion, the organization specifically asked the OIG if the arrangement would be grounds for sanctions under the civil monetary penalty provision of the federal anti-kickback statute.

The OIG opinion in 15-17 is similar to that of 15-16. The OIG found minimal risk of inducing referrals since no donor exerts control, the patient would have selected a provider prior to applying for assistance, and no data would be provided to donors that would allow the donor to draw conclusions about influence of donations on drug utilization. Furthermore, the donor certified that it would establish the fund for a broadly defined disease state and in a manner that would cover a broad spectrum of available drugs, and except for limiting the fund to stage 3 and stage 4 patients, the fund would not determine assistance based on specific symptoms, severity of symptoms, or type of drug treatment.

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Figure 1: DVA Model

	2011A	2012A	2013A	2014A	2015A				2015A	2016E				2016E	2017E	2018E
	FY	FY	FY	FY	Mar 1Q15A	June 2Q15A	Sept 3Q15A	Dec 4Q15A	FY	Mar 1Q16A	June 2Q16A	Sept 3Q16E	Dec 4Q16E	FYE	FYE	FYE
Dialysis Gross Revenue	**6,491**	**7,316**	**8,032**	**8,516**	**2,166**	**2,252**	**2,301**	**2,316**	**9,035**	**2,328**	**2,367**	**2,418**	**2,423**	**9,536**	**9,939**	**10,580**
Yr/Yr Change	7%	13%	10%	6%	6%	7%	6%	5%	6%	7%	5%	5%	5%	6%	4%	6%
PPM Gross Revenue		**453**	**3,155**	**3,424**	**914**	**934**	**969**	**930**	**3,747**	**978**	**1,034**	**1,076**	**1,036**	**4,125**	**4,401**	**4,665**
Yr/Yr Change		na	596%	9%	10%	11%	9%	8%	9%	7%	11%	11%	11%	10%	7%	6%
Other Revenue	**497**	**704**	**871**	**1,173**	**307**	**359**	**365**	**401**	**1,432**	**384**	**428**	**430**	**444**	**1,686**	**1,854**	**2,010**
	32%	42%	24%	35%	16%	26%	21%	24%	22%	25%	19%	18%	11%	18%	10%	8%
Total Revenue	**6,987.7**	**8,472.5**	**12,057.6**	**13,113.0**	**3,387.1**	**3,544.6**	**3,635.1**	**3,646.9**	**14,213.7**	**3,690.3**	**3,829.1**	**3,924.3**	**3,902.9**	**15,346.6**	**16,194.0**	**17,255.6**
Yr/Yr Change	8%	21%	42%	9%	8%	10%	8%	7%	8%	9%	8%	8%	7%	8%	6%	7%
Provision for Doubtful Accounts	198.0	235.2	293.5	366.9	99.2	106.0	109.5	113.3	427.9	109.2	111.4	114.9	115.4	450.9	509.0	559.9
% of Revenue	2.8%	2.8%	2.4%	2.8%	2.9%	3.0%	3.0%	3.1%	3.0%	3.0%	2.9%	2.9%	3.0%	2.9%	3.1%	3.2%
NET REVENUE	**6,789.7**	**8,237.4**	**11,764.1**	**12,746.1**	**3,288.0**	**3,434.6**	**3,525.7**	**3,533.6**	**13,785.8**	**3,581.1**	**3,717.7**	**3,809.4**	**3,787.6**	**14,895.7**	**15,685.0**	**16,695.6**
Yr/Yr Change	8%	21%	43%	8%	8%	9%	8%	7%	8%	9%	8%	8%	7%	8%	5%	6%
Sequential Change	NM	NM	NM	NM	(0%)	4%	3%	0%	NM	1%	4%	2%	(1%)	NM	NM	NM
Patient Care Costs	4,684.8	5,619.1	8,190.2	9,119.3	2,362.6	2,446.1	2,501.0	2,515.1	9,824.8	2,566.3	2,671.0	2,737.6	2,692.0	10,666.9	11,416.4	12,180.8
% of Revenue	69.0%	68.2%	69.6%	71.5%	71.9%	71.2%	70.9%	71.2%	71.3%	71.7%	71.8%	71.9%	71.1%	71.6%	72.8%	73.0%
General & Administrative	691.2	895.8	1,163.1	1,280.6	343.6	354.2	356.0	389.1	1,442.9	388.9	390.5	420.6	464.3	1,664.3	1,797.1	1,882.4
% of Revenue	10.2%	10.9%	9.9%	10.0%	10.5%	10.3%	10.1%	11.0%	10.5%	10.9%	10.5%	11.0%	12.3%	11.2%	11.5%	11.3%
Equity Income	(6.8)	(16.4)	(34.6)	(23.2)	(2.9)	(5.0)	(2.8)	(7.6)	(18.3)	(1.4)	0.5	(2.8)	(4.0)	(7.7)	(12.0)	(12.0)
EBITDA	**1,422.5**	**1,738.9**	**2,445.3**	**2,369.4**	**584.6**	**639.4**	**671.4**	**637.0**	**2,536.4**	**627.2**	**655.7**	**654.0**	**635.2**	**2,572.1**	**2,483.4**	**2,644.4**
EBITDA Margin	21.0%	21.1%	20.8%	18.6%	17.8%	18.6%	19.0%	18.0%	18.4%	17.5%	17.6%	17.2%	16.8%	17.3%	15.8%	15.8%
EBITDA Yr/Yr	16%	22%	41%	(3%)	(1%)	6%	11%	11%	7%	7%	3%	(3%)	0%	1%	-3%	6%
Depreciation & Amortization	267.1	343.6	528.7	590.9	153.8	158.8	162.1	163.3	638.0	169.4	180.4	174.4	177.2	701.3	684.8	711.0
% of Revenue	3.9%	4.2%	4.5%	4.6%	4.7%	4.6%	4.6%	4.6%	4.6%	4.7%	4.9%	4.6%	4.7%	4.7%	4.4%	4.3%
OPERATING INCOME	**1,155.4**	**1,395.2**	**1,916.6**	**1,778.5**	**430.8**	**480.5**	**509.4**	**473.6**	**1,898.4**	**457.9**	**475.3**	**479.6**	**458.0**	**1,870.8**	**1,798.5**	**1,933.5**
Operating Margin	17.0%	16.9%	16.3%	14.0%	13.1%	14.0%	14.4%	13.4%	13.8%	12.8%	12.8%	12.6%	12.1%	12.6%	11.5%	11.6%
Operating Income Yr/Yr	16%	21%	37%	(7%)	(4%)	5%	12%	13%	7%	6%	(1%)	(6%)	(3%)	(1%)	(4%)	8%
Minority Interest	95.4	102.2	123.8	140.2	34.5	37.3	45.4	40.5	157.7	40.7	41.1	44.0	40.2	166.1	160.5	171.0
Interest Expense and Other Income, Net	238.1	277.9	425.2	407.9	96.9	101.9	101.0	98.6	398.4	99.9	99.7	99.4	99.1	398.1	396.2	395.4
% of Revenue	3.5%	3.4%	3.6%	3.2%	2.9%	3.0%	2.9%	2.8%	2.9%	2.8%	2.7%	2.6%	2.6%	2.7%	2.5%	2.4%
PRE TAX INCOME (ex. non-recurring)	821.9	1,015.2	1,367.7	1,230.4	299.5	341.3	362.9	334.5	1,338.3	317.3	334.5	336.2	318.7	1,306.7	1,241.8	1,367.1
Pre-Tax Margin	12.1%	12.3%	11.6%	9.7%	9.1%	9.9%	10.3%	9.5%	9.7%	8.9%	9.0%	8.8%	8.4%	8.8%	7.9%	8.2%
Pre-Tax Income Yr/Yr	11%	24%	35%	(10%)	(5%)	7%	14%	20%	9%	6%	(2%)	(7%)	(5%)	(2%)	(5%)	10%
Provision for Taxes	328.8	411.2	550.8	488.2	119.8	136.5	145.2	133.8	535.3	126.9	132.1	134.5	127.5	521.0	496.7	546.8
Tax Rate	40.0%	40.5%	40.3%	39.7%	40.0%	40.0%	40.0%	40.0%	40.0%	40.0%	39.5%	40.0%	40.0%	39.9%	40.0%	40.0%
NET INCOME (ex. non-recurring)	493.2	604.0	816.8	742.2	179.7	204.8	217.8	200.7	803.0	190.4	202.4	201.7	191.2	785.7	745.1	820.3
Net Margin	7.3%	7.3%	6.9%	5.8%	5.5%	6.0%	6.2%	5.7%	5.8%	5.3%	5.4%	5.3%	5.0%	5.3%	4.8%	4.9%
Net Income Yr/Yr	11.0%	22.5%	35.2%	(9.1%)	(5.1%)	6.6%	12.3%	20.2%	8.2%	5.9%	(1.2%)	(7.4%)	(4.7%)	(2.2%)	(5.2%)	10.1%
EPS (ex. non-recurring charges)	**$2.33**	**$2.86**	**$3.80**	**$3.42**	**$0.82**	**$0.94**	**$1.00**	**$0.94**	**$3.71**	**$0.92**	**$0.97**	**$0.97**	**$0.94**	**$3.80**	**$3.75**	**$4.28**
EPS Yr/Yr Change	18%	23%	33%	(10%)	(6%)	6%	13%	23%	9%	11%	3%	(3%)	(1%)	2%	(1%)	14%
EPS Sequential Change	NM	NM	NM	NM	7%	14%	7%	(6%)	NM	(3%)	6%	0%	(4%)	NM	NM	NM
EPS ex-NonCash Amortization	**$2.33**	**$2.93**	**$4.20**	**$3.86**	**$0.94**	**$1.06**	**$1.12**	**$1.06**	**$4.18**	**$1.03**	**$1.10**	**$1.10**	**$1.07**	**$4.30**	**$4.21**	**$4.75**
EPS Yr/Yr Change	18%	26%	44%	(8%)	(4%)	7%	11%	20%	8%	9%	4%	(2%)	1%	3%	(2%)	13%
Diluted Shares Outstanding	211.89	211.28	214.76	216.92	217.99	217.61	216.69	212.78	216.27	207.93	208.05	207.05	204.30	206.83	198.55	191.55
Share Count Yr/Yr	(5.8%)	(0.3%)	1.6%	1.0%	0.9%	0.4%	(0.3%)	(2.2%)	(0.3%)	(4.6%)	(4.4%)	(4.5%)	(4.0%)	(4.4%)	(4.0%)	(3.5%)

Source: Company reports and J.P. Morgan estimates.

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Investment Thesis, Valuation and Risks

DaVita HealthCare Partners *(Neutral; Price Target: $65.00)*

Investment Thesis

Although we believe both of DVA's segments are well positioned even within a long-term industry thesis that favors payors over providers, we still see near-term growth as challenged in DVA's key dialysis segment. DVA still enjoys solid FCF characteristics (approaching $1b annually) and a fairly conservative balance sheet (~3.4x net leverage) and is essentially tied for top U.S. market share (~35%) in the provision of dialysis services. Dialysis services constitute ~70% of DVA's total revenues and ~85% of total operating income. In addition, DVA is a large operator of capitated medical groups via its $4.4b acquisition of privately-held Healthcare Partners (HCP) in 2012. We view HCP as an important strategic asset that will remain a limited contributor to DVA's earnings growth over the near term.

Valuation

Our risk-adjusted, relative value model comps DVA vs. the S&P 500 on the basis of EPS growth, earnings quality, reimbursement risk, UFCF ROAA, and B/S leverage, deriving a target P/E of 14.3x (implied ~8.7 x 2018 EV/EBITDA-MI), which applied to our 2018E cash EPS yields a Dec-17 price target of $65.

Risks to Rating and Price Target

Upside risks include 1) thematic opportunity for HCP as a larger portion of FFS revenues moves into alternative risk-based payment models, 2) continued capital deployment given strong annual FCF, 3) competing ESAs given entry of Roche's Mircera in 2015 and the anticipated launch of Hospira's ESA in 2016, 4) ESCO---we think there is a possibly material long-term opportunity.

Downside risks include 1) margin pressures in dialysis as ~80% of DVA's patients are funded by MDCR, 2) HCP growth pains as its annual operating income has been nearly cut in half since DVA's 2012 acquisition, 3) government reimbursement risk, and 4) commercial reimbursement risk as DVA's large local market share position has historically supported commercial rates ~4-5x prevailing MDCR rates.

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DaVita HealthCare Partners: Summary of Financials

Income Statement - Annual	FY15A	FY16E	FY17E	FY18E
Revenues	13,782	14,896	15,685	16,696
Cost of products sold	(9,825)	(10,667)	(11,416)	(12,181)
Gross profit		4,251	-	-
SG&A	(1,377)	(1,605)	(1,736)	(1,816)
R&D	-	-	-	-
Operating income	1,894	1,871	1,799	1,933
Adjusted EBITDA	2,532	2,572	2,483	2,644
Net interest (income) / expense	10	12	12	13
Other income / (expense)	(408)	(410)	(409)	(409)
Income taxes	(535)	(521)	(497)	(547)
Net income - GAAP	803	786	745	820
Net income - recurring	803	786	745	820
Diluted shares outstanding	216	207	199	192
EPS - excluding non-recurring	3.71	3.80	3.75	4.28
EPS - recurring	3.71	3.80	3.75	4.28

Balance Sheet and Cash Flow Data	FY15A	FY16E	FY17E	FY18E
Cash and cash equivalents	1,499	1,616	1,735	1,939
Accounts receivable	1,724	1,630	1,671	1,781
Inventories	186	201	212	226
Other current assets	663	752	804	858
Current assets	4,480	4,593	4,817	5,198
PP&E	2,780	2,934	2,897	2,876
Total assets	18,482	18,800	19,086	19,547
Total debt	9,130	9,085	9,085	9,085
Total liabilities	12,534	12,838	12,877	12,917
Shareholders' equity	5,084	5,025	5,272	5,692
Net income (including charges)	803	786	745	820
D&A	638	701	685	711
Change in working capital	(403)	(89)	(97)	(137)
Other	807	261	0	0
Cash flow from operations	1,557	2,090	1,571	1,616
Capex	(708)	(672)	(648)	(690)
Free cash flow	843	1,411	916	918
Cash flow from investing activities	(882)	(1,121)	(748)	(790)
Cash flow from financing activities	(142)	(852)	(705)	(622)
Dividends	-	-	-	-
Dividend yield	-	-	-	-

Income Statement - Quarterly	1Q16A	2Q16A	3Q16E	4Q16E
Revenues	3,581A	3,718A	3,809	3,788
Cost of products sold	(2,566)A	(2,671)A	(2,738)	(2,692)
Gross profit	-	-	-	-
SG&A	(373)A	(376)A	(406)	(450)
R&D	-	-	-	-
Operating income	458A	475A	480	458
Adjusted EBITDA	627A	656A	654	635
Net interest (income) / expense	3A	3A	3	3
Other income / (expense)	(103)A	(103)A	(102)	(102)
Income taxes	(127)A	(132)A	(134)	(127)
Net income - GAAP	190A	202A	202	191
Net income - recurring	190A	202A	202	191
Diluted shares outstanding	208A	208A	207	204
EPS - excluding non-recurring	0.92A	0.97A	0.97	0.94
EPS - recurring	0.92A	0.97A	0.97	0.94

Ratio Analysis	FY15A	FY16E	FY17E	FY18E
Sales growth	8.1%	8.1%	5.3%	6.4%
EBIT growth	6.5%	(1.2%)	(3.9%)	7.5%
EPS growth - recurring	8.5%	2.3%	(1.2%)	14.1%
Gross margin	-	28.5%	-	-
EBIT margin	13.7%	12.6%	11.5%	11.6%
EBITDA margin	18.4%	17.3%	15.8%	15.8%
Tax rate	40.0%	39.9%	40.0%	40.0%
Net margin	5.8%	5.3%	4.8%	4.9%
Net Debt / EBITDA	301.3%	290.4%	296.0%	270.3%
Net Debt / Capital (book)	56.2%	55.6%	54.2%	51.9%
Return on assets (ROA)	4.4%	4.2%	3.9%	4.2%
Return on equity (ROE)	15.4%	15.5%	14.5%	15.0%
Enterprise value / sales	1.6	1.5	1.4	1.3
Enterprise value / EBITDA	8.9	8.7	9.0	8.4
Free cash flow yield	5.8%	10.1%	6.8%	7.1%

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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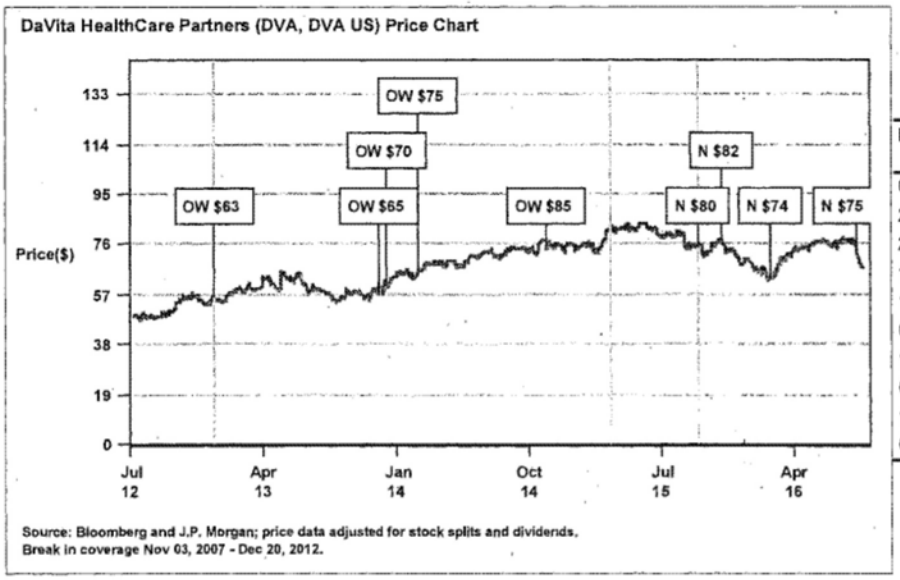

Date	Rating	Share Price ($)	Price Target ($)
03-Nov-07	OW	48.68	--
20-Dec-12	OW	56.32	63.00
25-Nov-13	OW	56.54	65.00
10-Dec-13	OW	62.17	70.00
12-Feb-14	OW	64.33	75.00
07-Nov-14	OW	74.49	85.00
16-Sep-15	N	75.15	80.00
04-Nov-15	N	77.45	82.00
12-Feb-16	N	62.56	74.00
08-Aug-16	N	72.31	75.00

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	Overweight (buy)	Neutral (hold)	Underweight (sell)
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IB clients*	52%	49%	37%
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IB clients*	68%	65%	51%

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"Other Disclosures" last revised July 9, 2016.

Boughton, Teri

From: Tim Valderrama <tim@weidemangroup.com>
Sent: Monday, April 02, 2018 2:58 PM
To: Boughton, Teri
Cc: Golly, Jessica
Subject: Fw: Dialysis/AKF Background Materials
Attachments: Dialysis Infection and Staffing Background Information 071317.docx; 2017-08-24 _LettertoAG_AmericanKidneyFund.pdf; FACT SHEET_Dialysis industry_updates_ 6.22.17.pdf

Hi Teri -

Here is the AKF background that you asked for at our meeting as well as some additional background that you didn't ask for. Please let us know if you need anything else you'd like from us. We're happy to meet again if there are other things you'd like to discuss. Jessica has reached out to DMHC and asked for a meeting, we will keep you updated on how that goes.

Tim

Industry overview:

- John Oliver's Last Week Tonight ran an overview of the dialysis industry, including showing how dialysis companies have discouraged patients from getting transplants, defrauded Medicare, and cut corners on quality care (5/14/2017): https://youtu.be/yw_nqzVfxFQ?t=1s
- Washington Post description of the Last Week Tonight segment (5/15/2017): https://www.washingtonpost.com/news/to-your-health/wp/2017/05/15/john-oliver-on-kidney-dialysis-taco-bell-and-death/?utm_term=.ed1fd5d13ddf
- Attached is a brief overview of California's dialysis industry, highlighting DaVita and Fresenius, the two companies that control the dialysis market.

American Kidney Fund:

The American Kidney Fund is a large nonprofit that dialysis companies contribute to that then uses the contributions to pay commercial insurance premiums and copays for dialysis patients.

- CMS published a fact sheet that describes the problems with the AKF scheme. Dialysis companies make an additional $100,000-$200,000 per patient annually compared to Medicare reimbursement, but there are consequences for patients including making it more difficult for patients to meet the requirements for a kidney transplant and increasing out-of-pocket costs. This fact sheet accompanied 2016 CMS regulations that were unfortunately enjoined in 2017 and haven't been reissued by the Trump Administration: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ESRD-IFC-FactSheet-FINAL-2-12-12-16.pdf
- St. Louis Post-Dispatch article that gives an overview of the AKF's patient steering. This was the first comprehensive article to lay out the entire scheme (10/23/2016): http://www.stltoday.com/business/local/davita-encouraged-some-low-income-patients-to-enroll-in-commercial/article_ec5dc34e-ca4d-52e0-bc26-a3e56e1e2c85.html
- New York Times article that gives a history of the AKF and describes how clinics were pressured into contributing to the AKF in order for their patients to receive premium assistance (12/25/2016): https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html?_r=0
- DaVita disclosed that approximately 5,800 patients whose primary commercial insurance coverage was paid by the AKF were expected to generate at least $495 million in annual operating income for the company

(10/10/2017): http://pressreleases.davita.com/2017-10-10-DaVita-Provides-Disclosures-Regarding-Charitable-Premium-Assistance

- According to the AKF's own guidelines, patients who receive a kidney transplant are only eligible for continued AKF premium assistance through the end of the plan year (unless the transplant occurs in the last quarter of the plan year, in which case the assistance would continue through the next plan year): http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-guidelines.pdf (page 6). It is critical for patients to have continuous insurance coverage after a transplant because post-transplant immunosuppressant medications can cost $15,000 annually. Medicare continues coverage for at least three years after a transplant, and advocates say that even that is too short of a coverage guarantee: (12/22/2016) https://www.npr.org/sections/health-shots/2016/12/22/506319553/medicare-pays-for-a-kidney-transplant-but-not-the-drugs-to-keep-it-viable; (12/6/2017) https://www.washingtonpost.com/opinions/our-medicare-policy-for-kidney-transplants-is-totally-irrational/2017/12/06/ecda8828-d9ec-11e7-b859-fb0995360725_story.html?utm_term=.81372b87a3cd
- Attached is a letter sent on behalf of SEIU-UHW to the California AG explaining the AKF scheme (8/24/2017).

Quality problems at California dialysis clinics:

- Op-ed by California dialysis patient Richard Elliott about quality issues he has experienced (3/29/2018): http://www.sacbee.com/opinion/op-ed/soapbox/article207146074.html
- Op-ed by California dialysis patient Irene Botello about quality issues she has experienced (8/29/2017): http://www.fresnobee.com/opinion/readers-opinion/article170022647.html
- Op-ed by Senator Ricardo Lara regarding quality issues in dialysis clinics (8/7/17): https://www.mercurynews.com/2017/08/07/opinion-23/
- Attached is an overview of infection problems and issues caused by understaffing at California dialysis clinics.

SENATE RULES COMMITTEE SB 1156
Office of Senate Floor Analyses
(916) 651-1520 Fax: (916) 327-4478

VETO

Bill No: SB 1156
Author: Leyva (D)
Amended: 8/24/18
Vote: 21

SENATE HEALTH COMMITTEE: 8-0, 4/18/18
AYES: Hernandez, Nguyen, Leyva, Mitchell, Monning, Newman, Nielsen, Pan
NO VOTE RECORDED: Roth

SENATE APPROPRIATIONS COMMITTEE: 6-0, 5/25/18
AYES: Lara, Beall, Bradford, Hill, Nielsen, Wiener
NO VOTE RECORDED: Bates

SENATE FLOOR: 34-1, 5/30/18
AYES: Allen, Atkins, Beall, Berryhill, Bradford, Cannella, Dodd, Fuller, Galgiani, Glazer, Hernandez, Hertzberg, Hill, Hueso, Jackson, Lara, Leyva, McGuire, Mitchell, Monning, Moorlach, Newman, Nguyen, Nielsen, Pan, Portantino, Roth, Skinner, Stern, Stone, Vidak, Wieckowski, Wiener, Wilk
NOES: Anderson
NO VOTE RECORDED: Bates, De León, Gaines, Morrell

SENATE FLOOR: 26-8, 8/30/18
AYES: Allen, Atkins, Beall, Bradford, Cannella, De León, Dodd, Galgiani, Hernandez, Hertzberg, Hill, Hueso, Jackson, Lara, Leyva, McGuire, Mitchell, Monning, Nguyen, Pan, Portantino, Skinner, Stern, Wieckowski, Wiener, Wilk
NOES: Anderson, Bates, Chang, Gaines, Moorlach, Morrell, Nielsen, Stone
NO VOTE RECORDED: Berryhill, Delgado, Fuller, Glazer, Roth, Vidak

ASSEMBLY FLOOR: 50-21, 8/29/18 - See last page for vote

SUBJECT: Health care service plans and health insurance: 3rd-party payments

SOURCE: Author

OFFICE OF THE GOVERNOR

SEP 30 2018

To the Members of the California State Senate:

I am returning Senate Bill 1156 without my signature.

This bill attempts to prohibit the questionable practice of financially interested entities providing premium assistance payments to patients for the purpose of obtaining higher fees for medical services.

I believe, however, that this bill goes too far as it would permit health plans and insurers to refuse premium assistance payments and to choose which patients they will cover. I encourage all stakeholders to continue to work to together to find a more narrowly tailored solution that ensures patients' access to coverage.

Sincerely,

Edmund G. Brown Jr.

Rate-Setting Scheme

In an effort to remove the financial incentive for providers to pay patient premiums and steer them to commercial coverage with higher reimbursement rates, this bill creates a new rate-setting scheme. The bill would require health plans to pay financially interested providers the Medicare rate or contracted rate, whichever is lower. Health plans, on the other hand, would collect the full commercial premium and yet would pay only this lower rate. This type of rate-setting scheme in the commercial market does not exist anywhere else, other than in the limited setting for surprise balance billing. The bill is also largely silent with respect to the process or procedures plans would have to put in place in order to determine which providers would receive this lower rate. As such, the DMHC would have to conduct complicated financial audits for each health plan in order to determine if plans are complying with the law.

Finally, this provision of the bill goes much further than other states that have attempted to tackle this issue of financially interested third-party premium payers. Given that the sponsors of this bill appear to be primarily focused on prohibited the payments made by the American Kidney Fund (AKF), a financially interested third-party premium payer that funds approximately 1,000 ESRD patients in California, this bill is much too broad given that it would significant impact and set a new precedent.

LEGISLATIVE HISTORY

SB 1290 (Bates, 2018) addresses insurance fraud related to substance abuse treatment and aims to prevent providers from making treatment decisions based on self-interest and financial motives rather than cost, quality or care, or necessity of services. The bill was held in the Senate Appropriations Committee.

AB 251 (Bonta, 2017) would have required dialysis clinics to spend at least 85% of treatment revenue on direct patient care, quality improvements, taxes, and fees; designed to prevent anti-competitive price markups for costs of dialysis care. The bill was held last year on the Senate floor and was re-activated July 5, 2018, but the bill was subsequently gutted and amended.

AB 2470 (De La Torre, Chapter 658, Statutes of 2010) prohibits the cancellation or nonrenewal of health plan contracts and health insurance policies with specific exceptions, such as nonpayment of premiums after at least a 30-day grace period or fraud.

PROGRAM BACKGROUND

The DMHC protects consumers' health care rights and ensures a stable health care delivery system. As part of this mission, the DMHC licenses and regulates health plans under the Knox-Keene Act. The DMHC regulates the majority of health coverage in California including 95 percent of commercial and public health plan enrollment. Health plans licensed by the DMHC provide health care services to approximately 26 million Californians.

OTHER STATES' INFORMATION

Other states have taken actions on the issue of third-party premium payments, as described below.

Delaware. The Department of Insurance issued Bulletin No. 93 (January 18, 2017) stating "as ongoing discussions concerning these [Charitable Premium Assistance] programs continue at the

federal level, the DOI maintains that it is permissible for bona fide 501(c)(3) organizations to operate Charitable Premium Assistance Programs so long as the organization has no financial interest in the services being rendered."

Idaho. The Department of Insurance issued Bulletin No. 16-04 (June 28, 2016) requiring carriers to accept third-party payments from family and friends on behalf of an enrollee and "carriers must also accept third-party payments made by religious institutions and other not-for-profit organizations when each of the following three criteria is met: the assistance is provided based on the basis of the insured's financial need; the institution/organization is not a healthcare provider; and the institution/organization is not financially interested. Financially interested institutions/organizations include institutions/organizations that receive the majority of their funding from entities with a pecuniary interest in the payment of health insurance claims, or institutions/organizations that are subject to direct or indirect control of entities with a pecuniary interest in the payment of health insurance claims."

Louisiana. On June 5, 2014 the state passed Revised Statute 22:1080, which requires insurers and health maintenance organizations to accept premium payments made by the AKF.

Minnesota. The Minnesota Department of Health issued Administrative Bulletin 2016-3 (June 23, 2016) requiring insurance carriers to accept third-party premium payments when assistance is based on financial need, the third-party is not a health care provider, and the third-party is financially disinterested. However, a subsequent Administrative Bulletin 2016-4 was issued which repealed Administrative Bulletin 2016-3.

New Mexico. The Superintendent of Insurance sent an email to Blue Cross Blue Shield (BCBS) New Mexico (January 21, 2016) asking the insurer to notify the Superintendent prior to rejecting any third-party premium payments. The email also stated that BCBS New Mexico "only take action in compliance with any final rule on third-party premium payment, including allowing potential third-party payors to continue premium assistance programs that comply with federal regulations and guidance."

North Carolina. In a letter from the state's Insurance Commissioner to Blue Cross Blue Shield of North Carolina (May 31, 2016), the Commissioner stated "the public's interest is best served by *all* insurers in the state allowing third-party payments of premiums from AKF, a non-profit foundation. When AKF wishes to provide premium assistance to insurance consumers who are financially needy, then I believe all parties should work to support that as good public policy."

Oregon. The state's Insurance Division issued a memorandum (November 4, 2015) reminding health insurers that they must comply with guaranteed availability and renewability requirements and that insurers may not terminate or not renew due to Medicare eligibility or entitlement.

Washington. On May 5, 2017, the Office of the Insurance Commissioner issued a Cease and Desist Order on DaVita Kidney Care to immediately stop engaging in the business of unauthorized insurance via steering dialysis patients into higher reimbursing plans by offering to pay premiums. After a demand for hearing, the state's Office of Administrative Hearings issued a stay on the Cease and Desist order with specific conditions.

EXHIBIT 1e

Excerpts from State of Washington Office of the Insurance Commissioner, produced in Defendants' Production No. 6

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Producer Enforcement Group Review
SUMMARY
September 13, 2016

Legal Affairs Division
Office of the Insurance Commissioner
State of Washington

Name of Entity:	**Cary Ancheta; DaVita Kidney Care**
SIMBA No.:	**1340003**
Referred By:	**Investigations (Allison Hanson)**
Staff Attorney:	**Darryl Colman**

Facts:

This investigation was instigated from a complaint received from Premera/Lifewise ("Premera"). Premera was concerned that DaVita Kidney Care (DaVita), a major nationwide kidney dialysis medical provider, was directing their state of Washington Medicaid patients to specifically enroll in Premera's Lifewise Health Plan. Premera alleged that DaVita was attempting to enroll some 30 patients in the Lifewise plan because Premera's plan pays higher insurance benefits to providers for kidney dialysis treatments than does Medicaid. Premera further alleged that DaVita employees, and in particular, Cary Ancheta, were encouraging prospective insureds to submit falsified insurance applications.

Ancheta, who is a financial/insurance counselor for DaVita Kidney Dialysis, was recorded when she called Premera customer service saying she was trying to sign up approximately 30 kidney dialysis patients, most of whom are receiving Medicaid, onto Premera's Lifewise Health Plan.

Premera provided the OIC with one audio recorded telephone call and written transcripts of two additional calls Ancheta made to Premera customer service representatives. Ancheta told the Premera customer service representative that she needed the paper application for the patient so it could be sent to the American Kidney Foundation (AKF) who would pay the patient's health Insurance premium. Ancheta knows that Premera does not accept third party payments therefore the AKF would send the patient's health insurance premium to the patient who would then pay Premera.

A former DaVita social worker provided the OIC with a copy of a Power Point presentation that was sent to DaVita financial/insurance counselors and social workers directing them to "target" Medicaid eligible patients to get them to purchase commercial insurance. They were instructed to tell the patients that by purchasing commercial insurance, they would have access to better services. However, the level and quality of care that DaVita provides to patients is not affected by whether the patient has Medicaid or commercial insurance. The patient was given a list of "kidney

friendly carriers" but the former social worker could not say if the patient or someone with DaVita selected the carrier. The patient then filled out an application for the AKF a non-profit organization that pays insurance premiums for kidney dialysis patients.

Premera has a policy which prohibits premium payments from third-party vendors, either directly or indirectly. According to Premera, DaVita attempts to circumvent this requirement by having the AKF send the premium funds to the patient directly, the patient cashes the check, and pays Premera directly. Premera's insurance application form asks the prospective insured to affirm that the premium payments are not being made directly or indirectly by third-party payers. The prohibition to accept third-party payments was a Premera company policy.

The attorney representing Ancheta and DaVita denied the allegations and did not agree to allow the OIC to interview Ancheta.

Prior Violations:

None.

Summary of Applicable Law:

RCW 48.17.060(1) provides a person shall not sell, solicit, or negotiate insurance in this state for any line or lines of insurance unless the person is licensed for that line of authority in accordance with this chapter.

RCW 48.17.063 provides if the Insurance Commissioner has cause to believe that any person has violated the provisions of RCW 48.17.060, the Insurance Commissioner may issue and enforce a cease and desist order in accordance with the provisions of RCW 48.02.080; suspend or revoke a license; and/or assess a civil penalty of not more than twenty-five thousand dollars for each violation.

Penalties Imposed in Similar Cases:

National Vehicle Service Contract dba Magnetized Marketing and Wayne Craig, Order to Cease and Desist, Order No. 16-0060, without being registered as a service contract provider or authorized to conduct the business of insurance in the state of Washington, advertised on website and solicited purchase of vehicle service contracts from Washington residents, acting as auto service contract broker.

Integrity Health Essentials Inc., Order to Cease and Desist, Order No. 15-0273, without being licensed or appointed with insurer, was advertising health plans for sale on its website, which identified it as a co-op and that stated that its goal is to provide its members with affordable, quality healthcare that delivers on their needs. Even though the company claimed that that it was in the "start up" stage and was not currently offering or selling any insurance plans, the website allowed financial information to be inputted and plans purchased, while not indicating that plans were not available in Washington.

Cesar Emmanuel Bernal, Explora Travel, and Nadine Mendoza, Order to Cease and Desist, Order No. 15-0236, without being licensed or appointed with insurer, was advertising discount auto insurance on Facebook, charging consumers a fee to sign them up for insurance and referring consumers to Explora to set up policies and complete payment.

Recommendation:

Order to Cease and Desist

SETTLEMENT AGREEMENT

RECITALS

This Settlement Agreement ("Settlement") is agreed to and entered into by and among the Washington State Office of the Insurance Commissioner ("OIC") and DaVita Inc. ("DaVita") and Cary Ancheta (collectively, "Appellants") as of the date below written.

On May 5, 2017, the OIC issued Orders to Cease and Desist, Nos. 16-0239 and 16-0240 ("the Orders"), against Appellants. On June 15, 2017, Appellants timely requested hearings to appeal, contest and vacate the entry of the Orders. On the same date, DaVita moved for a stay of the Orders. On June 22, 2017, the OIC and the Appellants stipulated to a stay of the Orders, which stay was entered by Presiding Officer, William G. Pardee, on the same date.

The OIC and the Appellants engaged in continuous and diligent discussions to determine if the parties could come to an agreement to settle this matter in order to avoid the expense and inconvenience associated with an administrative hearing expected to take several days to complete.

The OIC and the Appellants acknowledge and confirm that the parties, through representatives of the Appellants and representatives of the OIC, conducted their discussions in good faith and a spirit of cooperation throughout.

Appellants categorically denied and continue to deny the factual and legal allegations and statements set forth in the Orders, and specifically that they engaged in any conduct that requires licensure or registration with the OIC.

The OIC and Appellants have agreed to settle this Matter pursuant to the terms and conditions set forth in this Settlement and the attached Stipulation and Motion for Withdrawal of Cease and Desist Orders, Dismissal of Demands for Hearing and Order ("Stipulation"), and have further agreed that, upon satisfaction of all such terms and conditions, this matter shall be terminated as evidenced upon such further order determined to be reasonable and necessary by the Presiding Officer and entered herein.

The OIC and the Appellants confirm their agreement to be bound by and comply with the terms and conditions of the Settlement, set forth below.

TERMS AND CONDITIONS

On November 1, 2017, the Appellants and the OIC agreed to a Settlement of this matter without a hearing. The terms and conditions of the Settlement include the following:

1. The OIC agrees to rescind and withdraw the Orders and upon full execution of this Settlement Agreement by all parties the OIC declares and confirms that the OIC has rescinded and withdrawn the Orders and that such Orders are of no force and effect.

2. The Appellants agree to withdraw their demands for hearing, and do hereby confirm that they will file the attached Stipulation upon full execution of this Settlement Agreement by all parties.

3. The Appellants and the OIC have prepared and have executed the attached Stipulation that executes the agreements in paragraphs 1 and 2 above. This Settlement Agreement shall not be effective unless and until the Order in the attached Stipulation is entered by the Presiding Officer. If the Presiding Officer rejects the Stipulation by not executing its included Order, litigation of this matter will continue.

4. Appellant DaVita agrees to the following procedures by its insurance counselors interacting with patients in Washington State. By agreeing to such procedures, DaVita does not concede that it has violated any insurance laws or regulations, nor does DaVita concede that its processes and practices at all times were insufficient or not in conformance with the requirements of Washington law:

    a. When DaVita insurance counselors advise DaVita dialysis patients about insurance options, they will advise each such patient about all public and private insurance options then known to DaVita and that satisfy the patient's expressed needs and preferences regarding their insurance needs.

    b. DaVita counselors will not ask or urge dialysis patients to enroll in any particular kind of insurance from any particular insurer.

    c. DaVita will obtain a written acknowledgement from patients that the information counselors provided is consistent with subparagraphs 4 (a) and (b) above.

    d. DaVita counselors will not accept commissions from insurers for their counseling services.

    e. DaVita will not pay its insurance counselors any commission, bonus, or other compensation contingent on patient insurance enrollment;

f. If DaVita personnel sell, solicit or negotiate insurance, such personnel will first obtain licensure as an insurance producer.

5. The OIC agrees that it will not take any further action against Appellants with regard to any of the allegations and statements set forth in the Orders. The Appellants agree that they will not seek any further remedy or administrative review regarding the allegations and statements set forth in the Orders.

6. This Settlement Agreement shall expire two years from the date of its execution. The expiration of this Settlement Agreement shall not be construed by any party to suggest that the parties intend or believe that regulatory requirements of insurance producers will change at that time.

7. This Settlement Agreement is enforceable by any party to it as an order of the Insurance Commissioner. Each party to this settlement shall be afforded all rights of hearing and appeal under Chapters 48.04 and 34.05 RCW, including the right of judicial review in state Superior Court under RCW 34.05.510, *et seq*. The initial hearing in any action shall be before the OIC Chief Presiding Officer.

EXECUTED AND ENTERED this 6th day of November, 2017.

DAVITA INC.

By:_____

Printed Name: Kathleen Waters

Title: Chief Legal Officer

EXECUTED AND ENTERED this _____ day of _____, 2017

CARY ANCHETA

By:_____

Printed Name:_____

Title:_____

EXECUTED AND ENTERED this 7th day of November 2017.

MIKE KREIDLER
Insurance Commissioner

By and through his designee

DARRYL E. COLMAN
Insurance Enforcement Specialist
Legal Affairs Division

DaVITA RECORDED CALL

(Caller: Kerri Ancheta)

November 16, 2015

TRANSCRIBED FROM RECORDING BY:

CHERYL J. HAMMER, RPR, CCR 2512

--oOo--

(BEGINNING OF TRANSCRIPTION)

(Beginning of recording.)

OPERATOR LINDSEY: Individual sales. My name is Lindsey. May I have your name, please?

MS. ANCHETA: Hi Lindsey. My name is Kerri. How are you today?

OPERATOR LINDSEY: I'm good. How are you doing?

MS. ANCHETA: Good. I've got a quick question. I have about 40 patients that I'm trying to assist in enrolling in individual insurance through the open enrollment period.

OPERATOR LINDSEY: Okay.

MS. ANCHETA: Do you guys -- do you guys have a application that can be printed and filled out by the patient and then sent in?

OPERATOR LINDSEY: So let me ask you this question. Where are you calling from?

MS. ANCHETA: Okay. I am calling from DaVita. It's a kidney dialysis provider, and I'm not a broker. I'm not a producer. I'm an insurance counselor employed by DaVita to help patients understand their insurance and, you know, navigate the

insurance waters and so on, so forth, and I have about 40 patients who are all Medicaid only patients that we're trying to help them get expanded insurance so they have more access to care.

OPERATOR LINDSEY: Okay.

MS. ANCHETA: And so these are the patients. Most of them don't speak English, so going -- you know, if it's -- if we're doing it over the phone, it's a three-way call and it's a language line and so on and so forth. A lot of back and forth.

So we're hoping that there's -- is there an application that can be printed out that we can sit down with a patient and their -- you know, they usually have a support person or I have an interpreter coming onsite to help.

OPERATOR LINDSEY: So, unfortunately, right now we aren't able to speak to you guys. I do believe that information has been provided to you guys. That's what we were instructed. But since we are not able to identify you guys as producers or having been licensed to represent LifeWise or Premera or that you guys aren't being -- that you're not navigators by definition, we actually aren't able to speak to you guys at this time.

MS. ANCHETA: You're not able to speak

to a provider who's helping an insurance -- or helping a patient directly apply?

OPERATOR LINDSEY: Correct.

MS. ANCHETA: Well, that's dumb. So you're telling me there's no way I can download an application for a patient and hand it to them and have them fill it out?

OPERATOR LINDSEY: Yeah, unfortunately, we're just not able to speak to you guys at this time.

MS. ANCHETA: Awesome. Okay. Thanks.

OPERATOR LINDSEY: Thank you.

MS. ANCHETA: Bye.

(End of recording.)

(END OF TRANSCRIPTION)

TRANSCRIPTION CERTIFICATE

I, CHERYL J. HAMMER, the undersigned Certified Court Reporter in and for the state of Washington, do hereby certify:

That the foregoing transcript was transcribed under my direction; that the transcript is true and accurate to the best of my knowledge and ability to hear the audio; that I am not a relative or employee of any attorney or counsel employed by the parties hereto; nor am I financially interested in the event of the cause.

WITNESS MY HAND this 5th day of December 2015.

Cheryl J. Hammer

CHERYL J. HAMMER
Certified Court Reporter
CCR No. 2512
chammer@yomreporting.com

EXHIBIT 2a

AKF letter about non-contributing renal providers; AKF letter about leaving California

American Kidney Fund

June 19, 2015

Dear Renal Care Provider:

We are writing to remind you of the importance of your company contributing its fair share to the American Kidney Fund (AKF) Health Insurance Premium Program (HIPP) pool. We remain concerned about the growing trend among some providers, which refer patients for HIPP assistance but do not make fair-share contributions to the HIPP pool, to maintain HIPP pool solvency.

The American Kidney Fund HIPP program pays Part B Medicare, Medigap, commercial, and COBRA premiums for dialysis patients who have insufficient income and savings. These premium payments allow patients to continue their health insurance coverage, enabling vital access to physician care and medical treatment. HIPP is funded 100% by voluntary contributions from dialysis providers. HIPP serves as a “last resort” source of financial assistance. This assistance can only continue with the strong support and fair share contributions from the entire dialysis community.

We have noticed several trends. In some cases, a facility that refers a patient to AKF for HIPP does not make a contribution to the program. In other cases, the facility makes a contribution, but the amount of the contribution is well below an amount which is fairly reasonably proportionate with HIPP grants to the facility's patients. In both cases, the facility fails to contribute its fair share which jeopardizes HIPP pool solvency. A facility can reasonably determine its "fair share" contribution to the HIPP pool by considering the number of patients it refers to HIPP, as well as increases its patients are experiencing in health insurance premium costs. The “fair share” concept is the equitable guideline which facilities voluntarily should monitor in terms of deciding what is an appropriate target for contributions to HIPP.

All contributions are, of course, voluntary. There is no "earmarking" of contributions to specific patients within the HIPP pool. This is strictly prohibited by AKF which operates the HIPP program in accordance with the U.S. Health and Human Services, Office of Inspector General's Advisory Opinion 97-1. AKF focuses solely on patients' needs without considering the facility where they are receiving dialysis. Nonetheless, it should be obvious to all facilities that if each one does not contribute its fair share, the HIPP pool cannot continue to help all patients who need assistance. We believe all facilities share a common ethical commitment to contribute their respective fair shares to ensure that the HIPP pool can continue to assist all patients. We regard this as a mutual "honor system," which is the only way whereby AKF can operate HIPP to continue to aid patients.

We know that you share our commitment to serving patients. Working together and with your company making its fair share to the HIPP pool, we can continue to provide needy patients with the financial assistance that they need to obtain and maintain health insurance.

11921 Rockville Pike | Suite 300 | Rockville, MD 20852
301.881.3052 voice | 301.881.0898 fax | 800.638.8299 toll-free | 866.300.2900 Español
Member: CFC 11404 | www.**KidneyFund**.org

Please discuss this letter with your management and finance staff. If your company cannot make fair share contributions, we respectfully request that your organization not refer additional patients to the HIPP program in order that we may preserve this important program for your currently enrolled patients, as well as the tens of thousands of other patients nationwide who rely on HIPP to maintain their insurance coverage.

If you have any questions, please contact Don Roy, Executive Vice President and Chief Operating Officer at (301) 984-6645 or David Frazer, Vice President of Patient Services & Education at (301) 984-6664.

Sincerely,

LaVarne Burton
President and Chief Executive Officer

American Kidney Fund®
FIGHTING ON ALL FRONTS

December 23, 2019

Mark A. Ghaly, MD, MPH
Secretary
State of California
Health and Human Services Agency
1600 Ninth Street, Room 460
Sacramento, CA 95814

Via email to Michele Cunningham – Special Assistant to the Agency Secretary
Michele.Cunningham@chhs.ca.gov.
Also sent via USPS

Dear Dr. Ghaly:

I am writing on behalf of Ms. LaVarne Burton who is out on leave this week. We can confirm that this fact sheet has been posted on AKF's website at this web address:
https://www.kidneyfund.org/assets/pdf/advocacy/coverage-options-fact-sheet.pdf

We have sent messages to our patients and their renal professionals to visit this section of our website often to get information about their options. https://www.kidneyfund.org/advocacy/ab-290-update-and-resources/ The latest message was sent on December 23, 2019.

We would like to point out that we were told this fact sheet would also be publicly available on your website, but the link provided is not functional. Here is the link we were provided:
https://www.dmhc.ca.gov/Portals/0/Docs/DO/CoverageOptionsFactSheet&FAQs.pdf

Sincerely,

Donald Roy
EVP and COO

11921 Rockville Pike | Suite 300 | Rockville, MD 20852
301.881.3052 voice | 301.881.0898 fax | 800.638.8299 toll-free | 866.300.2900 Español
Member: CFC 11404 | KidneyFund.org

EXHIBIT 2b

Excerpts from AKF HIPP Guidelines, May 2014

American Kidney Fund®

HIPP

Health Insurance Premium Program

WHAT IS HIPP?

In 1997, AKF collaborated with the renal community to establish and administer the Health Insurance Premium Program (HIPP). HIPP is 100% funded by voluntary contributions from the dialysis community. Today, through HIPP, AKF provides assistance to more than 60,000 dialysis patients annually. AKF pays Part B Medicare, Medigap, commercial, EGHP, and COBRA premiums for dialysis patients who lack the resources to pay for them. The financial assistance provided by HIPP enables patients to maintain their health insurance coverage, thus providing continued access to vital health care. HIPP serves as a "last resort" for financial assistance to dialysis patients who have no other means or other sources of financial assistance to pay health insurance premiums.

Assistance is available to all eligible patients on an equal basis. In general, eligibility for participation in HIPP requires a signed grant application by a social worker employed by or an administrator of a dialysis provider. The grant application requires the patient to provide detailed financial information for his or her entire household. Applications must be submitted on the patient's behalf by a social worker employed by or an administrator of a dialysis provider.

Following receipt by AKF of the patient's application, an AKF employee assigned to HIPP reviews the application, gathers additional information, if necessary, and makes an evaluation as to the disposition of the application based upon AKF's needs assessment and eligibility criteria. All determinations are made by AKF employees who have no financial interests in dialysis providers. Such determinations are solely based upon AKF's assessment that the applicant is in financial need and meets HIPP eligibility criteria.

Because of limited financial resources, HIPP insurance premium assistance is provided only for a specific time period. Upon expiration of the period, the patient must submit another grant application for assistance. Grant requests are reviewed on a "first-come, first-served" basis, subject to the availability of funds in the HIPP "pool."

HOW HIPP WORKS

In 1997, the U.S. Department of Health and Human Services Office of Inspector General issued a written opinion (Advisory Opinion 97-1) that enabled AKF to establish HIPP. AKF operates HIPP strictly in accordance with the guidelines set forth in Advisory Opinion 97-1. A hallmark of HIPP is that AKF carefully evaluates each patient's application and provides assistance based solely on the patient's financial need, without regard to the facility where the patient is receiving dialysis. Another hallmark of HIPP is that dialysis providers make voluntary contributions (including an AKF programmatic fee) to the HIPP pool. Such voluntary contributions make it possible for AKF to have the resources to pay premiums that keep in force health insurance for the neediest patients. Providers which contribute are conclusively deemed to have knowledge of these Guidelines and Procedures, including, but not limited to, that AKF invariably will ignore any "earmarking" of any funds for the patients of any provider. All contributions to AKF are subject to these Guidelines and Procedures.

THE HIPP HONOR SYSTEM

In order for this program to work for patients and dialysis providers, each referring dialysis provider should make equitable contributions to the HIPP pool. A facility can reasonably determine its "fair share" contribution to the pool by considering the number of patients it refers to HIPP. Without an effort on the part of all providers to contribute equitably to the program, HIPP cannot continue to help existing and newly qualified patients who need assistance. We believe all facilities share a common ethical obligation to contribute their respective "fair share" to ensure that the HIPP pool is adequately funded. This is essential in order for AKF to have the resources to help dialysis patients who need premium assistance in order to keep in force their health insurance. We regard this as a mutual honor system. It is the only way in which HIPP can continue to help patients in need.

We know that your focus, like ours, is on assisting patients. Working together and with your company making its fair and equitable share to the HIPP pool, we can assure that patients in need continue to receive the assistance that they need to obtain and maintain health insurance. Please discuss this with your management and finance staff and contact us immediately if you require additional information.

All contributions are, of course, voluntary and there is no "earmarking" of contributions to specific patients within the HIPP pool. As you should be aware, AKF operates the HIPP program under the auspices of the Office of Inspector General's Opinion 97-1 and AKF focuses solely on patients' needs without considering the facility where they are receiving dialysis (reference the enclosed Guidelines). Nonetheless, it should be obvious to all facilities that if each one does not contribute its fair share, the HIPP pool cannot continue to help all patients who need assistance.

If your company cannot make fair and equitable contributions, we respectfully request that your organization not refer patients to the HIPP program in order that we may preserve this important program for the tens of thousands of patients nationwide who are currently enrolled in HIPP to maintain their insurance coverage.

THE VALUE OF HIPP

1. HIPP ensures that dialysis patients maintain coverage under the spectrum of insurance modalities: Medicare Part B, Medigap, COBRA and commercial (including policies purchased via the ACA marketplace exchanges) and EGHP plans.
2. AKF provides a quick turnaround (10 to 14 business days, on average) for HIPP applications that are fully and correctly completed and provides expedited handling for urgent requests that meet HIPP guidelines.
3. AKF provides "troubleshooting" with Medicare and private insurance carriers.
4. Through HIPP, patients maintain health insurance coverage and have access to comprehensive medical care.
5. AKF helps patients maintain continued access to comprehensive quality dialysis and healthcare which enhances treatment outcomes and reduces hospitalizations.

PROVIDER UTILIZATION RULES AND BEST PRACTICES

1. Provider must assign a corporate representative to be the principal HIPP liaison.
2. Provider must assign a corporate Finance Administrator (separate from HIPP liaison) to be the financial contact to AKF. The corporate Finance Administrator must have the financial authority from the Provider to make contributions to AKF's HIPP program.
3. Complete required training orientation in order to activate / sustain an account:
   - Both the HIPP liaison and the corporate Finance Administrator **must complete** orientation and/or additional training with AKF prior to submitting any grant application. Follow-up / additional training may be required, if deemed necessary by AKF. AKF reserves the right to require providers to complete training before submitting applications via GMS for new patients. AKF reserves the right to deny access for failure to complete required training and/or a failure to follow guidelines.
   - HIPP liaison and corporate Finance Administrator completes online course in GMS (training tab) within 90 days of account activation.
   - Corporate Finance Liaison: completes a "phone call" orientation with AKF's Director of Financial Analysis (301-984-6633) prior to the HIPP liaison account activation / sustainment.
4. Provider must use AKF's Grants Management System (GMS) at www.gms.kidneyfund.org for application submission.
5. Encourage your facility to make equitable contributions to AKF.

PROGRAM ELIGIBILITY

1. Applicants must reside and dialyze in the United States or its territories.
2. Applicants must meet the eligibility qualifications of the insurance policy for which premium assistance is being requested.
3. Transplant patients are not eligible for HIPP. Due to limited funding, HIPP enrollees are not eligible for premium assistance after they receive a kidney transplant.
4. Applicants must be verified and referred to AKF by a renal professional assigned to a Medicare certified dialysis provider/center. Patients are not permitted to apply directly to AKF for a grant. A renal professional must apply on their behalf.
5. HIPP is a "last resort" source of assistance. It is restricted to patients who have limited means of paying health insurance premiums (based on income-to-debt ratio) and who would forego coverage in the absence of assistance from HIPP. Alternative programs that pay for primary or secondary health coverage or provide financial assistance grants, and for which the patient is eligible, such as Medicaid, state renal programs, other organizations, etc. **must** be utilized first. Premiums deducted from income sources such as Social Security checks cannot be reimbursed.
6. AKF does not represent that a properly completed application will be approved or, if approved, that insurance premium assistance from HIPP will be ongoing. To the contrary, the decision to provide assistance in response to any given application or request is at all times subject to the sole and absolute

discretion of AKF. HIPP is not an entitlement program. There is no "right" to a grant or financial assistance, either initially or for any given period. AKF reserves the right to modify or withdraw at any time any commitment as to any grant or financial assistance. Without limiting the foregoing, a finding of eligibility does not give rise to entitlement to financial assistance which, upon other variables, depends on available funds in the HIPP pool. AKF reserves the right, exercisable in its sole and absolute discretion, to revise eligibility criteria, from time to time, and make such changes effective as of any date selected by AKF. AKF neither warrants nor represent that applications will be reviewed within any certain period of time. If an application is approved, AKF neither warrants nor represents that a HIPP grant or payment will be made within any certain period of time. AKF is not responsible for errors or delays, irrespective of the cause, either in the review of properly completed applications or issuance of checks or other forms of payments. Under no event shall AKF be liable for damages alleged to have been caused by denials of applications, errors or delays in the review of applications, errors or delays in the issuance of checks or other forms of payments or delays in the U.S. postal system or commercial delivery services. All applications to HIPP are irrevocably deemed submitted with the full acceptance of the foregoing both by the Provider and by the dialysis patient.

7. Applicants must demonstrate that they cannot afford health coverage. Monthly household income may not exceed reasonable monthly expenses by more than $600. If there is no income at the time of application, you will be required to provide an explanation. Total liquid assets, such as savings accounts and stocks/bonds may not exceed $7,000. (IRAs and other retirement accounts are excluded and will not be counted toward this amount.) AKF reserves the right to request additional information and documentation, as it relates to reported income, expenditures and all reported application information.

8. Savings up to $1,500 formally set aside for burial expenses in a bank account, other financial instrument or prepaid burial arrangement will be exempted as an asset. (This criterion was adopted from the Social Security Administration, which uses it for the purpose of Supplemental Security Income eligibility.)

9. HIPP only provides premium assistance in connection with primary and secondary insurance coverage. HIPP does not assist with tertiary coverage of any kind.

10. In some situations, AKF may choose to institute a premium cap. AKF currently has a cap on Medigap premiums at $550 per month. Before submitting an application, please contact AKF directly to obtain specific capped amounts and possible exceptions, due to transplant list status. AKF reserves the right to institute changes to grant maximums. Proper advance notice will be provided.

APPLICATION SUBMISSION

1. AKF will **ONLY** accept applications submitted **ONLINE** via the Grants Management System (GMS). Online applications may be submitted either as a "one-time" request or as recurring request.

2. AKF reserves the right to request additional backup documentation to validate application information.

3. AKF reserves the right to require new annual applications for all enrollees to ensure system accuracy and applicant eligibility.

4. All new applicants to HIPP shall be provided a copy of *HIPP Procedures and Guidelines,* along with the application. Confirmation of guideline receipt is included as a part of the patient's consent form. Copies are available through AKF's Grant Management System, our website at www.KidneyFund.org or by calling AKF.

   This procedure is intended to ensure that all prospective recipients of assistance from HIPP understand the benefits, responsibilities **and** limitations of "enrollment" in HIPP. Most importantly, patients need to be informed that HIPP assistance is limited to those receiving dialysis treatment. It is especially critical that HIPP enrollees who may be candidates for a kidney transplant understand this aspect of HIPP.

5. Once the patient is enrolled in the program through an online GMS submission and the premium amount and payee remain the same you **will not** have to provide another premium bill to AKF until the beginning of the next calendar year. Payments will automatically be issued by AKF through the end of the calendar year. **Note:** HIPP liaisons are required to approve and release all subsequent payments before AKF issues a grant check. This will help mitigate the possibility of making payments that are not needed.

6. You must submit a new online request and bill if your patient has **any** changes in insurance coverage or premium amount. This will update the automated payment information. Please also notify AKF immediately if your patient dies, transfers or receives a transplant, so that his or her record can be updated.

7. A new online application is required if your patient changes dialysis providers.

8. HIPP payment requests must be accompanied by an insurance bill or coupon when applying initially or if the request is modified thereafter. Please follow the following guidelines for bill submission:

   - Only bills/coupons from the current year will be accepted for the initial request. Subsequent requests may not be older than three (3) months from the payment request submission date.

   - All bills/invoices must reference the insured's name, policy number and coverage period. This information must match the payment request.

   - Original bills are always the best choice, but due to time constraints, you may change the dates and/or amounts to match your payment request. However, **do not** "white out" the original information. Simply draw one line through it and add your new information.

EXHIBIT 2c

Excerpts from AKF HIPP Guidelines, March 2015

American Kidney Fund®

HIPP

Health Insurance Premium Program

WHAT IS HIPP?

In 1997, AKF collaborated with the renal community to establish and administer the Health Insurance Premium Program (HIPP). HIPP is 100 percent funded by voluntary contributions from the dialysis community. Today AKF through HIPP provides financial assistance to more than 71,000 dialysis patients annually. AKF pays Part B Medicare, Medigap, EGHP, COBRA and commercial insurance premiums for dialysis patients who are eligible for those policies but who lack the financial resources to pay the premiums. The financial assistance provided by HIPP enables low-income patients to maintain their existing health insurance coverage, thus providing continued access to vital health care. HIPP serves as a "last resort" for financial assistance to dialysis patients who have no other means or other sources of financial assistance to pay health insurance premiums.

Assistance is available to all financially eligible patients on an equal basis. In general, eligibility for participation in HIPP requires a grant application and consent form signed by the dialysis patient who is applying for assistance. The grant application requires the patient to provide detailed financial information. Applications must be co-signed and submitted on the patient's behalf by a social worker employed by a dialysis facility, or by a dialysis facility administrator/coordinator. This enables AKF to confirm that the financial information is complete and accurate.

After AKF receives the patient's application, AKF reviews the application, requests additional information, if necessary, and makes the decision as to the disposition of the application based solely on HIPP eligibility criteria which include the financial need of the applicant. All determinations are made by AKF employees who have no financial interests in dialysis providers.

Once a patient is accepted into HIPP, AKF provides health insurance premium assistance to the patient for the term of the patient's policy. In the majority of cases, patients have one-year policy terms. Upon expiration of the policy term, the patient must submit another application to AKF for HIPP grant assistance, and AKF once again reviews the patient's eligibility. AKF reviews grant requests on a "first-come, first-served" basis. Grants are subject to the availability of funds in the HIPP funding pool.

HOW HIPP WORKS

In 1997, the U.S. Department of Health and Human Services Office of Inspector General issued a written opinion (Advisory Opinion 97-1) that enabled AKF to establish HIPP for the purpose of assisting people with kidney failure on dialysis. AKF operates HIPP strictly in accordance with the guidelines set forth in Advisory Opinion 97-1. These guidelines include making the decision to provide assistance on a "first come, first served" basis solely on the patient's financial need, without regard to the facility where the patient is receiving dialysis and without regard to the patient's overall health status.

Dialysis providers make voluntary contributions (including an AKF programmatic fee) to the HIPP funding pool. Such voluntary contributions make it possible for AKF to have the resources to pay premiums that keep in force

health insurance for the neediest patients. Without such voluntary contributions HIPP would not be able to fully support all grant applications.

THE HIPP HONOR SYSTEM AND FAIR SHARE CONTRIBUTIONS

In order for this program to work for patients and dialysis providers, each referring dialysis provider should make fair share contributions to the HIPP pool. A facility can reasonably determine its "fair share" contribution to the pool by considering the number of patients it refers to HIPP. Without the good faith cooperation of all providers to contribute equitably to the program, HIPP cannot continue to help existing and newly qualified patients who need assistance. We believe all facilities share a common ethical obligation to contribute their respective "fair shares" to ensure that the HIPP pool is adequately funded. This is essential in order for AKF to have the resources to help dialysis patients who need premium assistance to keep in force their health insurance. We regard this as a mutual honor system. It is the only way in which HIPP can continue to help patients in need.

We know that your focus, like ours, is on assisting patients. Working together and with your company making its fair share contribution to the HIPP pool, we can assure that patients in need continue to receive the assistance that they need to obtain and maintain health insurance. Please discuss this with your management and finance staff and contact us immediately if you require additional information.

All contributions are, of course, voluntary. Nonetheless, it should be obvious to all facilities that if each one does not contribute its fair share, the HIPP pool cannot continue to help all patients who need assistance.

If your company cannot make fair share contributions, we respectfully request that your organization not refer patients to the HIPP program in order that we may preserve this important program for the tens of thousands of patients nationwide who are currently enrolled in HIPP to maintain their insurance coverage.

THE VALUE OF HIPP

1. HIPP ensures that dialysis patients maintain coverage under the spectrum of insurance modalities: Medicare Part B, Medigap, COBRA, Commercial (including policies purchased via the ACA Marketplace exchanges) and EGHP plans.
2. AKF provides a quick turnaround (10 to 14 business days, on average) for HIPP applications that are fully and correctly completed and provides expedited handling for urgent requests that meet HIPP guidelines.
3. AKF provides "troubleshooting" with Medicare and private insurance carriers.
4. Through HIPP, patients maintain health insurance coverage and thereby have access to comprehensive medical care. Having access to care enhances treatment outcomes and reduces hospitalizations. In addition, many patients are able to have transplant workups, and are able to have kidney transplants, because they have insurance coverage through HIPP.

PROVIDER UTILIZATION RULES & BEST PRACTICES

1. Provider must assign a corporate representative to be the principal HIPP liaison.
2. Provider must assign a corporate Finance Administrator (separate from HIPP liaison) to be the financial contact to AKF. The corporate Finance Administrator must have the financial authority from the Provider to award voluntary fair share contributions to AKF's HIPP program.
3. Complete required training orientation in order to activate / sustain an account:
   - Both the HIPP liaison & the corporate Finance Administrator **must complete** orientation &/or additional training with AKF prior to submitting any grant application. Follow-up / additional training may be required, if deemed necessary by AKF. AKF reserves the right to require providers to complete training before submitting applications via GMS for new patients. AKF reserves the right to deny access for failure to complete required training &/or a failure to follow the HIPP guidelines and proper program administration.
   - HIPP liaison and corporate Finance Administrator completes online course in AKF's Grants Management System (training tab) within the specified time after account activation.
   - Corporate Finance Liaison: completes a phone call orientation with AKF's Director of Financial Analysis (301-984-6633) prior to the HIPP liaison account activation / sustainment.
4. Provider must utilize AKF's Grants Management System (GMS) at www.gms.kidneyfund.org for application submission.
5. Encourage your facility to make fair share contributions to AKF.
6. "Ear-marking" of contributions for specific patients or patients that receive dialysis at a particular facility is not permitted.
7. Providers are conclusively deemed to have knowledge of the HIPP Guidelines, Rules and Procedures and all contributions by providers are subject thereto.

PROGRAM ELIGIBILITY AND PATIENT RESPONSIBILITY

1. Applicants must reside and dialyze in the U.S. or its territories.
2. Applicants must meet the eligibility qualifications of the insurance policy for which premium assistance is being requested.
3. In keeping with AKF's 44-year core mission of assisting dialysis patients, HIPP is available to people with kidney failure who are on dialysis. People who have a functioning kidney transplant are not eligible for HIPP. When a patient has a successful transplant, providers must immediately notify AKF and the patient must cease to submit requests for HIPP grant assistance.
4. The patient is responsible for applying for HIPP assistance. Only the patient can apply for a grant and sign a consent form. The information contained within the application must be verified and submitted to AKF by a renal professional assigned to a Medicare-certified dialysis provider/center. AKF must receive confirmation from a qualified renal professional that the patient is on dialysis and, further, that

the renal professional has made the preliminary determination that the patient meets the eligibility requirements of HIPP.

5. The receipt of financial assistance from HIPP does not alter the fact that health insurance coverage represents a contractual relationship solely between the patient and his or her insurance carrier, not between AKF and the insurance carrier. The patient assumes all responsibilities of the contract.

6. HIPP is a "last resort" source of assistance. It is restricted to patients who have limited means of paying health insurance premiums (based on income to debt ratio) and who would lose coverage in the absence of assistance from HIPP. Alternative programs for which the patient is eligible that pay for primary or secondary health coverage or provide financial assistance grants must be utilized first. These include Medicaid, state renal programs, and aid from other organizations, etc. Premiums deducted from income sources such as Social Security checks cannot be reimbursed.

7. AKF does not represent that a properly completed application will be approved or, if approved, that insurance premium assistance from HIPP will be ongoing. To the contrary, the decision to provide assistance in response to any given application or request is at all times subject to the sole and absolute discretion of AKF. HIPP is not an entitlement program. There is no "right" to a grant or financial assistance, either initially or for any given period. AKF reserves the right to modify or withdraw at any time any commitment as to any grant or financial assistance. Without limiting the foregoing, a finding of eligibility does not give rise to entitlement to financial assistance which, among other variables, depends on available funds in the HIPP pool. AKF reserves the right, exercisable in its sole and absolute discretion, to revise eligibility criteria, from time to time, and make such changes effective as of any date selected by AKF. AKF neither warrants nor represents that applications will be reviewed within any certain period of time. If an application is approved, AKF neither warrants nor represents that a HIPP grant or payment will be made within any certain period of time. AKF is not responsible for errors or delays, irrespective of the cause, either in the review of properly completed applications or issuance of checks or other forms of payments. Under no event shall AKF be liable for damages alleged to have been caused by denials of applications; errors or delays in the review of applications; errors or delays in the issuance of checks or other forms of payments; delays in the US postal system or commercial delivery services; or denial of coverage by health insurance companies. All applications to HIPP are irrevocably deemed submitted with the full acceptance of the foregoing both by the Provider and by the patient.

8. Applicants must demonstrate that they cannot afford health coverage. Monthly household income may not exceed reasonable monthly expenses by more than $600. If there is no income at the time of application, you will be required to provide an explanation. Total liquid assets, such as savings accounts and investment accounts may not exceed $7,000. (IRAs and other retirement accounts are excluded and will not be counted toward this amount). AKF reserves the right to request additional information and documentation, as it relates to reported income, expenditures and all reported application information.

9. Savings up to $1,500 formally set aside for burial expenses in a bank account, other financial instrument or prepaid burial arrangement will be exempted as an asset. (This criterion was adopted from the Social Security Administration, which uses it for the purpose of Supplemental Security Income eligibility).

10. HIPP only provides premium assistance in connection with primary and secondary insurance coverage. HIPP does not assist with tertiary coverage of any kind.

11. In some situations, AKF may choose to institute a premium cap. AKF currently has a cap on Medigap premiums at $550 per month. Before submitting an application, please contact AKF directly to obtain specific capped amounts and possible exceptions, due to transplant list status. AKF reserves the right to institute changes to grant maximums. Proper advance notice will be provided.

APPLICATION SUBMISSION

1. AKF will **ONLY** accept applications submitted **ONLINE** via the Grants Management System (GMS). Online grant requests may be submitted either as a "one-time" request or as recurring requests. Patients may start the application process on their own by completing a paper worksheet, but must work through their dialysis social worker for online submission.

2. AKF reserves the right to request additional backup documentation to validate application information.

3. AKF reserves the right to require new annual applications for all enrollees to ensure system accuracy and applicant eligibility.

4. All new applicants to HIPP shall be provided a copy or directed to the AKF website to read AKF's *HIPP Procedures and Guidelines,* along with the application. When the patient signs the consent form the patient is confirming he/she has read and understands the HIPP guidelines. Copies are available through AKF's Grant Management System, our website at www.KidneyFund.org or by calling AKF.

   The procedure is intended to ensure that all prospective recipients of assistance from HIPP understand the benefits, responsibilities **and** limitations of participation in HIPP. Most importantly, patients need to be informed by providers that HIPP assistance is limited to those receiving dialysis treatment and that there are potential limits in the available HIPP funding pool. It is especially critical that HIPP enrollees who may be candidates for a kidney transplant understand this aspect of HIPP.

5. Once the patient is enrolled in the program through an online GMS submission and the premium amount and payee remain the same you **will not** have to provide another premium bill to AKF until the beginning of the next calendar year. Payments will automatically be issued by AKF through the end of the calendar year. **Note:** HIPP liaisons are required to approve and release all subsequent payments before AKF issues a grant check. This will help mitigate the possibility of making payments that are not needed.

6. You must submit a new online request and bill if your patient has **any** changes in insurance coverage or premium amount. This will update the automated payment information. Please also notify AKF immediately if your patient passes away or receives a transplant, so that his or her record can be updated.

7. In order to update the patient's HIPP data and ensure proper addresses, a new online application and grant request is required if the patient commences dialysis with another provider.

8. HIPP payment requests must be accompanied by an insurance bill or coupon when applying initially or if the request is modified thereafter. Please follow the following guidelines for bill submission:

   - Only bills/coupons from the current year will be accepted for the initial request. Subsequent requests may not be older than three (3) months from the payment request submission date.

   - All bills/invoices must reference the insured's name, policy number and coverage period. This information must match the payment request.

EXHIBIT 2d

Excerpts from AKF HIPP Guidelines, July 2015

American Kidney Fund®

HIPP

Health Insurance Premium Program

WHAT IS HIPP?

In 1997, AKF collaborated with the renal community to establish and administer the Health Insurance Premium Program (HIPP). HIPP is 100 percent funded by voluntary contributions from the dialysis community. Today AKF through HIPP provides financial assistance to more than 71,000 dialysis patients annually. AKF pays Part B Medicare, Medigap, EGHP, COBRA and commercial insurance premiums for dialysis patients who are eligible for those policies but who lack the financial resources to pay the premiums. The financial assistance provided by HIPP enables low-income patients to maintain their existing health insurance coverage, thus providing continued access to vital health care. HIPP serves as a "last resort" for financial assistance to dialysis patients who have no other means or other sources of financial assistance to pay health insurance premiums.

Assistance is available to all financially eligible patients on an equal basis. In general, eligibility for participation in HIPP requires a grant application and consent form signed by the dialysis patient who is applying for assistance. The grant application requires the patient to provide detailed financial information. Applications must be co-signed and submitted on the patient's behalf by a social worker employed by a dialysis facility, or by a dialysis facility administrator/coordinator. This enables AKF to confirm that the financial information is complete and accurate.

After AKF receives the patient's application, AKF reviews the application, requests additional information, if necessary, and makes the decision as to the disposition of the application based solely on HIPP eligibility criteria which include the financial need of the applicant. All determinations are made by AKF employees who have no financial interests in dialysis providers.

Once a patient is accepted into HIPP, AKF provides health insurance premium assistance to the patient for the term of the patient's policy. In the majority of cases, patients have one-year policy terms. Upon expiration of the policy term, the patient must submit another application to AKF for HIPP grant assistance, and AKF once again reviews the patient's eligibility. AKF reviews grant requests on a "first-come, first-served" basis. Grants are subject to the availability of funds in the HIPP funding pool.

HOW HIPP WORKS

In 1997, the U.S. Department of Health and Human Services Office of Inspector General issued a written opinion (Advisory Opinion 97-1) that enabled AKF to establish HIPP for the purpose of assisting people with kidney failure on dialysis. AKF operates HIPP strictly in accordance with the guidelines set forth in Advisory Opinion 97-1. These guidelines include making the decision to provide assistance on a "first come, first served" basis solely on the patient's financial need, without regard to the facility where the patient is receiving dialysis and without regard to the patient's overall health status.

Dialysis providers make voluntary contributions (including an AKF programmatic fee) to the HIPP funding pool. Such voluntary contributions make it possible for AKF to have the resources to pay premiums that keep in force

health insurance for the neediest patients. Without such voluntary contributions HIPP would not be able to fully support all grant applications.

THE HIPP HONOR SYSTEM AND FAIR SHARE CONTRIBUTIONS

In order for this program to work for patients and dialysis providers, each referring dialysis provider should make fair share contributions to the HIPP pool. A facility can reasonably determine its "fair share" contribution to the pool by considering the number of patients it refers to HIPP. Without the good faith cooperation of all providers to contribute equitably to the program, HIPP cannot continue to help existing and newly qualified patients who need assistance. We believe all facilities share a common ethical obligation to contribute their respective "fair shares" to ensure that the HIPP pool is adequately funded. This is essential in order for AKF to have the resources to help dialysis patients who need premium assistance to keep in force their health insurance. We regard this as a mutual honor system. It is the only way in which HIPP can continue to help patients in need.

We know that your focus, like ours, is on assisting patients. Working together and with your company making its fair share contribution to the HIPP pool, we can assure that patients in need continue to receive the assistance that they need to obtain and maintain health insurance. Please discuss this with your management and finance staff and contact us immediately if you require additional information.

All contributions are, of course, voluntary. Nonetheless, it should be obvious to all facilities that if each one does not contribute its fair share, the HIPP pool cannot continue to help all patients who need assistance.

THE VALUE OF HIPP

1. HIPP ensures that dialysis patients maintain coverage under the spectrum of insurance modalities: Medicare Part B, Medigap, COBRA, Commercial (including policies purchased via the ACA Marketplace exchanges) and EGHP plans.
2. AKF provides a quick turnaround (10 to 14 business days, on average) for HIPP applications that are fully and correctly completed and provides expedited handling for urgent requests that meet HIPP guidelines.
3. AKF provides "troubleshooting" with Medicare and private insurance carriers.
4. Through HIPP, patients maintain health insurance coverage and thereby have access to comprehensive medical care. Having access to care enhances treatment outcomes and reduces hospitalizations. In addition, many patients are able to have transplant workups, and are able to have kidney transplants, because they have insurance coverage through HIPP.

PROVIDER UTILIZATION RULES & BEST PRACTICES

1. Provider must assign a corporate representative to be the principal HIPP liaison.
2. Provider must assign a corporate Finance Administrator (separate from HIPP liaison) to be the financial contact to AKF. The corporate Finance Administrator must have the financial authority from the Provider to award voluntary fair share contributions to AKF's HIPP program.
3. Complete required training orientation in order to activate / sustain an account:
   - Both the HIPP liaison & the corporate Finance Administrator **must complete** orientation &/or additional training with AKF prior to submitting any grant application. Follow-up / additional training may be required, if deemed necessary by AKF. AKF reserves the right to require providers to complete training before submitting applications via GMS for new patients. AKF reserves the right to deny access for failure to complete required training &/or a failure to follow the HIPP guidelines and proper program administration.
   - HIPP liaison and corporate Finance Administrator completes online course in AKF's Grants Management System (training tab) within the specified time after account activation.
   - Corporate Finance Liaison: completes a phone call orientation with AKF's Director of Financial Analysis (301-984-6633) prior to the HIPP liaison account activation / sustainment.
4. Provider must utilize AKF's Grants Management System (GMS) at www.gms.kidneyfund.org for application submission.
5. Encourage your facility to make fair share contributions to AKF.
6. "Ear-marking" of contributions for specific patients or patients that receive dialysis at a particular facility is not permitted.
7. Providers are conclusively deemed to have knowledge of the HIPP Guidelines, Rules and Procedures and all contributions by providers are subject thereto.

PROGRAM ELIGIBILITY AND PATIENT RESPONSIBILITY

1. Applicants must reside and dialyze in the U.S. or its territories.
2. Applicants must meet the eligibility qualifications of the insurance policy for which premium assistance is being requested.
3. In keeping with AKF's 44-year core mission of assisting dialysis patients, HIPP is available to people with kidney failure who are on dialysis. People who have a functioning kidney transplant are not eligible for HIPP. When a patient has a successful transplant, providers must immediately notify AKF and the patient must cease to submit requests for HIPP grant assistance.
4. The patient is responsible for applying for HIPP assistance. Only the patient can apply for a grant and sign a consent form. The information contained within the application must be verified and submitted

to AKF by a renal professional assigned to a Medicare-certified dialysis provider/center. AKF must receive confirmation from a qualified renal professional that the patient is on dialysis and, further, that the renal professional has made the preliminary determination that the patient meets the eligibility requirements of HIPP.

5. The receipt of financial assistance from HIPP does not alter the fact that health insurance coverage represents a contractual relationship solely between the patient and his or her insurance carrier, not between AKF and the insurance carrier. The patient assumes all responsibilities of the contract.

6. HIPP is a "last resort" source of assistance. It is restricted to patients who have limited means of paying health insurance premiums (based on income to debt ratio) and who would lose coverage in the absence of assistance from HIPP. Alternative programs for which the patient is eligible that pay for primary or secondary health coverage or provide financial assistance grants must be utilized first. These include Medicaid, state renal programs, and aid from other organizations, etc. Premiums deducted from income sources such as Social Security checks cannot be reimbursed.

7. AKF does not represent that a properly completed application will be approved or, if approved, that insurance premium assistance from HIPP will be ongoing. To the contrary, the decision to provide assistance in response to any given application or request is at all times subject to the sole and absolute discretion of AKF. HIPP is not an entitlement program. There is no "right" to a grant or financial assistance, either initially or for any given period. AKF reserves the right to modify or withdraw at any time any commitment as to any grant or financial assistance. Without limiting the foregoing, a finding of eligibility does not give rise to entitlement to financial assistance which, among other variables, depends on available funds in the HIPP pool. AKF reserves the right, exercisable in its sole and absolute discretion, to revise eligibility criteria, from time to time, and make such changes effective as of any date selected by AKF. AKF neither warrants nor represents that applications will be reviewed within any certain period of time. If an application is approved, AKF neither warrants nor represents that a HIPP grant or payment will be made within any certain period of time. AKF is not responsible for errors or delays, irrespective of the cause, either in the review of properly completed applications or issuance of checks or other forms of payments. Under no event shall AKF be liable for damages alleged to have been caused by denials of applications; errors or delays in the review of applications; errors or delays in the issuance of checks or other forms of payments; delays in the US postal system or commercial delivery services; or denial of coverage by health insurance companies. All applications to HIPP are irrevocably deemed submitted with the full acceptance of the foregoing both by the Provider and by the patient.

8. Applicants must demonstrate that they cannot afford health coverage. Monthly household income may not exceed reasonable monthly expenses by more than $600. If there is no income at the time of application, you will be required to provide an explanation. Total liquid assets, such as savings accounts and investment accounts may not exceed $7,000. (IRAs and other retirement accounts are excluded and will not be counted toward this amount). AKF reserves the right to request additional information and documentation, as it relates to reported income, expenditures and all reported application information.

9. Savings up to $1,500 formally set aside for burial expenses in a bank account, other financial instrument or prepaid burial arrangement will be exempted as an asset. (This criterion was adopted from the Social Security Administration, which uses it for the purpose of Supplemental Security Income eligibility).

10. HIPP only provides premium assistance in connection with primary and secondary insurance coverage. HIPP does not assist with tertiary coverage of any kind.

11. In some situations, AKF may choose to institute a premium cap. AKF currently has a cap on Medigap premiums at $550 per month. Before submitting an application, please contact AKF directly to obtain specific capped amounts and possible exceptions, due to transplant list status. AKF reserves the right to institute changes to grant maximums. Proper advance notice will be provided.

APPLICATION SUBMISSION

1. AKF will **ONLY** accept applications submitted **ONLINE** via the Grants Management System (GMS). Online grant requests may be submitted either as a "one-time" request or as recurring requests. Patients may start the application process on their own by completing a paper worksheet, but must work through their dialysis social worker for online submission.

2. AKF reserves the right to request additional backup documentation to validate application information.

3. AKF reserves the right to require new annual applications for all enrollees to ensure system accuracy and applicant eligibility.

4. All new applicants to HIPP shall be provided a copy or directed to the AKF website to read AKF's *HIPP Procedures and Guidelines,* along with the application. When the patient signs the consent form the patient is confirming he/she has read and understands the HIPP guidelines. Copies are available through AKF's Grant Management System, our website at www.KidneyFund.org or by calling AKF.

   The procedure is intended to ensure that all prospective recipients of assistance from HIPP understand the benefits, responsibilities **and** limitations of participation in HIPP. Most importantly, patients need to be informed by providers that HIPP assistance is limited to those receiving dialysis treatment and that there are potential limits in the available HIPP funding pool. It is especially critical that HIPP enrollees who may be candidates for a kidney transplant understand this aspect of HIPP.

5. Once the patient is enrolled in the program through an online GMS submission and the premium amount and payee remain the same you **will not** have to provide another premium bill to AKF until the beginning of the next calendar year. Payments will automatically be issued by AKF through the end of the calendar year. **Note:** HIPP liaisons are required to approve and release all subsequent payments before AKF issues a grant check. This will help mitigate the possibility of making payments that are not needed.

6. You must submit a new online request and bill if your patient has **any** changes in insurance coverage or premium amount. This will update the automated payment information. Please also notify AKF immediately if your patient passes away or receives a transplant, so that his or her record can be updated.

7. In order to update the patient's HIPP data and ensure proper addresses, a new online application and grant request is required if the patient commences dialysis with another provider.

8. HIPP payment requests must be accompanied by an insurance bill or coupon when applying initially or if the request is modified thereafter. Please follow the following guidelines for bill submission:

   - Only bills/coupons from the current year will be accepted for the initial request. Subsequent requests may not be older than three (3) months from the payment request submission date.

EXHIBIT 2e

Premium Impacts of ESRD Patients in the Individual Market (Avalere)

FILED PROVISIONALLY UNDER SEAL

[AKF-DOE-0010130 - AKF-DOE-0010135]

EXHIBIT 2f

American Kidney Fund Annual Contributions by Requested Providers

FILED PROVISIONALLY UNDER SEAL

[AKF-DOE-0010136]

EXHIBIT 3

AKF's Objections and Responses to Defendants' First Set of Requests for Production of Documents, served on March 5, 2020

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and DIALYSIS PATIENT CITIZENS, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JANE DOE, et al.

Plaintiffs,

v.

XAVIER BECERRA, et al.

Defendant.

Case No. 8:19-cv-02105-DOC-ADS

PLAINTIFF AKF'S OBJECTIONS AND RESPONSES TO DEFENDANTS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS

PROPOUNDING PARTY: Defendants, XAVIER BECERRA, RICARDO LARA, SHELLEY ROUILLARD, SONIA ANGEL

RESPONDING PARTY: Plaintiff AMERICAN KIDNEY FUND, INC.

SET NO.: ONE (1)

Pursuant to Federal Rule of Civil Procedure 34 and the Local Rules of the United States District Court for the Central District of California, Plaintiff American Kidney Fund, Inc. ("AKF") objects and responds to the First Set of Requests for Production of Documents served by Defendants Xavier Becerra, Ricardo Lara, Shelley Rouillard, and Sonia Angel (collectively, "Defendants").

Unless specified otherwise below, Plaintiff will produce only responsive, non-privileged, and non-objectionable documents as they are kept in the usual course of business and that are in the possession, custody, or control of AKF's officers and employees. Plaintiff's electronically stored information will be produced as PDFs or in single page TIFFs. Plaintiff's production of documents may be on a rolling basis and, if necessary, a privilege log will follow.

RESPONSES AND OBJECTIONS TO

REQUESTS FOR PRODUCTION

REQUEST FOR PRODUCTION NO. 1:

Any and all communications between AKF and any Dialysis Provider operating in the State of California regarding patient applications for HIPP Assistance from 2014 to present, including, but not limited to, communications reflecting that patient applications were rejected if the patient received treatment from a Dialysis Provider who had not previously made a financial contribution or was not making ongoing financial contributions to AKF.

RESPONSE TO REQUEST FOR PRODUCTION NO. 1:

Plaintiff objects to the request for "any and all communications" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff also objects to the Request because it would require AKF to provide confidential and sensitive patient information. AKF also objects to the request to the extent it compels AKF to fall out of compliance with U.S. Department of Health and Human Services Office of Inspector General Advisory Opinion 97-1.

Subject to and without waiving these objections, Plaintiff will produce its policies, guidelines, and handbooks related to HIPP.

REQUEST FOR PRODUCTION NO. 2:

Any and all communications between AKF and HIPP Recipients or applicants for HIPP Assistance in the State of California regarding their applications, whether initial applications or renewal applications, including applications which were rejected and the reasons for the rejection, from 2014 to present.

RESPONSE TO REQUEST FOR PRODUCTION NO. 2:

Plaintiff objects to the request for "any and all communications" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff also objects to the Request because it would require AKF to provide confidential and sensitive patient information. AKF also objects to the request to the extent it compels AKF to fall out of compliance with U.S. Department of Health and Human Services Office of Inspector General Advisory Opinion 97-1.

Subject to and without waiving these objections, Plaintiff will produce its policies, guidelines, and handbooks related to HIPP.

REQUEST FOR PRODUCTION NO. 3:

Any and all communications reflecting any AKF policy or practice of requiring Dialysis Providers to make a financial contribution to AKF in order for the provider's patients to be eligible to receive HIPP Assistance, from 2014 to present.

RESPONSE TO REQUEST FOR PRODUCTION NO. 3:

Plaintiff objects to the request for "any and all communications" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff also objects to the Request because it would require AKF to provide confidential and sensitive patient information.

Subject to and without waiving these objections, Plaintiff will produce responsive, non-privileged documents if it discovers any in its possession, custody,

or control.

REQUEST FOR PRODUCTION NO. 4:

Any and all guidelines, manuals, or handbooks, or communications relating to the consideration of patient applications for HIPP Assistance, the criteria applied in making determinations regarding those applications, and the bases for granting or rejecting those applications, including, but not limited to, AKF's version of those guidelines, referenced in the New York Times article dated December 25, 2016, entitled "Kidney Fund Seen Insisting on Donations, Contrary to Government Deal," available at https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-ondonations-contrary-to-government-deal.html and attached hereto as Exhibit A.

RESPONSE TO REQUEST FOR PRODUCTION NO. 4:

Plaintiff objects to the Request, which is based on a news article containing inaccurate information about AKF and HIPP activities.

Subject to and without waiving these objections, Plaintiff will produce its policies, guidelines, and handbooks related to HIPP.

REQUEST FOR PRODUCTION NO. 5:

Any and all documents, including guidelines, manuals, handbooks or communications relating to AKF's policies on steering, directing, or advising HIPP Recipients about their health care service plans, commercial insurance plans, or government insurance options, from 2014 to present.

RESPONSE TO REQUEST FOR PRODUCTION NO. 5:

Plaintiff objects to the request for "any and all documents" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production.

Subject to and without waiving any objections, Plaintiff will produce policies, guidelines, and handbooks related to HIPP. Plaintiff also incorporates by reference the "Declaration of LaVarne Burton in Support of Motion for Preliminary

Injunction" dated November 7, 2019 (Dkt. No. 28-2).

REQUEST FOR PRODUCTION NO. 6:

Any and all documents, including handbooks, manuals, or communications relating to AKF's policies regarding the period of time post-kidney transplant that HIPP Assistance will continue to be provided, from 2014 to present.

RESPONSE TO REQUEST FOR PRODUCTION NO. 6:

Plaintiff objects to the Request as irrelevant to any party's claim or defense. Plaintiff also objects to the request for "any and all documents" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff also objects to the Request as vague and confusing.

Subject to and without waiving these objections, Plaintiff incorporates by reference AKF's "Patient Handbook: Health Insurance Premium Program" available at https://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-patient-handbook.pdf . Plaintiff also incorporates by reference the "Declaration of LaVarne Burton in Support of Motion for Preliminary Injunction" dated November 7, 2019 (Dkt. No. 28-2).

REQUEST FOR PRODUCTION NO. 7:

Any and all documents, including handbooks, manuals, or communications describing AKF's methods for providing HIPP Assistance to HIPP Recipients in the State of California, including but not limited to checks, debit cards, and direct payments to insurers.

RESPONSE TO REQUEST FOR PRODUCTION NO. 7:

Plaintiff objects to the Request as irrelevant to any party's claim or defense. Plaintiff also objects to the request for "any and all documents" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff also objects because the Request seeks documents from an unspecified time period.

Subject to and without waiving these objections, Plaintiff will produce

policies, guidelines, and handbooks related to HIPP. Plaintiff also incorporates by reference the "Declaration of LaVarne Burton in Support of Motion for Preliminary Injunction" dated November 7, 2019 (Dkt. No. 28-2).

REQUEST FOR PRODUCTION NO. 8:

Documents sufficient to show what information is provided to HIPP Recipients with regard to their applications, the payments they receive, or the period for which assistance will be provided, including but not limited to any contracts or agreements recipients are asked to sign as a condition of receiving HIPP Assistance.

RESPONSE TO REQUEST FOR PRODUCTION NO. 8:

Plaintiff objects to the Request as irrelevant to any party's claim or defense. Subject to and without waiving this objection, Plaintiff will produce the AKF Patient Handbook that is provided to HIPP applicants and grant recipients.

REQUEST FOR PRODUCTION NO. 9:

Documents sufficient to show what percentage of AKF's annual budget is spent on providing HIPP Assistance as opposed to other activities, including but not limited to the "awareness, advocacy, prevention, public education, professional engagement, clinical research, and financial assistance" mentioned in paragraph 37 of the Complaint.

RESPONSE TO REQUEST FOR PRODUCTION NO. 9:

Plaintiff objects to the Request as irrelevant to any party's claim or defense. Plaintiff also objects to the Request because it seeks information about immaterial background allegations in the Complaint.

Subject to and without waiving these objections, Plaintiff will produce public disclosure copies of its audit reports and annual reports from 2010 to 2018. Plaintiff also will provide data identifying itemized expenses for these activities from 2010 to 2018.

REQUEST FOR PRODUCTION NO. 10:

Documents sufficient to identify each and every dialysis provider in the State

of California that treats at least one recipient of HIPP Assistance from AKF, and the number of HIPP Recipients that receive treatment from each such provider.

RESPONSE TO REQUEST FOR PRODUCTION NO. 10:

Plaintiff objects to the Request as irrelevant to any party's claim or defense. Subject to and without waiving this objection, Plaintiff will produce a chart of the number of HIPP grantees treated by each dialysis provider in the State of California.

REQUEST FOR PRODUCTION NO. 11:

Documents sufficient to identify the sources of AKF's financial contributions that contribute more that 1% of AKF's total annual funding for each year from 2014 to present, including a breakdown of the amount contributed by each such source.

RESPONSE TO REQUEST FOR PRODUCTION NO. 11:

Plaintiff objects to the Request as irrelevant to any party's claim or defense. Plaintiff also objects to the disclosure of sensitive and protected donor information. *See* 26 U.S.C. § 6104(b). *See also* 26 U.S.C. § 6104(c)(3). Plaintiff also objects to the term "total annual funding" as vague. Subject to and without waiving these objections, Plaintiff is willing to stipulate that since 2010, AKF received approximately 80% of its funding for HIPP from DaVita and Fresenius.

REQUEST FOR PRODUCTION NO. 12:

Any and all documents relating to the Affordable Care Act and its effect on the population of patients eligible for HIPP Assistance for private insurance or on the available reimbursement rates for dialysis treatment, including but not limited to reports, analyses, and strategic planning documents.

RESPONSE TO REQUEST FOR PRODUCTION NO. 12:

Plaintiff objects to the Request as irrelevant to any party's claim or defense. Plaintiff also objects to the request for "any and all documents" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff also objects to the use of the term "effect" in this Request as vague.

REQUEST FOR PRODUCTION NO. 13:

Any and all documents listing dialysis providers, including clinics and hospitals, whose patients were "blocked" from receiving HIPP Assistance due to the providers' decision not to make financial contributions to AKF, including but not limited to the "blocked list" or "training list" referenced in the New York Times article dated August 2, 2019, entitled "Top Kidney Charity Directed Aid to Patients at DaVita and Fresenius Clinics, Lawsuit Claims," available at https://www.nytimes.com/2019/08/02/health/kidney-dialysis-kickbacks.html and attached hereto as Exhibit B.

RESPONSE TO REQUEST FOR PRODUCTION NO. 13:

Plaintiff objects to the request for "any and all documents" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff also objects to the Request, which is based on a news article containing inaccurate information about AKF and HIPP activities.

Subject to and without waiving these objections, Plaintiff will produce responsive, non-privileged documents if it discovers any in its possession, custody, or control.

REQUEST FOR PRODUCTION NO. 14:

Any and all communications between AKF and any Dialysis Provider, including Davita, Fresenius and U.S. Renal, regarding AB 290.

RESPONSE TO REQUEST FOR PRODUCTION NO. 14:

Plaintiff objects to the request for "any and all communications" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff interprets the request as excluding documents related to this Litigation (*Doe v. Becerra* and *Fresenius v. Becerra)*. Plaintiff also objects to the extent the Request seeks documents and communications protected by the common interest or attorney work product doctrines.

REQUEST FOR PRODUCTION NO. 15:

Any and all communications between AKF and any Dialysis Provider, including Davita, Fresenius and U.S. Renal, regarding SB 1156.

RESPONSE TO REQUEST FOR PRODUCTION NO. 15:

Plaintiff objects to the Request as irrelevant to any party's claim or defense. Plaintiff also objects to the request for "any and all communications" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff also objects to the extent the Request seeks documents and communications protected by the common interest or attorney work product doctrines.

REQUEST FOR PRODUCTION NO. 16:

Any and all documents that relate or refer to AKF's stated intention to cease to provide assistance to dialysis patients in California if AB 290 went into effect, including all internal analyses, reports, communications, memoranda, and board or executive determinations.

RESPONSE TO REQUEST FOR PRODUCTION NO. 16:

Plaintiff objects to the request for "any and all documents" regarding the subject matter as burdensome and not proportional to any benefit Defendants could receive from a production. Plaintiff also objects to the Request because it would require Plaintiff to disclose confidential and sensitive patient information. Plaintiff also objects to the extent the Request seeks documents and communications protected by the attorney client privilege or attorney work product doctrine.

Subject to and without waiving these objections, Plaintiff will produce copies of sample letters to patients and publicly available communications concerning responses to California's enactment of AB 290. Plaintiff also incorporates by reference the "Declaration of LaVarne Burton in Support of Motion for Preliminary Injunction" dated November 7, 2019 (Dkt. No. 28-2) and the "Supplemental Declaration of Donald J. Roy, Jr. in Support of Motion for Preliminary Injunction" dated December 18, 2019 (Dkt. No. 54-1).

REQUEST FOR PRODUCTION NO. 17:

Copies of AKF's financial statements, audit reports, and annual reports from 2010 to the present.

RESPONSE TO REQUEST FOR PRODUCTION NO. 17:

Plaintiff objects to the Request as irrelevant to any party's claim or defense.

Subject to and without waiving any objections, Plaintiff will produce public disclosure copies of its audit reports and annual reports from 2010 to 2018. The public copies of the audit report and annual report for 2019 are in development and will not be completed for several more weeks.

REQUEST FOR PRODUCTION NO. 18:

Copies of AKF's IRS Form 990 from 2010 to the present.

RESPONSE TO REQUEST FOR PRODUCTION NO. 18:

Plaintiff objects to the Request as irrelevant to any party's claim or defense.

Subject to and without waiving any objections, Plaintiff will produce public disclosure copies of its IRS Form 990s from 2010 to 2018. The public copy of the Form 990 is in development and will not be completed for several more weeks.

Dated: March 5, 2020

KING & SPALDING LLP

By: */s/Joseph N. Akrotirianakis*
JOSEPH N. AKROTIRIANAKIS
BOBBY R. BURCHFIELD

Attorneys for Plaintiffs
JANE DOE, STEPHEN ALBRIGHT, AMERICAN KIDNEY FUND, INC., and DIALYSIS PATIENT CITIZENS, INC.

CERTIFICATE OF SERVICE

On March 5, 2020, I served the following document(s) in the manner described below: **PLAINTIFF AKF'S OBJECTIONS AND RESPONSES TO DEFENDANTS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS**

☑ (BY ELECTRONIC SERVICE): By electronically transmitting a true and correct copy through King & Spalding LLP's electronic mail system to the email addresses set forth below in the attached Service List.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on March 5, 2020, at Los Angeles, California.

MINA TUNSON

SERVICE LIST

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE; STEPHEN ALBRIGHT; AMERICAN KIDNEY FUND, INC.; and DIALYSIS PATIENT CITIZENS, INC.,

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

8:19-cv-2105-DOC-(ADSx)

EXHIBITS 4a-16 TO THE DECLARATION OF LISA J. PLANK IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

PROVISIONALLY REDACTED PURSUANT TO PENDING APPLICATION FOR LEAVE TO FILE UNDER SEAL

Date:	May 2, 2022
Time:	8:30 a.m.
Courtroom:	9D
Judge:	The Honorable David O. Carter
Trial Date:	July 12, 2022
Action Filed:	November 1, 2019

EXHIBIT 4a

Excerpts from FMC Earnings Call on October 30, 2018

S&P Global
Market Intelligence

Fresenius Medical Care AG & Co. KGaA

XTRA:FME

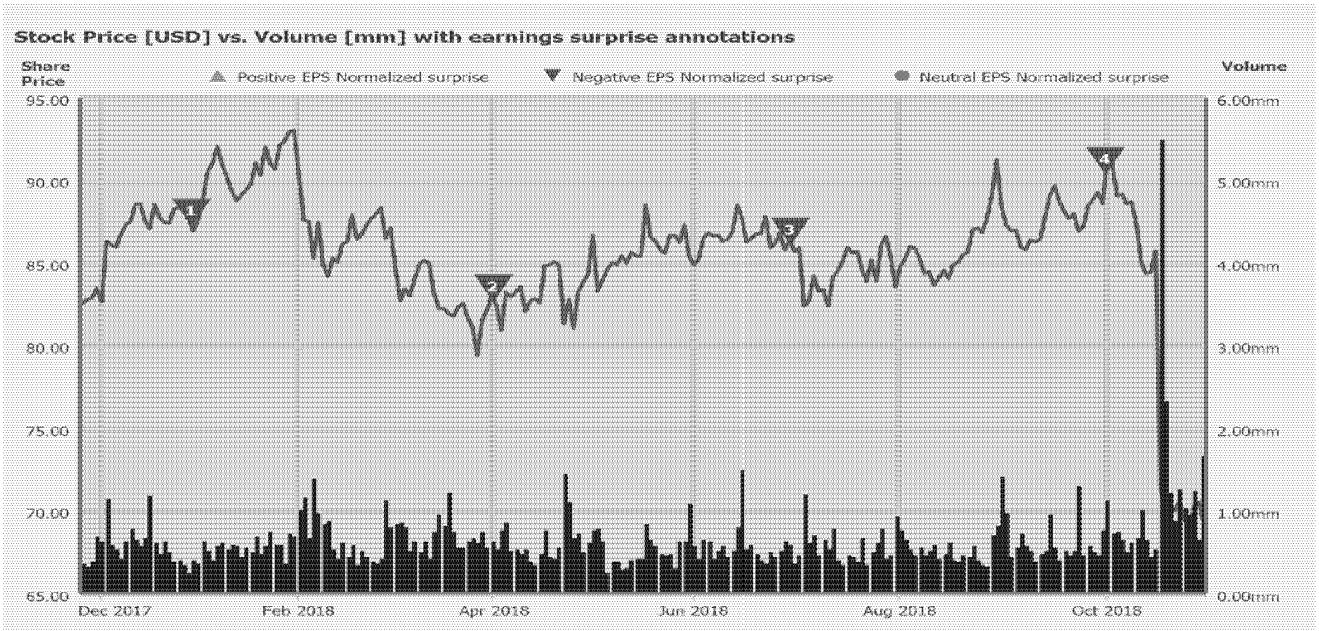
FQ3 2018 Earnings Call Transcripts

Tuesday, October 30, 2018 2:30 PM GMT

S&P Global Market Intelligence Estimates

	-FQ3 2018-			-FQ4 2018-	-FY 2018-	-FY 2019-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	1.23	1.15	▼(6.50 %)	1.55	4.82	5.54
Revenue (mm)	4639.93	4610.84	▼(0.63 %)	4704.15	18947.30	20785.09

Currency: USD
Consensus as of Oct-30-2018 12:32 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ4 2017	1.76	1.45	▼1 (17.61 %)
FQ1 2018	1.14	0.96	▼2 (15.79 %)
FQ2 2018	1.23	1.04	▼3 (15.45 %)
FQ3 2018	1.23	1.15	▼4 (6.50 %)

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Call Participants

EXECUTIVES

Dominik Heger
Senior VP, Head of Investor Relations & Corporate Communications

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

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Goldman Sachs Group Inc., Research Division

Presentation

Operator

Ladies and gentlemen, thank you for standing by. I'm Hailey, your Chorus Call operator. Welcome and thank you for joining the Fresenius Medical Care Earnings Call on the Third Quarter 2018. [Operator Instructions]

I would now like to the conference over to Dominik, Head of Investor Relations. Please go ahead.

Dominik Heger
Senior VP, Head of Investor Relations & Corporate Communications

Thank you, Hailey. We would like to welcome all of you to the Fresenius Medical Care Earnings Call for the Third Quarter 2018. We appreciate you joining today. I know you had a long call already.

As always, I'm happy to start out the call by mentioning our cautionary language that is in our safe harbor statement as well as in our presentation and in all the materials that we have distributed earlier today. For further details concerning risks and uncertainties, please refer to these documents as well as our SEC filings.

I am outstandingly aware that everyone was waiting for this call for quite a while, and therefore, we do not limit it to 60 minutes. Nevertheless, I would like to limit the number of questions to 2 in order to give everyone the chance to ask questions. If there are further questions, we are happy to go a second round. I hope this works for everyone.

With us today is, of course, Rice Powell, our CEO and Chairman of the management board. Rice will give you some more color around the business development, go through some of the major topics of the quarter. Of course, also with us is Mike Brosnan, our Chief Financial Officer, who will give you an update on the financials and the outlook.

I will now hand over to Rice. The floor is yours.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Thank you, Dominik. Welcome to the FMC third quarter earnings call. I do appreciate your interest in our business and the company.

Before I begin my formal presentation, I would like just to make comment that I understand that some of you were disappointed that we did not have a conference call immediately after the October 16, 17 ad hoc. We made the decision, Mike and I, to stay within our process and take the 2 weeks to get clarity and as much detail as we possibly could in order to answer your questions today and give you our commentary.

I also imagine that there will be questions regarding guidance for 2019 today. Please understand, that we are just beginning the budget process for 2019 and we are not in a position today to discuss 2019 and to try to give you guidance several months ahead of the normal process that we go through. So I do ask for your understanding and forbearance on this, but that's where we sit at the moment.

Moving to Slide 4 to begin my prepared remarks. This is a new chart for you. We wanted to do the very best that we could to give you a sense of the growth trend, particularly looking at North America on the parameters of organic growth and volume growth on the services business and then also to give you a view of the dialysis products' organic growth for the larger regions in the product business, which are EMEA and Asia Pacific.

And we did this in an attempt to make sure people did not think that the basic fundamentals of the service business in North America were fractured or broken, something to that nature. Did we meet the expectations that we had for ourselves? No. We'll take you through that. But the underlying fundamentals

in that business in that region of the world are still there. We have issues to deal with as any business does, but not to the degree I was concerned. Mike and I felt some of you thought the world was ending, and it's not.

Looking at this slide, if you look at the dialysis services organic growth, what we've done is given you the group view at the broken line with the broken line, then we gave you North America, and we backed calcimimetics out of that to give you a picture of the organic growth across 3 quarters of the year.

Now looking at dialysis services and the volume growth, we've done a similar thing and to give you the full group view for FMC and to highlight specifically North America at 2.5% volume growth. And then lastly, when you look at the products growth on an organic basis, you see the reddish or brown line for EMEA. They're down 2.1%. Then you see the broken line for the group, and you see better performance coming from Asia Pacific. We will address a number of the questions I know that you have about the product business, in particular, EMEA, in a couple of slides as I traditionally do on my product slide.

Now moving to Slide 5, the growth continues. As we always have done, we show for you the progression in our clinic growth, our patient growth and our treatment growth. I won't belabor those. They're there for you to see, as we typically do.

Looking at Slide 6. Our quality outcomes in the quarter remain at a very high level. We continue to operate in a very tight clinical band. Any of these parameters you'd like to look at for any region, you can see that we're very close and we're in a very tight band here. Happy to address any of this in Q&A, if you like, but I'm going to move on to get to more substantive discussion topics.

Looking at Slide 7, our update within the quarter, key for you to know. We've seen improved sequential quarterly growth in the dialysis business in North America. We'll talk more about that in Mike's presentation and on the Q&A. But the business acceleration has been muted due to a couple of factors: lower revenue from commercial payers as a result of seeing some drop out of the ordinary range in our commercial mix, and Mike and I will take you through that; and also, delayed de novos have created an issue for us.

Remember this number, 79 delayed de novos. It's a significant number. We'll come back to that. And I will go and say now that we do not expect in the fourth quarter to get 79 de novo clinics certified. Roughly, there are 41 working days left in the quarter. So this is going to be a knock-on effect in Q4, and it's obviously colored our view of what we can do in the quarter. Please remember that the Bipartisan Budget Act of 2018 allows us January 1 of next year to use third-party surveyors to get our clinics certified. And we've already contracted with someone to do that, so this will help us get out of this situation that we're in with the U.S. government where they cannot get us certified in any sort of timely manner.

We have seen a lower-than-expected contribution from the vascular access business in our Care Coordination book. If you recall, we told you we had planned to try to convert 40 site 11 facilities to ambulatory surgical centers in this calendar year. Today, it appears to us that 29, perhaps 30, will be all that we get done in this time frame. And much of that issue sits in the state-to-state requirements for certification that we must get done in order for us to bring those facilities up into the new classification, and that is not going according to our expectations. We've talked every quarter about difficult environment in the emerging economies. Obviously, things have gotten worse, hyperinflation in Argentina, a couple of other countries where we've seen issues and we'll talk about that, but this continues to be a drag and interrupt the expectations that we've had for the business.

We do have some good news. Our Care Coordination margin has improved. Looking at our tables in the back, you'll see that it was 12.1% in the quarter. Keeping in mind, we want you to know that there's a transaction effect on the Sound gain that makes that 12.1%. But looking at the real margin, the way we look at it, we're standing right around 9%., a little bit more on a constant currency basis, I think 9.4%. So we're within the range in the guidance that Mike had given you earlier in the year. We're happy with that.

We had -- we have and continue to have, and it will get bigger, our commitment to home. We are at 12.4% in terms of home penetration at the end of September. That is up from 11.8% at the end of Q2. So very good progress there.

NxStage will close. We are later in the year than any of us imagined we would be, but we still believe that it will close. And you'll notice probably sometime in the next day or 2 that we've extended the agreement with NxStage to February 5 in order to allow ourselves ample time to get this done with the Federal Trade Commission, and then finally get on with the integration of NxStage into Fresenius Medical Care.

Moving to Slide 8. We are trying to give you as simple look as we can on a comparable basis. If you will note, at the bottom right of the page, we have Slide 25 and 26, given you the same fulsome accounting of everything we've done in the reconciliation process. But Mike and I feel that we have done enough of that and we wanted to give you a simple slide to look at. And as you can see, on this comparable basis, we are at 3% constant currency growth on revenue, EBIT at 4%, and then you see the net income on a comparable at 19% and then the adjustment. Okay? So hopefully, that's easier for you to see. But we do have the details, should you require.

Moving to Slide 9 and looking at our organic growth in the services side of the business, what you -- just in the organic growth, I'm sorry. I'm one chart ahead of myself. Asia Pacific at 4% constant currency revenue growth and organic growth of 5%. Obviously, Latin America, those are pretty large numbers you see there. That's driven from the hyperinflation obviously. We're going to want to talk some about EMEA and a 1% constant currency revenue growth and no organic growth. You're going to have questions on that, we understand it. And North America, I think we've talked about it extensively, as to what's driving the organic growth and then the constant currency drop in the revenue growth. But we're happy to go through that in the Q&A.

Now turning to Slide 10 and looking at the services side of the business on the organic growth. I tend to focus my commentary on the 2 right columns, organic growth for the total group at 4%, same market treatment at 3%. And I won't read those to you detail to detail, but we will get into more color on this as we look at your questions. And I think Mike's going to cover some of that in his slides as well.

Moving to products on Slide 11. Let's go directly to EMEA, as you can see, 2% constant currency growth down in the quarter. A couple of things are driving this. We saw high-single-digit-million-euro impact with a lack of sales in Egypt. We addressed the Egyptian market through the United Arab Emirates. That's our hub, and we saw a significant drop-off in sales in that particular country. We also had good growth in Libya in the second quarter. It did not materialize as to our expectations in the third quarter. And in the case of Saudi Arabia, we have slowed down the sales because they simply are not addressing the days sales outstanding as quickly or as significantly as we think they should, so we've slowed that down ourselves.

If you look at Asia Pacific, good growth there at 6% constant currency growth, predominantly driven from their chronic and their acute product lines. And then looking at North America, 1% constant currency growth. Quickly, good job in renal drugs, up 24%. PD's up 8%. Let me just remind you that with IFRS 15, we had a high-single-digit-million-dollar impact on our HD machine business. And if we had done that on a like-for-like basis, we would have seen about 5% growth, just I think 4.9% in our hemodialysis equipment. So I point that out just to give you some better clarity on what's going on, on the product book of business.

Lastly, Slide 12, in conclusion. Again, I don't think I have anything more to add to what's on this slide, other than to say to you we have adjusted Q3 based on not getting to the expectations that we wanted and we see the knock-on effect in the fourth quarter. There truly are, if you count them, 40 to 41 working days left in the quarter. So we have to be pragmatic and realistic about how quickly and deeply our countermeasures are going to turn some of these issues around, and we'll talk more about that.

The patient growth and the market dynamics, we do not think the fundamentals are disruptive or destroyed particularly in North America. And yes, where we've been able to get at what has gone wrong, we have got countermeasures in place. We're working on those. But again, 40 to 41 days, and that assumes I don't take Thanksgiving off in the U.S. We will still be working to get that done, but it's not quite enough time in our estimation.

And with that, I'll turn it over to Mike.

Michael Brosnan

CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Thank you, Rice, and hi, everybody. So I'll continue on Chart 14, the usual comparison with regard to our revenue growth that walks you from reported numbers to the basis we use for guidance. You can see the high-level reference to the revised guidance at the top of the chart, 2% to 3% constant currency revenue growth. And as you work through the chart, we've got the blue box in the middle, which is what we believe is the comparable measure for the quarter. So we were at the 3%, and you see the items that we've considered outside of that to the left and the right.

Turning to Chart 15. We do continue to show you 2 views with regard to our earnings. This was -- initially, we had guided only to the top view at the beginning of the year. And having listened to the feedback from some of you on the call, we then supplemented that with the second view, which became the more operational view. That's why we've continued to show both sets of earnings and performance metrics as the year has progressed. So you can see on the top of the chart, the details about what's in and what's out. And as Rice indicated, the detailed reconciliation for that, both for the 3 months and the 9 months, is in the back of the material that was distributed with the slides today.

Business growth at EUR 57 million produces about 19% on a constant currency basis for after-tax earnings. That 19% obviously influenced by a benefit that we took in the third quarter related to some true-ups on the opening balance sheet associated with the tax reform in the U.S. end of '17. There were certain aspects of that that needed further research and study, which is very common. We see a number of companies -- U.S. companies taking adjustments to the opening balance as 2018 has progressed. So that's in the comparable reported earnings at 19%.

When you look at the bottom of the page, you see again in the blue box, a decline in earnings, minus 2% constant currency. That is in part for some of the things that we're talking about today overall. But I would say more specifically, what drove that against the revised targeted growth for the year was the fact that we took an adjustment for the hyperinflationary accounting in Argentina. And as a reminder, that is not tax-effected. That's in the operational numbers that you see there on the page.

Turning to chart -- the following chart, Chart 16, and starting to talk about the margin performance in the regions around the world. I would say that if you looked at margin on an adjusted basis for all of the elements that we detail routinely, you would see for total company globally, our margins would be flat year-over-year at about 15.1% compared to 15.2% in the prior quarter. But these charts are shown and explained on an as reported basis with nothing taken out beyond what you see on the page.

So for North America, the reported operating income was up EUR 42 million to EUR 525 million, 9% in current or 2% in constant currency. The EBIT margin, as you can see, was 18.5%. And the operating income includes EUR 17 million currency translation gains from the divestiture of the Care Coordination activities and also cost of EUR 23 million associated with the spending we had on the ballot initiative in California in the third quarter.

We did see, in total, personnel costs growing at a slower rate than revenues, which obviously has a beneficial effect on the margins. That includes some adjusted -- some true-ups of accruals with regard to our health care costs and our other employee-related insurance matters in the quarter. It also includes payment we received with regards to our consent, and that contributed to the margin improvement in the third quarter.

I typically comment a little bit about the dialysis business margins, even though it doesn't appear on the page. Those margins increased from 18.1% to 19.2%. Again, that was largely driven by the consent agreement and by the effect of personnel costs growing at a lower rate than revenues. Also these figures were impacted by the natural disasters in the base of last year, the implementation of IFRS 15 and the state ballot initiative. Calcimimetics also plays a role in the margin performance in the dialysis service business in North America.

In terms of revenue per treatment, what you see here on the page is the sequential revenue and cost per treatment. If you think in terms of year-over-year and you adjust for the VA agreement and the

implementation of IFRS in the base period, you see -- you would see an increase of $15 per treatment from $341 in '17 to $356 in '18. And the cost per treatment would increase by $19 from $271 to $290.

On the revenue side, the drivers for the increase in revenue of roughly EUR 17 million for the calcimimetics, A Medicare rate increase, an increase in Medicare Advantage treatments. And this was partly offset by lower commercial revenues, which we've had in our guidance for the year and a relatively small effect with regard to other items.

On the cost per treatment side, the increase was driven largely again by the calcimimetic drugs at $16 a treatment. I'll remind you that I had indicated that we probably have a relatively minimal margin effect associated with calcimimetics this year as we sort out both the billing side and the operational side in terms of utilization of the various drugs and patient dosing. That's continued to be the case as the year's progressed. We did see higher occupancy costs in the cost per treatment and higher costs associated with medical supplies and ancillaries.

In Care Coordination, the margins frankly do get a bit distorted as a consequence of the translation into euros and also the fact that as you progress through the year, you have to revise your operating results to the year-to-date weighted average exchange rates. When you have an unusual gain, as we did in the second quarter, that tends to distort the impacts when you're converting dollars to euros. I think the important thing on a dollar basis, as Rice has already commented, we indicated that we would see an improvement in Care Coordination margins this year. We are seeing that, frankly, 9% approaching the 10% range potentially for the year.

That said, in Care Coordination, the drivers of the margin improvement were a favorable impact in the pharmacy, because we continue to see good pricing on the products that we're distributing to patients through the pharmacy. The rebasing of calcimimetics through services also helped the pharmacy margins. This was offset a bit in the quarter due to lower earnings related to the ESCOs. And just to remind folks, this is principally because we had the initial recognition of revenues in Q3 last year associated with the new ESCO locations that were approved in 2017. So the earnings recognition for the first 9 months associated with those new locations was recognized in the third quarter.

And as Rice already mentioned with regard to the vascular access business, we are seeing a delay associated with our plan to convert site 11s to ASCs. And we did have some pricing pressure with regard to reimbursement on the NCP side of the business, the cardiovascular, endovascular business.

In talking about Care Coordination and in particular the ESCOs, I would say in Q3 last year, we also had received the final reconciliations from the government on the first year, which was October 1 to 15 through December 16. These reports were in line with our expectations for year 1. We have not yet received those reports for year 2, so that reconciliation will be forthcoming either in Q4 or possibly spilling over into 2019. You know we've grown the program. We continue to work closely with CMMI to ensure the program develops appropriately. We believe in the value-based care initiative for services in the U.S. And we've shown our commitment to this approach by significantly growing our ESCO site participation in 2017 and then our patient enrollments for all of our locations in 2018.

So turning to the next chart and continuing the margin analysis. For EMEA, operating income was down EUR 18 million, about 16% on a constant currency basis. The margin decrease was driven by a favorable impact that we had last year. We had a settlement in the third quarter of last year, so that obviously impacted the decline this year. We did see higher personnel costs in some countries, particularly on the services side of the business. And we did have one less dialysis day as we aggregate the region.

We had unfavorable foreign currency transaction effects, which have been a headwind for us this year. And we did see higher bad debt expense, and this is the case in a number of the regions, partly driven by our economic circumstances and the currency volatilities that drives credit default swap rates, which is what we base our bad debt provisions on in many countries around the world. So you see an uptick in bad debt expense because the swap rates have increased.

In Asia Pacific, operating income decreased from EUR 77 million to EUR 66 million, about 14% both in current and constant currencies. The decrease in margin was principally attributable to foreign currency

transactions effect again and also an unfavorable impact associated with our business growth in the region as we continue to invest for growth in the mid and the long term. This was partly offset by some favorable effects of translation in the quarter.

In Asia, the Care Coordination operating margins declined a bit from 17.7% to 16.2%, but still our investment in Cura in Australia is performing very nicely. Latin America operating income declined from EUR 18 million to about EUR 1 million. Margin decreased as you can see on the page. This was, as you can imagine, mainly due to the hyperinflation in Argentina, which was recorded for the first time in the third quarter. I'll come back and comment on that further later in my presentation.

Corporate cost increased by EUR 76 million from EUR 75 million in '17 to EUR 151 million, obviously largely driven by the fact that we increased our reserves for our settlement discussions with the U.S. government by EUR 75 million in the third quarter.

So turning to Chart 18 and cash flows. In terms of absolute dollars, very little change over the period, EUR 609 million this year versus EUR 612 million. As a percentage of revenue, a little bit better at 15% compared to 14% last year. That's a combination of several effects. We did have higher tax payments in the U.S. because we did make a tax payment associated with the gain we took on Sound in the second quarter. That was partly offset by lower tax payments in the current year, obviously driven by the new lower tax rate associated with tax reform.

We took the opportunity in May to do an incremental contribution to our pension plan in the U.S. for USD 50 million or EUR 42 million. And these effects were nearly fully offset by a decrease in accounts receivable due to our collection efforts in a number of countries around the world, but in particular, in the U.S., seeing payments coming in on the calcimimetics, which reduced our overall AR. The result, as I indicated, gives you a sense of strong cash flow and revenues in the quarter.

The DSO, days sales outstanding, those reflect an increase in receivables of a couple of days from year-end. This is in part associated with calcimimetics, in part associated with just normal practice on the ESCOs, and has been helped a little bit by the divestiture of Sound because Sound overall had higher DSOs than the rest of North America. So there was a benefit in North America associated with that. CapEx for the third quarter is about 6% of revenues, so, in line; and free cash flow just over EUR 350 million. As a result of the developments in our operating cash flows, our net debt has continued to decrease from December 2017. And our leverage ratio is slightly down from the end of '17 at 2x.

So turning to the next chart, Chart 19. You see what we've tried to do here is give you an appreciation of the relative impact, both in terms of revenues and in terms of net income on a comparable basis. So the first line of net income, if you will, going back to the charts I showed at the beginning of our discussion. And I'll walk through each of these and try to give you some additional perspective.

So starting on the left and just working down the page, we have North American dialysis business. And what we had indicated in our earlier release, and what Rice commented on, is we did see lower growth in the commercial dialysis services revenues. We saw a drop in our commercial mix, which is influenced in part by higher growth in Medicare Advantage relative to commercial growth. But when you look at our commercial mix on a sequential quarter basis, Q2 to Q3, we did see a lower number of commercial treatments in the third quarter. And this was not our expectation with regard to the guidance that we confirmed in the second quarter. So when you think in terms of commercial mix and the commercial book of business, obviously when we're reporting year-over-year, you have one effect. When you're looking at it against what our expectations were for the back half of this year, we were disappointed.

So Rice has commented a bit on countermeasures. I would add my voice in that. We have had this experience in the past. We believe that we can refocus the business and regain some of the ground that we've lost. Our de novo plan development also impacted our expectations, and that's represented in the chart that you see in terms of the relative size of the effects we've been discussing.

The second one, mergers and acquisitions, we continue to actively evaluate opportunities and we're always focused on doing what makes good business sense to us. We have started the year with guidance in the EUR 1 billion range, so we had anticipated we would tick up a bit our acquisition activities this year.

We took that down to about EUR 600 million to EUR 800 million in the second quarter, and we've now dropped it further to EUR 400 million to EUR 500 million for the year. This still would allow us to achieve what you're used to seeing, roughly about 1% growth associated with acquisitions. But this was something that we had hoped to get a little bit more out of in fiscal 2018. We have worked on deals this year, make no mistake, some that we think would have been very attractive and they just didn't proceed to close.

Also it's not a bubble on the page, but I'll just reiterate, the -- because it's slightly different than what I had indicated at the beginning of the year, Rice mentioned the impact of IFRS 15 relative to the machine business in North America. And when we adopted IFRS 15 at the beginning of the year, we anticipated the fact that that accounting pronouncement would require the installation and the training of people prior to the recognition of revenues, to be de minimis effect on 2018.

As we've gone through the year and as we've been monitoring this, we do see that it creates a bit more of a pipeline, so machines that have been sold and have been delivered but have not yet been installed. So that created a little bit of the softness, particularly as you're getting into Q3 and the back half of the year. Rice referenced North America specifically. We see a similar effect in particular in Asia which, not surprising, also has much longer lead times in terms of getting the equipment on site.

In Care Coordination -- excuse me, that machine influence does have an impact in terms of the emerging countries. The other thing I would say with regard to the emerging countries, which I have commented on already, is with these currency volatilities, you saw in the first quarter, we indicated a relatively strong effect associated with transaction losses, given currency volatilities, particularly in emerging markets. You saw increases in bad debt, which I've explained. That moderated a bit in the second quarter, which gave us some optimism associated with what we might see in the back half. When we saw the preliminary figures for Q3 and we saw an effect on earnings similar to what we saw in the first quarter, that also contributed to our decision to revise the guidance.

The Care Coordination, lower revenues and earnings in our vascular access and cardiovascular business was considered. In the vascular business, it does relate to the conversion from site 11 to ASCs being a bit slower than we had anticipated and lower revenue rates in the cardiovascular business.

Hyperinflation, you see is indicated as a positive effect and a different color on the left-hand side of the chart that's because with the accounting associated with hyperinflation, you actually have an uplift in your revenues. I wish it were also the case on the earnings side of the business. But again an uplift in revenues, and typically there is a cost associated with the earnings side.

So these are the factors and a little bit more of an explanation in terms of what led to the revision in our revenue guidance a couple of weeks ago.

Going on the right-hand side of the page and looking at net income reported on a comparable basis, you see that the emerging countries takes on a larger effect. And that is principally due to the fact that the hyperinflationary adjustment that we took in Argentina is not tax-deductible. So that contributed to the quarter. In addition to that, I would tell you that our expectation coming into the third quarter was that under the accounting guidelines, we would be required to only address the hyperinflationary effect as it developed in the quarter. And that was clarified as the -- and actually was definitively clarified just after the close of the quarter, that you have to book the full year effect associated with conversion to a hyperinflationary accounting. So we took a 9-month effect in the third quarter where we had anticipated a much smaller adjustment only relating to the 3 months. So that contributes to the size of that bubble. We do have -- when we look at that inflationary expectations coming into the fourth quarter, we have considered that we expect that we'll see a similar effect in the fourth quarter that we saw in Q3.

I've already commented that we saw the currency volatilities and resurgence of the transaction losses in the third quarter. And have already commented on the influence of the credit default swaps with regard to our provisioning of bad debts. All of that contributes to why you see the emerging countries reflected proportionately higher than some of the other impacts.

So North American dialysis service business, we have -- you are seeing effectively the earnings effect associated where I've already discussed on the revenue side relative to commercial mix, some of the

other effects in services. I would take the opportunity here, talking on the earnings side, to say that at the beginning of the year, I have guided on revenue per treatment from the services business in the U.S. This was adjusted for the Veterans Administration, IFRS 15 and the calcimimetics to be flat to slightly down. I would expect that will be down around 1% to 1.5% for the year, so within the range of guidance. But on the wrong end of that guidance, if you will, I would have preferred it to be flat. On the cost per treatment, I had guided to cost to be flat to slightly up. This was also adjusted for IFRS 15 and the 2017 natural disasters as well as Sensipar. I expect it will be up around 1% to 1.5%. So there is a little bit of pressure in the services business in the U.S. because you're dealing with the spread.

And then last, again, a different color indicating a positive effect. Obviously, you get a beneficial effect on the minorities associated with the lower earnings. And you also get a benefit in the comparable net income associated with the additional benefit we took for tax reform in the third quarter.

So turning to my last chart. The top of the chart reflects the revised outlook that we've previously published that I think I just described the drivers that contributed to our decision to do that. I will just take a moment to talk about the bottom part of the chart, for the most part, highlighting some of the things that we've carried in the footnotes for some time. And I'm doing it in principle because Rice also indicated that we're just not going to comment on the 2019 now. We'll do that in accordance with our normal process.

We are just beginning our budget cycle. We have obviously a number of items that are relevant to that process. On the footnotes, we do anticipate the closing of NxStage soon, albeit later than we have hoped. Frankly, NxStage has continued to develop very nicely since we announced the transaction last August of '17. So we will refresh our expectations once that deal closes, and that will take us some time as a part of our process to come out with the guidance for these periods.

In addition, we'll update for the changes we've made in our Care Coordination portfolio, the sale of Sound and Shiel, but also as well for the fact that we have expanded Care Coordination in Australia with Cura. We'll address the implementation of both IFRS 15 and also IFRS 16, the new leasing standard, which we're continuing to work on in order to meet the deadlines that we have related to announcing 2019 guidance. And we'll also provide a more current view with regard to currencies.

Couple things just to keep in mind, particularly as it relates to the fourth quarter, coming back to 2018. We will have some additional spend on the ballot in the fourth quarter, and that will also not be tax-effected. The -- I've already commented that from a hyperinflationary perspective in Argentina, I expect a similar consequence in the fourth quarter that I've seen in Q3. And last year, 2017, from time to time, I commented on Latin America and just -- with the volatility we have down there with some of the economies, we always have to be thinking about whether any of this contributes to the possibility of an impairment charge. We do not have an impairment at the end of Q3, but obviously, this is something that we'll have to watch closely as we finish off the year and move into 2019.

So thank you. I appreciate it. That's the end of my remarks. Back to you, Dominik.

Dominik Heger
Senior VP, Head of Investor Relations & Corporate Communications
Thank you, Rice, thank you, Mike for the presentation. I'm happy to open the Q&A for more insights now. Hailey, can you open the Q&A please.

Question and Answer

Operator

[Operator Instructions] The first question is from the line of Veronika Dubajova of Goldman Sachs.

Veronika Dubajova
Goldman Sachs Group Inc., Research Division

I will keep it to 2, please. My first question is on the North America revenue per treatment and commercial mix. I appreciate there are a lot of moving parts. But Rice and Mike, can you maybe comment on what exactly has gone wrong with the commercial business, and why you are seeing a worsening of the mix above and beyond what you had anticipated this year? And is this in any way related to some of the escalators you had previously guided to for in the fourth quarter? So that's my first question. My second question is actually on the EMEA margin, also lots of moving parts. But I'd like to understand what impact in the margin was underlying this quarter versus what was driven by currency? And is this a new margin level that we should be assuming for your EMEA business going forward? Or are there things you can do to improve the profitability?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Okay. So relative to revenue per treatment and commercial mix in North America, and Rice may want to comment as well, I would say that there's always some volatility in commercial mix that we manage year in and year out, quarter-to-quarter. Our thinking, frankly, at the moment is the midyear open enrollments are frankly becoming more popular. And what drove the surprise to us was not something that we were seeing organically as every quarter moved it was -- the surprise was we just saw a bigger reduction in our commercial book coming out of those July 1 open enrollments.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes. Veronika, what I would tell you is, as well, we see a couple of things going on that I don't think we put the proper detail into. We did see some of our transient commercial patients, travelers, vacationers. We saw a drop-off in those volume of treatments that we would normally see in the third quarter. That concerned us, trying to understand that, so we're ripping that apart. But as I've always told you guys, your whole approach of the commercial book is a process. You figure out how best to take new patients on, do that effectively, quickly and make it attractive for those patients to come into your clinic. So we're going to go back and relook at that. We've already figured some things out that we will want to do differently. And I have to be honest and say we've also made a management change. We made a change in the senior executive that was running the kidney care business in North America in order to do some things I think in a more focused way around our commercial book and perhaps not have too many initiatives that our people are focused on. We want to kind of skinny that down. I'm a big believer in 3 or 4 key things, not 8 or 9 or 10. And so we're kind of going back to basics on this, and we will get this sorted out. But as Mike says, we have seen chatter every year, every quarter, up and down a little bit. But this was a move that was different than what we expected. And so we've done what we've done. Go ahead, Mike.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Okay, thanks. So yes, so we don't attribute it at all to any kind of pricing consideration, just more of the open enrollment. On the EMEA margins, if I think in terms of what I just presented, last year was enhanced by the gain, which is nonrecurring, so that would probably put you down in the range of 16% in terms of the base period. And if I think of the currency influence this year, I think 14% is a bit on the low side. Maybe a normalized expectation might be along -- maybe 100 basis points higher.

Veronika Dubajova

Goldman Sachs Group Inc., Research Division

Okay. That's clear. And can I just confirm, I think there has been a little bit of speculation that part of the reason why the commercial business deteriorated is that one of your smaller competitors has renewed their relationship with one of the private insurers. Did that have any impact, in your opinion, on your commercial growth?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes, Veronika. We don't think so. I get asked that question a lot. We can't answer it with absolute clarity. But as we rip apart what we're doing and we look at it from a geographic standpoint, obviously, we don't see that. So I'm going to tell you I don't think so, but I can't bet my 2 children on it, explicitly. But we do go at it from a market-to-market view. And given what we know about that competitor and where they were in that relationship we don't think that's the case.

Operator

The next question is from the line of Ian Douglas-Pennant from UBS.

Ian Douglas-Pennant
UBS Investment Bank, Research Division

Could you just -- just a quick question, the clinic counts that you give in the press release, is that before or after the certifications? Just for a start.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

It's after they've been certified.

Ian Douglas-Pennant
UBS Investment Bank, Research Division

Okay. So in that case, we saw that the total clinic is actually up 5.2% year-over-year. I mean, that's twice the long-term run -- over twice the long-term run rate of around 2%. So I am slightly surprised you calling out the lack of new centers or the lack of acquisitions as a headwind. It feels like -- it certainly sounds like as if de novo is it could have been a tailwind and if you'd actually had those additional clinics certified, it would have been a huge tailwind. So maybe you could comment on that. And then I'm afraid I am going to ask about 2019 guidance, but I think a question that you can answer. And what format do you think you'll give that in? May I suggest moving away from the current metrics with large number of adjustments, in favor of something simpler like organic growth and reported EBIT margins?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes, okay. Let me comment initially on your questions. So relative to the de novo as being a headwind, it's a headwind against our expectations for the year. It's not a headwind against our historical trend. I think in our view, as we came into '19, we felt that we should be in -- doing a bit more in that regard. So that's what led to the 79 that Rice was referring to. And in terms of the measure, I would say, if you go back to the beginning of the year relative to treatment growth for fiscal '18, I had indicated 3-plus percent. And we're trending to a little bit under 3%. So -- yes. So that's how you can kind of fit in Rice commenting about the approval of de novo as being a little bit of a headwind. It's really against what our expectations and our guidance was when we started the year. In terms of format, I'm not going to prejudge 2019. We actually -- and I'm not going to be defensive about it. We made a change in Q1 because we tried to keep it simple in '18 with one revenue guidance and one earnings guidance. And we got very, very strong feedback even before we had the call in February, basically insisting that we had to provide something with more transparency about the underlying operations, taking out all of the knock-on effects from 2017. And frankly, you don't sell a business for a couple of billion dollars every day. So we felt it was appropriate to also take that effect out of the reported earnings for transparency. It does make life difficult. There are

people out there that like it, but it does make things more difficult for us. So it's not something that we're crazy about doing. When I think about '19, and we've made no decision yet, I just need to think about the implementation of the leasing accounting standard. And folks might want some comparability and some within the line associated with that, potentially. So we'll take a hard look at it. And we'll still have the legacy effects associated with the Care Coordination divestitures to deal with. But we would like to find a better way where more people in the investment community are satisfied with the clarity we're giving, with the detail we're giving, with the transparency we're providing. So the objective is not to confuse people. The objective is to give people reported, and 1 or 2 dimensions that we think they may be more interesting in, which gets down to operational results.

Ian Douglas-Pennant
UBS Investment Bank, Research Division

Great. Thank you. Just one last, if I may, and I'm sorry if I missed it. Have you broken out the actual impacts of calcimimetics in your North American dialysis care organic growth number?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

On the...

Ian Douglas-Pennant
UBS Investment Bank, Research Division

Or just a dollar number is fine.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Oh, no. We give you the dollar number every quarter. I reported it every quarter. But you're talking about the growth rate. I believe it's -- we're just double checking a couple of things here.

Ian Douglas-Pennant
UBS Investment Bank, Research Division

I can follow up, Dominik.

Dominik Heger
Senior VP, Head of Investor Relations & Corporate Communications

It's 2.3 without calcimimetics in the quarter.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Okay. So with calcimimetics -- which is what I thought. I was hesitating, but the rate is not adjusted, my revenue and cost per treatment is.

Operator

The next question is from the line of Tom Jones of Berenberg.

Thomas M. Jones
Joh. Berenberg, Gossler & Co. KG, Research Division

I had 2 questions. I hate to harp on about it, but I wanted to just ask another question on the commercial payer mix. I think what would be helpful is if you could just give us a bit of color on whether the challenges you're seeing or the reasons you think your payer mix suffered a little bit in Q2 were 100% related to your own kind of operations. Or there was any shift in the commercial insurance market external to FMC that you saw that you're now having to deal with. I think the reason I ask the question is, the former, if it's just operational on your side, you've been there before. You were in a similar position back in 2011, 2012, and in a couple of quarters and you were back on track. But if the actual commercial

market that you're operating in is becoming more difficult, more challenging, then that's maybe a bit of a bigger concern for investors. So maybe if you could just make some comment in that regard. And then the second question, I guess the bigger picture one probably for Rice, emerging markets, I mean, how is that, the kind of last couple of quarters, affected your thinking about your willingness to deploy capital in emerging markets? Because they by and large, just generally seem to be a pain in the proverbial. When they grow, it's a relatively small number. And it doesn't really move the needle, given the size of the EMEA and the North American business. But when they go wrong, they seem to go wrong in a big way and create a huge headache for everyone. So are you as keen on the emerging market opportunity as you once were? Or has your enthusiasm kind of softened somewhat?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes, Tom. So 2 good questions. On the first question, it pains me greatly to say it's self-inflicted. I don't see something going on in the commercial book on a global or U.S. national basis, if you will. I'm not seeing something there. I simply think that we were not doing things that we should have been doing. Lessons we learned a while ago, we seem to have forgotten. So it is self-inflicted, which pains me to say it, but that is the case, and we will fix it. We'll sort through what needs to be done and get it fixed. On the emerging markets, today is not a good day to ask me that question given what Mike has been talking about. But look, let's take a minute and let me just run through this. No, we can't have it both ways. We hear all the time from people, "My God you're so consistently centered in the U.S. You should be doing something more internationally. Are you going to grow your business?" And so you got to kind of take the good with the bad. Having said that, just imagine though, you can't sit on the sidelines in China. China is a unique place that one person will make a decision that everybody's going to get health care, they're going to open up the markets. And you need to be there because the one thing we've learned in some of these countries, as those markets open up, if you don't have a presence, if you're not perhaps manufacturing, and they want to keep out foreigners, if you will, from coming into the country, they have ways to do that. Being an early adopter in getting there tends to make sense, but you do have to take some of the good with the bad. Am I ready to change the strategy today? No. But remember, we tried to go in as products first before we make a move to be a service provider. And there is a reason that we're in 150 countries with products but only 50 with services. But I have to say, as I sit here today and I read everything that's going on in the world, we have to be more diligent in looking at these opportunities. But at the same time, I need some flexibility from you guys. I can't turn those opportunities down and stay anchored in the U.S. and Germany and no place else when everybody's telling me, you need to diversify and you need to look to grow more. So we take a very long-term view as you know and we'll continue to do that. But it's a fair point that you raised today. And today, I'm not big on emerging markets at this very moment, but I will calm down and think about this differently tomorrow.

Thomas M. Jones
Joh. Berenberg, Gossler & Co. KG, Research Division

That's understandable. And just one pausing comment, we do appreciate the granularity on the various adjustments, it does help us to tease out the underlying trends in the business.

Operator

The next question is from the line of Patrick Wood of BAML.

Patrick Andrew Robert Wood
BofA Merrill Lynch, Research Division

2 for me, please. I'm sure it was clear to a lot of other people. But it will just be a little bit helpful if you could help me understand a little bit more the product side of things. And obviously the weakness in the 3Q, I understand some of the adjustments that have gone on there, but really trying to get my head around how that looks going forward, given the gross margin profile of that business, how we should expect growth then. I guess on that same topic, I was a little surprised in when we got the final numbers, looking at the prerelease, why the product side wasn't called out as partly driving the weakness and the adjustment. Did you not call products out as part of that weakness in the prerelease because of the

expectation that is going to improve materially going forward? Just to be helpful to understand why that wasn't sort of part of the commentary.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

So I would say on the prerelease, and then I'll let Mike jump into the margins here for products going forward, fourth quarter, what we think. Looking at the prerelease when we first looked at this -- and it's interesting Patrick, lots of folks haven't really wanted to accept what I'm about to say to you. But when we first looked at the signals that we were getting and got concerned that our expectations were not going to develop as we have wanted them to, it all kind of sat right there in the emerging markets. And the more we were able to dig into it and really talked to people with feet on the ground in some of these markets, it became clearer to us, it had to be a bigger situation than we were first looking at it first blush. Maybe you people don't realize what 2 weeks of detailed study and being able to rip things apart and talk to people on the ground is worth quite a lot to Mike and I. And again as I said earlier, to have done the prerelease and try to have a conference call the next day, we wouldn't have had the clarity to address some of this that we've gotten over the last 2 weeks. Mike, if you want to add anything?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes, I would just say a lot of this is timing. Not that you need to -- the expression is see how the sausage is made, but literarily when we looked at this and what the obligations are under the ad hoc rules, we had operated only off of our flash data. We did not get our closing information until literally the day that we have to release the FR. So that's what you're getting a lot more specificity today than you did 2 weeks ago, because we didn't have an opportunity to do a great deal of analysis of the details. We have to look at the big picture and then make some judgments.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Now looking at products for fourth quarter, I'll make a comment and then I'll let Mike jump in. As we have traditionally seen in the fourth quarter, we can see better equipment sales as a result of people trying to spin their budget and get the equipment ordered on order and then by the beginning of the next year. But when we look at what's happening in some of these emerging markets, I'm not as bullish that we're going to see a normal fourth quarter flood of equipment orders as we've seen. And as Mike has pointed out with IFRS 15, there is a lag time there. So we're not going to see the same kind of contribution that we may have seen in prior years. When I do look at the disposable book of business, which I think is more repeatable and easier to measure, I think we'll see some of that to come back, but it's a matter of, is it going to meet the expectation that we had. And so we're just not sure it's going to develop that way. Mike, and I don't know what you want to say on -- relative to the growth that we think we're going to see, but that's kind of my commentary.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes, I wouldn't add anything to what you said.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

So hopefully, that's helpful, Patrick?

Patrick Andrew Robert Wood
BofA Merrill Lynch, Research Division

Sure, helpful.

Operator

The next question is from the line of Lisa Clive of Bernstein.

Elisabeth Decou Bedell Clive
Sanford C. Bernstein & Co., LLC., Research Division

2 questions. First on home dialysis. You've had very impressive growth on your HHD population, from I believe 2% to 4% over the course of this year. But I'm trying to get an idea of the margin impact of this. It really depends on how you're growing this business. And so am I right in understanding that most of the new patients are PD patients who had rolled off that therapy? And if that's the case, since they've been dialysis patients for a while, I assume all of them are Medicare. Meanwhile, it really seems the bigger opportunity in home as being able to attract those privately insured patients as HHD can enable them to dialyze at night, stay employed and stay privately insured. How do we think about how you've been scaling up that business? And then I'll ask a follow-up question after that.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes, so Lisa, your instinct or your gut feeling is correct. The growth, the bigger growth that we're seeing in our home penetration, much of that is coming off of the PD side of the business. So if you go back and you were to look at our PD growth in the U.S. over the last couple of quarters, it has been high single-digit to low double-digit. And so they're coming in through the PD side of the house, if you will. Yes, your second point about privately insured patients that want to work and can work, bringing them in through home therapy is clearly a way to do that. Because as we've said, part of what led us down this path of acquisition with NxStage was seeing the trend that there are more people, as the younger people are coming onto dialysis, they have no desire to going into a clinic. They want to be at home. And many of them were employed and are working. So all of those comments that we made a year ago in August when we were welcoming you guys through the deal rationale, that still is applicable today. You're correct.

Elisabeth Decou Bedell Clive
Sanford C. Bernstein & Co., LLC., Research Division

Okay. And just given the commentary, at least in the prerelease, around the extra cost around HHD, most of those new patients are Medicare, right? I mean, I don't think that that's particularly profitable, is it?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes. So many of them are Medicare. And the increased cost wasn't directed just at HHD. Remember, a part of what you see when you're growing your home book of business, either way, but particularly one is PD in the case of the U.S. and us, we run our own fleet of trucks. We do our own deliveries. When the business grows, you got to have trucks, you got to deliver, there are things that go into that, in addition to a tremendous amount of training that has to go on that sits in the clinic side of the house and not necessarily in the product side of the house. So there's a little bit of division of labor, I guess, I'll call it for the lack of a better word. I don't know Mike, if you want to jump in on that. But I think that's the way I would say that.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes. No, I agree with that. And then I'd just say bigger picture when we think about life after the close of NxStage, as we've talked about it, we think that gives us opportunities to approach home and in-center a bit differently, and in the midterm, generate some synergies.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes.

Elisabeth Decou Bedell Clive
Sanford C. Bernstein & Co., LLC., Research Division

Okay. And then second question, just on Care Coordination, when you first launched this division in 2014, it was really segmented into the dialysis-related business lines like FreseniusRx, ESCO vascular access. And then nondialysis service expansion in other areas of health care services like Sound and NCP. And frankly, the latter really hasn't turned out how we initially expected. Sound has obviously been divested, albeit with a nice gain. But NCP, if I've modeled it, it's seen something of a decline in its profitability since you bought it, with it sounds like a further step down this quarter. Have you rethought your sort of nondialysis aspirations, also given how big ESCO and other integrated care platforms are and your increased focus on home dialysis? Where should you really be expending your energy and money in Care Coordination?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes. I think it's a fair question. I have not turned from facing north and gone south on NCP yet, Lisa. We are looking at that. It hasn't delivered to our expectations. But at the same time, there is so much back and forth and in and out about where vascular access rates are going to be and where the procedures that offer the best opportunity for increased margin are going to go, we're not ready to cut that loose yet in any stretch of imagination, but we are looking at it and watching it. But if there's any level of comfort people should have, I think we've shown you we will move when we think the time is right, i.e. Sound. We're not there yet. And the other piece that you didn't miss -- mention are the urgent care, I'm more facing south than the north on that one. We're going to do what we need to do. So I would say, just keep in mind that we will act when we need to, but the converse of that is when we see a good opportunity, like Cura in Australia where it's really working, we're going to jump on that as well. So it is still fluid. Let me say it that way without going much more in any specific organizational discussion.

Operator

The next question is from the line of Ed Ridley-Day of Redburn.

Edward Nicholas Ridley-Day
Redburn (Europe) Limited, Research Division

My first question would be regarding the FCPA provision. Mike, just can you catch up on this? Because we had the big provision a year ago. And then there was, obviously, you guided for lower costs related to that investigation. And then we have this additional charge and indeed in your prerelease commentary around nonfinancial matters are still under discussion. So could you clarify what those are and how we should think about this investigation and the costs related to it going forward?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Ed, so it's Rice. I'll turn Mike loose on you here in a minute, but I do want to make a comment. We're not going to get into a whole lot of detail about what the other financial -- nonfinancial discussions are. Let me say it this way. Any time you come to a settlement of this nature on the FCPA, you've got to agree on how it's going to be characterized and published when you have had that settlement. So that means back-and-forth discussion about what's actually on the paper, where is it going. There's also been how are you going to carry on your business post having reached a settlement that everybody is comfortable with, and that has to be discussed. We might want to do things differently than they do, and you have to go back and forth on that. So that's probably as much color as I think I can give you. Mike, I don't know if you want to walk in through a little bit of the charge componentry?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Beyond that, I would say that when we first took the charge, we had just indicated we had started settlement discussions. We had a view of what we think the financial elements of the -- we actually had several points that we looked at from probability perspective to arrive at an estimate. As we indicated in the release, we've reached an understanding. And I use the word understanding because for us to reach a full agreement, we have to agree on all terms. But we have reached an understanding with the SEC and

the DOJ in terms of the financial piece, which was a little bit higher than what our probability estimate was at the time we established the reserve. In addition to that frankly, it's taking us longer to get through the process and when things take longer that involve lawyers, your legal costs go up. So we've kind of topped it off in that regard as well on the financial side in the $75 million.

Edward Nicholas Ridley-Day
Redburn (Europe) Limited, Research Division

Okay. Fair enough. And then second one, just, I'm sorry if I missed it. But what was the materiality of the new consent agreement on pharmaceuticals on the dialysis margin in the quarter?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

We haven't given an exact figure because we are limited in terms of what we can say under our confidentiality agreement. But it's listed prominently. So I think it had a meaningful impact on the quarter. And this is not a onetime thing, but I think probably the influence in the quarter is more significant than we'd see going forward.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Think of it, we did this in the second quarter of last year, Ed. And what happened is, we are allowing, if you will, certain activities to be done by the partner that we're not undertaking, but they have to get our consent for that. So I think that's kind of the way I would leave it, because Mike's right, we can't get into a whole lot of detail on that. Hopefully, that gives you a little color.

Edward Nicholas Ridley-Day
Redburn (Europe) Limited, Research Division

So it's a -- we should see some benefit going forward, but incremental relative to the effects in the third quarter?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

You say incremental, less...

Edward Nicholas Ridley-Day
Redburn (Europe) Limited, Research Division

I mean, a fraction of what we thought in the third quarter.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

A fraction, yes. That's fair.

Operator

The next question is from the line of Michael Jungling of Morgan Stanley.

Michael Klaus Jungling
Morgan Stanley, Research Division

2 questions, please. Firstly, on the California ballots. Can you describe your lobbying efforts? And also what you think of the wording on the ballot? It's kind of interesting, I think the way it's been worded. And also what do you think the financial impact would be if there is, unfortunately, a yes vote against the dialysis industry. And question number 2 is on ESCOs. Can you describe the profit or the booking of profits going forward for the next 4 quarters? How do you see the volatility of those ESCO profits being booked into your P&L?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes. Michael, it's Rice. Relative to California and the wording on the ballot initiative, it's certainly not what we would have wanted. It was not in a way that I thought was fairly unfair, but I'm not going to cry about it. But the way it works is it was -- wording was developed and we, both the parties got to comment on the wording and it just didn't go our way as I guess the way I would say it. We continue to say that this is going to be too close to call. We will know, probably sometime during the day on November 7 how it went. What I would tell you then is, I'm not going to make any commentary until I know whether it went our way or not. If it didn't go our way then we'll talk to you about what we're going to do and what we think those impacts could be, but let's not get the cart before the horse at this particular point in time. And then secondly, I think Mike can talk about ESCOs and profit, but that may be another cart before the horse, but go ahead Mike.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes. No, and I take it because you're really talking about the year-over-year change related to the expanded sites in '17. And when you think of the program, they are not allowing additional sites in '18. So as we introduce new sites in '17, we went through the same kind of process with them that we had with the original sites. For '18, since you're dealing with just new patients in existing sites with all the control procedures set up, it's much -- it's a much smoother process. So thinking about when you said next 4 quarters, I think relative to the expansion, since we're dealing with the same sites and just new patients, it's very smooth. We're pleased with the performance and what we're doing for the patients in these ESCOs. And then we'll have to just go through the reconciliation process, which is an annual event.

Michael Klaus Jungling
Morgan Stanley, Research Division

Okay. Mike, just a follow-up on these ESCOs, what is the chance or so that we'll be surprised in a quarter or so of booking a material amount like we've seen in the past? Is that likely? Or is the smoothness that you've described, as the volatility that we've seen in the past, is no longer an issue?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes. I think -- well, the smoothness I'm referring to relates to operationally new sites, new patients and going all the way back to the being -- establishing the whole process, we went through the same thing with BPCI. The -- relative to any abrupt change, I'm not anticipating anything operationally in that regard in terms of the patient care aspects. I think relative to discussing the reconciliations with the government, these are very detailed discussions because you're dealing with benchmarks, you're dealing with adjustments to the benchmarks. So I can't really comment on that today because we have to just sit around the table, work through the questions that you typically have from year to year and then come to an agreement.

Michael Klaus Jungling
Morgan Stanley, Research Division

Great. And Rice, on this ballot, just a follow-up question, please. Given that the industry -- or the dialysis industry has spent over $110 million fighting maybe around 15,000 patients, is that spend an indication that this is such a material win for the future of, let's say reimbursement of -- or reimbursement rates or profitability in the U.S?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Well a couple of things, Michael. You're mixing things here. The $110 million was an industry-wide spend. The 15,000 patients is just our patients. The total number of patients in California I think runs around 65,000. So it's quite a large number. Without waxing too political on this, what I would say is we're

fighting this fight because we think what's happened is egregious. We think they're putting patient lives at risk versus them dealing straightforwardly about do we want to unionize or not. And the answer is, there is a process for that in the U.S. We can't stop it, we don't stop it. But they just decided to not make that effort and just go take this to the public in California. So I'm a pretty rational guy until you poke me in the eye, and then I can get aggressive back. So we're just defending our territory and we'll see where this goes. And that's probably as much as I'll say.

Operator

The next question is from the line of Oliver Metzger of Commerzbank.

Oliver Metzger
Commerzbank AG, Research Division

The first one is on M&A. So could you comment how -- or to which territory your external growth projections have changed? So you mentioned that you still project 1% plus this external growth. So can you give us an indication at which level you were earlier this year? That's my first question. My second question is on health care products in Europe again. So your decline is your first decline for more than 2 years in a quarter. So can you just comment on how long you expect this negative momentum to last?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

So Oliver, I'll turn it over to Mike here on the M&A. The one thing I do kind of just want to point out to people, and I think Mike said this earlier, is obviously we had pretty big expectations on the M&A front as we had big budget and we took that down. I would also just -- trying to get people to realize, the same folks that buy things for us sell things for us. So you just have to keep in mind the business development team in the U.S. spent a number of months selling Sound. And when you're selling something, you're not necessarily looking to buy other things right at that point in time. So there's a little bit of just priority on what was going on here. I know you want a more technical answer, and I'll turn it over to Mike. But I wanted to give you just a sense of kind of how we're looking at this big picture.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes. And I wouldn't add much to that, Rice. I would say that as we did our planning for this year as a board, we wanted to see an accelerant there. And part of why we're not seeing what we had hoped to see was as Rice described, you have the same people very focused on the divestiture. We did look at some deals that did take some time from these folks and we ultimately didn't get to a close. So we'd be having a different conversation if we had.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Your second question on the product side of the business, relative to EMEA. We see ups and downs when you look at that book of business, 40 countries spread from central Europe to Eastern Europe to the Middle East and Africa. So we do see puts and takes there. I think one of the things that has put us in this downward trend, remember a bunch of this business, probably 50% of it or so, is tender related. And so we do lose tender from time today. And those tenders aren't for necessarily 3 months or 6 months. They can be a year-long on the product side. And then if it's a service tender, it can be multiyear. So we've had some of that going on. The competition is there. We fight it, but we also have to make decisions about, do you want to fight it to the point that you trash your pricing and you destroy value? Or do you not do that, sit on the sidelines, have a bad quarter or 2, have to deal with that, and then come back in at the next opportunity? So I believe that we are going to see continued pressure from our expectations in the fourth quarter, and we've hinted that to you. Where will it go next year, we're not there yet. As I said, we're just starting our budgeting process. But if there's anything that I've seen, Oliver, in my 21 years with the company is that we generally find a way to continue to grow our product business. R&D is a big piece of that obviously and coming out with a new products. So I'm not worried or panicked, but we are recognizing that we see a lot more competition around the world. Everybody's elevated their game. And

so the battle is on, but we'll get our fair share. But it may not be ratable quarter to quarter to quarter. Sometimes, you get these expectation surprises that you have to deal with, and we just have to lay it out for you that way.

Operator

The next question is from the line of David Addington from JPMorgan.

David James Adlington
JP Morgan Chase & Co, Research Division

Firstly on just your Care Coordination business in North America, just wondered, the 12% margin in Q3, is that at least a good starting point to where we are with the business now and how we should be thinking from here? And secondly just on EM, Mike, I think you said that you sort of, on the hyperinflation side, think about Q4 being the same as Q3. But I'm pretty sure that Q3 had a catch-up for the entire first 9 months. So I just wanted to clarify the Q4 expectations versus Q3.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes. So David, I'll take on the Care Coordination. So I wouldn't lock and load on that 12.1%. As Mike took you through there, once you strip out that transactional gain from the Sound gain, I think you should think about that in terms of 9%. That's kind of where we are. So that's right in the range, the sweet spot that we gave you, we thought we'd be in. Then on the emerging markets...

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

I've missed the question.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Okay. So he was asking about inflation in the emerging markets, knowing that in Q3, we had to deal with Argentina and kind of the step up there. Do we really think it's going to continue that way? But I think I know your answer on that. We believe it will be another bad quarter in the fourth quarter.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes. For Argentina, when you look at the indices that we're using, they're already prognosticating into Q4. So that's why I said I think I'll see -- we'll see a similar effect in the fourth quarter that we saw in the third, which is in the teens -- mid-teens I would say in terms of millions of euros.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

But we have taken that into our consideration the way we've adapted our guidance and our expectations. That's -- we assume that in there, so that's...

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

It's in the guidance.

David James Adlington
JP Morgan Chase & Co, Research Division

Correct me if I'm wrong, but I think that mid-teens in Q3, you captured Q1, Q2 and Q3 more than Q3, right?

Michael Brosnan

CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Right.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

For Argentina, that's correct. But I think what Mike's given me the hand signal here that it accelerated as we got into the latter part of the year. It wasn't such a big deal in the first quarter and in the second quarter. It's not symmetrical.

Operator

The next question is from the line of Gunnar Romer of Deutsche Bank.

Gunnar Romer
Deutsche Bank AG, Research Division

Gunnar Romer, Deutsche Bank, the first one again on Care Coordination. I think when you last guided on the business, you set around 9% to 11% or around 10% margin. And now given your 9 months' performance, even to get to the lower end, what I believe -- assume quite a significant step up in the margin in the fourth quarter. So can you help us understand how you really look at the earnings contribution from Care Coordination in the fourth quarter? Are you expecting sequential improvement here? And what is this going to be related to? Then the second question would be on the transactional effects that you've seen in international. Can you comment what the combined effect was on EBIT if you take together the international markets? Because that would really help us stripping out the operational performance here. And then last question on corporate cost, can you update the guidance here now, in or excluding the FCPA charge, I don't mind. But just help us understand what your current thinking is on the corporate cost?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Going -- on Care Coordination margins, we're trying to take a look. Because I would have said year-to-date, I'm probably still in the range where the 9% or 10% that I gave you would probably mean you're coming down a bit off Q3, but you're still much better than we were at the beginning of the year. But I just don't have the year-to-date figures in front of me. So I think there's a little bit of moderation, but I think, I still believe that very high-single digits, possibly teens.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

We'll get it for you Gunnar, hang on, we'll answer your questions, then we'll come back.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

On your second question, I have -- I don't do this all the time, but a couple of years ago, we saw this effect. I did kind of disclose the transactional effects in the aggregate for the international markets. And as I said before, we saw something substantial in Q1, which was about $15 million EBIT effect that moderated in Q2. Yes, that's just a little over $1 million in Q2. And now we're back in Q3 in the range of the mid-teens, around $17 million. So there's a -- you see the boomerang effect there.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes, it's a saw tooth, but you can understand now coming out of where we were in Q2, the surprise and the change, the missed expectation for us seeing that in Q3.

Gunnar Romer
Deutsche Bank AG, Research Division

That makes perfect sense. But the $17 million does not include the hyperinflation charge, right? I mean, otherwise it doesn't make...

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

You're correct, Gunnar. That is correct. It's just transaction. The corporate costs, we're taking a look, I didn't come into the room today with an answer on that one. So why don't we go to the next and I'll come back.

Gunnar Romer
Deutsche Bank AG, Research Division

Maybe then a follow-up question, just around your expectations regarding the conversions of the site 11s. What's the current thinking on how fast you can get these approvals?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

It's the tough one, Gunnar, because we're dealing state by state. So I'm going to kind of say it this way. I don't expect, where we had an appetite for 40 to be done this year, where now we're looking at 29. I don't see anything that's going to tell me that I'm going to get the remainder done in the fourth quarter, so I think there's going to be some spillover effect into Q1. What I would tell you that I would hopefully come out of Q1 of next year with the 40 that we wanted converted done, certified and up and running. But I don't think we're going to get there in the fourth quarter, given the delays and the issues we saw, getting the various states to certify for us over the course of Q3.

Gunnar Romer
Deutsche Bank AG, Research Division

And how many more would then be left once you've reached the 40?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes, so we have a total of, I think it's 60 centers. And we didn't anticipate, we didn't expect that we would convert all 60 of them. So getting 40 of those done, we may still have another handful that we would do. And part of that will kind of depend on geography and do we stay in at site 11 or do we combine some. So I think you probably got another handful that we would consider that we would probably do over the course of next year. But we can give you color on that when we get to guidance for '19.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes, Gunnar, just to come back to you on the Care Coordination, and we may -- you may need to do this offline with Investor Relations. What I'm looking at year-to-date through September is around 7%. So to get to the 9% to 10%, we would have to see an uptick in the fourth quarter.

Gunnar Romer
Deutsche Bank AG, Research Division

Quite a significant uptick then in the fourth quarter in terms of margin, I guess.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

It would have to be -- it would have to be on the, I'd say, the mid- to high teens.

Gunnar Romer
Deutsche Bank AG, Research Division

And revenue-wise, I guess, sequentially, Q4 should look pretty similar to Q3 for the Care Coordination business.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Yes, I think. I think that's accurate.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Just up a bit, yes.

Operator

The next question is from the line of Hassan Al-Wakeel of Barclays.

Hassan Al-Wakeel
Barclays Bank PLC, Research Division

I've got a couple. Firstly, could you elaborate on the countermeasures that you've identified, particularly in the U.S., other than the changes to management as you highlighted? To this end, was the de novo delay here largely avoidable. And secondly you pushed out the NxStage deadline for the second time now to February 2019, although you note that you still expect the closing this year. What is driving this delay? And do you think other disposals may be required?

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

We'll go -- we'll work backwards to forwards. No, I do not believe there are other disposals that will be required. The reason is in the February 5, is we used 90-day windows of planning that was what we agreed to in the merger agreements. So there's no magic to that. We just stuck to the formula that we've been using. And that's why, no more discussion on having to divest something else. That's why I'm still bullish we'll close this year. No magic around using a 90-day -- an additional 90-day window. Then on the countermeasures relative to the commercial situation. Relative to de novos, we had for years traditionally done around 45 to 50 de novos in a year. And then we decided to step that up. And so we had a much bigger appetite over the last year or 2. There is not anything that we could do. This is not a self-inflicted gunshot wound, if you will, to our de novo practice. This is simply building them, literally hounding the government from an inspect and certify the facility so that we can begin to take patient and they are just very, very backlogged. And so the use out of this is as an industry we went to Congress and complained bitterly and said, "Guys, we're not going to match the growth in the market if we can't get these facilities certified." And that's how we ended up with the balance budget act that was passed back in July that will allow us to utilize third parties effective in February -- or in January of next year. So this is not something that I think is self-inflicted. I think we're dealing with kind of the cards that we've got dealt. But when the government doesn't get things done quick enough, we were able to go to Congress to try to get that speeded up and I think that should help us tremendously in that regard.

Operator

There are no further questions at this time. I'll hand back to Dominik for closing comments.

Gunnar Romer
Deutsche Bank AG, Research Division

Just wanted to understand it better.

Dominik Heger
Senior VP, Head of Investor Relations & Corporate Communications

Okay.

Michael Brosnan

CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

So we begin. One comment, we're doing our best, but I would say I think we have guided to flat to maybe slightly up on corporate cost. And I would say we're probably slightly up. So fairly consistent with our guidance, that's in current currency.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Go ahead. I can't hear.

Gunnar Romer
Deutsche Bank AG, Research Division

Excluding FCPA?

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Yes. Excluding FCPA.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

So Gunnar, we're managing the cost, pretty much is the way we've laid them out to you ex FCPA.

Michael Brosnan
CFO & Member of the Mgmt Board at Fresenius Medical Care Mgmt AG

Does that give you -- answer your...

Gunnar Romer
Deutsche Bank AG, Research Division

Yes.

Dominik Heger
Senior VP, Head of Investor Relations & Corporate Communications

Good. Thank you, ladies and gentlemen. The conference has now concluded. And you may disconnect. Afterwards, we would like to say thank you very much for sticking with us for that long call. We hope it was helpful, and you gained a little bit more understanding of the topics you hadn't had 2 weeks ago. Okay. So thank you very much.

Robert Maurice Powell
Chairman of the Mgmt Board & CEO of Fresenius Medical Care Mgmt AG

Thank you, folks. Take care.

Operator
Ladies and gentlemen, the conference has now concluded and you may now disconnect your telephone. Thank you for joining and have a pleasant day. Goodbye.

EXHIBIT 4b

FMC Insurance Counselor training program

FILED PROVISIONALLY UNDER SEAL

EXHIBIT 4c

2018 Insurance Coordinator Goals

FILED PROVISIONALLY UNDER SEAL

[FMC-AB290-00004940]

EXHIBIT 4d

Financial Coordinator Bonus Proposal, November 4, 2017

FILED PROVISIONALLY UNDER SEAL

FMC-AB290-4941 - FMC-AB290-4943]

EXHIBIT 5a

DaVita 2018 and 2019 Donation Letters to AKF

32275 32nd Ave. S
Federal Way, WA 98001
Tel: (253) 272-1916
www.DaVita.com

Donation Adjustment Letter
November 8, 2019

American Kidney Fund
11921 Rockville Pike, Suite 300
Rockville, Maryland 20852

Attn: Don Roy

RE: Monetary Donation Adjustment to American Kidney Fund

Dear Don:

DaVita Inc. (DaVita) supports the American Kidney Foundation (AKF) in its mission to improve the lives of those patients suffering from kidney disease. At the beginning of this year we determined an annual donation amount of [redacted] based on our estimate of the AKF's financial need. In June 2019, we contributed a one-time supplemental donation of [redacted] increasing our annual donation amount to [redacted]. In reviewing our contribution amount again, we have decided to modify the amount, such that the new annual donation amount will be [redacted], with [redacted] having been paid to date, [redacted] left to donate in monthly payments and a one-time supplemental donation of [redacted].

The Donation is not intended to induce the AKF to refer any beneficiaries to any particular provider for any particular treatment, including, but not limited to DaVita. The Donation is not in any way contingent upon the volume or value of any referrals and the Donation is not contingent upon the AKF's use of the Donation to support DaVita's patients or any individual or group of individuals identified by or associated with DaVita.
In making its Donation, DaVita understands that the:

(a) AKF has sole authority over its operations, including the choice of whether to market or provide its services to any individual or class of individuals;
(b) AKF's acceptance of the Donation does not obligate or otherwise influence the AKF to purchase, use, recommend or arrange for the use of any products of DaVita or any affiliate of DaVita; and
(c) AKF's determinations of patient eligibility for assistance are made solely on the AKF's good faith assessment of a patient's financial need and the AKF does not take the identity of a referring provider or the amount of any provider's donations into consideration when assessing patient applications or making grant determinations.

DaVita supports the AKF's mission to improve the lives of patients suffering from kidney disease. If you have any questions related to this letter or the Donation made, please do not hesitate to contact me.

Sincerely,

Amanda Olson
Senior Director, Corporate Accounting
DaVita Inc.

DaVita

32275 32nd Ave. S
Federal Way, WA 98001
Tel: (253) 272-1916
www.DaVita.com

Donation Adjustment Letter
June 25, 2019

American Kidney Fund
11921 Rockville Pike, Suite 300
Rockville, Maryland 20852

Attn: Don Roy

RE: Monetary Donation Adjustment to American Kidney Fund

Dear Don:

DaVita Inc. (DaVita) supports the American Kidney Foundation (AKF) in its mission to improve the lives of those patients suffering from kidney disease. At the beginning of this year we determined an annual donation amount of [redacted] based on our estimate of the AKF's financial need. In reviewing our contribution amount, we have decided to modify the amount, such that the new annual donation amount will be [redacted], with [redacted] having been paid to date, [redacted] left to donate in monthly payments and a one-time supplemental donation of [redacted].

The Donation is not intended to induce the AKF to refer any beneficiaries to any particular provider for any particular treatment, including, but not limited to DaVita. The Donation is not in any way contingent upon the volume or value of any referrals and the Donation is not contingent upon the AKF's use of the Donation to support DaVita's patients or any individual or group of individuals identified by or associated with DaVita.

In making its Donation, DaVita understands that the:

(a) AKF has sole authority over its operations, including the choice of whether to market or provide its services to any individual or class of individuals;

(b) AKF's acceptance of the Donation does not obligate or otherwise influence the AKF to purchase, use, recommend or arrange for the use of any products of DaVita or any affiliate of DaVita; and

(c) AKF's determinations of patient eligibility for assistance are made solely on the AKF's good faith assessment of a patient's financial need and the AKF does not take the identity of a referring provider or the amount of any provider's donations into consideration when assessing patient applications or making grant determinations.

DaVita supports the AKF's mission to improve the lives of patients suffering from kidney disease. If you have any questions related to this letter or the Donation made, please do not hesitate to contact me.

Sincerely,

Amanda Olson
Senior Director, Corporate Accounting
DaVita Inc.

DaVita

32275 32nd Ave. S
Federal Way, WA 98001
Tel: (253) 272-1916
www.DaVita.com

Annual Donation Letter
November 27, 2018

American Kidney Fund
11921 Rockville Pike, Suite 300
Rockville, Maryland 20852

Attn: Don Roy

RE: Monetary Donation to American Kidney Fund

Dear Don:

This letter is to inform you that DaVita Inc. (DaVita) anticipates making donations in the amount of [redacted] to the American Kidney Fund (AKF) during the period of February 1, 2019 through January 31, 2020. This Donation is intended to help ensure that the AKF can continue to provide vital services to those suffering from kidney disease. DaVita's Donation will be made monthly. This letter in no way obligates DaVita to make any donations, and DaVita explicitly reserves the right to increase, decrease, or terminate its donation at any time.

The Donation is not intended to induce the AKF to refer any beneficiaries to any particular provider for any particular treatment, including, but not limited to DaVita. The Donation is not in any way contingent upon the volume or value of any referrals and the Donation is not contingent upon the AKF's use of the Donation to support DaVita's patients or any individual or group of individuals identified by or associated with DaVita.

In making its donations, DaVita understands that the:

(a) AKF has sole authority over its operations, including the choice of whether to market or provide its services to any individual or class of individuals;

(b) AKF's acceptance of the Donation does not obligate or otherwise influence the AKF to purchase, use, recommend or arrange for the use of any products of DaVita or any affiliate of DaVita; and

(c) AKF's determinations of patient eligibility for assistance are made solely on the AKF's good faith assessment of a patient's financial need and the AKF does not take the identity of a referring provider or the amount of any provider's donations into consideration when assessing patient applications or making grant determinations.

DaVita supports the AKF's mission to improve the lives of patients suffering from kidney disease. If you have any questions related to this letter or our anticipated Donation, please do not hesitate to contact me.

Sincerely,

Amanda Olson
Senior Director, General Accounting
DaVita Inc.

EXHIBIT 5b

Video of WebEx presentation about Medicaid Opportunity program
(and transcription of presentation)

VIDEO LODGED WITH THE COURT

[CA-DAVITA-000014359]

Fresenius Medical v. Xavier Becerra

Corey Danko

September 2, 2015

COREY DENKO: All right. Good afternoon, everyone. This is Corey Denko. I am the IMT Manager for Polaris. I'm joined today with Seth Miller, the group (indiscernible) for Pacific Gold and Caroline Van Oakland, the divisional lead social worker.

A few housekeeping items before we jump in. We -- this will be a recorded Webex for those teammates who are not able to join, so they can reference it at a later time. Additionally, this conference is on mute, so silent, until the end of the call. Once we get to the Q&A portion, I will then instruct everyone on how we can unmute your lines and be able to ask questions.

So I'll go ahead and get started. So thank you, everyone, once again for joining. We're here today really to talk about a really exciting opportunity that we're embarking upon for a lot of our patients which really could just be an absolutely amazing opportunity for some of our patients.

So right now, what our main opportunity is is that some of our Medicaid patients may have an opportunity in this upcoming open enrollment period to obtain an individual plan primary and

maintain their Medicaid plan secondary. This is just an absolutely really exciting opportunity for our patients because in many cases, can really help them to improve their access to care in some cases, as well as potentially their quality of life.

So one of our goals, as we go through the next few slides and the next few months, is that every single appropriate patient who we think may be also have the opportunity to get onto an individual plan, will have that opportunity to learn about insurance improvements. And so really excited about this. It's going to be a strong partnership between the operations team and IMT. I'm really excited to tell you a little bit more about it.

So as I briefly just outlined, there is a great opportunity for us to educate our Medicaid patients on the potential benefits of getting onto an individual plan primary, this upcoming open enrollment period. Now, I -- we all understand that this may not apply to of our patients, and may not be all-inclusive. But we would still like to walk through why we believe this opportunity could really benefit a lot of

our patients, and why it's important that we start focusing in on this over the coming months.

Looking at the potential for better access to care and quality of life for our patients who may choose to get onto an individual plan primary and maintain their Medicaid secondary, a few of these benefits really stuck out for myself, specifically. Some of those being better access to specialists or even out of state travel benefits. Some items that a lot of our current Medicaid patients may not have access to. And so looking at the opportunity of potentially assisting these patients and educating them on getting onto an individual plan primary could really help them to increase their access to care in these areas.

Additionally, looking at this, if our patients have the opportunity to maintain an individual plan primary and keep Medicaid secondary, in many cases, it provides them the opportunity to keep low to no cost on their Medicaid -- on any of their out-of-pocket costs, as well as for those who are currently utilizing transportation benefits through their Medicaid plans, what this would allow them to do is still

maintain those benefits through Medicaid and also potentially gain increased access to care. And so overall, this could be a really great win/win for a lot of our patients in minimizing their costs and allowing them to have better access to care.

So last year, during the open enrollment period, we saw in some divisions, up to over 90 patients choose to enroll into an individual plan primary and maintain their Medicaid plan secondary. And here's a few patient stories that I would love to share with you, to really display how this has been such a life-changing opportunity for some of our patients, and could potentially be, you know, a great improvement to the quality of life for additional patients.

So looking at this first patient, a really cool story that our patient was not able to get on the transplant list in their current state and was able to get on a transplant list out of state because they did end up getting onto an individual plan and had those benefits to go across those state lines. Just this May, that patient was transplanted, which is just an

incredible story, and something we definitely look forward to improve the quality of life for a lot of our patients.

Additionally, with the second patient, you know, just having the ability to travel. So one of our patients last year got onto an individual plan and was able then to travel for their mother's funeral. And we're just extremely grateful that they had the ability to travel by going onto an individual plan.

And so these are just a few items that I just wanted to share with you as to -- as we look into this opportunity during this open enrollment period, why it could be such a great added benefit to a lot of our patients.

Now, I'm going to change gears a little bit to look at which patients we believe could be eligible for this opportunity and how we're looking at educating them over the coming months. And so first of all, we've identified that there's a little over 900 patients in all of Pacific Gold, currently that are on Medicaid plans that we believe may be eligible to get onto an individual plan primary; a lot of those falling into the Sacramento, Bakersfield, and

Fresno areas, and so just really a great opportunity for a lot of these patients.

I'm going to move in a little bit more into what the next steps look like and walk you through how we're thinking about this process and where each one of us may fit into this in helping to educate our patients on the potential to expand their access to care.

So the first step, I'll start on the left in the prioritize box and move my way to the right. So first of all, the first step of the process is really identifying which patients we believe may be eligible. So we already know that all 900 of these patients are not going to be good candidates for this. And in no way are we saying that every single patient should be a good candidate for this. And so the first step in the process is really assessing which patients we believe could be good candidates for this, and I believe you've -- a lot of the social workers have already been working closely with the ICs in going through those patient lists and identifying whether or not a patient may be a good candidate for -- or maybe eligible to potentially move forward in getting individual plan.

Once we've gone through the process of paring down the list, is when we're enter the phase of what we're calling the interest phase. So once we get into next week, into the end of October, what that looks like is once we've, you know, narrowed down that list, we'll then educate those patients who we believe may be eligible, just on the potential opportunity of getting an individual plan. Really share more education on what an individual plan is, what the potential benefits may be, really walk through the pros and cons. And then, really just assessing their interest and seeing is this something that they believe will be beneficial to their situation and is it something that they show any interest in.

One other piece that I'll add here is once we identify that patients are interested, at this point in the process is where we will kick off the American Kidney Fund application process. So for those of you who may not know, the American Kidney Fund provides premium assistance to a lot of our patients. And so at this point in the process, when we identify that a patient may be interested in going onto an individual plan, we will start the AKF process at that point

in time to make sure that we can secure financial assistance for these patients before we even get to the enrollment phase.

And so overall, I'll jump into this a little bit more in further detail and further slides. But this interest phase is really where we're going to need a lot of support and collaboration between IMT and operations teams. And so the AA social workers and IMT are going to be working really closely during this process to make sure that we can help share this opportunity with our patients.

Once we get to the November/January timeframe is what we call open enrollment. And so every year, this is the opportunity for patients to enroll into individual plans, work directly with the carriers, and start filling out applications and start preparing to secure those plans for 2016.

So from November to January is where we're going to see some strong, you know, where we're going to continue have IMT partner with these patients, make sure that we can connect with brokers, and get these patients on plans, if this is something they decide is right for them

and their situation.

So in order for us to accomplish our goals that every single appropriate patient will have the opportunity to learn more about an insurance improvement, it's really going to require a lot of collaboration and coordination among everyone on the call. There's a lot of patients, as we mentioned, you know, starting with 900, and we want to make sure we can really narrow down that list and identify which patients are really going to -- could benefit from this opportunity and really would benefit from receiving additional education around this. And so it's really going to require a lot of collaboration over the next few weeks and months to make sure that we can accomplish this goal.

I'm going to jump into a little bit more detail around what we're looking at in terms of rules and responsibilities and how we're going to be able to coordinate over the coming months. So first of all, IMT's, you know, primary responsibility to date, is really in educating, you know, both operations and, you know, all parties included on what this opportunity is so that we can make sure that every patient has a

chance to hear more about the additional benefits that may be available to them.

IMT also was, we primarily tried to absorb as much of the conversations as possible into IMT. But with the sheer volume of patients, we're also going to need some assistance from the social worker team to assist in having some of these conversations. And so we're going to be working hand in hand and having these conversations between both the ICs and the social workers to make sure that our patients are well-educated on this opportunity.

And finally, IMT will be the main driver in terms of helping to document this process. I know that we've been working closely with the social workers and trying to identify this. And moving forward, IMT will continue to be updating the current tracker that we have so we can really track, going forward, where our patients fall within this process so we can make sure at any point in time we know exactly where all of our patients are in their decision-making process.

For social workers, how this impacts you, is first of all, our first ask would just be

please partner with your ICs and help to make patient introductions. So you know, as the insurance counselors go into the field, we ask that you help, you know, to make those introductions, help to build that credibility and that rapport, so we can make sure that the patients really feel comfortable having conversations with our insurance counselor.

As I eluded to a little bit earlier, as well, we will have a lot of social workers who we will be requesting to have some of these interest conversations with patients, as well. And so the ask would be that if you are one of those social workers, that you would please assist with those conversations timely and helping us to really educate our patients well around this really great opportunity for them. And more to come in the next slide around, what the training and communication will look like around that. But we will make sure that everyone has the necessary training to have these conversations.

And then, the final piece would just be our AAs and so the AKF HIPP application, what we're asking for is additional support that when a patient expresses that interest, that we could

help to fill out those applications to ensure that our patients would have the financial assistance that they need in order to move forward with potentially getting onto these plans.

And before I move on to plan of action and next steps, I'm going to open it up and see if Seth or Caroline have anything that they would like to add. Okay. Great.

So I'm going to move in to sort of a step-by-step as to what our plan of action is, you know, why this could, you know, what you can expect in terms of next steps and really how we can collaborate as a team. So once again, this is a village-wide effort. You know, it's going across the entire village. Really important that we collaborate and work together very closely. And so we want to make sure that everyone has the appropriate training, support, and resources through this opportunity to make sure that we can really educate our patients well.

So what you can expect is early next week, there will be a training that will be scheduled for the interest conversations for those social workers who we know will have a

patient load. So please be on the lookout for that so we can make sure that we get you all the necessary details surrounding those interest conversations.

Once again, for the HIPP and AKF application process, we will be providing additional materials, FAQs and a step-by-step process so everyone in the process really understands what's -- what the process looks like and what's expected of them. And then, finally, I know that you've been working very -- social workers have been working very closely with your ICs the past week, and you know, trying to identify the appropriate patient list. And so thank you so much for your continued efforts there. And our ask would be continue to partner with your ICs on that so we can make sure we can identify which patients may or may not be eligible for this opportunity.

As we move into the interest phase in the coming weeks, this was where, once again, we'll be having conversations with patients expressing their interest. The first ask would just be AAs, we want to continue to give you the necessary support. And so if you need

assistance, please partner with your social workers, ICs, and we want to make sure you have the right support when submitting those so there's no additional questions.

And then, once again, for those social workers who may have a patient load, we would ask that you assist in performing those interest conversations with the patients, working closely with your insurance counselors, so we can help document the process and make sure that we're all well-aligned on what decisions our patients are making through the process. And then, the continued effort as we move through -- into the open enrollment process, is that, you know, the AAs would continue to support us as those HIPP applications come through.

And so we're about to enter into the question answer session. In order to ask a question, please hit *6, and then we'll open up your line and you can ask some questions. So while we're waiting, I'll touch on the first two frequently asked questions. Excuse me, sorry, the bottom two frequently asked questions, and then we'll see if anyone else has some on the line.

And so one of the first ones is, you know, will my patients face any unexpected costs, you know, as many cases, these individual plans may have high out-of-pocket cost, and so how would this be beneficial to a patient? And so what we're looking at is these patients would have the opportunity to, once again, maintain that individual plan primary and keep the Medicaid plan secondary so that those out-of-pocket costs are not impacting them. And so those would be absorbed by the Medicaid plans, and, you know, is a reason why that could be a great added benefit for our patients. And then, the second piece, you know, by keeping Medicaid second -- Medicaid coverage secondary, you know, in most states, we've seen that there's been no issues with patients accessing their transportation benefits that they currently are utilizing through MediCal, so we can make sure that they continue to have those transportation services while increasing their access to care.

I'll see if we have any questions on the line. Once again, *6 to unmute.

CAROLINE: Corey, this is Caroline. I have a comment.

COREY DENKO: Yeah.

CAROLINE: So I just wanted to let everyone know, especially the social workers, that there are hours that are additional hours that are available, especially if you have a large number of patients that you're going to be having those interest conversations with. So we're looking at getting support to the social workers so that there is capacity to do what we're being asked to do.

COREY DENKO: Great. Thanks, Caroline.

CAROLINE: Thank you.

AMBER: Hi, I have a question.

COREY DENKO: Great.

AMBER: Hi, it's Amber. So if they buy into -- if we get these individual plans in place as primary, then does that allow them in California to be able to disenroll from the assigned MediCal plans and go, like, straight MediCal? Or does it have to, like coordinate, because we have, like, Blue Cross --

COREY DENKO: Right.

AMBER: -- and HealthNet, you know what I mean? Like, does it have to collaborate with that, or can they go straight MediCal?

COREY DENKO: Yeah. It's a great question. And so in many cases, what we've seen is a patient can have a managed Medicaid plan in the secondary position. So as we move forward, if a patient does express interest, we will be able to work with them, educate them on what the plan options are, and then we would want to make sure that it would coordinate between whichever plan they select primary, that that network would also coordinate with their managed MediCal plan. But once again, those plans have not been released yet for 2016. So at this point, we don't quite know how they're going to coordinate until they're released at the end of September. But in most cases, we have seen them coordinate between both the managed Medicaid plan and the individual plan.

AMBER: Great. Thank you.

COREY DENKO: Yeah. Great question. Other questions.

BREANDA: Hello?

COREY DENKO: Hi.

BRENDA: Hi, my name is Brenda and I'm at Alhambra. I wanted to find out with this exchange program and the people coming off the

MediCal, would that allow them if they travel outside of the state, to be able to use their insurance?

COREY DENKO: Yeah, that's a great question. And so one point of clarification, so these plans will not be through the exchange. They will be -- so if you were, you know, to buy an insurance plan, you can go, for example, directly to Kaiser, and say, "Kaiser, I want to buy a plan through you." So this is not an exchange plan. It's just directly through the carrier, which is important to call out because exchange plans and Medicaid do not coordinate, where an individual plan through a carrier and Medicaid do. So I just wanted to put that point of clarification, just so there's no confusion.

And then, Brenda, in terms of travel benefits, yes. So this would give a patient, you know, even with DaVita, if they want to travel out of state, they could do so. And if you know DaVita's policy, I mean, we -- if a patient has Medicaid secondary or Medicaid at all, we cannot collect on those if they decide to travel. So they would be able to travel without being billed, you know, without unexpected costs based

on what their MediCal will cover.

BRENDA: Thank you.

COREY DENKO: And as a reminder, *6 will unmute your line.

KIM: So this is Kim from Kim & Park. So is this pertaining to patients that are straight MediCal, or is it pertain to Medicare/MediCal patients?

COREY DENKO: Yeah. So this will be any patient who has any Medicaid or MediCal product in the primary position. So any patient who has Medicare are not going to qualify for this because Medicare and individual plans do not coordinate. So this only our patient population that either has MediCal, straight MediCal or a managed Medicaid plan in the primary position.

KIM: And this would be for undocumented, as well?

COREY DENKO: Yeah.

KIM: So like emergency plans?

COREY DENKO: Right.

KIM: Okay. Thank you.

COREY DENKO: Yeah. For any additional questions, *6 will unmute your line.

BRENDA: Hi.

COREY DENKO: Hi.

BRENDA: This is Brenda again.

COREY DENKO: Hi, Brenda.

BRENDA: So people who are undocumented, I know at the beginning of the year, there was some kind of change to give them through (indiscernible), additional services. So people who are undocumented can still get the benefits of this program? And if so, will -- how will they pay for it? Will it just automatically come out of their allotment?

COREY DENKO: Yeah. So a few comments on that one. So yes, undocumented patients can be eligible for this. What we've found is the American Kidney Fund does not require a social security number for patients to get premium assistance. And second of all, we're currently in the process of identifying which payors do not require patients to have a social security number to have an individual plan. We do know that there's a few to date. But as I mentioned, we won't know until October what plans will be available to our patients. But we do know that, historically, there have been a lot of payors who allow undocumented patients to get on to

individual plans. But Brenda, their premiums would be paid for through the American Kidney Fund and then those carriers would allow them to get onto those plans.

BRENDA: Oh, great.

COREY DENKO: Yeah. Any other questions? Once again, *6 will help you unmute.

ROBIN: Corey, this is Robin. I just want to do a clarification for Amber's question regarding managed care, Medicaid, MediCal. Under the (sound drop) California, regardless if it fall -- where the MediCal plan falls, it still needs to be managed care so they cannot disenroll and have straight MediCal. And I'm hoping that clarifies for Amber.

COREY DENKO: Thanks, Robin.

AMBER: Thank you, Robin.

ROBIN: You're welcome.

COREY DENKO: All right.

SETH MILLER: Hey, Corey and everybody. This is Seth Miller. I am sorry I'm joining so late. I apologize. So I just want to let you know I'm on and happy to answer any questions or provide any feedback.

COREY DENKO: Yeah. So I just think as

we're closing in on the last three minutes, I'll walk through the next steps. But Seth, if you wouldn't mind just providing a little bit more detail around, you know, how we're thinking about this in terms of partnership between operations and IMT and how we want to make sure that, you know, we have a strong collaborative effort going into these next few months.

SETH MILLER: Okay. Thanks, Corey. And it sounds like there's quite a few people on the phone. So thank you very much for taking time and joining this call. I hope you can feel the importance of this opportunity. There are sometimes few opportunities where it's a true win/win situation. And this is one of those that we get to participate in. And we believe that it's a true win for those patients who it applies to and who want to pursue this route. And it's a really great opportunity for us to really make an impact on their lives. So thank you for your interest.

It is important that we understand how to partner. We know that there is some additional work that's going to go into this. And there's a lot of ways that we can go about

doing that, and we are still considering different ways. But one of the things that we will not do is not complete this work and not get it done to the best of our ability. So we appreciate your support. Caroline, as probably has been mentioned, is the lead on this. And so if you have additional questions, please direct them to her and/or to me, or your local insurance counselor and we will, you know, we will work together, and we're really excited just to be a part of this.

We have the biggest opportunity in all of Polaris. And so anyway. This is a huge opportunity for us to make a difference and to really come out ahead and make a big impact on the village. So if you're, you know, if you have any direct questions for me, I'm happy to respond to those, as well.

COREY DENKO: Great. Thanks, Seth. And so yeah, just to reiterate at this point, this is going to be a huge opportunity for all of us to be working together. And so we really want to make sure it's resourced well and that everyone has the necessary support. So as Seth just called out, please reach out to Caroline or

myself or your local insurance counselor if you have questions or issues. We want to make sure everyone has the necessary support.

Before we drop, I just want to reiterate what our next steps will be so you know what to expect. Once again, for those social workers who will be impacted by this in terms of having interest conversations with patients, you can expect a call on your calendar from Robin early next week so we can make sure you have access to those training materials.

On Friday, you will also receive some materials around the AKF application process. Once again, so that you have all the details you need around that. And then, hopefully by late next week -- excuse me -- after those interest conversation trainings have taken place, then we can work very closely between the social workers and ICs and start to have those interest conversations with the patients.

Once again, this Webex was recorded and so we'll send out recaps, we'll send out the materials, so if you have any questions, please reach out to Caroline, Seth, or myself, and we'll definitely make sure that we get those addressed

quickly. Well, thank you everyone for your time today. And really appreciate your partnership and hope you have a wonderful day.

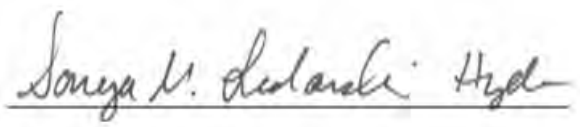
SETH MILLER: Thanks, Corey, Robin.

COREY DENKO: Thank you.

C E R T I F I C A T I O N

I, Sonya Ledanski Hyde, certify that the foregoing transcript is a true and accurate record of the proceedings.

Date: February 16, 2022



Sonya Ledanski Hyde

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EXHIBIT 6

Expert Report of Randolph Wayne Pate, JD, MPH, dated December 17, 2021

Expert Report of Randolph Wayne Pate
December 17, 2021

Introduction/Summary of Opinions

1. Premium assistance programs can generate significant financial benefits for health care providers. This is especially true to the extent premium assistance can facilitate enrollment into coverage based on the typically higher reimbursement rates for providers offered by commercial health insurers when compared with public programs such as Medicare.

2. The existence of this financial incentive can result in inappropriate steering of dialysis patients into individual market health insurance coverage based on the financial interests of the health care provider rather than the best interests of the patient.

3. While serving as Director of the Center for Insurance Information and Insurance Oversight (CCIIO) in the federal Centers for Medicare & Medicaid Services (CMS), I was made aware of substantial evidence of the significant financial incentives of dialysis providers to steer individuals to private coverage rather than public programs for which they may be eligible.

4. While there are multiple ways to address inappropriate steering and to ensure patients are able to make the coverage selection that best meet their needs, AB 290 is designed to mitigate the existence of this financial incentive by limiting the reimbursement that providers can receive when premium assistance is used to support private coverage enrollment.

5. The Patient Protection and Affordable Care Act was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010 (together, these two statutes are referred to herein as the ACA).

6. Before the guaranteed issue, modified community rating, and single risk pool provisions of the ACA were implemented, dialysis facilities had little incentive to steer patients toward individual health insurance coverage or pay their premiums via third-party premium assistance.

7. However, after the main ACA provisions took effect in 2014, end-stage renal disease (ESRD) patients could no longer be charged higher premiums or denied coverage due to their pre-existing health conditions. Guaranteed issue and modified community rating—the latter of which requires issuers to spread the cost of covering expensive conditions like ESRD across both healthy and sick enrollees in the individual market—in effect created a financial incentive for dialysis facilities to leverage higher reimbursement rates available through private coverage when compared with Medicare by providing premium assistance to ESRD patients and inappropriately steering them to purchase coverage in the individual market (whether subsidized or unsubsidized).

8. Medicare provides health care coverage to qualifying individuals diagnosed with ESRD,

regardless of age, including coverage for kidney transplantation, maintenance dialysis, and other health care needs. The ESRD benefit was established by the Social Security Amendments of 1972. This benefit is not a separate program, but allows qualifying individuals of any age who have ESRD to become Medicare beneficiaries and receive coverage.

9. Under previous law, individuals under 65 who are entitled to Medicare through the ESRD program, or individuals over age 65 who are diagnosed with ESRD while in original Medicare, generally could not enroll in Medicare Advantage (MA) except in limited circumstances.[1] Beginning in 2021, section 1851 of the Act (42 U.S.C. 1320a–7a), as amended by section 17006 of the CURES Act allows individuals with ESRD to enroll in MA plans without the limitations that formerly restricted such enrollment to beneficiaries with ESRD who meet other criteria. Additionally, federal law provides individuals access to Medicare supplement (Medigap) policies on a guaranteed issue basis in certain circumstances.[2] Many states provide additional Medigap guaranteed issue rights, including for beneficiaries with ESRD under the age of 65.

10. In addition to Medicare, Medicaid provides coverage for some individuals with ESRD. Many individuals enrolled in Medicare may also qualify for benefits under the Medicaid program on the basis of their income, receipt of Supplemental Security Income, being determined medically needy, or other eligibility categories, although the eligibility rules and the benefits covered may vary by state. Individuals who are enrolled in both Medicare and Medicaid are often referred to as "duals" or "dual enrollees." Low-income individuals enrolled in Medicare may qualify for the Medicare Savings Program under which Medicaid covers some or all of the individual's Medicare premiums and, for some individuals, Medicare cost-sharing. Finally, some individuals who are not eligible for enrollment in Medicare may qualify for Medicaid coverage. Medicaid eligibility requirements and covered services vary by state.

11. Nothing in AB 290 conflicts with Advisory Opinion 97-1 issued by the Office of the Inspector General of the U.S. Department of Health and Human Services regarding the application of a specific statutory provision in Medicare and Medicaid to premium assistance programs operating with funding from dialysis facilities ("Advisory Opinion 97-1"). Claims to the contrary reflect significant misunderstandings about the nature of private coverage under the Affordable Care Act and the relationship between private and public coverage for patients with ESRD.

12. First, Advisory Opinion 97-1, like the anti-kickback and beneficiary inducement statute, is limited to federal health care programs. HHS has determined that Qualified Health Plans

[1] As a coverage alternative to traditional Medicare, beneficiaries have the option to enroll in Medicare Advantage (MA) plans. MA plans are operated by private health insurers that are paid by Medicare to provide services to beneficiaries. Under some MA plans, beneficiaries may receive additional benefits beyond those offered under traditional Medicare.

[2] Medigap policies are sold by private insurance companies to pay some of the health care costs that traditional Medicare does not cover, such as copayments, coinsurance, and deductibles.

(QHPs)[3] and other programs related to the Exchanges are not considered federal health care programs, and therefore, the federal anti-kickback statute does not apply.[4] Thus, Advisory Opinion 97-1, unlike AB 290, simply does not address or pertain to the Exchanges or the individual health insurance market.

13. Second, based on my understanding of the facts of this case and evidence of which I was previously made aware of as Director of CCIIO, Advisory Opinion 97-1 does not appear to apply to or protect the current AKF Health Insurance Premium Program (HIPP), which has expanded far beyond the agreement addressed by Advisory Opinion 97-1 to include payment of premiums for commercial coverage.

14. Furthermore, even if Advisory Opinion 97-1's safe harbor applied, AKF and the dialysis providers contributing to it have not adhered to some of the safeguards set forth in the opinion. For example, the AKF policy stating that AKF will be unable to assist patients if providers do not contribute their "fair share" (as documented in AKF's 2015 HIPP manual) is inconsistent with the safe harbor's prohibition against eligibility determinations made with regard to the identity of a referring provider or the amount of donations made by the referring provider.

Curriculum Vitae Summary

15. I am a health care executive and policy expert with experience in the health sector in both public and private roles.

16. I am currently employed as an independent consultant serving clients in the health care sector. I have been engaged by the State of California to serve as an expert witness independent from my employment.

17. I am being compensated for my time at an hourly rate of $450 per hour in developing this report and for my time spent in depositions and other proceedings related to the litigation; I spent approximately 40 hours in researching and writing this declaration. I will also be reimbursed for travel or other expenses incurred. Compensation and reimbursement for expenses is not contingent on the outcome of this litigation.

18. In my most recent government role, I served as Deputy Administrator of the Centers for Medicare & Medicaid Services (CMS) and Director of the Center for Insurance Information and Insurance Oversight (CCIIO). In that capacity, I was charged with overseeing implementation of the ACA provisions related to the individual and small group health

[3] Qualified Health Plans (QHPs) are insurance plans that are certified by federal or state health insurance marketplaces, provide essential health benefits, follow established limits on cost sharing, and meets other requirements under the Affordable Care Act.

[4] See Letter from HHS Secretary Kathleen Sebelius to The Honorable Jim McDermott, U.S. House of Representatives (October 30, 2013) https://www.hlregulation.com/files/2013/10/The-Honorable-Jim-McDermott.pdf.

insurance markets, as well as operation of the Federally Facilitated Exchange and oversight of the State-Based Exchanges around the country.

19. One of my responsibilities at CCIIO was to lead the agency's policy making agenda. I led the development of many regulations, guidance documents, and other policymaking vehicles, including a wide variety of rules related to the availability of financial assistance for low- and moderate-income health insurance consumers and policies relating to health insurance companies to ensure affordability, choice, and competition in the market.

20. Earlier in my career, I served in a number of roles on Capitol Hill, including Public Health Counsel for the House Energy and Commerce Committee and later as Health Counsel for Rep. Kevin Brady during the debate over passage of the Affordable Care Act; I also worked at the Heritage Foundation, a non-partisan public policy think tank in Washington, DC, as a Health Policy Fellow where my research focused on medical liability reform, and served as a Senior Advisor at the Department of Health and Human Services in the Office of the Assistant Secretary for Planning and Evaluation, where I advised on a range of federal health care policy issues.

21. From 2009-2011, I worked at the MITRE Corporation, a federally funded research and development center, where I participated in the development of the Medicare End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP).

22. A copy of my Curriculum Vitae, which includes a full list of publications, appears as Appendix A.

23. This report reflects my expert opinions based on my experience. In preparing this report, in addition to the documents cited herein, I reviewed the reports of plaintiffs' experts Laurence Freedman and Kevin McAnaney, the expert reports of John Bertko and Amy Waterman, and the certain briefings filed to date in this litigation.

Factual Background

Health Insurance Marketplace in 1997

24. The Patient Protection and Affordable Care Act was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010 (together, these two statutes are referred to as the ACA).

25. 45 CFR 147.104, the federal regulation implementing the ACA's guaranteed availability of coverage (also known as "guaranteed issue") requirement in the individual and group market, requires that a health insurance issuer that offers health insurance coverage in the individual, small group, or large group market in a state must offer to any individual or employer in the state all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products. Prior to the implementation of this provision, ESRD patients would typically be denied coverage or charged higher

premiums for individual coverage.

26. Under §147.102 (a), the federal regulation implementing the ACA's modified community rating requirement, there are a limited number of factors that can influence the rating including tobacco use and age.

27. Under 45 CFR 156.80, the federal regulation implementing the ACA's single risk pool requirement, a health insurance issuer must consider the claims experience of all enrollees in all health plans subject to section 2701 of the Public Health Service Act and offered by such issuer in the individual market in a state (including those enrollees who do not enroll in such plans through the Exchange) to be members of a single risk pool.

28. Before implementation of the main provisions of the ACA above related to guaranteed issue, modified community rating, and the single risk pool, dialysis facilities had little incentive to steer patients toward individual health insurance coverage or pay their premiums via third-party premium assistance.

29. This was in part because ESRD patients, like others with pre-existing conditions, could be charged higher premiums or denied enrollment in the individual market based on the actuarial risk associated with their condition. However, after the main ACA provisions took effect in 2014, patients could no longer be charged higher premiums or denied coverage due to their pre-existing health conditions. Guaranteed issue and modified community rating—the latter of which requires issuers to spread the cost of covering expensive conditions like ESRD across both healthy and sick enrollees in the individual market—in effect created a financial incentive for dialysis facilities to leverage higher reimbursement rates available through private coverage when compared with Medicare by providing premium assistance to ESRD patients and inappropriately steering them to purchase coverage in the individual market (whether subsidized or unsubsidized).[5]

Office of Inspector General Advisory Opinion 97-1

30. An Office of Inspector General (OIG) advisory opinion is a legal opinion issued by OIG to one or more requesting parties about the application of the OIG's fraud and abuse authorities to the party's existing or proposed business arrangement. An OIG advisory opinion is legally

[5] There are federal government programs, and other coverage, such as continuation coverage under the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1986, that are required to accept payment from third parties. However, an issuer in the individual market generally has some flexibility to reject third party payments, as long as payments are rejected based on fair, nondiscriminatory business rules or policies applied consistently across similarly situated enrollees, and those rules or policies are otherwise consistent with applicable federal or state law. Issuers that adopt fair, nondiscriminatory policies that otherwise comply with applicable state and federal law under which they reject third party payments, may return such rejected payments if the issuer determines the payment was made by a third-party organization in violation of its third-party payment policy. The issuer can then bill the patient for any unpaid premiums. If the patient cannot pay any amounts owed resulting from rejected or returned payments, the issuer may terminate the enrollee's coverage, consistent with regulations at 45 CFR 147.106 and, for QHPs, 45 CFR 156.270.

binding on the Department of Health & Human Services and the requesting party or parties. It is not binding on any other governmental department or agency. A party that receives a favorable advisory opinion is protected from OIG administrative sanctions, so long as the arrangement at issue is conducted in accordance with the facts submitted to the OIG. However, no person or entity can rely on an advisory opinion issued to someone else.

31. Dialysis providers seeking to support premium assistance for dialysis patients (including plaintiffs DaVita and Fresenius) and plaintiff American Kidney Fund, a 501(c)(3) that runs a program called Health Insurance Premium Program (HIPP), sought and obtained an advisory opinion on the applicability of the beneficiary inducement statute to HIPP. In Advisory Opinion 97-1, the HHS Office of the Inspector General (OIG) concluded that support of HIPP, as described to OIG by the dialysis providers seeking the advisory opinion, would not constitute grounds to impose a penalty for violating the beneficiary inducement statute.[6]

32. The primary basis for OIG's conclusion was that the program was "not likely to influence a beneficiary's selection of a particular provider." OIG explained that remuneration would be prohibited under the statute "only if the payments are likely to influence such beneficiaries to use a particular provider," and that the program was not problematic in that respect because "once in possession of [insurance] coverage, a beneficiary will be able to select any provider of his or her choice."[7]

33. Advisory Opinion 97-1 only considered the beneficiary inducement statute. The OIG was not called upon and did not express an opinion on the general propriety of the financial arrangement between dialysis providers, AKF's HIPP, and beneficiaries, or whether this arrangement violated other statutes.[8]

34. The scope of Advisory Opinion 97-1 is limited to the anti-kickback and beneficiary inducement statute. These statutes, in turn, are only applicable to "federal health care programs" as defined in section 1128B(f) of the Social Security Act. "Federal health care programs" include Medicare and Medicaid. However, HHS has determined that QHPs and

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[6] Office of the Inspector General, Advisory Opinion No. 97-1, https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf.

[7] *Id*.

[8] Historically, there has been little concern about ESRD patients receiving unnecessary or excess dialysis services because the clinical nature of ESRD requires frequent, specific, and ongoing treatment. However, recent evidence may call that assumption into question. A 2019 analysis of trends in dialysis care finds that when an independent dialysis provider is acquired by a large chain, they change their patterns of care in ways that increase their reimbursement, including by prescribing high-cost drugs (for which the facility is paid a percentage of the total costs) at statistically significantly higher rates than prior to their acquisition by the chain. *See* Paul J Eliason *et al.*, "How Acquisitions Affect Firm Behavior and Performance: Evidence from the Dialysis Industry," 135 QUARTERLY JOURNAL OF ECONOMICS230(February2020),https://academic.oup.com/qje/articleabstract/135/1/221/5607794?redirectedFrom=fulltext.

other programs related to the Exchanges are not "federal health care programs." [9] Therefore, Advisory Opinion 97-1 does not apply to the Exchanges or the individual health insurance market.

35. Nothing in AB 290 conflicts with Advisory Opinion 97-1, which addresses the application of a specific statutory provision in Medicare and Medicaid to premium assistance programs operating with funding from dialysis facilities. Claims to the contrary reflect significant misunderstandings about the nature of private coverage under the Affordable Care Act and the relationship between private and public coverage for patients with ESRD.

Health Insurance Marketplace in 2021

Premium Assistance and the Potential for Inappropriate Benefits

36. Despite the system of public and private subsidies for health insurance, some people may still find health insurance premiums prohibitively expensive, including people who do not qualify for the ACA's advance premium tax credits or cost-sharing reductions. In these and other instances, charitable premium assistance programs can help to pay the remaining premium after the applicable subsidy, or pay the full premium for those who do not qualify for or receive other subsidies.

37. Some charitable premium assistance programs are operated by governmental entities to provide additional support to particular vulnerable populations. For example, the Ryan White program is a federally funded program that supports health care costs (including premium assistance) for individuals with HIV,[10] and Indian tribes may pay health insurance premiums on behalf of their members.[11]

38. In fact, federal regulations at 45 CFR 156.1250 require that issuers offering individual health insurance coverage, including stand-alone dental plans, and the issuers' downstream entities, accept premium payments made on behalf of QHP enrollees from the following third party entities (in the case of a downstream entity, to the extent the entity routinely collects premiums or cost sharing): 1) a Ryan White HIV/AIDS Program under title XXVI of the PHS Act; 2) an Indian tribe, tribal organization, or urban Indian organization; and 3) a local, state, or federal government program, including a grantee directed by a government program to make payments on its behalf. However, CMS has emphasized that § 156.1250 does not

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[9] See Letter from HHS Secretary Kathleen Sebelius to The Honorable Jim McDermott, U.S. House of Representatives (October 30, 2013) https://www.hlregulation.com/files/2013/10/The-Honorable-Jim-McDermott.pdf.

[10] Health Resources and Services Administration, "About the Ryan White HIV/AIDS Program," https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program (last visited January 10, 2021).

[11] *See* "Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums," 79 Fed. Reg. 15240 (March 19, 2014), *available at* https://www.federalregister.gov/documents/2014/03/19/2014-06031/patient-protection-and-affordable-care-act-third-party-payment-of-qualified-health-plan-premiums.

prevent issuers from contractually prohibiting other third-party payments. CMS has also reiterated that it discourages premium payments and cost-sharing assistance by certain other entities, including hospitals and other health care providers, and discourages issuers from accepting premium payments from such providers.

39. Health care providers can also be involved in the operation and financing of premium assistance, whether by providing premium assistance directly or making financial contributions to other entities that provide such assistance. Health care providers have close relationships with patients, putting them in a position to identify those in need. However, health care providers also have a financial interest in whether, and how, their patients get health insurance coverage. This financial interest could have a significant effect on how and for whom health care providers make assistance available. Offering "charitable" premium assistance (directly or by supporting another entity) can generate a direct financial benefit to the health care provider that makes premium assistance available. This being the case, offering premium assistance is, to some extent, a business strategy rather than a form of charity.

40. There are at least three different ways that premium assistance (provided directly or indirectly) can generate financial benefits for a health care provider:

- First, premium assistance can influence which provider a patient chooses to see. If patients have a choice of multiple surgeons for a procedure, but one surgeon is offering her patients assistance for premium payment, then a patient might select that surgeon, generating revenue for her and her practice.

- Second, premium assistance can result in the delivery of additional care. If a patient is induced to seek more care than they otherwise would once they obtain the coverage that is paid for with premium assistance, those additional services will also translate into additional revenue for health care providers.

- Third, premium assistance can affect the prices paid for health care services. Different health care payers reimburse providers at different rates, with private insurance generally paying higher rates than public programs. Therefore, influencing which type of coverage a patient has – such as by prompting a patient to change from public to private insurance coverage – is very likely to increase revenue for health care providers.

41. On August 23, 2016, CMS published in the Federal Register a Request for Information (RFI) "Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans" (81 FR 57554) (referred to herein as the August 2016 RFI). CMS received public comments from stakeholders in response to the August 2016 RFI suggesting that premium assistance programs for dialysis patients such as AKF's HIPP financially benefitted facilities, since individual health insurance market coverage reimbursement rates for dialysis treatments are often substantially

higher than Medicare and Medicaid payments, adding up to a difference of $100,000 to $200,000 or more per patient per year.

42. Similarly, the Medicare Payment Advisory Commission (MedPAC) stated in its 2019 Report to the Congress on Medicare Payment Policy that dialysis facilities reported that fee-for-service (FFS) Medicare payment rates are significantly lower than commercial rates.[12] For example, USRDS data show that for individuals with ESRD enrolled in Medicare receiving dialysis, health care spending averaged $93,064 per individual in 2015,[13] including dialysis and non-dialysis services. By contrast, using the Truven MarketScan database, a widely-used database of health care claims, CMS estimated that average total spending for individuals with ESRD who are enrolled in commercial coverage was $187,000 in 2014. In addition, in a lawsuit filed in federal court by one insurance company, it was alleged that commercial coverage pays more than ten times more per treatment than public coverage ($4,000 per treatment rather than $300 per treatment), which illustrates the potential for significant financial benefit to a facility.[14] This shows that a clear financial incentive for dialysis facilities to steer patients toward private coverage exists. Of course, this same incentive did not exist over two decades ago when Advisory Opinion 97-1 was issued.

43. The Medicare and Medicaid programs have long been concerned with the potential for providers to obtain inappropriate financial benefits by delivering care to Medicare and Medicaid beneficiaries, and Congress has enacted a series of statutes intended to prevent certain types of financially-interested activities pertaining to Medicare and Medicaid beneficiaries that may financially benefit health care providers. These statutes include the Anti-Kickback Statute,[15] the Physician Self-Referral (or "Stark" Law),[16] and the beneficiary inducement statute.[17]

44. The referenced Medicare and Medicaid statutes are motivated by concerns about the first two kinds of financial benefits described above: influencing which provider a patient sees and influencing how much care is received. Medicare and Medicaid are not focused on the third type of financial benefit: benefits arising from providers manipulating the prices they are paid. This is because Medicare and Medicaid are administered pricing systems. Medicare and Medicaid providers are generally paid a fixed rate calculated based on provider and patient characteristics and the service delivered.[18] Therefore, there is little opportunity for providers

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[12] See Report to Congress on Medicare Payment Policy, page 171 http://medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0.

[13] https://www.usrds.org/reference.aspx

[14] Opinion and Order in the case of UNITEDHEALTHCARE OF FLORIDA, INC. and ALL SAVERS INSURANCE COMPANY vs. AMERICAN RENAL ASSOCIATES HOLDINGS, INC., et al., UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA CASE NO. 16-81180-CIV-MARRA/MATTHEWMAN page 3. https://www.govinfo.gov/content/pkg/USCOURTS-flsd-9_16-cv-81180/pdf/USCOURTS-flsd-9_16-cv-81180-0.pdf.

[15] 42 U.S.C. § 1320a-7b(b).

[16] 42 U.S.C. § 1395nn.

[17] 42 U.S.C. § 1320a-7a(a)(5).

[18] At the time these statutes were enacted, most Medicare and Medicaid beneficiaries were covered in a fee-for

to use financial relationships with beneficiaries or other entities to influence the prices they are paid by Medicare or Medicaid.

45. The federal beneficiary inducement statute[19] is of particular relevance here because it is the statute addressed in Advisory Opinion 97-1. That statute prohibits health care providers from offering any remuneration to patients to induce them to select a particular provider to deliver Medicare or Medicaid services. Premium assistance payments or transfers to entities that provide premium assistance may be considered remuneration that is prohibited or limited by the statute if the remuneration is provided to induce a patient(s) to select a particular provider to deliver Medicare or Medicaid services.

The Affordable Care Act and Premium Assistance

46. Because private health insurance generally pays substantially higher prices to providers than public programs, if a patient enrolls in private coverage rather than public coverage, that patient's providers will receive more revenue for delivering the same set of services. Therefore, it will generally be in a health care provider's financial interest for patients to obtain private rather than public coverage if possible.

47. Before enactment of the Affordable Care Act, opportunities for private dialysis patients to enroll in private health insurance were limited. Insurance companies in the individual market could deny coverage for people with pre-existing conditions or exclude their specific preexisting illness from coverage, so sicker individuals who needed extensive care could not usually be enrolled into individual market coverage.[20]

48. The passage of the ACA created a major new opportunity for premium assistance to generate financial benefits for providers. Specifically, the ACA made it possible for people with significant health care needs to enroll in private health insurance despite their pre-existing

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service system, with the government paying providers according to a series of fee schedules. Today, some Medicare and Medicaid beneficiaries are covered through managed care arrangements, either in Medicare Advantage or through Medicaid managed care organizations. In a managed care arrangement, the government pays a managed care entity (i.e. insurance company) and that entity pays health care providers. Even so, Medicare and Medicaid managed care contracts pay providers prices very similar to the fee-for-services rates established under the government fee schedule. *See, e.g.,* Jared Lane K. Maeda and Lyle Nelson, "How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare With Medicare Fee-for-Service Prices?," 55 INQUIRY (January 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6050995; Daria M. Pelech, "Prices for Physicians' Services in Medicare Advantage and Commercial Plans," MEDICAL CARE AND RESEARCH REVIEW, June 25, 2018, https://journals.sagepub.com/doi/abs/10.1177/1077558718780604; Elizabeth Hinton *et al.*, "10 Things to Know about Medicaid Managed Care," *Kaiser Family Foundation*, October 29, 2020, https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-managed-care. As a result, the introduction of managed care into these programs did not introduce a meaningful wedge in the prices providers are paid, and providers cannot generally use premium assistance to manipulate their reimbursement within Medicare or within Medicaid. *Id.*

[19] 42 U.S.C. § 1320a-7a(a)(5).

[20] However, since the mid-1990s, employer health insurance plans have been prohibited from discriminating based on preexisting conditions, 29 U.S.C. § 1182, so employer plans cannot reject enrollees with ESRD. This means dialysis facilities can potentially benefit financially by persuading unenrolled employees to enroll in employer coverage rather than public coverage.

conditions. As a result, there is now an option for providers to pay (or facilitate payment of) individual market health insurance premiums for patients under their care who might otherwise enroll in public coverage, and thereby generate increased revenue for the provider.

49. The federal government expressed concern about this behavior in a 2016 Request for Information.[21] As the government noted at the time, "there is potential for financial harm to a consumer when a health care provider or provider-affiliated organization (including a non-profit organization affiliated with the provider) steers people who could receive or are receiving benefits under Medicare and/or Medicaid to enroll in an individual market plan. The potential harm is particularly acute when the steering occurs for the financial gain of the health care provider through higher payment rates without taking into account the needs of these beneficiaries."[22]

50. In response to this request, the federal government received reports about potentially problematic behavior by dialysis facilities, including through their participation in AKF's HIPP. Because dialysis facilities have ongoing relationships with patients, they have a relatively long-term stake in the reimbursement rates associated with each individual under their care. Further, the payment disparity between Medicare and private insurance appears to be particularly large in the dialysis context, with several commenters suggesting private payment rates are four or even ten times higher than Medicare rates.[23] Commenters, including a number of social workers working in dialysis facilities, also provided detailed accounts of being directed to move patients into private coverage rather than public coverage, of having their compensation linked to success in facilitating private coverage enrollment, and of feeling that their ethical obligations to patients were compromised by their employers' attempt to encourage enrollment in private coverage.[24] Other commenters, including beneficiaries of HIPP, expressed support for premium assistance programs.

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[21] The federal government also expressed concerns about this practice in 2013. *See* Centers for Medicare & Medicaid Services, "Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces," November 4, 2013, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf ("It has been suggested that hospitals, other healthcare providers, and other commercial entities may be considering supporting premium payments and cost-sharing obligations with respect to qualified health plans purchased by patients in the Marketplaces. HHS has significant concerns with this practice because it could skew the insurance risk pool and create an unlevel field in the Marketplaces. HHS discourages this practice and encourages issuers to reject such third-party payments. HHS intends to monitor this practice and to take appropriate action, if necessary."). Further, a third-party payment has been under review at OMB since June 2019. *See* Office of Information and Regulatory Affairs, "Pending EO 12866 Regulatory Review, RIN 0938-AT11," https://www.reginfo.gov/public/do/eoDetails?rrid=129188 (last visited January 10, 2021).

[22] "Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans," 81 Fed. Reg. 57554 (August 23, 2016), https://www.federalregister.gov/documents/2016/08/23/2016-20034/request-for-information-inappropriate steering-of-individuals-eligible-for-or-receiving-medicare-and.

[23] "Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment, 81 Fed. Reg. 90211, 90214 (December 14, 2016), *available at* https://www.federalregister.gov/documents/2016/12/14/2016-30016/medicare-program-conditions-for coverage-for-end-stage-renal-disease-facilities-third-party-payment.

[24] *Id.*

51. Based on this feedback, the federal government promulgated an interim final regulation attempting to limit this behavior,[25] although the regulation was subsequently enjoined by a Texas District Court that found procedural deficiencies in the agency's rulemaking process.[26]

52. Commenters on the federal interim final rule repeated the same concerns that surfaced in response to the request for information. This included a group of "concerned dialysis workers" employed in California by DaVita Kidney Care,[27] who provided a detailed account of their employer's "Medicaid to Exchanges" initiative and the pressure that was placed on enrollees to switch to private coverage. Many other commenters, including HIPP recipients, expressed concerns about the impact of the interim final rule on their coverage.

53. AKF receives contributions, primarily from dialysis facilities,[28] and uses that funding to pay premiums for health insurance coverage for ESRD patients (or reimburse patients for premiums they have paid, which is economically equivalent). AKF may pay premiums for many different types of coverage.

54. As discussed above, since Exchanges are not considered federal health care programs, Advisory Opinion 97-1 did not provide a safe harbor for AKF's payment of premiums for individual market coverage. The same is also true for any AKF payments for employer-sponsored coverage, which is also not considered a federal health care program.

55. In general, individuals with ESRD can be enrolled in public coverage (Medicare and Medicaid) or private coverage (employer coverage, also called a group health plan), or individual market coverage. People can also be enrolled in some combination of these types of coverage. AKF may pay premiums for Medicare (where there are multiple different types of premiums), employer, or individual market coverage.

56. Table 1 illustrates the types of coverage people with ESRD may be enrolled in, the types of premiums charged for the coverage, and the premiums that HIPP may pay. Panel A considers scenarios where an individual is enrolled in only one type of coverage; Panel B considers scenarios where an individual is enrolled in multiple forms of coverage.

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[25] *Id.*

[26] *Dialysis Patient Citizens v. Burwell*, 2017 WL 365271 (E.D. Tex. 2017).

[27] Comment of Concerned Dialysis Workers Re: Medicare Program: Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment, https://www.regulations.gov/document?D=CMS-2016-0185-0222 (last visited January 10, 2021).

[28] *See, e.g.,* Office of the Inspector General, Advisory Opinion No. 97-1, https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf ("Additional funding will be donated primarily by the Companies.").

Table 1: Coverage Forms and Premium Payment

Panel A: People Enrolled in Only One Type of Coverage		
Form of Coverage	**Description**	**Premiums[29]**
Public: Medicare	Historically, most ESRD patients could be enrolled in "traditional Medicare." Traditional Medicare consists of Part A (hospitals), which is mandatory and has no premium, and Parts B (doctors) and D (prescription drugs), which are optional and do require premiums. Some people enrolled in traditional Medicare may also chose a supplemental Medigap plan to reduce their cost-sharing and/or a prescription drug plan. As of 2021, all Medicare-eligible individuals with ESRD may choose to enroll in traditional Medicare or in Medicare Advantage plans, which provide the same benefits as traditional Medicare. Enrollment into Medigap plans is limited for ESRD Medicare beneficiaries, and only some will qualify.[30]	There are three types of Medicare premiums that HIPP may pay: • Part B premiums for traditional Medicare. • Medigap premiums for supplemental coverage. • Medicare Advantage premiums. All Medicare enrollees owe the Part B premium and may owe an additional Medigap or Medicare Advantage premium, but usually not both. Individuals may also owe Part D premiums for Medicare drug benefits, but HIPP does not pay those premiums.[31]
Public: Medicaid	Very low income ESRD patients who do not qualify for Medicare may be enrolled in Medicaid.	No premiums are owed in California.[32]
Private: Employer	Some ESRD patients can enroll in coverage through their own employer, a former employer (called COBRA), or a spouse or parent's employer.	HIPP may pay premiums for employer coverage.

[29] *See also* Declaration of LaVarne Burton paragraph 27 (describing the forms and amounts of premium assistance HIPP provides in California).

[30] Unlike most other forms of health insurance, traditional Medicare does not include an out-of-pocket limit on total enrollee cost-sharing. For Medicare beneficiaries not eligible for Medicaid, traditional Medicare paired with a Medigap plan, or Medicare Advantage plans, can enable them to obtain the protection of an out-of-pocket limit, which is especially valuable for those with serious illnesses. States may decide whether those eligible for Medicare on the basis of ESRD can purchase Medigap plans, and California does not allow those sales. Prior to 2021, federal law prohibited ESRD enrollees from electing Medicare Advantage plans as well. However, Congress has lifted the prohibition on enrollment in Medicare Advantage by ESRD enrollees, effective in 2021. Therefore, as of 2021, in all states all ESRD Medicare beneficiaries can obtain coverage with an out-of-pocket maximum in Medicare. CMS estimates that 83,000 ESRD additional enrollees nationwide will enroll in Medicare Advantage by 2026, with half of that group enrolling in the first year. *See* "Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program," 85 Fed. Reg. 33796 (August 3, 2020), *available at* https://www.federalregister.gov/documents/2020/06/02/2020- 11342/medicare-program-contract-year-2021-policy-and-technical-changes-to-the-medicare-advantage-program.

[31] *See* American Kidney Fund, "Health Insurance Premium Program Guidelines," January 2, 2020, https://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-guidelines.pdf ("HIPP grants may not be used to cover stand-alone prescription drug plans, including Medicare Part D plans.").

[32] Some states have nominal Medicaid premiums. *See, e.g.,* Kaiser Family Foundation, "Premium and Cost-Sharing Requirements for Selected Services for Medicaid Adults," https://www.kff.org/health-reform/state indicator/premium-and-cost-sharing-requirements-for-selected-services-for-medicaid-expansion-adults (last visited January 10, 2021).

Private: Individual market	Anyone not enrolled in Medicare can enroll in an individual market plan. This includes enrolling through the Exchange (i.e., Marketplace or Covered California), or directly from an insurance company.	HIPP may pay premiums for individual market coverage. Individuals who do not qualify for other forms of coverage may qualify for federal premium subsidies that cover a portion of their premium if they enroll in Exchange coverage. It appears HIPP would cover the remaining premium, after the federal subsidy.

Panel B: People Enrolled in Multiple Forms of Coverage		
Forms of Coverage	**Description**	**Premiums**
Medicare and Medicaid (dual eligible)	Low-income people enrolled in Medicare can also be enrolled in Medicaid. Medicaid will cover their Medicare premiums and, depending on their income, some or all of their cost-sharing.[33]	No premiums are owed; Medicaid will cover the Medicare premium.
Medicare and employer	People with ESRD may be enrolled in both Medicare coverage and employer coverage. In general, the employer plan will be "primary" for 30 months, then Medicare will become primary. This will typically result in lower cost-sharing (e.g., deductibles, coinsurance and copays) for the patient compared to enrolling only in employer coverage.	The individual will owe a premium for the employer plan and some combination of Medicare premiums as noted above. HIPP may pay any of those premiums.
Medicare and individual market	It is unlawful for an individual market insurance company to knowingly enroll a Medicare beneficiary into their plan.	N/A, enrollment is unlawful.
Medicaid and private coverage (employer or individual market)	An individual could choose to enroll in Medicaid and a form of employer coverage or individual market coverage, though it will generally not be beneficial to do so compared to enrolling only in Medicaid. The private coverage will be primary, and Medicaid secondary.	No premium is owed for Medicaid. The individual will owe a premium for the private employer or individual market coverage and will not qualify for federal premium subsidies in the individual market. HIPP may pay the private coverage premium.

[33] *See, e.g.,* Centers for Medicare & Medicaid Services, "Medicare Savings Program," https://www.medicare.gov/your-medicare-costs/get-help-paying-costs/medicare-savings-programs (last visited January 10, 2021).

57. Table 2 indicates average monthly premium amounts for each of these types of coverage.

Table 2: Average Month Premium for Various Coverage Forms

Coverage Type	National Average Monthly Premium Amount (Year)
Medicare	
Part B	$149 (2021)[34]
Medigap	$143 (2018)[35]
Part D	$33 (2021)[36]
Medicare Advantage	$21 (2021)[37]
Employer	
Current employer	$174 (2019)[38]
Former employer/COBRA	$610 (2019)[39]
Individual market	

[34] Centers for Medicare & Medicaid Services, "2021 Medicare Parts A & B Premiums and Deductibles," November 6, 2020, https://www.cms.gov/newsroom/fact-sheets/2021-medicare-parts-b-premiums-and-deductibles.

[35] Hillary Hoffower, "Medicare Isn't Enough for Retirees," *Business Insider*, June 17, 2018, https://www.businessinsider.com/how-much-medigap-plans-cost-every-state-ranked-2018-6.

[36] Centers for Medicare & Medicaid Services, "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information," July 29, 2020, https://www.cms.gov/files/document/july-29-2020-parts-c-d-announcement.pdf.

[37] Kaiser Family Foundation, "Medicare Advantage in 2021: Premiums, Cost Sharing, Out-of-Pocket Limits and Supplemental Benefits," June 21, 2021, https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2021-premiums-cost-sharing-out-of-pocket-limits-and-supplemental-benefits/.

[38] Gary Claxton *et al.*, "Health Benefits In 2019: Premiums Inch Higher, Employers Respond To Federal Policy," 38 HEALTH AFFAIRS 290 (September 25, 2019), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2019.01026.

[39] *Id.* (reflecting 102% of the full premium amount).

Enrollment with federal subsidy	$92 (2021)[40]
Enrollment without federal subsidy	$512 (2021)[41]

Note: Averages reflect a variety of weighting and estimation methodologies and are intended to be illustrative. See sources for specific methodologies.

58. As illustrated in Panel B of Table 1, *supra*, it is possible for individuals to be enrolled in both Medicaid and private coverage. However, this is unlikely to provide any additional financial benefits to the individual, given that Medicaid coverage in general is likely to be at least as generous as private coverage and the individual's cost-sharing and benefits are likely to be the same whether they are dually enrolled in individual and Medicaid coverage or enrolled only in Medicaid. This arrangement may also expose the individual to significant financial risks, given that the individual will need to successfully coordinate multiple types of coverage and may be subject to higher cost-sharing in individual health insurance compared to Medicaid.

59. Patients eligible for Medicaid who enroll only in individual health insurance coverage are also exposed to substantial financial risk, depending on the level of coverage they choose. Many Medicaid enrollees face no cost-sharing or premiums at all, while enrollees in individual market coverage are subject to out-of-pocket costs of up to $8,700 for a bronze level plan in 2022. Therefore, enrolling in private coverage exposes these individuals to significant costs for both dialysis and non-dialysis related services.

60. Patients eligible for Medicare may also experience financial impacts from enrolling in individual health insurance coverage in lieu of Medicare. First, individuals with ESRD are likely to require medical services provided outside of a dialysis facility, but individual health insurance networks are generally more restrictive compared to Medicare (Part A and Part B). Seeing providers outside of this fixed network could lead to higher cost-sharing for the individual. Second, individuals who are entitled to Part A and do not enroll in Part B will be subject to a late enrollment penalty (equal to 10 percent of the premium for each 12-month period of non-enrollment) if they choose to enroll in Part B later on.

61. Although HIPP may cover premiums for a patient enrolled in family coverage, HIPP only pays the dialysis patient's share of the premium.[42] This means that the patient's family may have to acquire separate coverage for which they are responsible for paying premiums; there is therefore no substantive difference for patients between enrolling in Medicare or Medicaid coverage that does not cover their families and enrolling in commercial coverage for which

[40] Centers for Medicare & Medicaid Services, "Health Insurance Exchanges 2021 Open Enrollment Report," April 21, 2020, https://www.cms.gov/files/document/health-insurance-exchanges-2021-open-enrollment-report-final.pdf.

[41] *Id.*

[42] American Kidney Fund, "Health Insurance Premium Program Guidelines," January 2, 2020, https://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-guidelines.pdf ("We do not provide assistance for full family coverage. If the patient has a family plan, they must calculate the individual portion of the premium to determine the grant amount that they should request of AKF.").

HIPP does not cover the portion of the costs borne by their families.

AB 290 Does Not Conflict with Advisory Opinion 97-1

62. There is no apparent conflict between California's AB 290 and Advisory Opinion 97-1. Arguments suggesting a conflict reflect confusion about the market for private health insurance and the nature of that coverage under the ACA.

63. Advisory Opinion 97-1 expressed the opinion that providers' contributions to HIPP as described to OIG in 1997 would not constitute grounds to impose a penalty under the beneficiary inducement statute.

64. Advisory Opinion 97-1 refers only to the payment of premiums within Medicare. OIG does not make any reference to the fact that HIPP may pay private insurance premiums in the employer or individual markets. Specifically, the opinion refers to payment of Medicare Part B and Medigap premiums. (Medicare Part D and Medicare Advantage did not exist in their modern forms at the time Advisory Opinion 97-1 was issued.)

65. As noted earlier, the individual health insurance market also existed in a very different state at the time Advisory Opinion 97-1 was written. Prior to implementation of the main provisions of the Affordable Care Act related to guaranteed issue and community rating, there was little incentive for dialysis facilities to pay individual health insurance coverage premiums for patients via third-party premium assistance, given that patients with pre-existing conditions such as ESRD could be charged higher premiums or may have been denied enrollment altogether due to underwriting. There is no indication that AKF's payment of premiums for private health insurance played any role in OIG's evaluation of the program.

66. OIG's opinion does describe a variety of other features of HIPP. Of relevance here, one of the features that OIG notes is that in operating HIPP, AKF and dialysis facilities "will not disclose directly or indirectly to individual patients they refer that such [facilities] have contributed to AKF to fund the grants."[43]

67. The claim that compliance with AB 290 would require HIPP to operate in ways that are inconsistent with Advisory Opinion 97-1 turns on the idea that when AB 290 is implemented, dialysis companies will be required to "indirectly" disclose to patients that they participate in HIPP. Dialysis providers claim that AB 290 results in lower reimbursement rates to HIPP-participating providers in private coverage, which translates into lower cost-sharing for HIPP-enrolled patients who see HIPP-participating providers, and this lower cost-sharing is an "indirect" disclosure to patients of which providers participate in HIPP (as well as an inappropriate incentive for patients to use such providers).

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[43] *Id.*

68. It is probable that AB 290 will result in lower reimbursement to HIPP-participating providers for patients enrolled in private coverage (compared to the rates paid if AB 290 were not applicable), and this lower reimbursement could have some subtle effects on how patients enrolled in private coverage experience cost-sharing under their plan. (AB 290 does not affect reimbursement or cost-sharing in Medicare or Medicaid.) But these subtle cost-sharing effects in private coverage will not be an indirect disclosure by the provider to Medicare or Medicaid beneficiaries of a provider's HIPP participation.

69. Claims to the contrary rely on three different misunderstandings about how ESRD patients experience private health insurance: (1) most fundamentally, AB 290 does not affect cost sharing for Medicare or Medicaid patients, so the beneficiary inducement statute and Advisory Opinion 97-1 *do not apply* to any consumers for whom AB 290 may change cost-sharing;(2) even for consumers who do experience cost-sharing changes, AB 290 merely changes the *timing* of their cost-sharing, not the total amount (which is based on the structure of the health insurance plan); and (3) even the consumers who do experience these changes in the timing of their cost-sharing are unlikely to connect it to provider participation in HIPP.

AB 290 Does Not Affect Reimbursement for Medicare or Medicaid Beneficiaries

70. First, the patients whose cost-sharing is affected by AB 290 will not be Medicare or Medicaid beneficiaries; therefore the beneficiary inducement statute will not apply.[44] That is, the only patients who will experience cost-sharing impacts (the ostensible "indirect disclosure") are not patients for whom provider conduct is governed by the beneficiary inducement statute or Advisory Opinion 97-1.

71. Whether or not a patient may experience changes in cost-sharing will depend on whether they are enrolled only in private coverage, only in public coverage, or in private coverage alongside a form of public coverage, as described in Panel B of Table 1, *supra*.

72. Dialysis patients enrolled *only* in private coverage (in the individual market or employer coverage) may experience some changes in their cost-sharing, but those patients are, by definition, not Medicare or Medicaid beneficiaries.

73. Dialysis patients may also be enrolled *only* in public coverage (Medicare and Medicaid). In those cases, the provider reimbursement requirements of AB 290 will not apply, and patients cannot experience changes in their cost-sharing because of the law.

[44]The beneficiary inducement statute prohibits certain types of remuneration to "any individual eligible for benefits" under Medicare or Medicaid. The use of the phrase "eligible for benefits" might suggest that remuneration to an individual eligible for but not enrolled in Medicare or Medicaid could be prohibited under the statute. However, said remuneration must affect the choice of provider for services "for which payment may be made, in whole or in part, under" Medicare or Medicaid. Therefore, because an individual eligible for but not enrolled in Medicare or Medicaid cannot generate claims that Medicare or Medicaid may pay, the individual cannot trigger the statute.

74. Some patients may be enrolled in Medicaid and private coverage (in the individual market or employer coverage). For those individuals, Medicaid will be treated as secondary to the private coverage for Medicaid-covered services, and this will result in patients paying no more than the applicable Medicaid cost-sharing, which will be only a nominal amount, regardless of the reimbursement rate by the private plan.[45] That is, those enrolled in private coverage and Medicaid will not experience any changes in cost-sharing for Medicaid-covered services based on potential changes to provider reimbursement under AB 290.

75. Other patients may be enrolled in Medicare and in employer coverage. Payment in these cases is governed under the Medicare Secondary Payer Act; for ESRD patients, the employer coverage is the primary payer for the first 30 months and Medicare is primary thereafter. In either case, applicable regulations ensure that the patient is charged cost-sharing no higher than the cost-sharing he would have been charged if the employer plan reimbursed the provider at the Medicare rate.[46] As with Medicaid patients, then, AB 290 will not cause any changes in patient cost-sharing obligations.

76. Health insurance issuers, agents, and brokers are not permitted to sell individual market coverage to individuals entitled to benefits under Medicare Part A or enrolled under Medicare Part B, knowing that the private policy would duplicate their Medicare benefits. [47] If a patient is unknowingly enrolled in private coverage and in Medicare, there is no provision in law for coordination of benefits, meaning that services are either paid by the individual market (where reimbursement and thus cost-sharing might be affected by AB 290, but the beneficiary inducement statute does not apply) or by Medicare (where AB 290 will have no effect).

77. Together, this means that there will be no changes in cost-sharing for any Medicare- or Medicaid-covered services, i.e., the services to which the beneficiary inducement statute applies, and which are within the scope of Advisory Opinion 97-1.

For Private Insurance Enrollees, AB 290 Only Changes the Timing of Cost-Sharing

78. Second, lower reimbursement for a particular dialysis treatment will have no impact on a patient's total out-of-pocket spending during the calendar year.

79. Changes to patient cost-sharing based on lower reimbursement rates for a particular dialysis treatment do not change the structure of the patient's health insurance coverage. The ACA requires all employer and individual market health plans to impose a cap on the total amount of cost-sharing a patient can face in a year, called the out-of-pocket limit.[48]

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[45] *See, e.g.,* Medicaid and CHIP Payment and Access Commission, "How Medicaid Interacts with Other Payers," https://www.macpac.gov/subtopic/how-medicaid-interacts-with-other-payers (last visited January 10, 2021).

[46] 42 C.F.R. §§ 411.33, 411.35. *See also* Centers for Medicare & Medicaid Services, Medicare Secondary Payer (MSP) Manual, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/msp105c03.pdf.

[47] 42 U.S.C. §§ 1882(d)(3)(A)(i)(I)

[48] 42 U.S.C. §§ 300gg-6, 18022.

For 2022, the out-of-pocket limit was $8,700 per person or less.[49] Once a patient reaches their plan's limit, the plan pays 100% of all covered benefits and the individual has no cost-sharing obligations.

80. Patients with ESRD can incur thousands of dollars in dialysis costs per month. A review from the federal government suggested monthly dialysis costs in private coverage could reach $26,000,[50] though it is perhaps more reasonable to assume costs closer to $10,000 per month. Moreover, patients with ESRD need care beyond dialysis; dialysis represents only about 60% of total health care spending for ESRD patients in private insurance.[51]

81. In the individual market, health insurance coverage for high-cost services like dialysis and hospitalization is typically structured with a deductible of up to several thousand dollars,[52] followed by patient coinsurance of a fixed percent for amounts above the deductible and below the out-of-pocket limit. Employer coverage is similarly structured; deductibles are somewhat lower, but 55% of workers have deductibles exceeding $1,000.[53]

82. That means ESRD patients enrolled in private insurance will be expected to hit the out-of-pocket limit in their plan very quickly. In the first weeks of enrollment, they will incur deductible and coinsurance costs equal to exactly $8,700,[54] no matter the costs of the specific services they receive, and then all costs will be covered by the plan for the remainder of the plan year.

83. Changes in the reimbursement rate paid from insurers to dialysis providers will not affect the total amount of cost-sharing a patient must pay. It will merely shift when, within a few weeks, the cost-sharing is incurred.

84. For example, assume a patient's only form of coverage is a plan with a $4,000 deductible, 25% coinsurance, and an out-of-pocket limit equal to the legal maximum of $8,700,[55] and that he incurs non-dialysis costs of $1,000 per week. If weekly

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[49] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards," 86 Fed. Reg. 24140 (May 2, 2021), *available at https://www.federalregister.gov/documents/2021/05/05/2021-09102/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2022-and*.

[50] Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment, 81 Fed. Reg. 90211 (December 14, 2016), *available at* https://www.federalregister.gov/documents/2016/12/14/2016-30016/medicare-program-conditions-for-coverage-for-end-stage-renal-disease-facilities-third-party-payment.

[51] *Id.*

[52] For example, in 2016 63% of patients who did not receive federal cost-sharing assistance had a deductible above $3,000. Centers for Medicare & Medicaid Services, "Data Brief: 2016 Median Marketplace Deductible $850, with Seven Health Services Covered Before the Deductible on Average," July 12, 2016, https://www.cms.gov/newsroom/fact-sheets/data-brief-2016-median-marketplace-deductible-850-seven-health services-covered-deductible-average.

[53] Kaiser Family Foundation, "2019 Employer Health Benefits Survey," September 25, 2019, https://www.kff.org/health-costs/report/2019-employer-health-benefits-survey.

[54] Or the lower limit imposed by their plan.

[55] Under this plan design, a patient's cost-sharing obligation reaches $0 when he has received $20,600 in services.

dialysis costs are $2,500, the patient will hit the plan's out-of-pocket maximum in the seventh week of the year, i.e. around February 15. If weekly dialysis costs drop dramatically to $1,500, he will hit the out-of-pocket limit just three weeks later, around March 8. In both cases, he will incur exactly $8,700 in cost-sharing during this seven or ten-week period, and $0 in cost-sharing for the remainder of the year.

85. Each patient's experience may differ, depending on what non-dialysis services are required and when during the calendar year those expenses are incurred. But even in the extremely unlikely event that a patient has no health care spending other than dialysis, in the example plan described above, the patient would reach his plan's out-of-pocket limit during the tenth week of dialysis at $2,500 per week and during the sixteenth week of dialysis at $1,500.

86. That is, reduced reimbursement for dialysis services merely shifts when, within a few week period, a patient in private insurance incurs $8,700 in cost-sharing.[56] It will not change the total amount of expenses incurred.

Time-Shifted Cost-Sharing Is Unlikely To Be Connected to HIPP

87. Third, there is no reason to believe that patients who experience a time-shift in their cost sharing will be aware of or have a meaningful understanding of the cause.

88. Providers are generally required to collect cost-sharing amounts, but nothing in federal law requires them to include any information in their bills or receipts provided to patients about the reimbursement rate on which the cost-sharing is based. Health insurance companies will typically provide an explanation of benefits (EOB) that will include the, billed charge, negotiated rate, and member responsibility calculated on the negotiated rate,[57] but that information is provided by the insurer, not the provider, so cannot possibly form the basis for an "indirect" disclosure by the provider.

89. Therefore, the only information that must be provided to the patient by the provider

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Actual plan design is typically somewhat more sophisticated than this example, for example using fixed co-pays rather than deductibles and coinsurance for common lower-acuity services like primary care visits and generic drugs. *See* Centers for Medicare & Medicaid Services, "Data Brief: 2016 Median Marketplace Deductible $850, with Seven Health Services Covered Before the Deductible on Average," July 12, 2016, https://www.cms.gov/newsroom/fact-sheets/data-brief-2016-median-marketplace-deductible-850-seven-health services-covered-deductible-average. But for high cost services like dialysis, hospitalization, and specialty drugs, this plan design is typical. *See id.* Further, evidence from the Medicare program indicates that the majority of non-dialysis services for people with ESRD are for these high acuity services that would usually be subject to deductibles and co-insurance. *See* United States Renal Data System, "Annual Data Report, Volume 2," 2018, https://www.usrds.org/media/2283/2018_volume_2_esrd_in_the_us.pdf.

[56] Or the lower amount imposed by their plan.

[57] *See, e.g.,* California Department of Insurance, "Understanding Your Policy," http://www.insurance.ca.gov/01-consumers/110-health/30-have/understand-policy.cfm (last visited January 10, 2021).

is the amount of cost-sharing for a particular visit.

90. Patients have very little understanding of health insurance terminology. Studies of health insurance literacy reveal that consumers, including those with insurance, have limited understanding of terms like deductible, co-pay, and cost-sharing.[58] In a 2014 survey, only 20% of consumers could correctly answer even a basic question about calculating insurance cost sharing, and lower income consumers were less knowledgeable than higher-income consumers.[59] Given this very low level of understanding about how patient cost-sharing obligations are calculated, dialysis patients are unlikely to have any reason to draw a connection between modest changes in the timing during the year that they incur cost-sharing, the provider's reimbursement rate, and the dialysis facility's participation in HIPP.

91. This is especially true because patient cost-sharing will vary based on a number of factors that are entirely unrelated to HIPP participation. During the few weeks in which cost-sharing is being charged, the cost-sharing will frequently be in flux based on whether the patient has reached her deductible or out-of-pocket limit and the specific services received during the visit. Indeed, changes to services delivered in a visit will often be much more substantial than any changes associated with lower reimbursement rates under AB 290. That is, patients will not expect or experience uniform cost-sharing amounts, and so would have no reason to associate differences between facilities with HIPP participation.

92. There is some evidence that HIPP is operated in ways that make patients particularly unlikely to be aware of cost-sharing differences. Specifically, it appears that HIPP and/or dialysis facilities that refer consumers to HIPP do not always provide transparent information to consumers about the type of coverage they have. In response to a request for information from the federal government, one insurance company noted that they had conducted interviews with dialysis patients whose premiums were supported by premium assistance, and found that these enrollees were often not even aware that they were enrolled in private coverage at all.[60] Another insurance company reported that patients who appeared to be supported by HIPP "seemed confused about their enrollment in general."[61] If HIPP and dialysis facilities are not informing consumers that they are enrolled into private coverage in the first place, it is unlikely these consumers will make a connection between time-shifts in private insurance, cost-sharing, and HIPP participation.

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[58] Policy Genius, "Health Insurance Literacy Survey 2019," October 29, 2019, https://www.policygenius.com/blog/health-insurance-literacy-survey-2019.

[59] Kathryn A. Paez and Coretta J Mallery, "Wide Gap in What People Think They Know About Health Insurance and What They Actually Know," *American Institutes for Research*, October 2014, https://www.air.org/sites/default/files/Health%20Insurance%20Literacy%20brief_Oct%202014_amended.pdf

[60] Comment of Bridgespan Re: Medicare Program: Conditions for Coverage for End-Stage Renal Disease Facilities Third Party Payment, https://www.regulations.gov/document?D=CMS-2016-0145-0808 (last visited January 10, 2021).

[61] Comment of Blue Cross Blue Shield of Minnesota Re: Medicare Program: Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment, https://www.regulations.gov/document?D=CMS-2016-0145-0797 (last visited January 10, 2021).

Additional Reasons that AB 290 Does Not Conflict with Advisory Opinion 97-1

93. The disclosure requirements in AB 290 protect consumer choice and ensure that patients have the necessary information to make coverage selections that best meet their needs. Increased transparency regarding coverage options and third-party premium payments is important for patients to be able to make informed decisions and minimize their potential exposure to financial liabilities. Under the Trump Administration, the Centers for Medicare and Medicaid Services advanced new initiatives helping to ensure that individuals know how much their healthcare will cost in advance and allowing them to make fully informed, value-conscious decisions. AB 290 advances similar consumer protections to ensure that patients are able to make coverage decisions in line with their health and financial interests.

94. It is possible that AB 290 could lead to market-wide changes in reimbursement to dialysis providers by private health plans, such that dialysis at all facilities and for all patients would be reimbursed at rates much closer to the Medicare rate. If this transpires, then no patients will experience time-shifted cost-sharing, because all reimbursement will be roughly the same.

95. To the extent AB 290 would result in premium assistance dollars being used to support Medicare or Medicaid enrollment for those eligible, rather than private coverage in the individual market or an employer plan, this will be expected to *decrease* federal spending. This counterintuitive result arises for a number of reasons related to the structure of the individual market under the ACA.

96. As an example, assume total health care spending (absent AB 290) of $90,000 for a ESRD patient enrolled in Medicare and $190,000 in spending for that same patient enrolled in private coverage.[62] Total costs to the federal government if an individual enrolls in Medicare, after accounting for the Medicare Part B premium of $149 per month and cost-sharing equivalent to 20% of services, will be $70,212. By contrast, in private coverage, the individual (or assistance provided to the individual) will pay roughly $575 per month in premiums[63] and exactly $8,700 per year in cost-sharing, leaving $174,400 in additional costs. The incidence of those additional costs falls on the individual market as a whole; they must be collected as additional premiums from other individual market enrollees. That is, these costs translate directly into $174,400 additional premium dollars collected in the form of higher individual market premiums. Individual market premiums are heavily subsidized by

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[62] These figures are drawn from estimates provided by the federal government at Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment, 81 Fed. Reg. 90211 (December 14, 2016), *available at* https://www.federalregister.gov/documents/2016/12/14/2016-30016/medicare-program-conditions for-coverage-for-end-stage-renal-disease-facilities-third-party-payment.

[63] *See* Centers for Medicare & Medicaid Services, "Summary Report on Permanent Risk Adjustment Transfers for the 208 Benefit Year," June 28, 2019, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium Stabilization-Programs/Downloads/Summary-Report-Risk-Adjustment-2018.pdf.

the federal government, and the subsidy is structured so that the federal subsidy increases as premiums increase. Available evidence indicates that the federal government bears 69% of the total cost of premium increases.[64] Therefore, the federal government will bear $120,336 in increased premium costs for an ESRD enrollee in the individual market (and other individual market enrollees will bear another $54,064 in increased premiums). Thus, it is more costly to the federal government for an ESRD enrollee to be covered in private coverage rather than Medicare.

97. Costs to the federal government of supporting enrollment in Medicaid are generally lower than in Medicare. Therefore, the federal government will face lower costs if AB 290 moves individuals from private coverage into public coverage.

98. Available evidence suggests that AKF's HIPP has historically engaged in activity that create significant risk of disclosure to patients that a facility participates in HIPP.

99. In 2016, a health insurance company provided to the federal government a copy of the 2015 AKF HIPP manual that was reportedly in force through August 2016.[65] The manual explains that dialysis providers were expected to make "equitable" contributions to HIPP based on the "number of patients it refers to HIPP." Providers who could not make equitable contributions were requested to "not refer patients to the HIPP program."

100. This statement by AKF suggests a conflict with multiple components of the OIG advisory opinion, including OIG's statement that "the Companies will be free to determine whether to make contributions to AKF and, if so, how much to contribute. All the Companies have certified that they will not track the amount that AKF pays on behalf of patients dialyzing at their facilities in order to calculate future contributions."[66]

101. Moreover, it may have created an "indirect" disclosure by the providers to patients that the facility participates in HIPP. The manual indicates that it was the stated policy of the HIPP program that only participating providers could refer to HIPP, and therefore the act of referring to HIPP constituted a disclosure by the facility to the patient that the facility participated in HIPP.

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[64] More precisely, because of the structure of individual market subsidy, a dollar of premium increase that falls on a subsidized enrollee is borne by the federal government. Subsidized enrollees constituted 69% of the individual market in 2018, and therefore 69% of the incidence of premium increases will fall on them and be borne by the federal government. *See* Centers for Medicare & Medicaid Services, "Trends in Subsidized and Unsubsidized Enrollment," August 12, 2019, https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other Resources/Downloads/Trends-Subsidized-Unsubsidized-Enrollment-BY17-18.pdf.

[65] Comment of Blue Cross Blue Shield of Minnesota Re: Medicare Program: Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment, https://www.regulations.gov/document?D=CMS-2016-0145-0797 (last visited January 10, 2021).

[66] Office of the Inspector General, Advisory Opinion No. 97-1, https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf.

HIPP can operate in California under AB 290

102. There are several different plausible options for HIPP to continue operating in California in compliance with AB 290.

103. First, HIPP can make the required disclosures to issuers, resulting in reimbursement to providers consistent with the statutory limits. For all of the reasons noted above, there is no reasonable basis for concern that changes in reimbursement would represent an "indirect" disclosure by the provider of its HIPP participation status.

104. Second, HIPP could cease making premium payments for private insurance coverage, limiting its reimbursement to premiums for Medicare Part B, Medigap, and Medicare Advantage coverage. Indeed, Advisory Opinion 97-1makes no reference to the availability of HIPP funds for private coverage. If HIPP were limited in this way, AB 290 would not affect any reimbursement from health plans to dialysis providers through HIPP.

105. Third, HIPP could limit premium payments for private coverage to those not eligible for and/or not enrolled in Medicare or Medicaid coverage. AB 290 would still limit the reimbursement paid to providers in those cases, but taking this additional step would ensure that the beneficiary inducement statute would not apply to the patients for whom reimbursement was affected.

106. All three of these options may result in lower revenue for dialysis facilities that participate in the HIPP program compared to the status quo, but reduced revenue does not pose any colorable problem under Advisory Opinion 97-1.

107. Finally, HIPP and the participating dialysis providers could seek a new OIG Advisory Opinion, which would delay implementation of certain AB 290 requirements. The process could take some time, during which time HIPP could continue to operate under old rules unaffected by AB 290. Stakeholders may be concerned that the passage of time and emerging concerns about the conduct of dialysis providers associated with operation of premium assistance programs may lead OIG to take a different and more restrictive view of the safeguards necessary in a subsequent opinion. However, this is not a basis for suggesting conflict with Advisory Opinion 97-1.

Conclusion

108. Nothing in AB 290 creates a conflict with Advisory Opinion 97-1. AB 290 will cause minor changes in the timing of health plan cost-sharing for consumers enrolled in private insurance. But these changes will impact only consumers who are not Medicare or Medicaid beneficiaries and are therefore beyond the reach of Advisory Opinion 97-1 and the beneficiary inducement statute it purports to interpret. Moreover, consumers will not experience changes in the total cost-sharing charged, and they are unlikely to connect these changes to the HIPP program.

Dated: December 17, 2021

Randolph W. Pate, JD, MPH

PROFESSIONAL EXPERIENCE

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- Provide strategic advisory, research, and management consulting services to leading health care organizations and governments, including payors, providers, states, and technology companies working to make America's health care system more accessible, affordable, and consumer-focused

Centers for Medicare & Medicaid Services, Deputy Administrator & Director, Center for Consumer Information, and Insurance Oversight WASHINGTON, D.C. | APR. 2017- NOV. 2020

- Oversaw the development and implementation of Affordable Care Act regulations applicable to small group and individual health insurance markets and operateHealthCare.gov, a federal website facilitating nearly 10 million American's enrollment each year.
- Led and managed center of approximately 400 career and political staff and dozens of federal contractors, including organization, operations, personnel, and public outreach.
- Regularly briefed and interfaced with senior White House officials, Secretary, CMS Administrator, and other fellow senior officials in carrying out duties
- Led major policy initiatives and development of economically significant regulations, including annual payment notice

- Made regular public appearances, including speaking engagements, television and radio interviews, and other media
- Handled sensitive relationships with insurance industry executives, trade associations, consumer advocates, state officials, and provider organizations.

Health Care Service Corporation, Vice President of Public Policy
WASHINGTON, D.C., WITH HEADQUARTERS IN CHICAGO, IL | MAY 2011 - JAN 2017

- Provided policy and advocacy support for the largest non-investor-owned health insurer in the US, covering approximately 15 million members and 2 million individual market members
- Oversaw regulatory and legislative developments in issue areas, including Affordable Care Act (ACA), health insurance marketplaces, ACA risk mitigation programs, health information technology (including HIPAA privacy and security and cybersecurity), and tax issues
- Kept senior leadership and key ads updated on regulatory and legislative developments and assist in developing and executing priorities and advocacy strategy
- Developed written advocacy materials, including talking points and presentations
- Liaison with trade associations, including Blue Cross Blue Shield Association, America's Health Insurance Plans, American Benefits Council, Health Leadership Council, and the US Chamber
- Led internal development of public comments on pending regulations and guidance

The MITRE Corporation, Senior Health Policy Consultant
MCLEAN, VA | MARCH 2010 - APR. 2011

- Provided full-service policy consulting to federal government clients including CMS, FDA, and HHS
- Analyzed federal health statutes and regulations, including conducting thorough analysis of the Affordable Care Act (ACA) and keeping abreast of latest health insurance reform developments
- Assisted in drafting major federal regulations, including Medicare pay-for-performance/value-based purchasing draft and final rules

Office of Representative Kevin Brady, US House of Representatives
Legislative Counsel | WASHINGTON, D.C. | MARCH 2009- AUG. 2009

The Heritage Foundation
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Office of the Assistant Secretary for Planning & Evaluation, US Department of Health and Human Services
Senior Health Policy Advisor | WASHINGTON, D.C.| DEC. 2006 - JAN. 2009

Committee on Energy and Commerce, US House of Representatives
Public Health Counsel | WASHINGTON, D.C. | MAY. 2006 - DEC. 2006

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Rural Alabama Diabetes and Glaucoma Initiative, University of Alabama at Birmingham
Research Assistant | BIRMINGHAM, AL | AUG. 2003 - JAN. 2005

Office of Representative Spencer Bachus, US House of Representatives
Legislative Counsel/District Director | BIRMINGHAM, AL | JAN 2002 - AUG. 2003

Office of Senator Jeff Sessions, United States Senate
Legislative Counsel | WASHINGTON, D.C. | APR. 2001 - JAN. 2002

The Johns Hopkins Bloomberg School of Public Health
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Degree: Master of Public Health | 2005
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University of Alabama School of Law
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Degree: Juris Doctor – 2000

University of Alabama
Tuscaloosa, Alabama
Degree: Bachelor of Arts, *magna cum laude* | 1997

LICENSURES

Alabama Bar Association (since 2000)

HHS Contracting Officer Technical Representative Training

CLEARANCE

US Secret Security Clearance (Active)

AFFILIATIONS

American Health Lawyers Association
University of Alabama Alumni Association, National Capital Chapter
Farrah Law Society

SELECTED PUBLICATIONS

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EXHIBIT 7

Expert Report of Amy D. Waterman, PhD, dated March 10, 2020

Expert Report

Jane Doe, et al. v. Xavier Becerra, et al. and Fresenius Medical Care Orange County, et al. v. Xavier Becerra, et al.

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Expert Report

Jane Doe, et al. v. Xavier Becerra, et al. and Fresenius Medical Care Orange County, et al. v. Xavier Becerra, et al.

Expert Report Prepared by
Amy D. Waterman, PhD
Professor in Residence, UCLA Nephrology
Director, Transplant Research and Education Center

My opinions on issues related to AB 290 are as follows:

- When patients' kidneys fail, they need an objective, independent assessment of which renal replacement treatments, dialysis or transplant, will help them live the longest and which insurance coverage is best for covering their treatments and out-of-pocket costs.
- While life-saving, on average, patients who remain on dialysis live shorter lives and report poorer quality of life than those who can receive a kidney transplant.
- Dialysis is most profitable when: (1) patients do not pursue transplant and remain on dialysis, and (2) dialysis chains charge the maximum reimbursement rates to private insurance companies for their care.
- While the American Kidney Fund (AKF) is attempting to bridge funding gaps for disadvantaged patients with premium assistance, there is a potential conflict of interest when companies steer referrals to private insurance coverage, which increases dialysis center profits. A useful model to ensure neutrality already exists in transplant where independent living donor advocates evaluate the care of potential living donors to ensure that any biases based on kidney patients' health are eliminated. Assigning an independent advocacy organization in the form of the Health Insurance Counseling and Advocacy Program to help patients navigate the complexities of their different insurance options would reduce perceived and actual conflicts of interest.
- Dialysis organizations have a duty to educate and refer interested patients for transplant. Currently the AKF Health Insurance Premium Program (HIPP) charitable assistance programs limit transplant benefits to 12 months or less. This can create challenges for patients pursuing transplant or paying for it long term, challenges that could result in more patients remaining on dialysis.
- AB 290 supports transparency for ESRD patients to assist them in making informed decisions about how to finance their own care by removing potentially ethically compromising dynamics between AKF, dialysis providers, and private insurance companies.

Kidney Disease Background & Burden

Kidneys are small organs that remove waste and extra fluid from the body, help make urine, control blood pressure and keep bones healthy. Kidney disease, also called chronic kidney disease (CKD), happens when the kidneys are damaged and don't work well. Treatment for early stages of CKD includes medication and dietary changes to maintain some level of kidney function for as long as possible. CKD affects one in seven Americans, about 37 million people.[1]

Kidney failure, or End Stage Renal Disease (ESRD) occurs when patients' kidneys are no longer able to sustain life on their own and waste builds up to unsafe levels in the body. Chronic health conditions like hypertension and diabetes are risk factors of CKD and ultimately ESRD. Patients with ESRD must either start dialysis or receive a kidney transplant in order to survive. **As of December 31, 2016—the most recent data available from the US Renal Data System—there were 726,331 cases of ESRD in the United States.**[1] Of those, 124,675 were newly reported cases of ESRD in 2016. African American and Hispanic patients are more likely to have kidney failure compared to Whites, largely due to greater prevalence of diabetes or hypertension, the two main causes of ESRD.[1]

Treatment Options: Dialysis & Transplant

Patients whose kidneys fail have two treatment options: (1) dialysis, a filtering machine or special fluid that removes waste out of the body, or (2) kidney transplant, where a patient receives a kidney from either a person who has died or a living donor. Dialysis treatments can only replace 10-15% of what a normal kidney does, while a transplanted kidney can replace 50-85%. Patients feel better with a transplant, since it is working 24 hours a day, versus having multiple dialysis treatments weekly. Dialysis patients also have to limit their water intake, restrict their diet, and spend 12-15 hours each week undergoing treatments.

Patients who can receive deceased or living donor transplants live longer than patients who remain on dialysis. **Patients' five year life expectancy on dialysis is only 42% compared to 77% or 84% with a deceased or living donor transplant, respectively.**[1] They also have more freedom to eat and drink what they want and travel. However, more patients remain on dialysis than obtain transplants; in 2016, 70% of ESRD patients were on dialysis with only 30% living with a functioning kidney transplant.[1]

For interested patients, early transplant is highly recommended. **Starting dialysis more than 1.5 years before transplant is associated with higher rate of death** compared to those with less or no time on dialysis pre-transplant.[3,4] In 2019, there were almost 100,000 patients waiting on the list for a deceased donor kidney transplant (DDKT) (Appendix 1).[2]

National rules determine who gets a kidney from the waitlist first and can be viewed on the Organ Procurement and Transplantation Network (OPTN) website.[5] OPTN operates as a public-private partnership with federal oversight through Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (DHHS).[6] These rules consider factors like blood type, medical condition, where the patient lives, and how long the patient has been on dialysis and on the waitlist. Children and previous living kidney donors receive priority positions on the waitlist. Kidneys that are expected to last the longest are given to candidates who are expected to need the organ longest. Income, ethnicity, gender, insurance type and sexual orientation have no impact on priority for a kidney.[7,8]

While early transplant is better, most patients in the United States wait 3-5 years for a deceased donor kidney, facing the risks of serious complications from dialysis including heart and muscle problems related to fluid and protein deposits, and complications with the fistula or port access site.[9] **In California patients wait, on average, 7-10 years for a DDKT.** Because the demand for deceased donor kidneys outstrips supply, only 23,401 US patients received a transplant in 2019, 2,619 in California.[2]

Dialysis and transplant centers must work together to increase transplant rates. As of January 1, 2020, dialysis facilities are required to report their Percentage of Prevalent Patients Waitlisted (PPPW) on the kidney or kidney-pancreas transplant waitlist as part of the Centers for Medicare and Medicaid Services (CMS) new ESRD Quality Incentive Program (QIP).[10] The PPPW is the percentage of patients at each dialysis facility during a 12-month period who were on the kidney or kidney-pancreas waitlist. Dialysis centers that do not show an increase in their PPPW may lose up to 2% of their federal funding.[11] Dialysis centers also are required to educate patients about the transplant process and refer them for transplant evaluation.[12] Failing to provide comprehensive education leaves dialysis patients unprepared and unmotivated to pursue transplant.[13,14]

The Kidney Transplant Toolkit is a publicly available resource that can help providers learn the basics of transplant, how to prepare health literate patient education, including for sensitive groups (minorities, low health

literacy, medical mistrust etc.) who may require special outreach, ways to assess patient readiness level, and how to tailor communication to each readiness stage.[10,15] The Toolkit was developed by the Forum of ESRD Networks' Medical Advisory Council (MAC) and a working group of national kidney health and health education experts, including Dr. Waterman.

Studies have shown a 1.4-fold higher rate of dialysis patients joining the deceased donor waitlist when receiving care from dialysis centers that provide more comprehensive transplant education.[16 17] Centers that use more than one educational strategy or that use intensive methods show the greatest waitlisting rates.[18] Unfortunately, only a few (18%) of centers are carrying out detailed discussions about the risks/benefits of deceased and living donor transplantation.[17,19] Also, many dialysis providers report having suboptimal knowledge about transplant themselves.[17] **Furthermore, in comparisons between for-profit vs. non-profit dialysis companies, studies have reported that for-profit centers are less likely to administer high quality transplant education[17,20] and more likely to have lower access to kidney transplant compared to their non-profit counterparts.[22]** This variation in education practices and referral casts doubt on the ability of all dialysis patients to make informed choices about transplant.

In addition to pursuing a deceased donor kidney transplant (DDKT), patients also can seek a living donor kidney transplant (LDKT) from someone they know, usually a friend or a family member. Once a matching living donor is found, transplant usually occurs within one year. LDKTs happen faster and last longer than DDKTs. The recipient's insurance coverage, either Medicare or private insurance, covers the costs of the recipient and donor evaluation and surgeries. LDKTs usually last for 15-20 years, DDKTs usually last for 10-15 years.[5,23]

Compared to White patients, patients of racial/ethnic minority groups are more likely to have kidney failure but less likely to receive transplants.[1] Overall transplant and LDKT rates are lower for both African American (40% and 75%, respectively) and Hispanic (8% and 25%, respectively) patients compared to White patients. There are many reasons for these disparities including inconsistency of transplant education or transplant referral outside of transplant centers,[24-26] poorer health literacy,[27,28] language barriers,[29,30] and financial disincentives for donors.[31] Low socioeconomic status and lack of sufficient coverage influenced listing rates more than race for many.[32] Medicaid expansion has yielded increased coverage for minority patients, and increased listings for pre-emptive transplants.[33]

Costs and Coverage for Different Renal Replacement Therapies (RRTs)

Any individual diagnosed with ESRD, regardless of age, is eligible for Medicare (part A and B).[34] For dialysis, this covers 80% of dialysis costs, physician ordered surgeries for dialysis preparation, physician services, and most injectable or oral drugs (like those for anemia).[34] For transplant, Medicare covers registry fees, costs of finding a matching kidney, full cost of kidney donor surgery and hospital stay, with immunosuppressant drugs covered for 36 months (if an individual is Medicare eligible due to ESRD).[34] ESRD costs for dialysis and transplant care makes up 7 percent of the total Medicare budget for fewer than 1% of Medicare beneficiaries.[1]

The costs of the multiple weekly dialysis treatments add up; the most recent data shows that $28 billion was spent in 2016 on dialysis costs with per patient per year cost of $90,971.[1] Reimbursement for dialysis care varies by whether the patient has private insurance or Medicare. **A recent assessment in dialysis spending between 1996 and 2016 found that suppliers charge private/commercial insurance holders four times the Medicare rate.**[35] For example, in one analysis of DaVita Inc. financial statements, researchers discovered that the dialysis provider charged a per treatment rate of $1,041 for private insurance holders and $269 for Medicare

beneficiaries. This yielded 33% of the company's revenue from private insurance holders who made up only 10.5% of their patient volume.[35]

Transplant is better for the patient and cheaper for taxpayers; recent comparisons between transplant and dialysis costs demonstrated a median savings of $89,599 per LDKT patient and $50,699 per DDKT patient compared to maintenance dialysis.[36] Compared to dialysis, Medicare spending on kidney transplantation was lower overall ($3.4 billion) and per patient per year ($34,780).[1] Recent estimates put the one-time cost of an LDKT at around $110,000.[37] Furthermore, post-transplantation immunosuppressive drug coverage under Medicare Part B amounts to $2,300 per patient per year.[4]

Recent calls for expansion in immunosuppressant coverage beyond 36 months post-transplant are projected to save Medicare $74 - $120 million over a 10-year period.[38,39] As an example, if a mere 12 patients could be moved from maintenance dialysis to receiving a functioning LDKT, taxpayers and insurers would save more than $1 million. **Providing consistent, comprehensive education about transplant in dialysis centers and prioritizing strategies to ensure higher rates of wait-listing and LDKT rates are important priorities for increasing the length of life of kidney patients and lowering ESRD costs.[18]**

Type of Insurance and Patient Access to Transplant

Patients with public (Medicare) or private insurance are eligible for kidney transplantation, if their insurance coverage has a contract with the transplant center of their choice. For patients who have Medicare only, many transplant centers—including UCLA—require that they have a secondary policy to cover the 20% not covered by primary Medicare insurance. This can be through supplemental public coverage (Medi-Cal), commercial programs (MediGap coverage), or through charitable organizations (i.e. American Kidney Fund).[40]

Before patients can receive a transplant, they must demonstrate sufficient financial stability to care for their organ post-transplant; this includes having comprehensive coverage for their immunosuppressant medication out-of-pocket costs for years afterwards. As stewards of a rare and valuable resource in organs for transplant, transplant centers assess ahead of time whether a patient can maintain their transplanted kidney through adherence to a daily regimen of immunosuppressant drugs. If they do not have sufficient coverage, it is possible that their eligibility for transplant could be denied. Once placed on the transplant waitlist, patients must communicate any changes to their insurance or health status to their transplant center. A change in insurance may require re-verification of the new plan's ability to sufficiently cover post-transplant and immunosuppressant drug costs. Moving from private insurance to Medicare only, without also enrolling in a secondary plan could result removal from the waitlist.

In the other direction, moving from Medicare to private insurance only may have consequences as well. To become eligible for post-transplant coverage, AKF requires patients to have had at least three consecutive months of AKF-supported dialysis pre-transplant. For a patient seeking a preemptive LDKT, **this caveat could potentially harm patients by forcing them to stay on dialysis for longer than necessary or having to utilize dialysis as a precursor to transplantation just to obtain financial assistance.** Previous studies have shown that the hospitalization and mortality risk is highest for patients during the first 90 to 120 days after dialysis initiation (or 3-4 months).[41-44] Likewise, as it was pointed out earlier in this report, outcomes post-transplant are poorer for those spending longer time on dialysis pre-transplant.[3,45]

AKF's HIPP assistance ends within 12 months of transplant, which means that patients with private insurance supported by HIPP assistance, must make other arrangements within that time. By contrast, Medicare covers immunosuppressive drugs for 36 months post-transplant, with potential for further expansion of this rule soon.[34] If AKF were to end their charitable program in California, patients who rely on it to pay for these drugs would face high out of pocket expenses. Additionally, should Medicare expand its coverage of these drugs to lifetime coverage, there would be a clear disadvantage to private plans.

American Kidney Fund (AKF) & Health Insurance Premium Program (HIPP)

AKF'S HIPP is a nonprofit organization providing one of the supplementary programs that helps pay for the remaining costs not covered by Medicare and/or a secondary insurance policy. To qualify, patients must demonstrate that they have insufficient income and savings to pay their premium, must be on dialysis, and must reside in the US or a US territory.[46] AKF reports serving more than 75,000 low-income dialysis and transplant patients through health insurance premium grants in 2018.[47] About 3,700 Californians receive assistance through this program. Patients served were 35% African-American, 20% Hispanic/Latino, and 6% Native American/Asian/Pacific Islander, with an average income less than $25,000 and average out-of-pocket dialysis costs of $7000 per year.[47] AKF provides premium assistance for various insurance plans, yet more than half of these plans (Medigap, EGHP/COBRA, Exchange, etc.) are provided through private insurance companies.[47]

Limits to the AKF Premium Assistance for Transplants

The AKF website confirms that, "If a patient receives a transplant, AKF's health insurance premium assistance ends at the end of the calendar year in which the patients gets the transplant," unless received in the last quarter of year, in which case its coverage extends through the next year. Patients who present for evaluation can be confused about what their AKF premium assistance covers related to transplant and when it ends. Patients receiving AKF premium assistance who receive transplants may have to find a supplementary insurance program. If they have difficulty doing this or cannot cover the out-of-pocket costs themselves, post-transplant, their immunosuppressant drugs may not be fully covered and they may stop taking them, resulting in greater non-adherence and the risk of their transplant failing. Pre-transplant, to protect their AKF assistance, they could also stop seeking a transplant and remain on dialysis for their lifetime, which could limit how long they live.

Optimal Kidney Patient Care and AB 290

Dialysis patient bill of rights,[48,49] national consensus conferences on recipient and donor health and protections,[24-26,50-52] and the 2019 Executive Order on Advancing American Kidney Health[47,53,54] align on key priorities for excellence in kidney patient care. Kidney patients must be supported to make informed choices through provider transparency and comprehensive education. Information presented to patients must disclose the risks and benefits of both dialysis and transplant. Patient groups, national conferences, and the President's Order all recognize that transplant is the optimal treatment for most ESRD patients, and that lower cost treatments should be supported through policy and system reforms, better use of existing resources, and new research initiatives.

There also is a need for comprehensive, supplementary insurance programs that overcome financial and insurance barriers for all patients and particularly for low income and racial/ethnic minorities. **Oversight and guidance is needed to ensure both transparency and neutrality to allow patients to choose which treatment choices best support them and evaluate the quality of various insurance options to do so.**

In another area of transplant care, there is already a model as to how to do this. Federal regulations require all transplant centers to appoint an "independent living donor advocate (ILDA)" for every prospective kidney donor to ensure that the donor is fully protected, has education to make an informed decision, and that the prospective recipient's health condition do not in any way bias the decision about whether or not a donor should be eligible to donate. The American Society of Transplantation describes the role and responsibilities of the ILDA and hosts an annual web series to train new ILDAs.[55]

Assigning an independent advocacy organization in the form of the Health Insurance Counseling and Advocacy Program would help patients navigate the complexities of their different insurance options and reduce perceived and actual conflict of interest. When patients are currently approached by insurance counselors at their own dialysis centers, those counselors may not provide a patient with unbiased advice and may intentionally or unintentionally steer a patient towards a suboptimal insurance solution for them. At present when patients or care teams call AKF to find out about HIPP options for patients, they may not be aware of the totality of insurance plans and premium assistance available.

AKF's website shows support for this approach, stating "We help you to pay for health coverage you've already chosen that best meets your needs. We don't help you choose or enroll in an insurance plan. You must carefully review all forms of health insurance coverage (Medicare, Medicaid, Medigap, COBRA, EGHP, and commercial insurance) and available assistance for paying health insurance premiums (Medicaid, state and local assistance, charitable organizations) and select the combination that best serves your specific financial needs and medical condition."[56] For patients interested in transplant, evaluating which insurance options would help cover immunosuppressant drug costs would be particularly important. Capping payments to providers at the Medicare rates for patients who are receiving charitable premium assistance would not directly affect dialysis or transplant patient care, unless the chains changed the policies of what they would do. The changes brought about by AB290 and those recommended here would honor the tenets of excellent care recommended by our field.

Amy D. Waterman, PhD

Amy D. Waterman, PhD, is a national transplant innovator and a Professor in Residence at the University of California Los Angeles in the Division of Nephrology. She is Director of the Transplant Research and Education Center (TREC) and Deputy Director of the Terasaki Research Institute. In addition to many national transplant leadership positions, Dr. Waterman is a Fellow of the American Society of Transplantation and serves as the Research Committee Chair for the National Kidney Registry. In 2018, she received the ClearMark Award of Distinction from the Center for Plain Language for her interactive digital application, *My Transplant Coach,* as well as a National Health Information Merit Award for two educational initiatives developed by Explore Transplant, a nonprofit consortium Dr. Waterman founded. In 2016, Dr. Waterman was invited to be the keynote speaker at the White House Organ Donation Summit. In 2019, Dr. Waterman received the American Society of Transplantation 2019 Clinician of Distinction Award. Please see Appendix 2 for her full CV.

Through her research and educational initiatives, Dr. Waterman seeks to 1) understand the critical, modifiable patient, provider, and system barriers to donation and 2) design interventions to overcome them. Dr. Waterman's research has been supported by over $25 million in federal grants, and she has authored approximately 100 research articles and book chapters. She has designed 13 educational programs to help patients and potential living donors make informed transplant decisions. These programs have been disseminated to patients in hundreds of dialysis and transplant settings in the United States and Canada and in multiple languages. Dr. Waterman received her PhD in Social Psychology from Washington University, St. Louis, MO.

Dr. Waterman was asked to provide her opinion about the challenges that ESRD patients face and to discuss how Assembly Bill 290 might address some of those challenges. Dr. Waterman has not been retained as a testifying expert at any time in the past four years. Her compensation for her time is $250 per hour and $60 per hour for each of her research associates.

3/10/2020

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38. Assessing the Costs and Benefits of Extending Coverage of Immunosuppressive Drugs Under Medicare. *Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.* 2019.

39. Proposal to Extend Coverage of Immunosupressive Drugs *Centers for Medicare & Medicaid Services, Department of Health and Human Services.* 2019.
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55. Waterman A, Peipert J, Xiao H, Goalby C, Lentine K. Dissemination of Transplant Education Resources in For-Profit and Non-Profit Dialysis Centers: Barriers to Optimal Practice and Waitlist Access. American Transplant Congress; Under Review; Boston, MA.
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Appendix 1

Table 1. Patients on the Deceased Donor Waitlist for Transplant

	UCLA^	NATIONAL
White	17%	36%
Hispanic	48%	21%
Asian	19%	9%
African American	14%	32%
All Others	2%	3%
Total on Wait list	2,233	94,668*

** OPTN Listing data as of January 15, 2020*
^ OPTN UCLA listing data, 01/01/2018 – 12/31/2018

Appendix 2

AMY DOGGETTE WATERMAN, PH.D.

CURRICULUM VITAE

DATE: February 3, 2020

PERSONAL HISTORY:

David Geffen School of Medicine
University of California, Los Angeles
Division of Nephrology
1018 Westwood Blvd.
Los Angeles, CA 90024
Phone: 314-322-3880
Fax: 424-372-7278

ORCID ID: 0000-0002-7799-0060

SCOPUS AUTHOR ID: 7005141363

EDUCATION:

1989 – 1992	B.A., Psychology and English, Indiana University, Bloomington, Indiana
1993 – 1996	M.A., Social Psychology, Washington University, St. Louis, Missouri
1996 – 2001	Ph.D., Social Psychology, Washington University, St. Louis, Missouri

MEDICAL LICENSURE AND BOARD CERTIFICATION: None

PROFESSIONAL EXPERIENCE:

2018 – Present	Professor in Residence, Division of Nephrology, David Geffen School of Medicine at UCLA.
2017 – Present	Senior Quality Consultant, UCLA Kidney Transplant Program
2017 – Present	Deputy Director of the Terasaki Research Institute
2013 – 2018	Associate Professor in Residence, Division of Nephrology, David Geffen School of Medicine at UCLA.
2012 – 2013	Associate Professor of Medicine, Division of General Medical Sciences, Washington University School of Medicine.
2004 – 2011	Assistant Professor of Medicine, Division of General Medical Sciences, Washington University School of Medicine.
2003 – 2004	Instructor of Medicine, Department of General Medical Sciences, Washington University School of Medicine.
2001 – 2003	Post-Doctoral Associate, Department of General Medical Sciences, Washington University School of Medicine.

1999 – 2013	Instructor, General Medical Sciences, Washington University School of Medicine, St. Louis, MO. Course: Designing Outcomes and Clinical Research
1995 – 2001	Research Associate, Department of General Medical Sciences, Washington University School of Medicine, St. Louis, MO.
1994 – 1999	Research Associate, Department of Psychiatry, Washington University School of Medicine, St. Louis, MO.
1996 – 1999	Instructor, Psychology Department, Washington University, St. Louis, MO. Course: Experimental Research Design (1998-99) Course: Psychology of the Self-Concept (1997-98) Course: Personality Psychology (1996-98)
1994 – 1997	Teaching Assistant, Psychology Department, Washington University, St. Louis, MO. Course: Personality Psychology (1996) Course: Social Psychology (1995-96) Course: Experimental Research Design (1994)

PROFESSIONAL ACTIVITIES:

UCLA and University Service:

2002	Institutional Review Board Committee Member, Washington University School of Medicine, St. Louis, MO.
2012 – 2013	Barnes-Jewish Transplant Center Quality Manager, St. Louis, MO.
2013 – 2014	NIDDK T32 Mentor, UCLA Nephrology, Los Angeles, CA.
2015 –2018	UCLA Department of Medicine Legislative Assembly Representative, Los Angeles, CA
2015 – Present	Member, UCLA Department of Medicine Committee on Appointments and Promotions (MedCAP)
2016 – 2017	UCLA Clinical and Translational Science Institute (CTSI) Scientific Review Committee (SRC)
2016 – Present	Member, Immunology, Inflammation, Infection and Transplantation (I3T) Executive Committee, David Geffen School of Medicine, UCLA
2017-present	UCLA Course Host, Steering Committee: Being a Leader and the Effective Exercise of Leadership: An Ontological/ Phenomenological Model, Course presented by UCLA Anderson School of Business in 2018 and 2019.
2018- present	UCLA Medical Education Redesign Committee Member
2019	UCLA Leadership Academy Attendee and Graduate
2019	Completed UCLA LEAN Training, Project: UCLA Kidney and Pancreas Transplant Center Modular Redesign of Kidney Patient Education

Professional Associations and Scholarly Societies:

American Society of Transplantation (AST)
North American Transplant Coordinators Organization (NATCO)
International Transplant Nurses Society (ITNS)
Society of Behavioral Medicine (SBM)
National Kidney Foundation (NKF)

	American Society of Transplantation Women's Health Community of Practice (WHCoP) American Society of Transplantation Psychosocial Community of Practice (PSCoP) American Society of Transplantation Living Donor Community of Practice The Transplantation Society Women in Transplantation

National Transplant Leadership:

2008	Conference Chair of Organ Donation Intervention and Methodology Working Group, St. Louis, MO. Conference funded by American Society of Transplantation and Health Resources and Services Administration.
2008	Explore Transplant education program chosen as an official Centers of Medicare and Medicaid Services' ESRD Network 12 Quality Improvement Project for dissemination to 25,000 dialysis patients.
2009 – 2015	Founded Explore Transplant, a Missouri nonprofit organization, whose mission is to "increase informed transplant decision-making to promote the highest possible quality of life for patients." The nonprofit corporation educated medical professionals, patients, potential living donors and the public about transplant and living donation and improved access to transplant education in underserved communities. 4000 dialysis providers representing over 3000 dialysis centers were trained to use the Explore Transplant program in over 100 trainings.
2014	Led Workgroup developing national recommendations on Recipient Education about Living Donation, Consensus Conference on Best Practices in Live Kidney Donation, June 5-6, 2014, Rosemont, Illinois, funded by the American Foundation for Donation and Transplantation, American Kidney Fund, American Society of Transplantation, American Society of Nephrology, American Society of Transplant Surgeons, American Transplant Foundation, Interlink, NATCO, National Kidney Foundation, The Transplantation Society, and United Network for Organ Sharing.
2015	Co-Chair of the End-Stage Renal Disease Access to Kidney Transplantation Technical Expert Panel (TEP), Centers for Medicare and Medicaid Services (CMS) contract number HHSM-500-2013-13017I, which reviewed the available ESRD and Medicare regulations on steps in the transplant process: referrals, wait-listing, transplant education, and receiving a transplant.
2016	National Transplant Education Speaker at White House Organ Donation Summit
2016	Speaker at Rogosin Institute Annual Roundtable Event on Organ Donation, New York, New York.
2015 – 2017	AST Psychosocial Executive Committee Member
2017 – Present	AST Living Donor Executive Committee Member
2016 – Present	The Transplantation Society Women in Transplantation Steering Committee Member
2018 – Present	National Kidney Registry Research Committee Lead

2019	ESRD Quality Innovators Program, Explore Transplant Member

International Transplant Leadership:

2010	Visiting Transplant Expert at the National Medicine Academy Seminar on Organ Procurement and Transplantation, Paris, France.
2015 – 2016	Design of Explore Transplant Ontario video and print education for use with provincial randomized controlled trial for 40,000 CKD patients in Ontario Province of Canada.
2016	Ontario Living Donor Symposium Steering Committee
2017	Visiting Transplant Expert at the Singapore General Hospital & National University Hospital
2017 – present	Consultant, Ontario Province Living Donation Intervention within Five Centers
2019 – present	Consultant, United Arab Emirates, Organ Donation Initiatives

Editorial Services:

Manuscript reviewer (Present):

American Journal of Kidney Diseases
American Journal of Transplantation
Clinical Journal of the Society of Nephrology
Clinical Transplantation
Ethnicity & Disease
Health Education and Behavior
Health Communication
Journal of Consulting and Clinical Psychology
Journal of Medical Internet Research
Journal on Quality and Patient Safety
Progress in Transplantation
Transplant International
Transplantation

Editorial Board:

2013 – 2017	*Progress in Transplantation*
2019 – Present	*Clinical Journal of Transplantation*

Consulting Relationships and Board Memberships:

2007 – 2010	National Kidney Foundation of Eastern Missouri, Board Member
2009 – 2015	Explore Transplant Nonprofit Corporation, Founder
2008 – 2011	American Society of Transplantation, Organ Donation Advisory Council
2009 – 2012	United Network of Organ Sharing, Living Donor Committee
2010 – 2012	National Kidney Foundation End the Wait Executive Council
2010 – 2012	United Network of Organ Sharing, Vice-Chair, Living Donor Committee
2010 – 2012	United Network of Organ Sharing, At-Large Member, Policy Oversight Committee
2010 – 2014	Donate Life Rose Parade Float Committee
2014 – Present	American Society of Transplantation Psychosocial Community of Practice Executive Committee (PSCoP)
2016 – 2017	Donate Life California Advisory Board

2017- Present	Health Literacy Media, Transplant Education Expert

HONORS AND SPECIAL AWARDS:

1996 – 2001	Recipient of Washington University PhD Tuition Remission Scholarship and University Fellowship.
1999	Recipient of Arts and Sciences Dean's Award for Teaching Excellence by a Graduate Student.
2002	Society of General Internal Medicine, Best Published Research Paper. Given for the following manuscript: Gage BF, Waterman, AD et al. *Validation of Clinical Classification Schemes for Predicting Stroke: Results from the National Registry of Atrial Fibrillation (NRAF) Project.* JAMA 2001; 285:2864-70. PMID: 11401607.
2004	Society of General Internal Medicine, Best Published Research Paper. Given for the following manuscript: Gallagher T, Waterman AD, Ebers AE, Fraser VJ, Levinson W. *Patients' and Physicians' Attitudes regarding the Disclosure of Medical Errors.* JAMA 2003; 289(8):1001-1007. PMID: 12597752.
2006	Society of Behavioral Medicine, Boston, MA. Citation given for the following abstract, *Why African-Americans Don't Pursue Living Kidney Donation.*
2006	World Transplant Congress, Boston, MA. Poster of Distinction given for the following abstract, *Missing a Window of Opportunity: Recruiting Incompatible Donors for Paired Donation.*
2006	National Kidney Foundation Annual Meeting, Orlando, FL. Outstanding Poster given for the following abstract, *Knowledge and Attitudinal Barriers to Transplantation for Dialysis Patients.*
2008	Telly Award, Health and Wellness Category. Given for *Explore Transplant* Video Program.
2009	American Transplant Congress, Boston, MA. Poster of Distinction given for the following abstract, *Immunosuppressant Drug Costs: A Barrier to Transplant for Dialysis Patients?*
2009	NATCO Organization of Transplant Professionals' Quality of Care Award, 2009. Given for *Explore Transplant* educational initiative.
2010	United Network of Organ Sharing Transplant Administrators' Forum, Orlando, FL, Transplant Center Initiatives to Increase Organ Donation, 1st Place: Training Dialysis Providers to Deliver Transplant Education.
2010	17th Annual Health Information Awards, Silver for Total Health Information Program. Given for *Explore Transplant* educational initiative.
2012	YouthBridge Social Enterprise and Innovation Competition, Skandalaris Award, for *Explore Transplant* nonprofit corporation, founded by Dr. Waterman.
2014	World Transplant Congress, San Francisco, CA. Poster of Distinction given for the following abstract, *Can Improved Spanish-Language Kidney Transplant Education Reduce Barriers to Educating Hispanics?*
2014	World Transplant Congress, San Francisco, CA. Poster of Distinction given for the following abstract, *A Cluster Randomized Trial of an Educational Intervention to Increase Knowledge of Living Donor Kidney Transplant Among Potential Transplant Candidates.*

2015	Fellow of the American Society of Transplantation (FAST), First Class of Inductees.
2018	Center for Plain Language, ClearMark Award of Distinction. Given for Educational Resource, *My Transplant Coach.*
2018	25th National Health Information Merit Award. Given for *Explore Transplant* and *Explore Living Donation* educational initiatives.
2019	American Society of Transplantation (AST) Clinician of Distinction Award
2019	Los Angeles County (LAC) Department of Health Services (DHS)
2019	Safety Net Research Fast Pitch Competition First Runner-Up

RESEARCH GRANTS AND FELLOWSHIPS RECEIVED:
(Amounts include indirect costs):

Pending Governmental Support
Role: Principal Investigator (Co-Investigator: Guterman, Los Angeles County Department of Health Services Office of Research and Innovation)
Title: A Multilevel Intervention to Increase Informed Decision-Making about Living Donor Transplant in the Safety Net
Agency: HRSA
Date: 08/01/20 – 7/31/23
Amount: $1,200,000

Pending Non-Governmental Support
Role: Principal Investigator
Title: Increasing Access to Transplant and Living Donation in the Safety Net
Agency: Mendez National Institute of Transplantation Foundation
Date: 4/1/20 – 5/31/21
Amount: $150,000

Role: Principal Investigator
Title: My Paired Donation Coach
Agency: Bridge to Life
Date: 3/1/20-2/28/21
Amount: $25,000

Role: Principal Investigator
Title: My Paired Donation Coach
Agency: University of Iowa
Date: 3/1/20-2/28/21
Amount: $25,000

Role: Principal Investigator
Title: My Paired Donation Coach
Agency: CareDx
Date: 3/1/20-2/28/21
Amount: $25,000

Active Governmental Support
Role: Principal Investigator
Title: Ensuring Informed Decision-Making for Paired Kidney Donation: A National Kidney Registry Education Collaborative
Agency: Department of Health and Human Services, Health Resources and Services Administration (R39OT31888)
Date: 09/16/18 – 8/31/21
Amount: $1,198,569

Role: Co-Investigator (PI: Cameron, Johns Hopkins)
Title: Expanding Live Donor Kidney Transplantation through Advocacy Training and Social Media
Agency: NIH/NIDDK (R01DK111966)
Date: 04/01/17 – 3/31/21
Amount: $99,417

Role: Principal Investigator
Title: Working Within an Integrated Learning Healthcare System to Improve Living Kidney Donation Knowledge across the CKD Continuum for all Racial Groups
Agency: Department of Health and Human Services, Health Resources and Services Administration (R39OT29879)
Date: 09/01/16 – 8/31/21
Amount: $1,343,808

Role: Co-Principal Investigator (PI: Weng, St. Barnabas)
Title: Modifiable Factors Affecting Racial Disparities in Live Kidney Donation
Agency: NIH/NIMHD (R01MD007664)
Date: 07/10/14 – 03/31/21
Amount: $621,307

Active Non-Governmental Support
Role: Principal Investigator
Title: Dean's Office of the David Geffen School of Medicine
Agency: University of California, Los Angeles
Date: 7/1/19 – 6/30/21
Amount: $500,000

Role: Deputy Director, Transplant Research and Education
Title: Research Collaboration
Agency: Terasaki Research Institute
Date: 04/01/17 – ongoing
Amount: $300,000 per year

Role: Principal Investigator
Title: Chair's Commitment Fund, David Geffen School of Medicine
Agency: University of California, Los Angeles
Date: 7/1/16 – 6/30/19
Amount: $861,000

Role: Principal Investigator
Title: Expanding the Number of Kidney Paired Donations in Southern California and Nationally: An NKR Consortium
Agency: OneLegacy
Date: 10/10/18-10/09/2020
Amount: $150,000

Role: Principal Investigator
Title: Expanding the Number of Kidney Paired Donations in Southern California and Nationally: An NKR Consortium
Agency: The National Kidney Registry
Date: 10/10/18-10/09/2020
Amount: $150,000

Role: Co-Investigator
Title: The Living Donation Storytelling Project / Explore Living Donation
Agency: Sanofi
Date: 12/1/19-11/30/20
Amount: $50,000

Past Governmental Support
Role: Co-Investigator; Brian F. Gage, MD, MSc, Principal Investigator
Title: Risk Assessment in Chronic Atrial Fibrillation
Agency: American Heart Association
Date: 01/1/02 – 12/31/04
Amount: $369,360

Role: Principal Investigator
Title: Increasing Donation by Helping Recipients Ask, K01
Agency: National Institute of Diabetes, Digestive, and Kidney Disease

Date: 03/1/04 – 02/29/09
Amount: $551,271

Role: Principal Investigator
Title: Increasing Living Donation in Transplant-Eligible Dialysis Patients (R39OT05429)
Agency: Department of Health and Human Services, Health Resources and Services Administration
Date: 08/1/05 – 07/31/09
Amount: $899,663

Role: Principal Investigator
Title: Understanding Racial Disparities in ESRD Patients with and Without Diabetes (5 P60 DK20579)
Agency: Diabetes Research Training Center
Date: 12/1/08 – 11/30/10
Amount: $96,656

Role: Principal Investigator
Title: Educating Missouri Patients about Preemptive Living Donor Transplantation: A Randomized Controlled Trial (R39OT08449)
Agency: Department of Health and Human Services, Health Resources and Services Administration
Date: 08/1/07 – 07/31/11
Amount: $911,595

Role: Principal Investigator
Title: Training Dialysis Providers to Promote Living Donation: A Four-State *Explore Transplant* Intervention (R39OT10582)
Agency: Department of Health and Human Services, Health Resources and Services Administration
Date: 09/1/08 – 08/31/11
Amount: $1,049,070

Role: Co-Investigator; James Rodrigue, PhD, Principal Investigator
Title: A Randomized Trial to Reduce the Disparity in Live Donor Kidney Transplantation
Agency: National Institute of Health, NIDDK (R01DK079665)
Date: 03/1/09 – 06/30/12
Amount: $75,166

Role: Principal Investigator
Title: Improving Dialysis Providers' Ability to Educate Patients about Living Donation: A Multi-State Explore Transplant Intervention
Agency: Department of Health and Human Services, Health Resources and Services Administration (D71HS19216)
Date: 09/01/10 – 08/31/12
Amount: $799,955

Role: Principal Investigator
Title: Training Dialysis Providers to Educate English & Spanish-Speaking Patients about Living Donation: A National Explore Transplant Intervention
Agency: Department of Health and Human Services, Health Resources and Services Administration (D71HS22064)

Date: 09/01/11 – 08/31/13
Amount: $599,447

Role: Co-Investigator (PI Bunnapradist)
Title: Prospective Study Comparing Brand and Generic Immunosuppression on Transplant Outcomes, Adherence, & Immune Responses
Agency: FDA (U01FD005271)
Date: 09/01/14 – 08/31/15
Amount: $393,615

Role: Co-Investigator (PI: Weng, St. Barnabas)
Title: Increasing Live Donor Kidney Transplant among Blacks on the Transplant Waitlist
Agency: NIH/NIDDK (R01DK098744)
Date: 09/27/12 – 08/31/17
Amount: $94,750

Role: Principal Investigator
Title: Tailored Computer Education to Increase Living Donation in African-Americans
Agency: NIH/NIDDK (R01DK088711)
Date: 09/15/11 – 07/31/17
Amount: $1,333,498

Role: Principal Investigator
Title: Improving Low-Income ESRD Patients' Transplant Knowledge: A Case Management Trial
Agency: Department of Health and Human Services, Health Resources and Services Administration (R39OT25725)
Date: 09/01/13 – 07/31/17
Amount: $1,042,527

Past Non-Governmental Support
Role: Principal Investigator
Title: Increasing Living Donor Volunteer Rates, Comfort, and Satisfaction: A Comparison of Three Educational Approaches
Agency: International Transplant Nurses Society, Fujisawa Research Grant
Date: 01/01/01 – 12/31/01
Amount: $2,500

Role: Principal Investigator
Title: Increasing Living Donor Volunteer Rates, Comfort, and Satisfaction: A Comparison of Three Educational Approaches
Agency: Missouri Kidney Program
Date: 08/1/01 – 07/30/02
Amount: $24,500

Role: Principal Investigator
Title: How to Make the Donation Request: Improving Recipient Education
Agency: Missouri Kidney Program
Date: 05/01/02 – 08/01/02
Amount: $14,675

Role: Principal Investigator
Title: Making the Donation Request: Increasing Donation Rates through Recipient Education
Agency: BJH Foundation
Date: 01/01/03 – 12/31/05
Amount: $80,000

Role: Principal Investigator
Title: The Final Option: Kidney Recipients' Interest in Donor-Swapping Options
Agency: American Society of Transplantation
Date: 07/01/03 – 06/30/05
Amount: $100,000

Role: Principal Investigator
Title: Improving Kidney Transplant Education to Increase Living Donation Rates (5 UL1 RR024992-04)
Agency: Institute of Clinical and Translational Sciences, Washington University School of Medicine
Date: 06/01/09 – 05/31/11
Amount: $199,434

Role: Sub-contract (PI: Axelrod)
Title: Development of a Patient Education Tool Regarding ESRD Transplantation Options
Agency: Xyn Management
Date: 12/01/13 – 11/30/14
Amount: $94,500

Role: Faculty
Title: Gift
Agency: OneLegacy Foundation
Date: 2014 – 2016
Amount: $74,360

Role: Co-Investigator (PI Dubinett)
Title: UCLA CTSI, Matching Funds
Agency: NIH/NCRR (UL1TR000124)
Date: 06/01/11 – 12/31/16
Amount: $400,000

Role: Conference Presenter, American Transplant Congress 2017
Title: AST Psychosocial Community of Practice (COP) Presenter Travel Grant
Agency: American Society of Transplantation (AST)
Date: 04/3/17 – 05/02/17
Amount: $1,280

Role: Principal Investigator
Title: Catalyst Grant
Agency: UCLA CTSI
Date: 06/01/2018-12/31/2018
Amount: $5,000

LECTURES AND PRESENTATIONS

International Presentations:

1. Gage BF, Zahid M, McMullin T, **Doggette AL**, Goldstein N, Shry E. Watchful Waiting versus Vitamin K1 in Overanticoagulated Nonbleeding Patients: A Retrospective Study. Poster presentation at the Anticoagulation Forum- 4th National Conference; 1997 March; Toronto, Canada.

2. **Waterman AD**. Are Dialysis Patients Making Informed Transplant Decisions? A U.S. Perspective. National Medicine Academy Seminar, Conceptions Guiding the Organization of Organ Procurement and Transplantation in France, Canada and the United States; 2010 April; Paris, France.

3. **Waterman AD**, Goalby CJ, Herrington ER, Hyland S, Schenk E, Dinkel K. Ensuring Informed Transplant Choices for Dialysis Patients: An ESRD Network Quality Improvement Initiative. UNOS Transplant Administrators Forum; 2012 April; Puerto Rico.

4. Cooper M, Davis C, Dew MA, Forland C, Thomas C, **Waterman AD**. Living Donor Follow-Up Attitudes and Practices in US Donor Programs. 6th International Conference Living Donor Abdominal Organ Transplantation: State-of-the-Art; 2012 October; Puglia, Italy.

5. **Waterman AD**, Lane MA. Supporting Physicians after Errors through Peer Mentoring: Lessons Learned. Well-Med Symposium; 2014 May; Alexandroupolis, Greece.

6. **Waterman AD**. Helping a Transplant Candidate Pursue Living Donation: Educational Recommendations. Oral presentation at the University of Toronto; 2014 August; Toronto, Canada.

7. **Waterman, AD.** Helping a Transplant Candidate Pursue Living Donation: Educational Recommendations. Oral presentations (5) at all Ontario Province Transplant Centers, Canada; 2015 March; London, Hamilton, Toronto, Ottawa, Kingston, Canada.

8. Ethnicity as a potential barrier to pre-transplant evaluation in a Canadian setting Bansal A, Jeannette M, Novak M, **Waterman AD**, Famure O, et al. European Association of Psychosomatic Medicine; 2015 July; Nuremberg, Germany.

9. **Waterman, AD.** Helping a Transplant Candidate Pursue Living Donation: Lessons Learned. McGill University; 2015 November; Montreal, Canada.

10. **Waterman, AD.** Helping a Transplant Candidate Pursue Living Donation: Educational Recommendations. Kidney Foundation of Ontario; 2015 November; Hamilton, Canada.

11. Talamantes E, Norris KC, Mangione C, **Waterman AD**, Peipert JD, Bunnapradist S, Huang E. Incidence of Conversion to Active Waitlist Status among Temporarily Inactive Transplant Candidates from Linguistically Isolated Communities. Oral presentation at SGIM 2015 Annual Meeting, 2015 April. Toronto, ON, Canada

12. **Waterman, AD.** Transplant Education Outside of Transplant Centers: Lessons Learned, University of British Columbia Provincewide Rounds; 2016 Feb; Vancouver, Canada.

13. **Waterman, AD.** The Art and Science of Transplant Education to Increase Living Donation Rates, Visiting Expert Lecture on Transplant Research and Education at the Singapore General Hospital and National University; 2017 Jan; Singapore.

14. **Waterman, AD.** Applying Best Practices and Theory to Improving Transplant Discussions: An Explore Transplant and Explore Living Donation Introduction, Visiting Expert Lecture on Transplant Research and Education at the Singapore General Hospital and National University; 2017 Jan; Singapore.

15. **Waterman, AD.** Recommendations for Improving Transplant Education and Increasing Living Donor Transplant Rates in Singapore, Visiting Expert Lecture on Transplant Research and Education at the Singapore General Hospital and National University; 2017 Jan; Singapore.

16. **Waterman AD,** Peipert JD, Beaumont JL. Efficacy of At-Home Transplant Education on Transplant Knowledge and Pursuit in Low-Income and Black Dialysis Patients with Varying Educational Characteristics. Poster Presentation at the Transplant Society 2018 International Congress; 2018 July; Madrid, Spain.

17. Beaumont JL, Kawakita S, Peipert JD, **Waterman AD.** Understanding Race and Gender Disparities in Living Donor Kidney Transplant Readiness, Actions, Knowledge, and Socioeconomic Barriers to Transplant Evaluation. Poster Presentation at the Transplant Society 2018 International Congress; 2018 July; Madrid, Spain.

18. Belenko D, Richardson C, Li A, Edwards N, Lam J, Waterman AD, Garg A, Novak M, Mucsi I. Creating an on-line transplant education hub for patients and frontline staff to promote kidney transplant education outside the transplant center. Poster presentation at the Ethical, Legal, Psychosocial Aspects of Transplant Conference 2019; Krakow, Poland.

19. Waterman AD, Education to Increase Pursuit of Transplant: State of the Field and New Innovations, Oral Presentation at the Canadian Society of Transplantation Summit 2019; Banff, Canada.

National Presentations:

1. **Doggette AL**, Burroughs TE, Strube MJ. From the Outside Looking In: The Effect of Self-Monitoring and Self-Complexity on Self-Presentation. Poster presentation at the American Psychological Society; 1996 June; San Francisco, CA.

2. Gage BF, Boechler M, Flaker G, **Doggette AL**, Fortun G. Utilization of Antithrombotic Therapy in Medicare Beneficiaries with Nonvalvular Atrial Fibrillation: An Opportunity Lost. Poster presentation at the 20th Annual Meeting of the Society of General Internal Medicine; 1997 May; Washington DC.

3. **Doggette AL**, Burroughs TE, Strube MJ. Accuracy in Self and Other Ratings: A Combined Idiographic and Nomethetic Approach. Poster presentation at the Midwestern Psychological Association; 1997 May; Chicago, IL.

4. **Doggette AL**, Lefkowitz ES, Garfield LJ. Why did the Unabomber Bomb? - Applying Personality Theories to One Case Study. Poster presentation at the American Psychological Society; 1998 May; Washington DC.

5. Gage BF, Boechler MB, **Doggette AL**, Fortune G. Outcome of Antithrombotic Therapy in Missouri Medicare Beneficiaries Who Have Nonvalvular Atrial Fibrillation. Poster presentation at the 22nd Annual Meeting of the Society of General Internal Medicine; 1999 May; San Francisco, CA.

6. **Waterman AD**, Banet GE, Milligan PE, Frazier A, Verzino E, Walton B, Gage B. Patient and Physician Satisfaction with a Telephone-Based Anticoagulation Service: A Randomized Controlled Trial. Poster presentation at the Society of General and Internal Medicine Annual Meeting; 2000 May; Boston, MA.

7. Mulligan PE, Banet GA, **Waterman AD**, Gatchel SK, Gage BF. Substitution of Generic Warfarin for Coumadin® in an HMO Setting. Poster presentation at the Anticoagulation Forum; 2001 May; Washington D.C.

8. Gage BF, **Waterman AD**, Banet GA, Milligan PE. Clinical Trial of Standard Warfarin Management versus a Telephone-Based Anticoagulation Service. Poster presentation at the 24th Annual Meeting of the Society of General Internal Medicine; 2001 May; San Diego, CA.

9. Gage BF, **Waterman AD**, Banet GA, Milligan PE. Clinical Trial of Standard Warfarin Management versus a Telephone-Based Anticoagulation Service. Poster presentation at the Anticoagulation Forum; 2001 May; Washington D.C.

10. Gage B, **Waterman AD**, Radford M. Risk Adjustment in the Atrial Fibrillation Population. Poster presentation at the Longer Life Foundation Annual Meeting; 2001 October; St. Louis, MO.

11. Gage BF, **Waterman AD**, Shannon W, Boechler M, Rich MW, Radford MJ. Validation of Clinical Prediction Rules for Stroke: Results from the National Registry of Atrial Fibrillation (NRAF) Project. Oral presentation at the American Heart Association 26th Annual Stroke Conference; 2001 February; Ft. Lauderdale, FL.

12. Gage BF, **Waterman AD**, Banet GA, Milligan PE. A Comparison of a Telephone-Based Anticoagulation Service versus Warfarin Management by Physicians. Oral presentation at the Annual American Heart Association Stroke Conference; 2001 February; Ft. Lauderdale, FL.

13. Banet GA, **Waterman AD**, Milligan PE, Gatchel SK, Gage BF. Warfarin Dose Reduction versus Watchful Waiting for Mild Elevations in the International Normalized Ratio. Oral presentation at the Saint Louis University School of Nursing's 28th Annual Research Conference; 2001 October; St. Louis, MO.

14. **Waterman AD**, Bayer L, Milligan P, Banet GA, Gatchel S, Gage BF. Prevalence and Predictors of Warfarin Non-Adherence in an Anticoagulation Service. Poster presentation at the Society of Behavioral Medicine Conference; 2002 April; Washington D.C.

15. **Waterman AD**, Hong BE. Increasing Living Kidney Donor Comfort and Satisfaction through Education. Oral presentation at the International Transplant Nurses' Society, 11th Annual Symposium and General Assembly; 2002 September; Pittsburgh, PA.

16. **Waterman AD**, Schnitzler M, Caisley LE, Covelli T, Mahon M, Hong BA. A Final Option: Living Kidney Donors' Interest in Donor-Swapping Options after Being Ruled Out. Poster presentation at the American Transplant Congress; 2003 May; Washington D.C.

17. **Waterman AD**, Caisley LE, Covelli T, Adams DR, Hong BA. The Enormous Request: Kidney Recipients' Unwillingness to Ask Living Donors to Donate. Poster presentation at the American Transplant Congress; 2003 May; Washington D.C.

18. **Waterman AD**, Garbutt J, Fraser VJ, Dunagan WC, Fischer ID, Krauss MJ, Ebers AG, Levinson W, Gallagher TH. Physicians' Need for Support Following Medical Errors. Poster presentation at the Society of Behavioral Medicine; 2004 March; Baltimore, MD.

19. **Waterman AD**, Barrett AC, Stanley SL, Schenk EA, Hong B. Kidney Recipients' Use of Health Education about Transplantation. Poster presentation at the Society of Behavioral Medicine Conference; 2004 March; Baltimore, MD.

20. **Waterman AD**, Burroughs TE, Garbutt J, Fraser V, Waterman BM, Levinson W, Gallagher T. Hospitalized Patients' Comfort with and Participation in Medical Error Prevention. Poster presentation at the Society of Behavioral Medicine Conference; 2004 March; Baltimore, MD.

21. **Waterman AD**, Zacharias J. Support Following Errors: Healthcare Providers' Needs and Available Resources. Oral presentation at the BJC Patient Safety Forum; 2004 March; St. Louis, MO.

22. **Waterman AD**, Hong B, Brennan D, Schenk E, Covelli T, Davis T, Barrett A, Stanley S, Schnitzler M. Unethical or Helpful? Ruled Out Kidney Donors' Attitudes about Financial Compensation for Donor Swapping. Oral presentation at the American Transplant Congress; 2004 May; Boston, MA.

23. **Waterman AD**, Brennan D, Hong B, Schenk E, Covelli T, Davis T, Barrett A, Stanley S, Schnitzler M. Whatever It Takes? Kidney Donors' Willingness to Participate in Donor-Swapping. Poster presentation at the American Transplant Congress; 2004 May; Boston, MA.

24. Woodle ES, Rees M, **Waterman AD**, Bohnengle A, Goldfarb D, Aeder M, Henry M, Alonso M, Taylor A. Barriers to Reaching the Potential of Consortium-Based Kidney Exchange Programs: A Survey of Program Directors and Program Policies. Poster presentation at the American Transplant Congress; 2004 May; Seattle, WA.

25. Woodle ES, Bohnegle A, **Waterman AD**, Rees M, Goldfarb D, Aeder M, Henry M, Taylor A, Alonso M. Variability in Patient Referral Rates Within a Multicenter Living Donation Kidney Exchange Consortium and Estimation of Potential Volume. Poster presentation at the American Transplant Congress; 2004 May; Seattle, WA.

26. **Waterman AD**, Garbutt J, Fraser VJ, Dunagan WC, Fischer ID, Krauss MJ, Ebers AG, Levinson W, Gallagher TH. Physicians' Need for Support Following Medical Errors. Oral presentation at the Society of General Internal Medicine; 2004 May; Chicago, IL.

27. **Waterman AD**, Burroughs TE, Garbutt J, Fraser V, Waterman BM, Levinson W, Gallagher T. Hospitalized Patients' Comfort with and Participation in Medical Error Prevention. Oral presentation at the Society of General Internal Medicine; 2004 May; Chicago, IL.

28. **Waterman AD**, Hong B, Brennan D, Schenk E, Covelli T, Davis T, Barrett A, Stanley S, Schnitzler M. Unethical or Helpful: Donors' Attitudes about Financial Incentives for Donor Exchange. Oral presentation at the American Transplant Congress; 2004 May; Boston, MA.

29. **Waterman AD**, Barrett AC, Stanley SL, Brennan DC, Hong BA. Predictors of Kidney Recipients' Unwillingness to Pursue Living Donation. Oral presentation at the 6th Biennial Conference on Psychiatric, Psychosocial, and Ethical Issues in Organ Transplantation at UCLA; 2005 February; Santa Monica, CA.

30. **Waterman AD**, Whitlock R, Barrett AC. Race and Income Differences in Community Attitudes about Diabetes and Organ Donation. Poster presentation at the Centers for Disease Control Conference on Chronic Disease Prevention and Control; 2005 March; Atlanta, GA.

31. **Waterman AD**, Barrett AC, Stanley SL, Schnitzler MA, Hong BA, Brennan DC. Kidney Recipients' Interest in Transplantation Health Education. Poster presentation at the 2005 Society of Behavioral Medicine Annual Meeting; 2005 April; Boston, MA.

32. Garbutt JM, **Waterman AD**, Krauss MJ, Brownstein DR, Klein EJ, Fraser VJ. Pediatricians' Communication about Medical Errors with the Hospital and Colleagues. Poster presentation at the Pediatric Academic Societies Annual Meeting; 2005 May; Washington D.C.

33. **Waterman AD**, Whitlock R, Barrett AC. Race and Income Differences in Community Attitudes about Diabetes and Organ Donation. Poster presentation at the 2005 National Kidney Foundation Spring Meetings; 2005 May; Washington D.C.

34. **Waterman AD,** Garbutt JM, Fraser VJ, Dunagan WC, Gallagher TH. Pediatricians Need for Support Following Medical Errors. Oral presentation at the Pediatric Academic Societies Annual Meeting; 2005 May; Washington D.C.

35. **Waterman AD**, Stanley SL, Barrett AC, Gradala BH, Schenk EA, Highstein G, Hong BA, Brennan DC. Explaining Health Disparities: Why African-Americans Don't Pursue Living Kidney Donation. Oral presentation at the Society of Behavioral Medicine Conference; 2006 March; San Francisco, CA.

36. **Waterman AD**, Barrett AC, Stanley SL, Gradala BH, Schenk EA, Highstein G, Brennan DC, Hong BA. Understanding Patients' Living Donation Decision-Making. Poster presentation at the Society of Behavioral Medicine Conference; 2006 March; San Francisco, CA.

37. **Waterman AD**, Stanley SL, Barrett AC, Gradala BH, Schenk EA, Hong BA, Brennan DC. Knowledge and Attitudinal Barriers to Transplantation for Dialysis Patients. Poster presentation at the National Kidney Foundation Spring Clinical Meetings; 2006 April; Chicago, IL.

38. **Waterman AD**, Barrett AC, Stanley SL, Gradala BH, Schenk EA, Hong BA, Brennan DC. Prevalence and Predictors of Suicidal Ideation in ESRD Patients. Poster presentation at the National Kidney Foundation Spring Clinical Meetings; 2006 April; Chicago, IL.

39. Gallagher TH, **Waterman AD**, Garbutt JM, Larson EB, Fraser V, Dunagan WC, Levinson W. How Physicians Would Disclose Harmful Medical Errors to Patients. Oral presentation at the SGIM Annual Meeting; 2006 April; Los Angeles, CA.

40. **Waterman AD**, Barrett AC, Stanley SL, Waterman BM, Burroughs TE, Highstein G, Rodrigue JR, Hong BA, Brennan DC. Psychosocial and Knowledge Barriers Preventing Renal Patients from

Pursuing Living and Deceased Donor Transplantation. Poster presentation at the World Transplant Congress; 2006 July; Boston, MA.

41. **Waterman AD**, Schenk EA, Barrett AC, Shenoy S, Jendrisak M, Woodle S. Missing a Window of Opportunity: Recruiting Incompatible Donors for Paired Donation. Poster presentation at the World Transplant Congress; 2006 July; Boston, MA.

42. **Waterman AD**, Stanley SL, Barrett AC, Rothstein M, Gellens M, Hong BA, Brennan DC. Transplant Knowledge and Referral Differences May Explain Why Dialysis Patients Don't Pursue Transplant. Oral presentation at the World Transplant Congress; 2006 July; Boston, MA.

43. **Waterman AD**, Stanley SL, Barrett AC, Waterman BM, Shenoy S, Brennan DC. Refusing Living Donors? Renal Patient Predictors of Not Having Living Donors Evaluated. Oral presentation at the World Transplant Congress; 2006 July; Boston, MA.

44. **Waterman AD**, Barrett AC, Stanley SL, Rothstein M, Burroughs TE, Brennan DC, Hong BA. Why African-Americans are Not Pursuing Living Kidney Donation. Oral presentation at the World Transplant Congress; 2006 July; Boston, MA.

45. **Waterman AD**, Stanley SL, Barrett AC, Schenk EA, Hong BA, Brennan DC. Knowledge and Attitudinal Barriers to Transplantation for Dialysis Patients. Oral presentation at the National Kidney Foundation's Clinical Meetings; 2007 April; Orlando, FL.

46. **Waterman AD**, Barrett A, Schenk E, Stanley SL, Leander S, King K, Hong B. Suicidal Thoughts of Transplant-Eligible Dialysis Patients. Oral presentation at the National Kidney Foundation's Clinical Meetings; 2007 April; Orlando, FL.

47. Browne T, **Waterman AD**, Gladstone EH, Waterman BM. African-Americans' Knowledge and Behavior Regarding Early Detection of Kidney Disease. Poster presentation at the National Kidney Foundation Clinical Meetings; 2007 April; Orlando, FL.

48. Young A, Karpinski M, Parikh CR, Treleaven D, Theissen-Philbrook H, **Waterman AD**, Yang RC, Garg AX. Acceptable Risks for Living Kidney Donors Differ between Potential Donors, Potential Recipients and Transplant Professionals. Poster presentation at the American Transplant Congress; 2007 May; San Francisco, CA.

49. **Waterman AD**. Getting Patients Through Transplant Fast and Without Dropping Out: What Really Makes the Difference? Oral presentation at the National Kidney Foundation 2008 Clinical Meetings; 2008 April; Dallas, TX.

50. **Waterman AD**. Living Donation Intervention Approaches. Oral presentation at the Organ Donation Intervention and Methodology Working Group; 2008 May; St. Louis, MO.

51. **Waterman AD**, Deych E, Hyland SS, Paiva AL, Robbins ML. Living Donation Willingness Explained. Find a Volunteer, Don't Ask. Oral presentation at the American Transplant Congress; 2009 May; Boston, MA.

52. **Waterman AD**, Hyland SS, Stanley S, Barrett A, Millinger R. Improving Education Increases Dialysis Patients' Pursuit of Transplant: Explore Transplant RCT Findings. Oral presentation at the American Transplant Congress; 2009 May; Boston, MA.

53. **Waterman AD**, Goalby C, Hyland SS. Dialysis Providers' Ability to Educate Patients about Transplant: Good Education Partners? Oral presentation at the American Transplant Congress; 2009 May; Boston, MA.

54. **Waterman AD**, Frazer L, Hyland SS. Immunosuppressant Drug Costs: A Barrier to Transplant for Dialysis Patients? Poster presentation at the American Transplant Congress; 2009 May; Boston, MA.

55. **Waterman AD**. Education about Preemptive Transplantation: Lessons Learned. Oral presentation at Swedish Medical Center Nephrology Day; 2010 January; Seattle, WA.

56. **Waterman AD**. Ethically and Effectively Advancing Living Donation: How Should it be Done? Oral presentation at 11th Annual Southwest Nephrology Conference; 2010 February; Phoenix, AZ.

57. **Waterman AD**, Goalby C, Hyland SS, Ridolfi G, Bowe J, Dinkel K. Training 300 Dialysis Providers to Deliver Transplant Education. Poster presentation at UNOS Transplant Management Forum; 2010 April; Orlando, FL.

58. **Waterman AD**. Improving Transplant Education in Dialysis Centers to Reduce Health Disparities. Oral presentation at American Transplant Congress Annual Meeting; 2010 May; San Diego, CA.

59. **Waterman AD**, Hyland SS, Schenk EA. Preemptive Transplant Decision-Making and Receipt of Transplants: How Do Patients Pursing Transplant Before and After Starting Dialysis Differ? Poster presentation at NATCO 35th Annual Meeting; 2010 August; Hollywood, FL.

60. **Waterman AD**, Goalby C, Herrington E, Peipert J, Munigala S, Hyland S, Dinkel K. Improving Patient Decision-Making and Access to Kidney Transplant: A Regional Explore Transplant Initiative. Washington University in St. Louis Institute for Public Health 5th Annual Public Health Conference; 2012; St. Louis, MO.

61. Davis LA, Ryszkiewicz E, Schenk E, Peipert JD, Miller CJ, Richardson G, Ridolfi G, **Waterman AD**. Lung Transplant or Bust: Patient Recommendations for Ideal Lung Transplant Education. Washington University in St. Louis Institute for Public Health 5th Annual Public Health Conference; 2012; St. Louis, MO.

62. **Waterman AD**, Peipert J, Hyland SS, McCabe N, Schenk E, Liu J. Reducing Racial Disparities in Evaluation Completion and Living Donor Transplant: What Modifiable Patient Characteristics Matter? Washington University in St. Louis Institute for Public Health 5th Annual Public Health Conference; 2012; St. Louis, MO.

63. **Waterman AD**, Goalby CJ, Herrington ER, Hyland S, Dinkel K. Improving Patient Decision-Making and Access to Kidney Transplant: A Regional Explore Transplant Dissemination & Implementation Project. Oral presentation at National Institutes of Health Conference on the Science of Dissemination and Implementation Research; 2012 March; Bethesda, MD.

64. **Waterman AD**, Brown J, Witten B, Goodnight V, Mallery C, Schenk E, Goalby C, Frazier L, Peace L, Hyland S. Preemptive Transplant Knowledge and Decision-Making: Impact of a Community CKD Education Class. Poster presentation at National Kidney Foundation; 2012 May; Washington DC.

65. **Waterman AD**, Goalby CJ, Herrington ER, Hyland S. Evaluation of Transplant Education in 550 Dialysis Centers in 21 States: Are Dialysis Patients Making Informed Treatment Choices? Poster presentation at National Kidney Foundation; 2012 May; Washington DC.

66. **Waterman AD**, Hyland SS, Liu J, Peipert J, Schenk EA, McCabe M. Understanding Racial Disparities and Effective Predictors of Successful Completion of Transplant Evaluation. Oral presentation at American Transplant Congress; 2012 June; Boston, MA.

67. **Waterman AD**, Goalby CJ, Herrington ER, Hyland S, Dinkel K. Improving Patient Decision-Making and Access to Kidney Transplant: A Regional Explore Transplant Initiative. Poster presentation at American Transplant Congress; 2012 June; Boston, MA.

68. **Waterman AD**, Goalby CJ, Herrington ER, Hyland S. Evaluation of Transplant Education Practices in 550 Dialysis Centers: Are Dialysis Patients Making Informed Treatment Choices? Poster presentation at American Transplant Congress; 2012 June; Boston, MA.

69. Rodrigue JR, Paek MJ, Egbuna O, **Waterman AD**, Pavlakis M, Mandelbrot DA. Wait-Listed Patients with HIV Are Less Likely to Pursue Live Donor Kidney Transplantation. Poster presentation at American Transplant Congress; 2012 June; Boston, MA.

70. **Waterman AD**. Explore Transplant: Expanding Live Donor Transplantation Through Improved Dialysis Patient Education. Oral presentation at American Transplant Congress Annual Meeting; 2013 May; Seattle, WA.

71. **Waterman AD**, Peipert J, Hyland S, Munigala S. Explore Transplant vs. Standard of Care: Which Increases Dialysis Patients' Pursuit of Transplant. Poster presentation at Washington University Comparative Effectiveness Symposium; 2013; St. Louis, MO.

72. **Waterman AD**, Peipert J, Xiao H, Goalby C, Herrington E, Munigala S, Dinkel K, Lentine K. Understanding Transplant Education Practices in Dialysis Centers: Comparing Dialysis Educator and Medicare Patient Data. Poster presentation at American Transplant Congress; 2013 May; Seattle, WA.

73. Robbins ML, Paiva AL, Davis L, Hyland SS, Brick L, Peipert J, Schenk E, Amoyal N, **Waterman AD**. Measuring Kidney Patients' Motivation to Pursue Living Donor Kidney Transplant: Development of Stage of Change, Decisional Balance and Self-Efficacy Measures. Poster presentation at the American Transplant Congress; 2013 May; Seattle, WA.

74. Brick LA, Sorensen D, Robbins M, Paiva A, McSorley AM, Peipert J, **Waterman AD**. Factorial invariance of decisional balance and self-efficacy measures to understand kidney patient decision making for pursuing living donor kidney transplant. Poster presentation at Society of Behavioral Medicine; 2014. Philadelphia, PA.

75. **Waterman AD**, Munigala S, Peipert J, Goalby C, Baldwin K, Schenk E. Can Improved Spanish-Language Kidney Transplant Education Reduce Barriers to Educating Hispanics? Poster presentation at World Transplant Congress; 2014 July; San Francisco, CA.

76. Weng FL, Brown DR, Holland B, Peipert J, **Waterman AD**. A Cluster Randomized Trial of an Educational Intervention to Increase Knowledge of Living Donor Kidney Transplant Among Potential Transplant Candidates. Poster presentation at World Transplant Congress; 2014 July; San Francisco, CA.

77. Hicks EM, Maliski SL, Kwan L, **Waterman AD**, Connor SE, Veale JL. The Health and Experiences of Living Donors Participating in Kidney Donation Chains: A Preliminary Study. Poster presentation at World Transplant Congress; 2014 July; San Francisco, CA.

78. **Waterman AD**. Improving Living Donation Education for Recipients. Oral presentation in Sunrise Symposium on Helping a Transplant Candidate Pursue Living Donors at World Transplant Congress; 2014 July; San Francisco, CA.

79. **Waterman AD**, Peipert J, Goalby C, Munigala S, Baldwin K. Training Dialysis Providers to Educate about Transplant: In-Person vs. E-Learning Delivery Approaches. Oral presentation at World Transplant Congress; 2014 July; San Francisco, CA.

80. Peipert J, Weng FL, Schenk E, Hyland S, **Waterman AD**. Development and Validation of the "Knowledge about Renal Transplantation" Scale (KART). Oral presentation at World Transplant Congress; 2014 July; San Francisco, CA.

81. Treat E, Peipert JD, **Waterman AD**, Kwan L, Connor S, Melcher M, Flechner S, Kapur S, Leeser D, Sinacore J, Veale JL. The First 1000 Kidney Paired Donation Transplants through the National Kidney Registry: Graft Function and Survival Outcomes. Oral presentation at World Transplant Congress; 2014 July; San Francisco, CA.

82. Flechner S, Turgeon N, Tullius S, **Waterman AD**, Cuffy M, Agarwal A, Waterman A, Veale JL, Peipert J, Treat E, Kapur S, Leeser D, Melcher M, Sinacore J. The First 1000 Kidney Paired Donation Transplants Through the National Kidney Registry: Characteristics of Donors and Recipients. Oral presentation at World Transplant Congress; 2014 July; San Francisco, CA.

83. **Waterman AD**, Peipert JD, Goalby CJ, Davis L, Schenk E, Baldwin K, Robbins M, Paiva A, Kynard-Amerson C. Your Path to Transplant: A Cultural Competency Study of a Tailored Computer Education Program to Reduce Disparities in Living Donor Kidney Transplant. Poster presentation at UCLA Department of Medicine Research Day; 2014 October; Los Angeles, CA.

84. **Waterman AD**, Munigala S, Peipert JD, Goalby C, Baldwin K, Schenk E. Can Improved Spanish-Language Kidney Transplant Education Reduce Barriers to Educating Hispanics? Poster presentation at UCLA Department of Medicine Research Day; 2014 October; Los Angeles, CA.

85. **Waterman, AD.** Helping a Transplant Candidate Pursue Living Donation: Educational Recommendations. Oral presentation at Renal Grand Rounds, Division of Nephrology, University of Southern California; 2014 November; Los Angeles, CA.

86. **Waterman, AD.** Understanding Racial Disparities in Transplant Decision-making: How Can We Help? Oral presentation at Renal Grand Rounds, Harbor-UCLA Medical Center; 2014 November; Los Angeles, CA.

87. **Waterman, AD.** Understanding Racial Disparities in Transplant Decision-making: How Can We Help? Oral presentation at Nephrology Journal Club, Cedars Sinai Comprehensive Transplant Center; 2015 January; Los Angeles, CA.

88. **Waterman, AD.** Helping a Transplant Candidate Pursue Living Donation: Educational Recommendations. Oral presentation at Transplant Conference, University of Minnesota; 2015 January; Minneapolis, MN.

89. Pham, T, **Waterman, AD**, Veale JL, Melcher ML**.** Demographic and Clinical Characteristics of 207 Non-Directed Donors Participating in Paired Exchange through the National Kidney Registry. Poster presentation at ASTS Winter Symposium; 2015 January; Miami, FL.

90. **Waterman, AD.** Helping a Transplant Candidate Pursue Living Donation: Educational Recommendations. Oral presentation at Mayo Clinic Arizona Transplant Center Grand Rounds; 2015 February; Phoenix, AZ.

91. **Waterman, AD.** Helping a Transplant Candidate Pursue Living Donation: Educational Recommendations. Oral presentation at the 16th Annual Southwest Nephrology Conference; 2015 February; Scottsdale, AZ.

92. **Waterman, AD.** Helping a Transplant Candidate Pursue Living Donation: Educational Recommendations. Oral presentation at the 2015 Nephrology and Transplantation Conference; University of California Davis; 2015 March; Sacramento, CA.

93. **Waterman AD,** Peipert J, Kynard-Amerson C, McSorley AM, Paiva A, Robbins M, Peace L. Controlling for Socioeconomic Barriers Reduces Racial Disparities in Transplant Pursuit. Poster presentation at 2015 American Transplant Congress; 2015 May; Philadelphia, PA.

94. **Waterman AD,** Kynard-Amerson C, Parnicky A, Schenk E, Chahal J, Peipert J. Why Patients Are Unwilling to Ask for a Living Donor: A Mixed Methods Study. Poster presentation at 2015 American Transplant Congress; 2015 May; Philadelphia, PA.

95. **Waterman AD,** Peipert JD, Brann S, Kynard-Amerson C, Robbins M, Paiva A, Gaber AO. Educating the Less Prepared: Transplant Knowledge and Decision-Making Differences by Race at Onset of Evaluation. Poster presentation at 2015 American Transplant Congress; 2015 May; Philadelphia, PA.

96. Gander, J, Isenhour, C, McPherson, L, Basu, M, Tao, B, Smith, K, Pastan, S, **Waterman, AD,** Patzer, R. The Explore Transplant Program in GA: Is historical access to transplantation associated with kidney transplant knowledge and preparedness to educate ESRD patients? Poster presentation at 2015 American Transplant Congress; 2015 May; Philadelphia, PA.

97. Peipert, J, **Waterman, AD,** Tsai, E, Morisky, D, Zonana, M, Bunnapradist, S. Assessing the Association of Four Measures of Adherence to Tacrolimus for Organ Transplant Recipients. Oral

presentation at 2015 Pittsburgh Conference on The Science of Medication Adherence; 2015 June; Pittsburgh, PA.

98. **Waterman AD,** Peipert J, Kynard-Amerson C, McSorley AM, Paiva A, Robbins M, Peace L. Controlling for Socioeconomic Barriers Reduces Racial Disparities in Transplant Pursuit. Poster presentation at UCLA Department of Medicine Research Day; 2015 October; Los Angeles, CA.

99. **Waterman AD,** Kynard-Amerson C, Parnicky A, Schenk E, Chahal J, Peipert J. Why Patients Are Unwilling to Ask for a Living Donor: A Mixed Methods Study. Poster presentation at UCLA Department of Medicine Research Day; 2015 October; Los Angeles, CA.

100. **Waterman AD,** Peipert JD, Brann S, Kynard-Amerson C, Robbins M, Paiva A, Gaber AO. Educating the Less Prepared: Transplant Knowledge and Decision-Making Differences by Race at Onset of Evaluation. Poster presentation at UCLA Department of Medicine Research Day; 2015 October; Los Angeles, CA.

101. **Waterman AD**. Kidney Transplant: Improving Transplant and Living Donor Education for Kidney Patients and Potential Living Donors: Lessons Learned. Oral Presentation at 2016 Kaiser Transplant Symposium; 2016 March; Long Beach, CA.

102. **Waterman AD**. Beyond CMS Mandates: Education to Improve Equity in Transplant Access. Oral presentation at National Kidney Foundation Spring Clinical Meeting, Session: Kidney Transplant: Principles and Practice; 2016 April; Boston, MA.

103. **Waterman AD**. Reducing Disparities in Live Donor Transplantation Access Through Education and Outreach. Oral Presentation at National Kidney Foundation Spring Clinical Meeting, Session: Kidney Donation: What Every Nephrologist Needs to Know; 2016 April; Boston, MA.

104. McSorley A, Gonzalez C, Peipert JD, Norris KC, Goalby CJ, Peace LJ, Lutz PA, **Waterman AD.** Dialysis Providers' Perceptions of Transplant Barriers for Minority and Low-Income Patients Along Levels of the Socio-Ecological Model. Poster presentation at National Kidney Foundation Spring Clinical Meeting; 2016 April; Boston, MA.

105. Gonzalez C, McSorley AM, Peipert JD, Norris KC, Goalby CJ, Peace LJ, Lutz PA, **Waterman AD**. Implicit Bias in Dialysis Providers' Transplant Education Practices for Low-Income and Racial/Ethnic Minority Patients. Poster Presentation at American Transplant Congress; 2016 June; Boston, MA.

106. **Waterman AD**, Peipert JD, Xiao H, Goalby CJ, Lentine KL. Barriers to Comprehensive Transplant Education at U.S. For-Profit Dialysis Centers and Associations with Waitlist Access. Oral Presentation at American Transplant Congress; 2016 June; Boston, MA.

107. **Waterman AD**, Peipert JD, Xiao H, Goalby CJ, Lentine KL. Transplant Education Increases Wait-Listing Rates in Dialysis Centers with Supportive Administration and Knowledgeable Staff. Oral Presentation at American Transplant Congress; 2016 June; Boston, MA.

108. Peipert JD, Gonzalez C, McSorley AM, Norris KC, Goalby CJ, Peace LJ, Lutz PA, **Waterman AD**. Implicit Bias in Dialysis Providers' Transplant Education Practices for Low-Income and

Racial/Ethnic Minority Patients. Poster Presentation at UCLA Department of Medicine Research Day; 2016 October; Los Angeles, CA.

109. Alicic RZ, Bell D, Dai W, Mangione C, Duru K, McPherson S, Walsh D, Nicholas S, Moin T, **Waterman AD**, Ettner S, Shen J, Short R, Peipert JD, Craff M, Garget M, Vargas R, Norris KC, Tuttle KT. Electronic-Health-Records-Based Registry of Chronic Kidney Disease and At-Risk for Chronic Kidney Disease in Two Health Systems. Poster Presentation at American Society of Nephrology Kidney Week 2016 Annual Meeting; 2016 November; Chicago, IL.

110. Anderson C, Axelrod DA, Wojciechowski D, Jacobs M, Lentine KL, Schnitzler M, Peipert JD, **Waterman AD**. Cultural Competency of an Individually Tailored Mobile Education Tool for Improving Transplant Decision-Making. Oral Presentation at American Society of Nephrology Kidney Week 2016 Annual Meeting; 2016 November; Chicago, IL.

111. Novogrodsky E, Yaghoubian A, Connor S, Hicks E, Vargas GB, Nassiri S, Maghen A, Kwan L, **Waterman AD,** Maliski SL, Veale JL. Media Influence on Altruistic Kidney Donors. Poster Presentation at the David Geffen School of Medicine Senior Scholarship Day at UCLA; 2017 March; Los Angeles, CA.

112. **Waterman, AD,** Peipert JD, Xiao H, Goalby C, Lentine, K. Educational Strategies for Increased Wait-listing Rates: Opportunities for Dialysis Center Intervention. Oral Presentation at American Transplant Congress; 2017 April; Chicago, IL.

113. **Waterman, AD.** Concurrent Session on Transplant Strategies from Pediatric Recipients, Stepping Up: Strategies to Enhance Live Donation in Pediatric Transplantation. Moderator of Oral Presentations at American Transplant Congress; 2017 April; Chicago IL.

114. Maghen, A, Vargas GB, Connor SE, Nassiri S, Hicks EM, Kwan L, **Waterman AD,** Maliski SL, Veale JL. Spiritual and Religious Faith of Actual and Potential Non-Directed (Altruistic) Living Kidney Donors. Poster Presentation at American Transplant Congress; 2017 May; Chicago, IL.

115. Maghen, A, Vargas GB, Connor SE, Nassiri S, Hicks EM, Kwan L, **Waterman AD,** Maliski SL, Veale JL. Commonly Expressed Living Donation Fears and Concerns by Non-Directed (Altruistic) Living Kidney Donors in the United States. Poster Presentation at American Transplant Congress; 2017 May; Chicago, IL.

116. Maghen, A, Vargas GB, Connor SE, Nassiri S, Hicks EM, Kwan L, **Waterman AD,** Maliski SL, Veale JL. Post-Donation Experiences of Non-Directed (Altruistic) Living Kidney Donors in the United States. Poster Presentation at American Transplant Congress; 2017 May; Chicago, IL

117. Maghen, A, Vargas GB, Connor SE, Nassiri S, Hicks EM, Kwan L, **Waterman AD,** Maliski SL, Veale JL. Potential Barriers Hindering Non-Directed (Altruistic) Living Kidney Donors from Donating Their Kidneys. Poster Presentation at American Transplant Congress; 2017 May; Chicago, IL.

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REVIEWS None

EDITORIALS None

EDUCATIONAL RESOURCES DEVELOPED

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    a. Videos: *Exploring Transplant; Kidney Recipients' Transplant Experiences; Living Donors' Donation Experiences; Deciding What to Do.*
    b. Brochures: *Why Kidney Patients Get Transplants & Why People Donate their Kidneys; Explore Transplant: A Guide for Family and Friends; Explore Transplant: My Plan; How to Find a Living Donor*.
    c. Fact Sheets: *Advantages of Transplant; Deceased or Living Donation? Recipient Transplant Evaluation, Surgery and Recovery; Living Donor Evaluation, Surgery and Recovery; Possible Risks to Living Donors; Transplant Resources for Recipient and Living Donors.*

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        a. 12 Postcards: *Your Exploration of Kidney Transplant Begins at Home; Explore Transplant with Your Friends and Family; Learn How Life Can Improve After Transplant; Learn Something New About Receiving a Kidney; Compare the Risks and Benefits of Transplants; Learn What Transplant Evaluation is Like; Compare the Risks and Benefits of Living Donation; Learn Why People Want to Be Living Donors; Learn what it is Like to be a Living Donor; Weigh the Pros and Cons of All Your Options; Consider Living Donation; Plan Your Next Steps.*

b. Text Messages: An educational text messaging series that complements information provided within videos, brochures, factsheets and postcards.
c. Transplant Educator Guide and Patient Tracking Tool: Resource used by a Transplant Educator to provide information about kidney disease treatment options and support transplant decision making.

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10. **Waterman, AD** (2016). *Explore Living Donation: For Kidney Patients* and *Explore Living Donation: For Family and Friends*. Includes videos, brochures and fact sheets outlining answers to common living donation questions, real-life donation stories, and strategies for finding a living donor.
    a. Explore Living Donation: For Kidney Patients includes: *What You Need to Know (Booklet); How to Find a Living Donor (Booklet); Why People Donate Their Kidneys (Brochure); Inside Living Donation & Finding a Living Donor (DVD); Sample Letter to Family & Friends (Sheet); Online Resources.*
    b. Explore Living Donation for Family and Friends: Living Donation includes: *What You Need to Know (Booklet); Why Kidney Patients Get Transplants (Brochure); A Guide for Family & Friends (Brochure); Inside Living Donation (DVD); Kidney Failure and Dialysis (Sheet); Online Resources (Sheet).*

11. **Waterman AD**, Peipert JD, Lipsey AF, Goalby C, O'Leary C. (2019). ESRD Transplant Toolkit, published at www.ESRDNetworks.org.

12. **Waterman, AD** *(2019). Living Donation Storytelling Project.* Through this online digital library, anyone can view stories of people sharing their real experiences as living donors, recipients of living donor kidney transplants, and those in need of transplants. People also can upload their own personal stories to the library using any computer, smartphone, or tablet. Using innovative digital storytelling technology and guided prompts, the library will continue to grow to include more diverse voices and perspectives about living donation.

LEADERSHIP & COMMUNITY SERVICE

2015	TED Women Conference Attendee
2016-2018	TED Conference Attendee
2018-present	Mentor to TED Fellow, Essam Dodd, nonprofit institution, Humanity Crew, providing mental health services to refugees internationally.

EXHIBIT 8

Supplemental Expert Report of Amy D. Waterman, PhD, dated November 4, 2021

Expert Report Prepared by
Amy D. Waterman, PhD
Director, Patient Engagement, Diversity, and Education
Department of Surgery and J.C. Walter Transplant Center
Houston Methodist Hospital

Supplemental Report

This report supplements my Expert Report dated March 10, 2020. In this report, I highlight changes in end-stage renal disease (ESRD) care and policies since March 2020 and update my summary of opinions accordingly. Since the last report, the impact of COVID-19 on kidney and transplant patients has been severe. There also have been multiple federal policy changes and significant activity to support the promotion of transplantation as the optimal treatment option for ESRD. Since the American Kidney Fund (AKF)'s Health Insurance Premium Program (HIPP) activities assist patients in remaining on dialysis by paying insurance premiums that would end within one year of patients receiving a transplant, their policies are not consistent with these national transplant mandates.

As of the date of this report, my opinions on issues related to AB 290 are as follows:

- Many national initiatives related to the 2019 Advancing American Kidney Health Initiative (AAKH) have shifted the landscape for kidney health care and significantly increased the emphasis on home dialysis and transplant as preferred treatment options. In December 2020, Medicare Part B coverage was amended to cover lifetime immunosuppressive therapy costs for kidney transplant recipients, removing a significant financial barrier to transplant for patients.
- When patients' kidneys fail, they need an unbiased assessment of which renal replacement treatment - dialysis or transplant - will help them live the longest and which insurance coverage is best for covering their ESRD-related costs.
- Commonly, dialysis social workers and/or insurance counselors are tasked to help dialysis patients obtain insurance and apply for financial assistance. These staff may face a perceived or actual conflict of interest in doing so, since they may recommend insurance options that help patients remain on dialysis and maximize profits for the dialysis centers in which they work.
- The AKF provides financial assistance to kidney patients to cover insurance premium costs and some other dialysis-related expenses through HIPP. While the AKF states that it stands for equal access to health care for all kidney patients (AKF, 2021a), its policies fundamentally treat patients who want to pursue transplant differently than patients who remain on dialysis.
- From a review of the AKF website as of October 29, 2021, the AKF HIPP provides supplemental support for insurance premiums if a patient has kidney failure and has insufficient income and savings to pay their premium bills. Patients can continue receiving supplemental support from AKF as long as they remain on dialysis and meet specific financial requirements. However, if a patient receives a transplant, the AKF website states that support for post-transplant insurance premiums ceases at the end of the insurance plan year, a maximum of 12 months. The loss of coverage of AKF premiums post-transplant can increase out-of-pocket ESRD costs for patients, a possibility which might stop some patients from pursuing transplant at all.
- As this update stresses, keeping patients on dialysis and not reducing potential barriers to transplant for patients is out of step with the recent shifts in kidney care.

Kidney Disease Background & Burden

Since my last report, the COVID-19 pandemic has had devastating impacts on global health and on the health of kidney disease patients. Recent research shows that ESRD patients have higher mortality risk from COVID-19 and typically have comorbidities associated with worse COVID-19 outcomes. (Rastad *et al.* 2021.) In addition to the many other challenges they face, dialysis patients face higher risks of contracting COVID-19. (Kuehn, 2021.) At the same time, COVID-19 has decreased transplant activity and increased time for patients waiting for a transplant. (Alasfar and Avery, 2020; Ajaimy *et al*, 2021.) While both non-transplanted and transplanted patients face elevated risks due to COVID-19, research finds higher overall mortality amongst wait-listed candidates on dialysis (24%) than kidney transplant recipients (20%) relative to the 2019 baseline. (Mohan *et al* 2021.)

My initial report noted many disparities in the incidence of kidney disease and access to care. Recent investigations show that COVID-19 is exacerbating these issues through its disproportionate health and economic impacts on Black and Hispanic communities (Crews and Purnell, 2020.) For example, a study on patients in the United Kingdom found Black, Asian, and minority ethnic patients with ESRD were more than twice as likely to die from COVID-19 than other patients (Tabinor *et al.*, 2021.) Black and Hispanic hemodialysis patients in a New York study contracted COVID-19 at significantly higher rates than other patients (Tummalapalli *et al.*, 2021.) Simultaneously, patients facing socioeconomic challenges are delaying the initiation of treatment for kidney failure: "during the first 4 months of the pandemic (March 1 through June 30, 2020), the number of patients initiating treatment for incident kidney failure declined by 30%, with Black patients and patients living in counties with high COVID-19 mortality initiating treatment with significantly worse levels of kidney function when compared with prior years." (Nguyen *et al*., 2021.) Furthermore, recent research has shown that the consolidation of ownership among kidney dialysis clinics has led to higher costs and worse health outcomes for ESRD patients. (Eliason *et al.*, 2020.) Overall, kidney patients continue to be a highly vulnerable group.

Treatment Options: Federal Changes in Dialysis & Transplant

My initial report discusses dialysis and transplant as treatments for ESRD, compares their outcomes, and provides details on the transplant process and the role dialysis centers play in it. Since that time, actions taken in support of the 2019 Advancing American Kidney Health Initiative have shifted the landscape for kidney health care and significantly increased the emphasis on home dialysis and transplant as preferred treatment options. In the announcement of this initiative, Secretary Azar noted that

> Dialysis is also far from sustainable: One hundred thousand Americans begin this treatment each year, and approximately one in five of them are likely to die within a year. Further, the best option we currently have to offer those with kidney failure is a kidney transplant, but there are almost 100,000 Americans currently on a waiting list for new kidneys. (ASPE, 2019.)

The AAKH sets three goals, each with clear metrics: 1) to reduce ESRD by 25% by 2030 through earlier kidney disease detection and ESRD prevention; 2) to provide patients with more options for treatment by increasing access to home dialysis, transplant, and new treatment technologies (with 80% of new ESRD patients in 2025 receiving home dialysis or a transplant); and 3) to increase the number of kidneys available for transplant (doubling the supply by 2030).

Many national activities are underway to support the achievement of these goals, including testing Medicare payment adjustments linked to increasing transplant outcomes, scaling up practices that will increase transplant referrals, and reducing financial disincentives to living donation (Lentine and Mannon, 2020.) These changes began under the Trump administration, and they continue under the Biden administration. Examples of these actions include the formation of a Technical Expert Panel to decide on new dialysis Practitioner-Level Measures of Effective Access to Kidney Transplantation. (CMS, 2021a.). In July 2021, the Centers for Medicare and Medicaid Services announced that they will take further action to change payment rules to support patients facing healthcare disparities due to socioeconomic challenges. The proposed rule "would aim to encourage dialysis providers to decrease disparities in rates of home dialysis and kidney transplants among ESRD patients with lower socioeconomic status, making the model the agency's first CMS Innovation Center model to directly address health equity." (CMS, 2021b.)

As to the goal of increasing the supply of kidneys available for transplant, policymakers have focused on working with organ procurement organizations (OPOs) to improve efficiency and reduce waste. These efforts have taken on several forms. In November 2020, a House oversight subcommittee launched an investigation into 11 OPOs for poor performance and waste. (Maloney, 2020.) On the heels of this action, CMS published a new, final rule for OPOs designed to reduce organ discard through new outcome measures and increased competition in December 2020.[1] According to CMS,

> The rule creates new measures designed to hold OPOs accountable for seeking – and ensuring transplant of – as many organs as possible. (CMS, 2020.)

To ensure the successful navigation of these rules, CMS and Health Resources & Services Administration created the End Stage Renal Disease Treatment Choices Learning Collaborative (ETCLC) in August 2021. The ETCLC engages transplant centers, OPOs, large donor hospitals, patients, and donor family members to identify and share best practices for increasing the number of deceased donor kidneys transplanted (AST, 2021).

Costs and Coverage for Different Renal Replacement Therapies (RRTs)

In December 2020, Medicare Part B coverage was amended to cover lifetime immunosuppressive therapy costs for kidney transplant recipients effective as of January 2023, removing a significant financial barrier to transplant for patients.

American Kidney Fund (AKF) and the Health Insurance Premium Program (HIPP)

Overall, AKF's programs do not fully align with national mandates to move patients towards transplant and to reduce or remove barriers that may prevent them from doing so.

The population of patients served by AKF is socioeconomically marginalized and highly at risk of not pursuing transplant. AKF's HIPP provides supplemental financial support for patients with kidney failure who have insufficient means to pay their insurance premium bills. Patients can continue receiving supplemental support from AKF as long as they remain on dialysis and meet specific financial eligibility requirements. If a patient chooses to pursue transplant and succeeds, AKF support for his or her post-transplant insurance premiums ceases at the end of that insurance plan year. (AKF, 2021b). This cessation causes transplanted patients to have to find supplemental sources of insurance coverage or take on increased out-of-pocket costs. The

[1] See 85 FR 77898.

threat of cessation of health insurance benefits may induce some patients to remain on dialysis and never pursue transplant.

The Impacts of AB 290

The best insurance plan for patients and their families is not necessarily the plan that maximizes dialysis center profits. AB 290 supports transparency for ESRD patients to assist them in making informed decisions about how to finance their own care by removing potentially ethically compromising dynamics between AKF, dialysis providers, and private insurance companies. AB 290 would remove a potential conflict of interest by prohibiting dialysis staff, particularly social workers and insurance counselors, in chronic dialysis clinics from steering the insurance coverage choices of patients. AB 290's provisions would also eliminate preferentially high reimbursement rates for privately insured dialysis patients, which could serve as an added incentive to keep patients on dialysis.

AB 290 is part of this larger fabric of regulatory changes occurring nationwide in all areas of kidney and transplant care and reimbursement, and, in my expert opinion, would provide needed protections for kidney patients.

Amy D. Waterman, Ph.D.
Since my last report, I have changed institutions. I am now the Division Chief for Patient Engagement, Diversity, and Education, representing both J.C. Walter Transplant Center at Houston Methodist Hospital and the Center for Outcomes Research at the Houston Methodist Research Institute in Houston, TX. I also hold the Deborah C. and Clifton B. Phillips Endowed Centennial Chair for Clinical Research in Transplant Medicine and serve as the Director of the Transplant Research and Education Center.

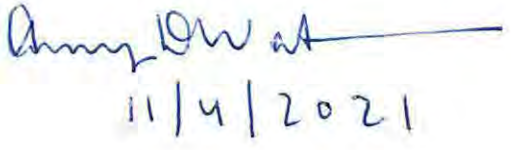

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EXHIBIT 9

Expert Report of John Bertko, F.S.A., M.A.A.A., dated March 10, 2020

Expert Witness Report
Regarding Potential Cost and Health Risk
Of Additional ESRD Enrollees in Covered California

John Bertko, F.S.A., MAAA

Independent Consultant

March 10, 2020

I Introduction

Purpose of the Engagement:

The office of Attorney General of the State of California has retained me to opine on issues related to AB290 and the effects on the risk pool and premiums for Covered California's Individual market and that of the off-Exchange Individual market (which enrolls consumers who do not use Covered California). As the Chief Actuary for Covered California, it has been my responsibility for the last five years to monitor the relative health risk levels and costs of enrollees in Covered California in order to help maintain stability of this crucial state program.

My opinion is based on an analysis of aggregated data provided through use of the Covered California 11-plan claims database and on publicly available information from government and other public sources. If new or additional data or information becomes available, I reserve the right to supplement and revise my report.

II Qualifications:

A. **Related Professional Experience:** I have been a practicing health actuary for over 40 years with experience in the health insurance industry, consulting for health insurance companies, state governmental units and private employers. I have also been employed by the Centers for Medicare and Medicaid Services (CMS) as the senior actuary working on implementation of the Affordable Care Act (ACA) and by Covered California, the State of California's ACA Marketplace, as its Chief Actuary since 2014. In addition, I was a member of the Medicare Payment Advisory Commission (MedPAC) for 6 years, serving as a Part D expert as a commissioner, and currently serve on the Congressional Budget Office's Panel of Health Advisors.

B. **Curriculum Vitae:** More information regarding my professional qualifications, along with degrees and certifications received is set forth in my Curriculum Vitae, which is at **Appendix 1**.

C. **List Of Publications Authored:** The list of publications that I have authored in the previous 20 years is set forth in my Curriculum Vitae, at **Appendix 1**.

D. **List Of Testimony or Expert Witness Cases:** I have served as an Expert Witness for three Prescription Drug Part D cases in the last two years. I have also provided testimony on Government Health Care Programs to the United States Congress, including the Senate Finance Committee. This testimony includes, but is not limited to:

a. U.S. Senate Finance Committee, *Health Insurance Market Rating Practices* (September 23, 2009);
b. U.S. Senate Joint Economic Committee, *Early Experience with Consumer-Centric Health Plans* (February 25, 2004);
c. U.S. Congress, *A Modest Proposal for a Competing Public Policy Plan* (August 19, 2009);
d. The Brookings Institution, *Bending the Curve, Effective Steps to Address Long-Term Health Care Spending Growth* (August 15, 2009);
e. Testimony to: The Consumer Operated & Oriented Health Plans Advisory Board under the Affordable Care Act (January 13, 2011).

These matters and other instances of testimony are included in my Curriculum Vitae, at **Appendix 1**.

E. Statement of Compensation Paid: I am being compensated on an hourly basis for my time spent on this case, and my billing rate is $300 per hour.

III Summary of Opinions

The Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act, or ACA) included sweeping reforms for Medicare, expanded Medicaid dramatically, established subsidies for millions through the individual market and reformed the health insurance market nationally. With these changes – even in the face of opposition that arose immediately on its passage and has heightened with the change of Administrations in Washington, the nation made historic progress in reducing the number of uninsured Americans.

Through political leadership that crossed the partisan divide, California embraced the Affordable Care Act and sought to implement it as effectively and comprehensively as possible. The law that directed the state to establish a "state-based marketplace" and gave to Covered California the independent structure, public accountability and authority to actively structure the market on consumers' behalf was passed by a democratic legislature, and championed and signed by the Republican Governor Arnold Schwarzenneger. After that, Governor Jerry Brown oversaw the state's expansion of Medi-Cal – California's Medicaid program – such that now about one-in-three Californians under 65 benefit from its coverage. And most recently, Governor Gavin Newsom and the legislature have taken bold steps to both reinstate the penalty for not having health insurance that was lowered to zero by federal action and expand subsidies using state resources, including to middle-class Californians previously ineligible for financial help because of the ACA's "cliff" which ended subsidies for anyone making more the 400 percent of the federal poverty level (roughly $50,000 for a single individual).

A number of key factors led to the achievements made in California under the Affordable Care Act. California state leaders embraced the Affordable Care Act following its passage and moved quickly to implement many of its groundbreaking provisions. In 2010, through the leadership of a Republican Governor and Democratic legislature, California became the first state in the nation to enact legislation[1] to establish a state-based exchange. That same year, and in years following, California enacted a series of new laws to implement other Affordable Care Act policies expanding Medicaid, prohibiting plans from denying coverage on the basis of pre-existing conditions, ensuring dependent coverage up to age 26, and others.

A wide array of research shows that Medicaid expansion is linked to coverage gains, increased access to care, improved risk in the individual market, and economic benefits for states and providers including reduced expenditures for uncompensated care.[2] Additionally, California's policy action to expand Medicaid may partly explain its exceptionally low risk score, which contributes to slowed premium growth (as explained below).[3] To date, 14 states[4] have not expanded Medicaid, leaving millions of low-income adults without an affordable health coverage option. Additionally, following the establishment of Covered California, critical policy decisions were made to prohibit "transitional" plans from being sold in the market. In other states, these "transitional" plans allowed some insurers to sell or continue offering less than comprehensive coverage combined with underwriting restrictions that kept some consumers from gaining coverage, all at odds with the protections of the ACA.

This ensured that plans sold in the individual market were compliant with the protections for those with pre-existing conditions as defined in the Affordable Care Act, and helped create a common risk pool and more stable market. In contrast, 35 states around the nation did not convert their transitional plans, leaving out substantial portions of their individual markets from a common risk pool that in turn helped lower premiums.

Taken together with the Affordable Care Act's provision of federal premium and cost-sharing subsidies, and the federal individual mandate, California's early embrace of the Affordable Care Act led to the establishment of a strong foundation at the outset of the state's health reform. This foundation has largely enabled the state to withstand recent federal policy actions (such as the dramatic reduction in funding of federal states marketing and outreach programs for the Federal

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[1] SB 900 (Alquist), Chapter 659, Statutes of 2010 creates California's state-based exchange and establishes its governance, and AB 1602 (Perez), Chapter 655, Statutes of 2010 establishes the California Patient Protection and Affordable Care Act of 2010 to implement the federal Affordable Care Act in California and sets forth requirements related to Exchange administration, eligibility, enrollment, and contracting with health insurance carriers.

[2] "The Effects of Medicaid Expansion Under the ACA: Updated Findings from a Literature Review;" Antonisse, et al; Kaiser Family Foundation; August 15, 2019

[3] "National vs. California Comparison: Detailed Data Help Explain the Risk Differences Which Drive Covered California's Success;" Bingham, et al; Health Affairs Blog; July 2018

[4] Status of State Medicaid Expansion Decisions; November 2019; Kaiser Family Foundation

Facilitated Marketplaces) and the resulting uncertainty that has ensued in recent years and continue to maintain its coverage gains and a healthy, stable marketplace.

Covered California: An Exchange Empowered to Create a Patient-Centered, Effective Marketplace

California's governor and lawmakers exercised a great deal of foresight when establishing the state's exchange, putting it on solid footing from the start. Among various design elements of the exchange, the following three features are particularly important:

(1) Independence and Public Accountability

Covered California is established in state law as an independent entity in state government, enabling it to have a high degree of independence, but also a high degree of public accountability. Covered California is governed by a five-member board appointed by the governor and state legislative leadership. As an independent state agency, which uses no state or federal funds for its operations, Covered California has been able to operate nimbly, allowing for an effective launch and the latitude to adjust to federal and state policy change. Covered California's Board committed the exchange to basing its design and practices on evidence and expertise, attracting and retaining state and national experts in marketing, health plan purchasing, and actuarial science, to name a few. Covered California's structure also promotes transparency, with major policy setting, budget review and approval, and regulatory changes all performed publicly at routine, public board meetings. This transparency has engendered trust and collaboration among key stakeholders, including consumer advocates, health insurance carriers, providers, insurance agents, and others who know they play an active role in the decisions made by Covered California.

The state's decision to establish a state-based exchange, rather than opting to use the Federally Facilitated Exchange, has also allowed California to exercise a great deal of independence to enact state-level policies that have strengthened the exchange and the market to the benefit of consumers. For example, while the federal government has drastically reduced its investments in marketing and outreach, Covered California has maintained, and in some years bolstered, its marketing and outreach efforts, devoting a significant percentage of its annual budget to ensuring that consumers are continuously made aware of the value of health insurance coverage, and that financial assistance is available to help make coverage more affordable. Strong marketing is also likely to explain the much smaller reductions in subsidized and unsubsidized enrollment seen in California, and has helped keep overall enrollment stable and foster a healthier risk mix, keeping premiums low. The larger enrollment has also helped to motivate health insurance plans to participate on the exchange, ensuring consumer choice and more effective competition.

(2) Being an "Active Purchaser" for Consumers and Holding Health Insurance Plans Accountable

Rather than simply creating an expanded market for health insurance plans, the Exchange's charter is explicitly focused on serving consumers. Early policy decisions established Covered California as an "active purchaser" on behalf of consumers. First, rather than adopting a "clearinghouse" model in which any health insurance company and plan design is accepted, Covered California was empowered to selectively contract with health insurance plans and take a more active role to foster competition in the marketplace and value for consumers. A key design element was the early decision to establish uniform consumer-focused benefits (e.g. copays and deductibles) for each plan level (bronze, silver, etc), and requiring minimal copays for primary care outpatient services. These benefit designs enable consumers to make apples-to-apples comparisons based on price, provider network, and customer service. Furthermore, plans were selected based on their ability to serve multiple markets; the adequacy of their networks; competitive pricing; and, their willingness to be held accountable for measured quality, work to improve care delivery, and efforts to address important drivers of health system performance. Another example of active purchasing is Covered California's work on health disparities. All contracted plans are now identifying the race and ethnicity of their enrollees, have completed analyses of disparities in care, and selected a specific disparity to address through an improvement project (a process recommended as a best practice). Details on how Covered California holds plans accountable and plans' progress in improving the health care system are provided in another recent report .

(3) Effective partnerships and collaboration

Covered California has been able to make strides over the last five years in large part due to effective partnerships with key health care stakeholders, especially with its participating health plans. By restricting the number of plans in any regional market, the plans gain the assurance of meaningful enrollment and are in turn willing to meet the high expectations established by the exchange. This has led to stable participation, with ten of the initial eleven plans still participating on the exchange. In addition, Covered California has supported statewide efforts on alignment with other public and private payers in various areas, such as C-sections, hospital acquired conditions and opioid use, as mentioned above. Covered California has also participated in efforts to strengthen the infrastructure for performance measurement, led by the Integrated Healthcare Association (IHA), which draws on data for 29 million Californians and combines clinical, patient-reported, and claims measures to compare quality and costs for 220 medical groups. The dramatic variations in performance have highlighted opportunities for plans to work together to support improvement at the provider level, the benefits of which would accrue to all patients, not just those enrolled through Covered California.

As an "active purchaser," Covered California has sought successfully to keep rate increases to the minimum needed by insurers and to keep the health "risk mix" of enrolled consumers to a level that has been consistent over the six years plus

existence of Covered California. During that time, the Covered California enrollee risk mix has constantly been among the lowest five states in the country with the lowest average measured health risk. Patient steering practices, in which high-risk enrollees, including ESRD enrollees, are pushed toward Covered California plans would likely contribute to an influx of high risk and costly ESRD enrollees that would drive up the risk mix, since adding ESRD enrollees to the Covered California enrollee group would add a large number of consumers with very high per enrollee costs.

In particular, I have observed in data supplied to me in our Covered California 11-plan database that 2016 included an increase of at least 3000 high risk ESRD enrollees that are using expensive kidney dialysis service in the on-Exchange Covered California (and does not count off-Exchange ESRD enrollees). Other public data from the Association of Health Insurance Plans (AHIP)[5] that I reviewed suggests that on the high end, there may be at least twice that many more ESRD enrollees that are enrolled in the combined on- and off-Exchange enrollment than there were in 2015 and earlier.

Health risk is an actuarial concept used to determine the relative health status (e.g., poor, average, good or excellent) and relative cost of enrollees in a "risk pool" of consumers (such as the state of California Individual market). Since the risk mix is defined as 1.00, or "average" for the calculation in the state done by the Centers for Medicare and Medicaid Services (known as CMS), the addition of 3000 to 6000 high risk ESRD enrollees would have a big impact on premiums in the Individual health insurance market. Total on- and off-Exchange enrollment for the California Individual market in 2016 was approximately 2,100,000 (at an average risk of 1.00[6]). Per CMS risk adjustment documentation, the "risk weight" for each ESRD enrollee is a little over 38.0 (i.e., 38 times higher than the average Individual market enrollee). By adding 3000 ESRD enrollees, the risk would increase by a factor of 38 for each of the 3000 ESRD enrollees. Calculating the new, adjusted risk yields a risk increase of 5.3%, which likely translates into a premium increase of about 5.3%.

If the higher end of the range is used (namely twice as many or 6000 new ESRD enrollees), the projected risk increases by 10.4%, for a similar about 10.4% increase in average statewide premium.

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[5] AHIP letter of September 22, 2016 to Andy Slavitt, Acting Administrator, CMS, "RE: Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans (CMS-6074-NC) – AHIP Comments"

[6] For Risk Adjustment purposes, the statewide average risk is set at a "neutral" level of 1.00. Then, as each individual plan's risk is measured, it will most likely be more (e.g., 1.05) or less (e.g., .97) than that statewide average. This difference in risk will then enable the agency (CMS in this case) to make a risk transfer payment (if high risk is found) or collection (from plan's with lower risk) within the state and type of market.

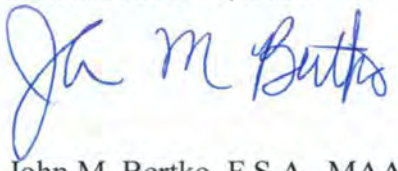
If only a few plans receive ALL of the ESRD enrollees, the ACA includes a risk adjustment mechanism, which means that all 11 plans share the added risk burden. Under the ACA's risk adjustment mechanism, all plans offering coverage in the statewide Individual market pool are measured. To the extent that one (or several) plans have higher-than-average scores (i.e., above 1.00), then other plans will have lower than average scores. A risk adjustment transfer formula will then move funds from those low-risk plans and make payments to high-risk plans. So, an increase in risk of 5.3% to 10.4% means that the average premium across all plans would increase by similar amounts, after these risk adjustment transfers. Thus, for each additional 1000 ESRD patient enrollees in the Individual block in California, an increase of approximately 1.7% of premium would need to occur, on average, for every one of Covered California's insurers, after risk adjustment transfers are completed.

IV. Conclusions

As shown in Section III above, it is likely that the effect of adding ESRD enrollees to Covered California (on-Exchange) or off-Exchange directly to the insurer group would be an increase in risk and average premium of about 5.3% to 10.4%. Given that most, if not all, of these consumers could be well-covered at a lower cost by Medicare coverage, the increase is an unnecessary burden to bear for state individual market consumers and for the federal government which would be supporting part of the premium increase through an increase in the Advance Premium Tax Credit (APTC) subsidies, which pay much of the premium for about 65% of enrollees.

All opinions are held to a reasonable degree of actuarial certainty. If other information later becomes available, I reserve the right to revise my opinion.

Dated: March 10, 2020



John M. Bertko, F.S.A., MAAA

Appendix 1: Curriculum Vitae

John M. Bertko, F.S.A., MAAA
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Experience

Feb 2014- Independent actuarial consultant and Chief Actuary of Covered California, the State of California Health Insurance Exchange

2011-2014 Director, Office of Special Initiatives and Pricing
Center for Consumer Information and Insurance Oversight
CMS/HHS

2007-2011 Senior Fellow at the LMI Center for Health Reform
Adjunct staff at RAND Institution
Guest Scholar at the Brookings Institution
Visiting Scholar in the Center for Health Policy at Stanford University

1999-2007 Vice President and Chief Actuary, Humana Inc. (Retired)
Louisville, KY

- Coordination of actuarial practices across Humana Inc., including student actuarial program and Continuing Education programs
- Oversight of reserve setting and statutory filings
- Development of pricing for Consumer Directed Health Plan products
- Oversight of Medicare Advantage pricing and strategy
- Development of strategy and pricing for Medicare Part D program
- Liaison to Capitol Hill, Centers for Medicare and Medicaid and health insurance industry

1996-1999 Chief Operating Officer/Principal, PM Squared/Reden & Anders
San Francisco, CA

- Management of small health data consulting firm
- Development of risk adjustment models
- Client relationship management for 15 very large health insurers

1980-1996 Principal, Coopers & Lybrand (now PriceWaterhouseCoopers)
San Francisco, CA

- Growth and management of large health actuarial consulting practice
- Consultant to large national health insurers and employers

- Managing consultant to state agencies for health reform projects (e.g., Oregon's prioritization program, California public-private agency program, Hawaii, Colorado, various Medicaid programs)
- Work on retiree medical care for FAS 106 estimates for Fortune 100 corporations

1976-1980 Senior Actuarial Associate, Metropolitan Life Insurance Company (now MetLife), San Francisco, CA and New York, NY

- Work on General Motors account – senior actuary
- Senior actuary and underwriter in San Francisco regional headquarters

1972-1976 U. S. Navy, Lt(jg), Instructor, US Naval Nuclear Power School Mare Island (Vallejo), CA

- Mathematics and physics instructor for officer and enlisted students in nuclear power school
- Division officer for students

Education and Professional Credentials

- B.S., Mathematics, Case Western Reserve University
- Fellow of the Society of Actuaries
- Member, American Academy of Actuaries

Publications

Bertko J, Feher A and Watkins J, "Amid ACA Uncertainty, Covered California's Risk Profile Remains Stable," *Health Affairs Blog*, May 15, 2017; http://healthaffairs.org/blog/2017/05/15/amid-aca-uncertainty-covered-californias-risk-profile-remains-stable/

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Shore K and Bertko J, "Comparison of Small Group Rates in California: HIPC vs. Non-HIPC," California Health Care Foundation paper, September 1999 Available online at: http://www.chcf.org/documents/insurance/hipcrates.pdf

Bertko J and Hunt S, "Case Study: The Health Insurance Plan of California" 35(2): 148-153. *Inquiry*, Summer 1998.

Health Care Projects and Committees

1989	Oregon Medicaid Prioritization Project – consultant
1992	Managed Risk Medical Insurance Board (MRMIB) – California, consultant for creation of Uninsurable Pool and California HIPC purchasing coop
1993	Actuarial Auditor for Clinton health care reform proposal
1994	State of Hawaii Initiative for the Uninsured -- consultant
1994	State of Colorado modeling of ColoradoCare -- consultant
1994-95	Vice President for the Health Practice, American Academy of Actuaries

1996-2002	Member, Actuarial Board for Counseling and Discipline, American Academy of Actuaries
1998-2001	Member, Competitive Pricing Advisory Commission (for Medicare)
2004	Member, Medicare Trustees 2004 Technical Advisory Panel
2005	Guest lecturer, Leonard Davis Institute, Wharton School, Univ. of Pennsylvania
2004-2010	Member, Medicare Payment Advisory Commission (MedPAC)
2003-2011	Member, National Advisory Committee for the California Health Benefits Review Program
2010	Recipient of The Actuarial Foundation's Wynn Kent Public Communications Award
2010-2012	Co-chair, Medicare Trustees 2010-12 Technical Advisory Panel
2014-2015	Member, Massachusetts Connector Board
2007-2011, 2015-present	Member, Congressional Budget Office Panel of Health Advisors

EXHIBIT 10

Supplemental Expert Report of John Bertko, dated October 26, 2021

Supplemental Expert Witness Report

Regarding Potential Cost of Additional ESRD Enrollees

John Bertko, F.S.A., M.A.A.A.

Independent Consultant

October 26, 2021

I. Introduction

Purpose of the Supplemental Report

The Office of Attorney General of the State of California has retained me to opine on issues related to AB290 and the effects on the risk pool and premiums for Covered California's Individual insurance market and that of the off-Exchange market (which enrolls consumers who do not use Covered California). As the Chief Actuary for Covered California, it has been my responsibility for the last eight-and-a-half years to monitor the relative risk levels and costs of enrollees in Covered California in order to help maintain the stability of this crucial state program.

This Supplemental Report provides additional analytic data that bolsters the findings in my previous report submitted March 10, 2020. It is based on newly published data analyzed by researchers from the University of Southern California (USC), the Brookings Institution and other organizations.

II. Summary of New Information

As described in my earlier report, adding additional enrollees with End Stage Renal Disease (ESRD, sometimes called End Stage Kidney Disease, or ESKD) means that a greater burden of risk (illness level) and related health care costs will occur and will increase average consumer premiums. A new study by Dr. Erin Trish, a nationally known health care economist (and colleagues) from USC-Brookings, contributes analysis from a wider database of 50 million member-months (approximately 4 million to 5 million members) from states across the country and adds support to the findings in my earlier report that had data only from Covered California.

As Dr. Trish notes early in her article in the Journal of the American Medical Association Internal Medicine (published March 22, 2021), "some policy makers allege that dialysis facilities encourage individual market enrollment by subsidizing individual market premiums through contributions to patient assistance foundations. This strategy could increase profits for the facilities because commercial plans pay more than Medicare, but also increase individual market spending if patients receiving dialysis have above average spending."[1]

Using 2016 data from a health care analytics firm, Dr. Trish's team estimated average monthly spending on dialysis services and all services in the Individual market. As mentioned above, the database had 50 million member months, about 28% of the 2016 total ACA-compliant enrollment, a very substantial portion of the market. Dr. Trish's team then created estimates of the expected increase in

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[1] Trish E, Fiedler M, Ning N, Gascue L, Adler L and Lin E, "Research Letter: Payment for Dialysis Services in the Individual Market," JAMA Internal Medicine, published online March 22, 2021, jamanetwork/2021/imd/03_22_2021/ild200084pap

Individual market spending if some non-Aged Medicare enrollees with ESRD instead had Individual market coverage, through an Exchange like Covered California.

Results were important: although a very small percentage of enrollment (about 0.1%), spending on these additional enrollees with ESRD was about 3.3% of total spending. Importantly, spending per ESRD person was $14,399 per month, about 33 times spending for individuals without ESRD. In the team's analysis, monthly dialysis spending in commercial market plants was more than 300% of the corresponding Medicare spending for the same service.

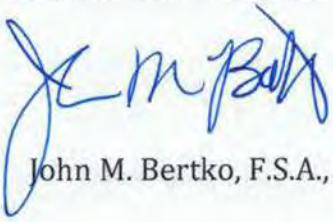
Further team projections indicated that if 10% of non-aged Medicare enrollees with ESRD were shifted into the individual market, overall individual market spending would increase by 4.1%. This estimate is directionally the same and similar to the 5.3% increase projected in my March 10, 2020 report based on only Covered California enrollee data.

III. Conclusion

As indicated in Dr. Trish's research and my earlier report, adding more ESRD enrollees (who could get coverage under Medicare) would increase premiums by from 4.1% (Dr. Trish's study) to 5.3% (specific to Covered California). This is an unnecessary burden for Covered California and its enrollees as well as enrollees in the off-Exchange market whose premiums are tied to premiums of Covered California.

All opinions are held to a reasonable degree of actuarial certainty. If other new or supplemental information becomes available, I reserve the right to revise my opinion.

Dated: October 26, 2021



John M. Bertko, F.S.A., MAAA

EXHIBIT 1

Letters

RESEARCH LETTER

HEALTH CARE POLICY AND LAW

Payment for Dialysis Services in the Individual Market

Although 80% of US patients who receive dialysis for end-stage kidney disease (ESKD) have Medicare as their primary payer, recent evidence suggests an increasing share with other coverage.[1] Some policy makers allege that dialysis facilities encourage individual market enrollment by subsidizing individual market premiums through contributions to patient assistance foundations.[2] This strategy could increase profits for facilities because commercial plans pay more for dialysis than Medicare,[3] but could also increase individual market spending if patients receiving dialysis have above-average spending.

Supplemental content

To our knowledge, little is known about the prevalence and spending of patients with ESKD in the individual market. Prior commercial market studies were limited to financial records of 1 chain, combined employer and individual plans, and only examined dialysis spending.[3] To address these gaps, we used claims data for individual market plans and analyzed dialysis and nondialysis spending.

Methods | Using 2016 US Affordable Care Act–compliant individual market claims data held by a health care analytics firm, we estimated the prevalence of patients with ESKD and average monthly spending on dialysis services and all services. The data encompass 50 million member months, comprising 28% of 2016 Affordable Care Act–compliant enrollment. We computed average monthly spending by dividing the total allowed amounts, including cost-sharing, by member months. The University of Southern California institutional review board determined that the study met the criteria for coded private information or biological specimens and thus was exempt from informed consent requirements.

We defined patients with ESKD as those who were assigned an ESKD hierarchical condition category code who received at least 1 outpatient dialysis service in 2016. Hierarchical condition category codes are derived from diagnosis codes and used to risk-adjust health plan payments.

We used these estimates to calculate the expected increase in individual market spending if some nonaged Medicare enrollees with ESKD instead had individual market coverage. To compare individual market dialysis spending with Medicare, we used claims from a 100% sample of traditional Medicare patients with ESKD. The eAppendix in the Supplement provides additional detail.

Results | Patients with ESKD comprised 0.10% of individual market member months (51 002 of 50 million) but 3.3% of spending ($734 million of $21 billion). Their average monthly spending on all services was $14 399, 33 times spending by enrollees without ESKD ($435) (**Table 1**).

Individual market enrollees with ESKD received 1 or more outpatient dialysis services in 85% of enrolled months. For months with at least 1 dialysis service, the average monthly outpatient dialysis spending was $10 149, or 302% of the corresponding estimate for Medicare ($3364). Shifting 10% of nonaged Medicare enrollees with ESKD who were receiving dialysis into the individual market would increase individual market ESKD prevalence to 0.24% and overall average spending by 4.1% (**Table 2**).

Discussion | Individual market plans paid approximately 3 times what Medicare paid for dialysis services, underscoring the incentive for facilities to encourage individual market enrollment. Steering Medicare beneficiaries into the individual market would raise premiums, which would increase spending by enrollees without federal premium subsidies. Additionally, higher federal spending on premium subsidies would likely exceed the offsetting Medicare savings.

Policy makers have options to discourage steering. Although a federal judge blocked a 2016 federal rule that directly limited third-party assistance, citing procedural problems,[4] the rule could be reissued or Congress could enact similar restrictions.[5] Similarly, California enacted legislation in 2019 that capped dialysis reimbursement at Medicare rates for patients who were receiving third-party assistance. An ongoing lawsuit alleges that California's law violates federal law, but even if it succeeds, Congress could implement similar restrictions nationally.[6]

Table 1. Average Monthly Spending for Patients With ESKD by Market Segment, 2016

	Enrollment months			
		With a dialysis service		
Patients	All individual market	Individual market	Medicare	Individual market as a percentage of Medicare
Patients without ESKD, $	435	NA		
Patients with ESKD, $				
Outpatient dialysis	8622	10 149	3364	302
All services	14 399	NA		

Abbreviation: ESKD, end-stage kidney disease; NA, not applicable.

Table 2. Prevalence and Spending Effect of Shifting Nonaged Medicare Beneficiaries With ESKD to the Individual Market, 2016

Share of nonaged Medicare beneficiaries with ESKD receiving dialysis shifting from traditional Medicare to individual market	%	
	Individual market ESKD prevalence	Change in average individual market claims spending
0% (status quo)	0.10	NA
10%	0.24	+4.1
20%	0.37	+8.2
40%	0.63	+16.4

Abbreviation: ESKD, end-stage kidney disease; NA, not applicable.

A limitation of our study is that we estimated the average spending for all patients with ESKD in the individual market and Medicare, who might not represent patients who are targeted by the steering efforts of facilities. Additionally, our individual market data might not represent the entire market.

We also could not examine how transitions to the individual market might affect patient cost-sharing and networks. Those effects depend on whether the patient had Medicare Advantage or Medicare supplemental coverage, the specific individual market plan selected, and whether patients receive other cost-sharing assistance.

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Matthew Fiedler, PhD
Ning Ning, PhD
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Author Contributions: Author x had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Trish, Fiedler, Adler, Lin.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Trish, Fiedler, Lin.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Trish, Fiedler, Ning, Gascue, Lin.
Obtained funding: Trish, Fiedler, Adler.
Administrative, technical, or material support: Fiedler, Adler.
Supervision: Trish, Fiedler, Gascue, Adler, Lin.

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Disclaimer: The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health nor any other funders. Some of the data reported here have been supplied by the United States Renal Data System. The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the US government.

1. Hoffman A, Sloan CE, Maciejewski ML, Wang V. Medicare enrollment among patients with end-stage kidney disease receiving dialysis in outpatient facilities between 2005 and 2016. *JAMA*. 2020;323(13):1314-1316. doi:10.1001/jama.2020.0704

2. Jost T. CMS acts on premium payments by dialysis facilities, special enrollment period eligibility. Accessed February 10, 2021. https://www.healthaffairs.org/do/10.1377/hblog20161213.057930/full/

3. Childers CP, Dworsky JQ, Kominski G, Maggard-Gibbons M. A comparison of payments to a for-profit dialysis firm from government and commercial insurers. *JAMA Intern Med*. 2019;179(8):1136-1138. doi:10.1001/jamainternmed.2019.0431

4. Centers for Medicare & Medicaid Services; US Department of Health and Human Services. Medicare Program; conditions for coverage for end-stage renal disease facilities-third party payment. *Fed Regist*. 2016;81(240):90211-90228.

5. Andrews M. Judge upends effort to limit charity funding for kidney patients' insurance. Accessed February 10, 2021. https://khn.org/news/judge-upends-effort-to-limit-charity-funding-for-kidney-patients-insurance/

6. Associated Press. Judge blocks California law on dialysis clinics. Accessed February 10, 2021. https://www.latimes.com/world-nation/story/2019-12-30/judge-blocks-california-law-on-dialysis-clinics

EXHIBIT 11

Report by the Office of Congresswoman Katie Porter, dated July 15, 2021

KATIE PORTER
Putting Orange County families first

Dying on Dialysis: Inside an Industry Putting Profits Over Patients

Report by the Office of Congresswoman Katie Porter (CA-45)

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Executive Summary

On July 23, 2019, **Representative Katie Porter sent a letter to the Department of Health and Human Services (HHS) Office of the Inspector General requesting that the agency open an investigation into the relationship of the American Kidney Fund (AKF) with leading dialysis providers**, specifically, DaVita and Fresenius Medical Care. This letter was based on troubling evidence suggesting that **these providers and AKF have collaborated to implement practices that benefit their bottom line at the expense of patients with kidney disease**.

This staff report—based on additional investigation and documents obtained by Rep. Porter's office, academic studies, and unsealed whistle-blower lawsuits—provides **significant new support for opening such an OIG investigation**. The evidence outlined below reveals practices that may interfere with patients' ability to receive kidney transplants, raise premiums, lead patients to enroll in plans that include less comprehensive coverage or higher out-of-pocket costs, and destabilize the private insurance market.

> **"Recent reports and this investigation suggest that AKF's for-profit benefactors are inappropriately steering patients to private insurance plans rather than Medicare or Medicaid, as the dialysis companies can receive up to four times more from the private plans for the very same dialysis treatment."**

Specifically, credible concerns exist about **possible conflicts of interest involving the structure and practices of AKF's patient assistance program**, in which dialysis clinics donate to AKF and provide dialysis treatment for patients whose insurance premiums were paid by AKF and in return receive payments many times the size of their donations from the patients' insurance. Recent reports and this investigation suggest that **AKF's for-profit benefactors are inappropriately steering patients to private insurance plans rather than Medicare or Medicaid, as the dialysis companies can receive up to four times more from the private plans for the very same dialysis treatment**. This not only distorts the health insurance market,[1] but more importantly it can make it more difficult for patients to get the kidney transplants they need and result in higher patient costs.

This report concludes that these developments – combined with Centers for Medicare and Medicaid Services (CMS) research and the major changes to the private health insurance market for those with kidney disease as a result of the Affordable Care Act's prohibition on insurers discriminating against patients with pre-existing conditions – warrant the Office of the Inspector General revisiting the conclusions of the 1997 Advisory Opinion that permitted the operation of the AKF's Health Insurance Premium Program (HIPP).[2] **It is also time for CMS to take action to bring transparency and accountability to third party premium payments through the rulemaking process**.[3]

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[1] Stephanie Hedt, "Dialysis Costs the Healthcare System Three Times More in the Individual Market." USC Leonard Schaeffer Center For Health Policy & Economics. https://healthpolicy.usc.edu/article/dialysis-costs-the-healthcare-system-3x-more-in-the-individual-market/.

[2] HHS OIG. Advisory Opinion No. 97-01. (1997). https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf

[3] CMS FACT SHEET: PROMOTING TRANSPARENCY AND APPROPRIATE COVERAGE FOR DIALYSIS PATIENTS, Centers for Medicare and Medicaid Services, Department of Health and Human Services. https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/esrd-ifc-factsheet-final-2-12-12-16.pdf.

End Stage Renal Disease and Dialysis Treatment

People whose kidneys are failing, otherwise known as a condition called end stage renal disease (ESRD), require dialysis treatment, which performs the functions otherwise performed by the kidneys.[4] A dialysis machine removes blood from the patient, cleans the blood as a healthy kidney would, and then gives the blood back to the patient. Dialysis usually involves treatments several times a week for several hours at a time.[5] **For patients with ESRD, there are few other options for care other than dialysis or kidney transplants**.[6]

In 1973, **President Richard Nixon signed legislation to ensure that patients with ESRD could afford dialysis care by making patients, regardless of their age, eligible for Medicare coverage**.[7] Starting in 1983, Medicare paid dialysis facilities a set rate for dialysis treatment. In 2011, Medicare began paying for dialysis care using a bundled, prospective payment system that "is intended to cover all operating and capital costs that efficient providers would incur in furnishing dialysis treatment episodes in dialysis facilities or in patients' homes."[8] Medicare spends more than $12.9 billion per year on dialysis treatments alone.[9]

Most patients with ESRD are low-income. According to a Loyola University Chicago Stritch School of Medicine study, the percentage of adults beginning dialysis treatment who live in zip codes with high poverty rates rose from 27.4% to 34% from 1995 to 2010.[10] At the same time, the general population beginning dialysis treatment saw a much smaller increase, from 11% to 12.5%.[11] Many ESRD patients have multiple health conditions, as ESRD is related to various other health concerns that cause the kidneys to deteriorate.

"Compared with white Americans, Black Americans are about 3.7 times more likely to have ESRD."

As a result of the Affordable Care Act (ACA), Medicaid expansion has improved dialysis patients' access to affordable care, particularly for patients with lower incomes. Many ESRD patients are "dual eligibles," and can enroll in both Medicaid and Medicare. **In the first three years of the ACA's implementation, the number of patients with ESRD who died within their first year of treatment decreased in expansion states, while it remained stagnant or worsened in non-expansion states**.[12]

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[4] "Dialysis | Hemodialysis | Peritoneal Dialysis." *MedlinePlus*, U.S. National Library of Medicine, 27 Dec. 2018, medlineplus.gov/dialysis.html.
[5] "What Is Dialysis?" National Kidney Foundation, 2 July 2018, www.kidney.org/atoz/content/dialysisinfo.
[6] "End Stage Renal Disease (ESRD)." *Johns Hopkins Medicine*, The Johns Hopkins University, www.hopkinsmedicine.org/health/conditions-and-diseases/end-stage-renal-failure.
[7] Eggers, Paul W. "Medicare's End Stage Renal Disease Program." *National Center for Biotechnology Information*, National Institutes of Health, United States Department of Health and Human Services, 2000, www.ncbi.nlm.nih.gov/pmc/articles/PMC4194691/.
[8] Medicare Payment Advisory Commission. *Outpatient Dialysis Services Payment System*. Washington, DC: Medicare Payment Advisory Commission; 2019. medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf#page=197.
[9] Ibid.
[10] Loyola University Health System. "More dialysis patients living in poor neighborhoods." ScienceDaily. ScienceDaily, 15 June 2015. <www.sciencedaily.com/releases/2015/06/150615162902.htm>.
[11] Preidt, Robert. "U.S. Dialysis Patients Increasingly Live in Poor Areas." *Consumer HealthDay*, HealthDay, 24 June 2015, consumer.healthday.com/diseases-and-conditions-information-37/misc-kidney-problem-news-432/u-s-dialysis-patients-increasingly-live-in-poor-areas-700497.html.
[12] Swaminathan, Shailender, et al. "Association of Medicaid Expansion With 1-Year Mortality Among Patients With End-Stage Renal Disease." Journal of the American Medical Association, vol. 320, no. 21, 2018, p. 2242., doi:10.1001/jama.2018.16504.

"Early reports found that up to 30% of patients hospitalized with COVID-19 in China and New York developed kidney problems, often severe enough to require dialysis."

Throughout the world, but especially in the United States, **ESRD disproportionately harms people of color**. Compared with white Americans, Black Americans are about 3.7 times more likely to have ESRD.[13] This disparity showcases one of the major inequities in our health care system: **Black Americans are 3.5 times more likely to progress from early stage kidney disease to kidney failure (ESRD).**[14] **In the Latinx community, ESRD is about twice as common as it is for white communities.**[15] And research shows that people who suffered from severe cases of COVID-19— which also disproportionately harmed people of color[16]—are showing serious signs of kidney damage. **Early reports found that up to 30% of patients hospitalized with COVID-19 in China and New York developed kidney problems, often severe enough to require dialysis.**[17]

The Dialysis Industry's "Duopoly" and Disregard for Patients

Since 1973, the nation's largest dialysis providers have seen record profits while rapidly consolidating. The number of patients receiving insurer-covered dialysis treatment has risen from 65,700 in 1982 to more than 500,000 in 2019. Despite this growth in treatment, nonprofit, independently owned, and hospital-based dialysis facilities have disappeared over time, as for-profit dialysis facilities affiliated with large dialysis organizations (LDOs) have consolidated power and money in the industry.[18]

"Since 1973, the nation's largest dialysis providers have seen record profits while rapidly consolidating."

Recent research published in the Journal of the American Medical Association (JAMA) found that "in 1995, 41% of all dialysis facilities were affiliated with 7 LDOs, which increased to 63% in 2005 when consolidation reduced the number of LDOs to 5. **This consolidation trend has continued to the point where the dialysis industry today can be characterized as a duopoly—with 2 corporations that together own nearly 70% of dialysis facilities in the United States.**"[19] Those two corporations are DaVita and Fresenius.

The Herfindahl-Hirschman index (HHI) is a commonly used measure of market concentration by the Department of Justice

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[13] Jenna M. Norton, et al.,"Social Determinants of Racial Disparities in CKD." Journal of the American Society of Nephrology Sept. 2016, https://jasn.asnjournals.org/content/27/9/2576.
[14] Jenna M. Norton, et al.,"Social Determinants of Racial Disparities in CKD." Journal of the American Society of Nephrology Sept. 2016, https://jasn.asnjournals.org/content/27/9/2576.
[15] Michael J. Fischer, et al., "CKD Progression and Mortality among Hispanics and Non-Hispanics." Journal of the American Society of Nephrology, Nov. 2016, https://jasn.asnjournals.org/content/27/11/3488.
[16] Health Equity Considerations and Racial and Ethnic Minority Groups. Centers for Disease Control and Prevention, Updated Apr. 19, 2021, https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.
[17] C. John Sperati, "Coronavirus: Kidney Damage Caused by COVID-19." Johns Hopkins Medicine, May 14, 2020, https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/coronavirus-kidney-damage-caused-by-covid19.
[18] Wang, Virginia, and Matthew L. Maciejewski. "Patient Outcomes and Dialysis Consolidation—Two Big to Fail?" *JAMA*, vol. 2, no. 5, 2019, doi:10.1001/jamanetworkopen.2019.3962.
[19] Ibid.

(DOJ).[20] The index ranges from less than 1 to 10,000. Increases in the index generally indicate a decrease in competition and increase in market power. **The Department of Justice defines a highly concentrated market at 2,500. A 2016 study published in the International Journal of Health Economics and Management estimated that the average HHI for outpatient dialysis services at the county level was 4,778.[21] In the state of California, the average HHI is over 6,000.[22]**

	DaVita	Fresenius	All Other
Number of Dialysis Clinics	279	127	191
Percent of Total Dialysis Clinics	46.7%	21.3%	32.0%
Total Stations	6,055	2,689	3,765
Percent of Total Stations	48.4%	21.5%	30.1%

Source: Dialysis Facility Compare Sets from CMS (2017)

This lack of competition combined with a focus on profits to the detriment of patients can have sharply negative results. A recently published academic study found that **Medicare per-treatment reimbursement increased by 6.9% at facilities acquired by large dialysis chains while patients experienced worse outcomes at these facilities**.[23] Additionally, for nearly every dimension of patient care measured, patient outcomes were worse at the facility after the acquisition, "most prominently in terms of fewer kidney transplants, more hospitalizations, and lower survival rates." The study found that independent facilities acquired by large chains end up replicating the business practices of the acquiring organization, including replacing high-skill nurses with lower-skill dialysis technicians, increasing the patient-load of each employee, and increasing the number of patients treated at each dialysis station, all of which potentially reduce the quality of care delivered to patients.[24] Moreover, "overall Medicare spending increases at acquired facilities, mostly as a result of higher drug reimbursements," meaning **taxpayer dollars are not being put to their best use**. Additional JAMA research found that independently owned dialysis facilities acquired by LDOs often had slower decreases in mortality and hospitalization rates than

"Additionally, for nearly every dimension of patient care measured, patient outcomes were worse at the facility after the acquisition, 'most prominently in terms of fewer kidney transplants, more hospitalizations, and lower survival rates.'"

[20] "Herfindahl-Hirschman Index." *Justice.Gov*, The United States Department of Justice, 31 July 2018, www.justice.gov/atr/herfindahl-hirschman-index.
[21] Wilson, Nathan E. "For-profit status and industry evolution in health care markets: evidence from the dialysis industry." International journal of health economics and management 16, no. 4 (2016): 297-319.
[22] "Datasets: Data.Medicare.gov." *Data.Medicare.Gov*, Centers for Medicare and Medicaid Services, 2018, data.medicare.gov/data/dialysis-facility-compare.
[23] P.J. Eliason, B. Heebsh, R.C. McDevitt, J.W. Roberts. (2019). *How Acquisitions Affect Firm Behavior and Performance: Evidence from the Dialysis Industry. https://economics.harvard.edu/files/economics/files/ms29704.pdf*
[24] Ibid.

would have otherwise occurred for the independently owned facilities.[25]

Anecdotal evidence tells a similar story. Megallan Handford, a nurse in a clinic in Fontana, California, told Medscape, that "it doesn't take much to kill a patient on hemodialysis. Just overlook a dislodged needle, and a patient can bleed out in a matter of minutes." He explained, "When you look on the floor and you see a pile of gelled blood, you know you've got a problem."[26] Reports of understaffing in LDOs are common, and place patients in Orange County and across the country at risk. During one ProPublica investigation, researchers "found blood encrusted in the folds of patients' treatment chairs or spattered on walls, floors or ceiling tiles."[27]

One explanation for these adverse patient outcomes may be the profit motives of the large LDOs. **In 2019, DaVita engaged in company stock buybacks in the amount of up to $1.2 billion, which intentionally increase companies' share prices and line the pockets of executives rather than investing in patient care.**[28] During the pandemic, in 2020, DaVita completed another stock buyback of more than $1 billion.[29] **The former CEO of DaVita, Kent Thiry, gave a speech at the University of California, Los Angeles to students where he described DaVita clinics as being similar to the fast food industry – and made clear "to me, it's not about the patients."**[30] In short, DaVita treats the provision of life-saving dialysis care as just another way to make the most money for their product, disregarding the sensitive nature of medical care for those with kidney disease and the substantial taxpayer funding dedicated to it. **According to Thiry, "If I had 1,400 Taco Bells and 32,000 people who worked in them, I would be doing all the same stuff."**[31]

"The former CEO of DaVita, Kent Thiry, gave a speech at the University of California, Los Angeles to students where he described DaVita clinics as being similar to the fast food industry – and made clear 'to me, it's not about the patients.'"

Though Thiry ended his nearly twenty-year tenure as the CEO of DaVita in May 2019, he remained the Executive Chairman of the company's Board of Investors, leaving in May 2020 to join KKR, a private equity firm.[32] **Current DaVita Board Chair Pamela**

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[25] Erickson, Kevin F., et al. "Association of Hospitalization and Mortality Among Patients Initiating Dialysis With Hemodialysis Facility Ownership and Acquisitions." *JAMA Network Open*, vol. 2, no. 5, 2019, doi:10.1001/jamanetworkopen.2019.3987.
[26] Harrison, Laird. "California First to Address Dialysis Staffing Problems." *Medscape*, 21 Apr. 2017, www.medscape.com/viewarticle/878870#vp_3.
[27] Fields, Robin. "In Dialysis, Life-Saving Care at Great Risk and Cost." *ProPublica*, 9 Mar. 2019, www.propublica.org/article/in-dialysis-life-saving-care-at-great-risk-and-cost
[28] "Improving Health, Health Care and Quality of Life." *DaVita News*, 22 July 2019, pressreleases.davita.com/2019-07-22-DaVita-Commences-Self-Tender-Offer-To-Purchase-For-Cash-Shares-Of-Its-Common-Stock-For-An-Aggregate-Purchase-Price-Of-No-More-Than-1-2-Billion-At-A-Purchase-Price-Of-Not-Less-Than-53-50-Per-Share-And-Not-More-Than-61-50-Per-Share.
[29] DaVita Stock Buybacks (Quarterly), Y Charts, https://ycharts.com/companies/DVA/stock_buyback.
[30] Foley, Katherine Ellen. "John Oliver Ripped into a CEO Who Proudly Compared His Healthcare Business to Taco Bell." *Quartz*, Quartz, 15 May 2017, qz.com/983716/john-oliver-rips-into-fresenius-fms-and-davita-dva-whose-ceo-proudly-compared-kidney-dialysis-to-taco-bell-yum/.
[31] Ibid.
[32] "DaVita CEO Kent Thiry Steps down and Is Named Executive Chair of Board of Directors." *Healio - Nephrology News and Issues*, 30 Apr. 2019, www.healio.com/nephrology/kidney-care-community/news/online/%7Bad74d628-76ef-

Arway has no health care background, joining the company from financial giant American Express.[33] Unfortunately, consolidation in the industry and attitudes like Thiry's have harmed patient outcomes. While in some industries consolidation can increase the provision of a service, LDOs have focused on volume over quality of care in the dialysis space.

Potential Conflicts of Interest That Harm ESRD Patients

The American Kidney Fund's work centers around a patient assistance program, the Health Insurance Premium Program (HIPP), which helps pay insurance premiums for individuals who need dialysis. Specifically, **HIPP covers premiums for Medicare, Medicaid, and private insurance plans.**[34] While this program has benefitted thousands of individuals over the years, **Rep. Porter wrote a letter in July raising concerns about possible conflicts of interest that could result in negative patient outcomes**. In short, dialysis clinics donate to AKF and provide dialysis treatment for patients whose insurance premiums were paid by AKF and in return receive payments many times the size of their donations from the patients' insurance.

"In short, dialysis clinics donate to AKF and provide dialysis treatment for patients whose insurance premiums were paid by AKF and in return receive payments many times the size of their donations from the patients' insurance."

Complaints from patients and providers have yielded reports that the country's largest dialysis providers are "intentionally and illegally" steering Medicare- and Medicaid-eligible patients "into commercial plans by paying their premiums for them through AKF."[35] Doing so increases dialysis center profits. Before the ACA, private insurance coverage was rarely an option because ESRD was an expensive pre-existing condition. Since the ACA prohibits insurance companies from discrimination based on pre-existing conditions, those with kidney disease now have access to private insurance through the ACA exchanges in addition to access to Medicare coverage. As discussed, many ESRD patients are also covered by Medicaid due to the ACA's expansion of eligibility.

It appears that **the large dialysis providers may have abused this reform and HIPP by pushing patients to private plans that generate more profit for the providers than Medicare or Medicaid, even though private plans may have higher premiums and may not be in the best interest of the patients**. The commercial plans reimburse the clinics at significantly higher rates, up to four times more than Medicaid, "adding up to an additional $200,000 per patient per year."[36] Since 2010, DaVita and Fresenius have experienced significant growth in annual profits, bringing in billions of dollars annually.[37] In January 2018, at

48fb-9cf1-b6343c64dc0d%7D/davita-ceo-kent-thiry-steps-down-and-is-named-executive-chair-of-board-of-directors.

[33] "Board and Management." *DaVita Inc.* https://investors.davita.com/corporate-governance/board-of-directors

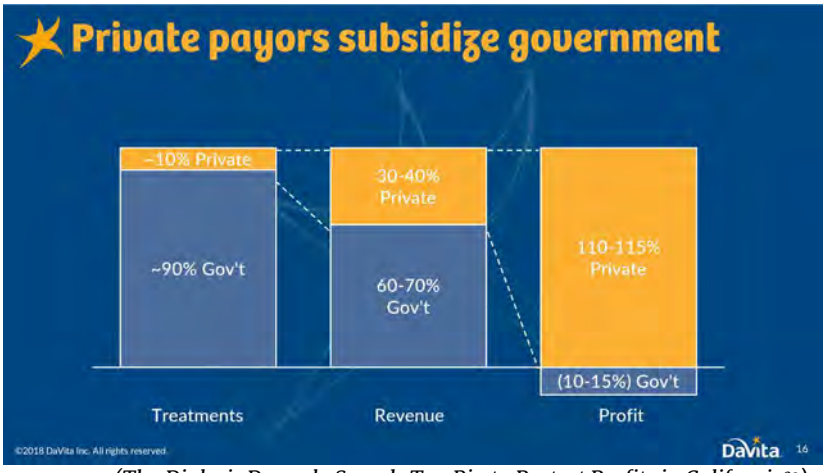
[34] "Health Insurance Premium Program (HIPP)." American Kidney Fund (AKF), www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/.

[35] United States District Court of Colorado, Case 1:17-cv-00304-WJM-NRN.

[36] Thomas, Katie, and Reed Abelson. "Kidney Fund Seen Insisting on Donations, Contrary to Government Deal." *The New York Times*, 25 Dec. 2016, www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html.

[37] "Fresenius Medical Care Gross Profit 2006-2019: FMS." *Macrotrends*,

the annual JP Morgan Healthcare Conference, DaVita displayed the chart below, which shows how the company relies on private plans to make its large profits despite far more patients being enrolled in Medicare.[38]



(The Dialysis Duopoly Spends Too Big to Protect Profits in California[39])

To bring in millions in annual profits, DaVita seeks to have a substantial number of patients in their treatment pool who are not on Medicare or Medicaid. While private coverage brings higher reimbursement rates and is consistently better for providers, it is not always in the best interest of patients. **AKF may provide premium support but often fails to pay for additional healthcare expenses, such as prescriptions or medical devices. For a patient on a private plan, especially a high deductible plan, these costs could be significantly higher than if they received insurance from Medicaid or Medicare**.

Moreover, this steering toward private plans also has potentially life-threatening consequences for patients. **Experts agree that a kidney transplant offers the best outcome for an individual with kidney disease, as a transplant allows the patient to stop dialysis treatments**.[40] Patient mortality rates increase after the first year of dialysis treatment. While in the first year, the chance of death is only 25%, it rapidly increases to 65% after five years.[41]

Additionally, **the cost per patient drops significantly after patients receive transplants**. Annual dialysis treatments are 3.5 times more expensive than annual post-transplant care. Dialysis treatment costs an average of $89,000 per patient annually in the United States. While the average cost of a kidney transplant is $32,000, post-surgery care and covering other

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www.macrotrends.net/stocks/charts/FMS/fresenius-medical-care-ag-kgaa/gross-profit.; DaVita Medical Care Gross Profit 2006-2019: FMS." *Macrotrends*, https://www.macrotrends.net/stocks/charts/DVA/davita/gross-profit; American Renal Association AG KGaA Gross Profit 2006-2019: FMS." *Macrotrends*, https://www.macrotrends.net/stocks/charts/ARA/american-renal-associates-holdings/gross-profit.

[38] Sammon, Alexander. "The Dialysis Duopoly Spends Big to Protect Profits in California." *The American Prospect*, 23 Aug. 2019, prospect.org/article/dialysis-duopoly-spends-big-protect-profits-california.

[39] Ibid.

[40] Wang, Jeffrey H., et al. "Current Status of Kidney Transplant Outcomes: Dying to Survive." *Advances in Chronic Kidney Disease*, vol. 23, no. 5, 2016, pp. 281–286., doi:https://www.srtr.org/media/1102/wang-jh_current-status-of-kidney-transplant-outcomes-dying-to-survive_2016-ackd.pdf.

[41] Foley, Katherine Ellen. "John Oliver Ripped into a CEO Who Proudly Compared His Healthcare Business to Taco Bell." *Quartz*, Quartz, 15 May 2017, qz.com/983716/john-oliver-rips-into-fresenius-fms-and-davita-dva-whose-ceo-proudly-compared-kidney-dialysis-to-taco-bell-yum/.

transplant-related concerns costs an average of $25,000.[42] However, this outcome is not in the financial interests of dialysis providers, who permanently lose patients once they receive transplants, especially if the providers are receiving higher payments from commercial insurers.

To be eligible for transplants, patients need to be able to show continuous access to medical care. Eligible patients on Medicare or Medicaid typically can meet this requirement, but many patients on private plans where premiums are supported by AKF cannot. This is because of an AKF policy that ends premium assistance for patients who receive transplants after a certain amount of time, despite patients needing proof of ongoing insurance in order to be eligible for a transplant. The HIPP guidelines on AKF's website as of September 2019 read that they would continue support "through the end of the insurance coverage plan year for the same insurance policy(ies) in which the patient was enrolled prior to the transplant."[43] Patients do not get to choose when they receive a transplant during their insurance coverage plan year.

"Consider a patient who receives financial assistance from AKF and becomes eligible for a transplant after a year on dialysis. If the patient received a transplant, the patient could cease undergoing dialysis and live a healthy life. But if the patient is denied support from AKF for the transplant, the patient could be forced to remain on dialysis for years. This result is in the interest of the dialysis providers, but it is not in the interest of the patient."

AKF informed Rep. Porter's office that if a patient receives a transplant in the last quarter of the plan year, AKF will continue support into the following plan year. Since that time, there have been no updates that this policy has changed. Still, those who receive a kidney transplant in the third quarter of the insurance plan year have little certainty or security. In contrast, Medicare covers patients for up to three years after transplants.[44]

In discussions with Rep. Porter's office, **AKF also claimed that they cannot continue assistance for longer periods after a patient receives a transplant because of funding concerns.** The effect of the policy, however, is to advance the financial interests of the dialysis providers at the expense of the health interests of the patients. Consider a patient who receives financial assistance from AKF and becomes eligible for a transplant after a year on dialysis. If the patient received a transplant, the patient could cease undergoing dialysis and live a healthy life. But if the patient is denied support from AKF for the transplant, the patient could be forced to remain on dialysis for years. This result is in the interest of the dialysis providers, but it is not in the interest of the patient.

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[42] Schools of Pharmacy and Medicine, Department of Bioengineering and Therapeutic Sciences University of California, San Francisco, The Kidney Project. https://pharm.ucsf.edu/kidney/need/statistics.
[43] "Health Insurance Premium Program (HIPP)." American Kidney Fund (AKF), www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/.
[44] United States Department of Health and Human Services., Centers for Medicare and Medicaid Services. "Medicare Coverage of Kidney Dialysis & Kidney Transplant Services." https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf

Rep. Porter's office asked AKF for financial data to support its claim that it could not afford to support patients receiving transplants, but AKF refused to provide this information. According to publicly available information from its 2019 tax filings, the American Kidney Fund received a total of $298,438,440 in contributions.[45] The majority of this funding goes to their patient assistance program. Yet **AKF paid a total of $974,338 in executive compensation, including the salary of $590,795 for CEO LaVarne Burton**.[46] In its federal lobbying filings, the AKF spent nearly $800,000 in 2018 and more than $500,000 in 2019 on lobbying fees, which does not include spending on state and local lobbying.[47] Additionally, it bears noting that Federal Street Strategies, which advocates on behalf of AKF, also lobbies for DaVita.[48]

Revelations Regarding Dialysis Industry Practices

In a whistleblower case unsealed in 2019, former AKF employee David Gonzalez accused the charity of creating a "so-called blocked list" of dialysis clinics whose patients did not receive financial assistance.[49] The 2016 lawsuit was unsealed in August 2019. **The lawsuit alleges that DaVita and Fresenius increased their profits by donating money to the AKF, "so that the patient can obtain government funding for dialysis treatment to be spent on providers."**[50] The case outlines complaints regarding alleged blocking of financial assistance when not requested from a provider that donates to AKF. One such allegation asserts that AKF disposed of applications for financial assistance from patients receiving dialysis at Methodist Hospital in Texas when the hospital would not donate to the program.[51]

"One such allegation asserts that AKF disposed of applications for financial assistance from patients receiving dialysis at Methodist Hospital in Texas when the hospital would not donate to the program"

The whistleblower was asked to ensure that patients at clinics operated by DaVita and Fresenius were approved.[52] The *New York Times* reported that:

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[45] "American Kidney Fund Inc - Nonprofit Explorer." *ProPublica*, projects.propublica.org/nonprofits/organizations/237124261.
[46] Ibid.
[47] "Lobbying Spending Database - American Kidney Fund, 2018." *OpenSecrets.org*, www.opensecrets.org/lobby/clientsum.php?id=D000046966&year=2018.
[48] "Lobbying Spending Database – Federal Street Strategies, 2018." *OpenSecrets.org*, https://www.opensecrets.org/lobby/firmsum.php?id=F222086&year=2018.
[49] Abelson, Reed, and Katie Thomas. "Top Kidney Charity Directed Aid to Patients at DaVita and Fresenius Clinics, Lawsuit Claims." *The New York Times*, The New York Times, 2 Aug. 2019, www.nytimes.com/2019/08/02/health/kidney-dialysis-kickbacks.html.
[50] Tozzi, John. *DaVita, Fresenius Broke Kickback Rules, Whistleblower Says*. Bloomberg, 2 Aug. 2019, www.bloomberg.com/news/articles/2019-08-02/davita-fresenius-violated-kickback-rules-whistleblower-says.
[51]Livingston, Shelby. *Whistleblower Alleges DaVita, Fresenius Involved in Kickback Scheme*. Modern Healthcare, 2 Aug. 2019, www.modernhealthcare.com/legal/whistleblower-alleges-davita-fresenius-involved-kickback-scheme.
[52] Abelson, Reed, and Katie Thomas. "Top Kidney Charity Directed Aid to Patients at DaVita and Fresenius Clinics, Lawsuit Claims." *The New York Times*, The New York Times, 2 Aug. 2019, www.nytimes.com/2019/08/02/health/kidney-dialysis-kickbacks.html.

> The lawsuit . . . says **the charity went to great lengths to ensure no aid was given to patients at clinics that were not donors**. Mr. Gonzalez said in his lawsuit that the charity began formally tracking donors in 2009, labeling those clinics that did not contribute as "free riders."
>
> When the charity was criticized for its use of a "blocked list" of clinics, it changed the name to "training list," according to the lawsuit. The charity would contact these clinics to request donations in specific amounts, calculated by looking at the payments made to patients at these clinics.[53]

In statements to the press and Hill offices, **DaVita has implied that DOJ's decision not to intervene proves it did nothing wrong. Not so. As the OIG told Rep. Porter's staff, a decision not to intervene is not a ruling on the merits of a case**. Indeed, even after DOJ has declined to intervene, whistleblowers have gone on to win large recoveries for the government.[54] In conversations with Rep. Porter's office and AKF, DaVita made similar claims, further asserting that "the DOJ and OIG (the Office of the Inspector General) fully investigated all of these related allegations and announced that no action would be taken by the government. . . Nothing in this unsealed document is new." This is a misleading characterization of the DOJ's decision not to intervene. The decision not to take action is a commonplace practice and does not imply that the defendant is fully absolved of anything alleged in the suit. Rep. Porter's office reached out to the Office of the Inspector General to further discuss the agency's involvement with the "full" investigation. OIG noted that DOJ's choice to decline to intervene in the case is, by definition, not a ruling on the merits of the case.

"AKF asks participating providers to sign a 'Code of Conduct.' But signing is voluntary, and AKF has informed Rep. Porter's office that it has no enforcement mechanism in place to ensure the Code is followed."

Similarly, the American Kidney Fund's President and Chief Executive Officer, LaVarne Burton, stated, "We now know that this suit was brought by a former employee who, prior to making this complaint, was terminated for cause. AKF strictly adheres to the federal advisory opinion that governs our charitable premium assistance program, and we have in place strict safeguards and conflict of interest policies to ensure that."[55] Rep. Porter's office asked AKF for copies of the "strict safeguards and conflict of interest policies" that they employ. At the request AKF provided the OIG compliance guidelines, a Code of Conduct for dialysis providers, and AKF's internal guardrails. These resources are intended to help providers participating in HIPP follow Advisory Opinion 9701. AKF's internal guardrails are not included out of respect for AKF's request that they remain confidential; however, Rep. Porter's office concluded that the guardrails are inadequate for ensuring compliance with Advisory Opinion 97-01.

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[53] Abelson, Reed, and Katie Thomas. "Top Kidney Charity Directed Aid to Patients at DaVita and Fresenius Clinics, Lawsuit Claims." *The New York Times*, The New York Times, 2 Aug. 2019, www.nytimes.com/2019/08/02/health/kidney-dialysis-kickbacks.html.
[54] Tozzi, John. *DaVita, Fresenius Broke Kickback Rules, Whistleblower Says*. Bloomberg, 2 Aug. 2019, www.bloomberg.com/news/articles/2019-08-02/davita-fresenius-violated-kickback-rules-whistleblower-says.
[55] Ibid.

AKF asks participating providers to sign a "Code of Conduct." But signing is voluntary, and AKF has informed Rep. Porter's office that it has no enforcement mechanism in place to ensure the Code is followed. The Code of Conduct is intended to be a set of guidelines for providers ("Companies") participating in HIPP. The "Company" reading and signing the Code of Conduct is, in the case of large dialysis providers like DaVita, the company itself and not each of its individual clinics. As of September 2018, DaVita "operated or provided administrative services at 2,625 outpatient dialysis centers located in the United States serving approximately 201,000 patients."[56] **AKF was unable to tell Rep. Porter's office if the Code of Conduct is shared with all staff at each of DaVita's clinics**.

Point 10 of the Code of Conduct states that the Company understand[s] that if AKF has reason to suspect any of our employees of violating this Code of Conduct, AKF will immediately notify the Company's compliance officer." **Rep. Porter's office inquired if AKF had ever investigated any of the reports that "Company" employees were violating the Code of Conduct in relation to the reporting published in the *Los Angeles Times, Washington Post,* and *New York Times*. AKF responded in an email, "We generally cannot discuss personnel matters. Having said that, many of the referenced articles have been either simply not true or are opinion pieces masquerading as news."**

The whistleblower case is not the only litigation alleging that **the major LDOs are responsible for a clearly articulated and well documented plan to push patients toward commercial plans and away from Medicare and Medicaid**. Allegations in another lawsuit brought against American Renal Associates (ARA) by UnitedHealth Group explain the ways in which AKF enables this process:

> As recently as 2016, AKF had posted its HIPP Guidelines, which included a section describing the "HIPP Honor System" on its website. In that section, **AKF set forth its requirement that "each referring dialysis provider should make equitable contributions to the HIPP pool"** and that each provider should 'reasonably determine its 'fair share' contribution to the pool [i.e., the funds available for premium assistance] by considering the number of patients it refers to HIPP.' AKF emphasized that all providers had an 'ethical obligation to contribute their respective 'fair share' to ensure that the HIPP pool is adequately funded.' **And AKF instructed providers that '[i]f your company cannot make fair and equitable contributions, we respectfully request that your organization not refer patients to the HIPP program.'**[57]

[56] "About DaVita® Kidney Care 2018." *DaVita News*, 2018, pressreleases.davita.com. pressreleases.davita.com › download › About+DaVita+Kidney+Care+2018

[57] United States District Court of Massachusetts, Case 1:18-cv-10622-ADB.

ARA settled this lawsuit and a similar lawsuit for $32 million.[58] Sometime after public reports emerged about this "fair share" requirement, AKF removed this language from its guidelines. Rep. Porter's office obtained the previous guidelines, which clearly include the fair share policy. While this "fair share" practice is no longer formally included in the HIPP program guidelines, **the *New York Times*, the *Los Angeles Times*, and social workers across the country assert that AKF continues to discriminate against patients at non-donor clinics.**[59] Insurers have also brought civil suits, which have since been settled, against DaVita in Pennsylvania.[60]

"The *New York Times*, the *Los Angeles Times*, and social workers across the country assert that AKF continues to discriminate against patients at non-donor clinics."

Additionally, on February 1, 2017, a securities class action lawsuit was filed against DaVita alleging that it "made false and/or misleading statements and/or failed to disclose its scheme to steer patients into unneeded insurance plans in order to maximize profits, using the AKF to facilitate the improper practices."[61] The court denied DaVita's motion to dismiss the case on March 28.[62] The securities class action suit revealed documents showing how **"DaVita tracked the acquisition of 'private pay' patients at its facilities, incentivized patient steering by offering bonuses to employees, prepared training and instructional materials for employees that disparaged Medicare and Medicaid, and designed materials to convince patients that Medicare and Medicaid were worse options than private insurance."**[63] Further, the plaintiffs cited comments from DaVita insurance counselors who would "assure ESRD patients that they would 'preapprove them for AKF' charitable premium assistance."[64]

"Receiving a transplant is nearly always the best option for a patient with ESRD, but if they do so while receiving premium assistance, they could be left on a healthcare plan they are unable to afford."

Perhaps most notably, DaVita confirmed in this lawsuit that it would lose $450 million in operating income if AKF stopped providing patients with assistance for commercial non-ACA plans.[65] Bringing in ACA plan

[58] Sweeney, Evan. "American Renal Associates Pays $32M to Settle Fraud Accusations from UnitedHealth." FierceHealthcare, 12 July 2018, www.fiercehealthcare.com/payer/american-renal-associates-unitedhealthcare-32m-settlement-premium-assistance.
[59] "The Profiteering Dialysis Industry Made Big Bucks from Killing Proposition 8. Here's How." *Los Angeles Times*, 9 Nov. 2018, www.latimes.com/business/hiltzik/la-fi-hiltzik-dialysis-20181109-story.html.
[60] Court of Common Pleas of Montgomery County, PA, Case 17-07795-0.
[61] "DAVITA INVESTIGATION INITIATED by Former Louisiana Attorney General: Kahn Swick & Foti, LLC Investigates the Officers and Directors of DaVita Inc. - DVA." AP NEWS, Associated Press, 6 Apr. 2019, www.apnews.com/ebe2ce6a64714fc884ad655241d3bfbb.
[62] Shareholders Foundation, Inc. "Update: Lawsuit for Investors in Davita Inc (NYSE: DVA) Shares Announced by Shareholders Foundation." GlobeNewswire Newsroom, 1 Apr. 2019, www.globenewswire.com/news-release/2019/04/01/1790632/0/en/Update-Lawsuit-for-Investors-in-Davita-Inc-NYSE-DVA-shares-announced-by-Shareholders-Foundation.html.
[63] United States District Court of Colorado, Case 1:17-cv-00304-WJM-NRN.
[64] Ibid.
[65] Ibid.

assistance as well, third-party reports found that as much as "60-80% of DaVita's earning derived from its AKF relationship."[66] In September 2020, DaVita and the parties entered into a settlement agreement for $135 million.[67] The Court granted final approval of the Settlement on April 13, 2021.[68]

These lawsuits make plain the tension between the best interests of patients and the financial interests of the dialysis providers. Dialysis providers appear to have, as described in one of the cases, "intentionally failed to inform patients that AKF's premium assistance program (as it existed prior to the filing of this lawsuit) was only available for patients receiving dialysis treatments. Consequently, **the patients did not know that they would be ineligible for premium assistance if they sought to cure their condition through a kidney transplant**."[69] This can make it difficult for patients who were steered into high premium private plans to pursue transplants, particularly since—as noted above and as CMS has stated—patients often must demonstrate proof of ongoing insurance to receive transplants. **Receiving a transplant is nearly always the best option for a patient with ESRD, but if they do so while receiving premium assistance, they could be left on a healthcare plan they are unable to afford**.

An administrator at an independent clinic told the *New York Times* that AKF "demanded that [his] clinic make a donation that at a minimum covered the amount it had paid for the patient's premium. If he did not pay, he said he had been told, the patient risked losing the financial help from the charity for his insurance."

The revelations in these lawsuits also reinforce the findings from media reports, state legislative hearings, and information gathered by CMS about AKF's practices, including the personal experiences of a number of social workers who had requested financial assistance from AKF.[70] **An administrator at an independent clinic told the *New York Times* that AKF "demanded that [his] clinic make a donation that at a minimum covered the amount it had paid for the patient's premium. If he did not pay, he said he had been told, the patient risked losing the financial help from the charity for his insurance."**[71]

Laura Fiallos worked in a DaVita clinic in Pasadena Foothills, California as an administrative assistant and insurance specialist for nearly twelve years until 2016. She testified about her experience before the California State Senate on July 3, 2019[72]:

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[66] Ibid.
[67] DaVita, Inc. Settles Shareholder Class Action for $135 Million, ISS Insights, October 2020, https://insights.issgovernance.com/posts/davita-inc-settles-shareholder-class-action-for-135-million/.
[68] Case Summary: DaVita Inc. Securities Litigation, Securities Class Action Clearinghouse, Stanford Law School, April 13, 2021, https://securities.stanford.edu/filings-case.html?id=106035.
[69] United States District Court of Florida, Case 9:16-cv-81180-KAM.
[70] Thomas, Katie, and Reed Abelson. "Kidney Fund Seen Insisting on Donations, Contrary to Government Deal." *The New York Times*, 25 Dec. 2016, www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html.
[71] Ibid.
[72] "Senate Health Committee, Wednesday, July 3rd, 2019." 2019. https://www.senate.ca.gov/media/senate-health-committee-20190703/video

> [B]efore the annual open enrollment period a few years ago, I was assigned to a new team that was instructed to persuade dialysis patients to apply for individual market health insurance plans, for which the American Kidney Fund would pay the premiums. **I was given a list of patients and told to approach them at the dialysis clinic and persuade them.**[73]

AKF denies these reports as hearsay and "inaccuracies," yet information from CMS buttresses these allegations.[74] In 2016, CMS issued a request for information regarding third party premium payments in the dialysis industry. One social worker employed by two California-based DaVita clinics wrote to CMS:

> They asked us to "educate" the patients with marketing material DaVita designed specifically to entice the patient into enrolling in a secondary private payer plan with the promise of being able to travel outside of the state and improved chances of passing financial clearance for kidney transplant. DaVita also assured our most vulnerable population of patients that they would not have to worry about paying their health insurance premium because our Insurance Counselors would preapprove them for the AKF HIPP Grant.[75]

Another social worker, who was unaffiliated with a clinic donating to AKF, also told CMS about AKF's misconduct. When a patient requested support from AKF, AKF sent the social worker a set of guidelines. "If your company cannot make fair and equitable contributions," the guidelines read, "we respectfully request that your organization not refer patients."[76]

Flaws in the 1997 Advisory Opinion Allowing AKF's Patient Assistance Program

On July 23, 2019, **Rep. Porter requested that the Office of the Inspector General revisit Advisory Opinion 97-01, which AKF requested and received in 1997.** AKF requested this opinion out of concern that receiving funds from dialysis providers could be considered an impermissible violation of federal anti-kickback laws designed to prevent financial conflicts from interfering in the referrals and advice provided by medical providers.

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[73] Ibid.
[74] Thomas, Katie, and Reed Abelson. "Kidney Fund Seen Insisting on Donations, Contrary to Government Deal." *The New York Times*, 25 Dec. 2016, www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html.
[75] Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans (CMS-6074-NC). https://www.regulations.gov/docket?D=CMS-2016-0145.
[76] Ibid.

The advisory opinion outlined conditions under which HHS would choose to exercise its enforcement discretion and not find this arrangement between AKF and the for-profit dialysis providers unlawful.[77] These conditions include treating all patient applications for assistance equally – regardless of the type of insurance patients have or whether the clinics from which they receive treatment donate to AKF. **In the advisory opinion, the HHS Office of the Inspector General made clear that "AKF staff involved in awarding patient grants will not take the identity of the referring facility or the amount of any provider's donation in consideration when assessing patient applications or making grant determinations."**[78] Essentially, AKF is not allowed to take into consideration whether or not a patient was receiving care at a provider that supported AKF financially.

In the advisory opinion, the HHS Office of the Inspector General made clear that "AKF staff involved in awarding patient grants will not take the identity of the referring facility or the amount of any provider's donation in consideration when assessing patient applications or making grant determinations."

A lot has changed since the advisory opinion was issued over 20 years ago. When the advisory opinion was issued in 1997, AKF assisted "over 12,000 patients with ESRD and received over $5 million in donations. Of that amount, less than 10 percent" was provided by the major dialysis providers.[79] **Based on AKF's 2018 990 tax form, AKF's current donations are 60 times larger than they were in 1997. Moreover, the vast majority of them – nearly 80% – come from DaVita and Fresenius.**[80] Over the same time period, DaVita and Fresenius have brought in record profits and acquired many smaller dialysis providers, while patients and clinicians at dialysis clinics owned by providers other than DaVita and Fresenius have reported discriminatory practices by AKF.[81] **Because of their larger market share, the likelihood of any given AKF dollar returning to these two providers is fairly high, even were AKF technically in compliance with the advisory opinion**.

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[77] HHS OIG. Advisory Opinion No. 97-01. (1997). https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf
[78] Ibid.
[79] Ibid.
[80] Karch, Lauren. "Dialysis Patients' Use of Charitable Funds Questioned in Kickback Investigation." *Nonprofit News | Nonprofit Quarterly*, 19 Jan. 2017, nonprofitquarterly.org/dialysis-patients-use-of-funds-questioned/.
[81] Thomas, Katie, and Reed Abelson. "Kidney Fund Seen Insisting on Donations, Contrary to Government Deal." *The New York Times*, 25 Dec. 2016, www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html.

"DaVita and Fresenius have brought in record profits and acquired many smaller dialysis providers, while patients and clinicians at dialysis clinics owned by providers other than DaVita and Fresenius have reported discriminatory practices by AKF."

Most concerning is the potential adverse impact on patients that result from steering patients from Medicare and Medicaid to private plans. This was essentially impossible in 1997 because private plans would reject dialysis patients through the underwriting process.

CMS recognized the changed circumstances in 2016 and issued a request for information (RFI) on "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans." In response to comments, CMS issued an interim final rule with comment (IFC). This rule would have established new "Conditions for Coverage" standards for dialysis facilities. The standard would have applied to any third-party premium payments, including "dialysis facility making premium payments for individual market health plans, whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments)."[82] Dialysis facilities subject to the new standard would be required to educate patients about all of their coverage options. CMS wrote:

> The comments in response to the RFI support the conclusion that, today, **enrollment in individual market coverage for which there are third party premium payments is hampering patients' ability to be determined ready for a kidney transplant**. Comments make clear that, consistent with clinical guidelines, in order for a transplant center to determine that a patient is ready for a transplant, they must conclude that the individual will have access to continuous health care coverage. (This is necessary to ensure that the patient will have ongoing access to necessary monitoring and follow-up care, and to immunosuppressant medications, which must typically be taken for the lifetime of a transplanted organ to prevent rejection.) However, **when individuals with ESRD are enrolled in individual market coverage supported by third parties, they may have difficulty demonstrating continued access to care due to loss of premium support after transplantation**.[83]

The IFC was published in December 2016 and would have taken effect on January 14, 2017, but **Judge Amos Mazzant of the U.S. District Court for the Eastern District of Texas postponed the implementation of the rule pending consideration of a request for a temporary restraining order from dialysis providers**.[84] Mazzant ultimately enjoined CMS from enforcing the rule, concluding that CMS failed to provide adequate public notice for comment on the proposed rule and lacked good cause to issue an IFC without notice and comment.[85]

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[82] 42 CFR Part 494. Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities – Third Party Payment. December 14, 2016. https://www.govinfo.gov/content/pkg/FR-2016-12-14/pdf/2016-30016.pdf.
[83] Ibid.
[84] United States District Court for the Eastern District of Texas, Case 4:17-cv-00016-ALM.
[85] Ibid.

Rep. Porter asked that the Inspector General revisit and update Advisory Opinion 97-01 as necessary rather than rescind it, since she understands the consequences that rescinding would have on patients currently receiving premium assistance. If OIG chooses to rescind the opinion in its entirety, HHS would bear the responsibility of implementing a program to help patients receiving premium assistance afford their care or transition to another plan.

In 2019, legislation (AB 290) passed in California that would place new disclosure and reimbursement requirements on dialysis third-party premium payment programs. The legislation includes a clause that prevents any piece of the legislation from going into effect until AKF has the opportunity to request confirmation from the Office of the Inspector General that the provisions in the bill do not put their program in conflict with their advisory opinion. This gives AKF the opportunity to request and receive a new advisory opinion that ensures their compliance with existing anti-kickback laws. At this time, AKF has refused to request a new opinion from the Office of the Inspector General.

"In 2019, legislation (AB 290) passed in California that would place new disclosure and reimbursement requirements on dialysis third-party premium payment programs… AKF threatened to leave California on January 1, 2020, regardless of the effect it may have on patients they support."

AKF threatened to leave California on January 1, 2020, regardless of the effect it may have on patients they support. The only part of the bill that immediately takes effect is a requirement that dialysis clinics will not "steer, direct, or advise" a patient towards any specific insurance options. This requirement is consistent with both the 1997 Office of the Inspector General advisory opinion and current AKF Patient Handbook guidelines, which state that "You have the right to independently choose the health care coverage that is best for you."[86] **The remainder of the bill would not take effect until months later, and may not be implemented in any form if AKF requests a new advisory opinion and OIG finds that the legislation would force them out of compliance.**

AKF submitted a request for an injunction to prevent the law from taking effect in California. **On December 9, 2019, Rep. Porter led a letter with 14 of her California colleagues, including Senator Dianne Feinstein and then-Senator Kamala Harris, requesting that AKF provide sufficient time or a clear pathway to alternative coverage for constituents currently receiving support from the organization, regardless of the court's decision.**[87] AKF refused to comment on its decision making while the case is ongoing. On December 30, the court granted AKF's motion for an injunction.[88] The case is still ongoing. AKF chose after this decision to remain in California for the remainder of 2020.

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[86] "Patient Handbook." American Kidney Fund (AKF), https://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-patient-handbook.pdf

[87] "Rep. Porter Slams American Kidney Fund for Abandoning California Dialysis Patients." *U.S. Representative Katie Porter*, 10 Dec. 2019, porter.house.gov/news/documentsingle.aspx?DocumentID=80.

[88] "Judge Blocks California Law on Dialysis Clinics." *AP NEWS*, Associated Press, 31 Dec. 2019, apnews.com/4abfe32e51972f95bb4b39be6e4ae853.

Conclusion: It's Time for an OIG Investigation and for CMS to Take Action

The Office of the Inspector General has previously reviewed and later rescinded other advisory opinions in order to address concerns raised by Members of Congress, lawyers, and patient groups.

For example, in April 2006, the OIG published Advisory Opinion 06-04 for the Caring Voice Coalition (CVC).[89] CVC was similarly providing financial assistance for premium and cost-sharing obligations, though they were funded by pharmaceutical companies and were providing assistance to patients who were unable to afford prescriptions manufactured by the companies donating to CVC. In November 2017, the Office of the Inspector General rescinded Advisory Opinion 06-04, based on the charity's "failure to fully, completely, and accurately disclose all relevant and material facts to OIG."[90] The letter states that CVC "provided patient-specific data to one or more donors that would enable the donor(s) to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products, and (ii) allowed donors to directly or indirectly influence the identification or delineation of Requestor's disease categories."[91]

"This evidence establishes credible concerns about possible conflicts of interest involving the structure and practices of AKF's patient assistance program that could have negative consequences for patient care, premiums, and the private insurance market. ESRD patients and taxpayers deserve action."

While the office will continue following this issue closely, as well as other cases in which large corporations in the healthcare industry may be placing patients at risk in order to increase profits, it is clear the time for an investigation is now.

In short, the findings of HHS' own agencies and OIG's past precedent, when combined with this new staff report based on additional investigation and documents obtained by Rep. Katie Porter's office, recent academic studies, and newly unsealed whistle-blower lawsuits, provides significant new support for opening an OIG investigation as soon as possible.

This evidence establishes credible concerns about possible conflicts of interest involving the structure and practices of AKF's patient assistance program that could have negative consequences for patient care, premiums, and the private insurance market. ESRD patients and taxpayers deserve action.

Further, CMS should reissue the 2016 rule to make long overdue changes to Medicare's dialysis policies to increase transparency regarding third-party premium payments. The procedural

[89] HHS OIG. Advisory Opinion No. 06-04. (2006). https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf
[90] "Increased Scrutiny of Patient Assistance Programs: Enforcement Overview and Considerations." K&L Gates, 20 Mar. 2018, m.klgates.com/increased-scrutiny-of-patient-assistance-programs-enforcement-overview-and-considerations-03-20-2018/.
[91] HHS OIG. Advisory Opinion No. 06-04. (2006). https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf.

suspension of the 2016 CMS rule marked a missed opportunity to hold AKF and dialysis providers to an appropriate standard and to protect vulnerable patients in the process. **CMS can and should reissue the rule through the appropriate rulemaking process required under the Administrative Procedure Act to reduce the cost of treatment for patients and taxpayers, improve quality of care, and increase access to transplants.**

EXHIBIT 12

New York Times Article by Katie Thomas and Reed Abelson, published on December 25, 2016

The New York Times https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html

Kidney Fund Seen Insisting on Donations, Contrary to Government Deal

By Katie Thomas and Reed Abelson
Dec. 25, 2016

The American Kidney Fund is one of the largest charities in the country, with an annual budget of over $250 million. Its marquee program helps pay insurance premiums for thousands of people who need dialysis, a lifesaving and expensive treatment for kidney failure.

The organization has earned accolades for its efficient use of the money.

Under an agreement with the federal government, the Kidney Fund must distribute the aid based on a patient's financial need. But the charity has resisted giving aid to patients at clinics that do not donate money to the fund, an investigation by The New York Times has found. The actions have limited crucial help for needy patients at these clinics. The agreement governing the relationship between the group and the companies forbids choosing patients based on their clinic.

In multiple cases, the charity pushed back on workers at clinics that had not donated money, discouraging them from signing up their patients for assistance. Until recently, the Kidney Fund's guidelines even said clinics should not apply for patient aid if the company had not donated to the charity.

"I watched many patients who were not able to get that assistance," said Elaine Brecher, a former social worker at a small clinic in rural Arkansas. After an application for one patient was declined, she said, she did not apply for others, because a colleague believed that only clinics that donated could refer patients.

Ms. Brecher now works at a clinic owned by Fresenius, one of the two largest dialysis companies along with DaVita. Together, the two companies provide nearly 80 percent of the charity's funding. She said her current patients benefited from the Kidney Fund, whose assistance can amount to thousands of dollars in financial aid a year.

"If our patients didn't get that assistance, they would be owing great big huge bills to hospitals and doctors," she said.

The financial help is available to patients with kidney failure, known as end-stage renal disease, many of whom are unable to work. The money covers the insurance premiums for many types of coverage, including Medicare and employer and individual private plans.

The Kidney Fund's payments are part of an unusual deal it made with the government and the dialysis industry 20 years ago. The arrangement allows the dialysis companies to avoid violating anti-kickback laws. It allows dialysis clinics to donate to the Kidney Fund, treat patients whose insurance premiums are paid by the charity and then collect money from the insurers for those patients' treatments — essentially guaranteeing a steady stream of paying customers for the companies.

But the agreement also has a caveat: It requires that all patient applications be treated equally, regardless of whether their clinic donates.

In an interview this month, LaVarne A. Burton, the Kidney Fund's chief executive, said that the charity treated all patients equally, and that the fund had never denied anyone assistance if they qualified financially.

"It is simply not true that we require any provider to contribute to the program," she said. "Never have, and never will."

She acknowledged, though, that the charity pushed clinics hard to donate, particularly if they applied on behalf of patients.

"We believe there is a moral obligation for providers to contribute to the organization," she said.

Ms. Burton said the concerns raised by social workers like Ms. Brecher and others arose because many in the industry misunderstood how the charity worked. The charity recently updated its guidelines, she said, to provide more clarity.

An examination of public documents, as well as interviews with more than a dozen social workers, employees of dialysis clinics, insurance officials and regulators, and a former executive at the charity, put the actions in a different light. Many of the clinic workers, from about a half-dozen states around the country, were called randomly, to limit any chance of coordinated talking points.

For years, The Times found, the Kidney Fund's preference for patients at the biggest clinics has been an open secret among many social workers, who said that as a result they had stopped applying for assistance entirely.

The findings also add to a list of concerns about the group's relationship with the dialysis industry.

A 2011 event for the American Kidney Fund in New York to raise awareness of kidney disease. The charity has resisted helping patients at clinics that do not donate to it, The New York Times found. Mike Coppola/Getty Images, for the American Kidney Fund

This year, for example, the fund faced questions about whether it was helping dialysis companies game the Affordable Care Act. In some cases, insurers and government officials have argued, the dialysis clinics used the charity's assistance program to push people who were eligible for Medicaid, government health insurance for the poor, into private health coverage available under the new law.

The private plans pay the clinics much more than Medicaid — up to four times as much, adding up to an additional $200,000 per patient per year — for the same dialysis treatment.

In recent months, the federal government has raised concerns about how patients are steered into private plans. UnitedHealthcare sued one company, American Renal Associates, over the practice, claiming it was harming patients by converting them to less generous coverage. American Renal, which declined to comment for this article, has denied the claims and is fighting the suit.

The suit against American Renal also says the Kidney Fund directed some donations directly back to patients at American Renal. As part of an investigation by Medicare, social workers and insurers have made similar accusations against the Kidney Fund.

Ms. Burton denied those accusations and attributed the recent scrutiny of the insurance assistance program to insurers that want to avoid covering the often costly medical bills of people who need dialysis.

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"The insurance industry has let us have it full force," she said.

A Costly Treatment

Dialysis filters toxins from the blood when a patient's kidneys no longer work. The process is lifesaving, but also onerous, often requiring that patients be tethered to a machine for hours at a time, three times a week. Patients on dialysis often cannot hold full-time jobs, studies have shown, and those receiving the treatment are disproportionately poor.

The poorest people with kidney disease qualify for Medicaid, which covers all of their costs. But Medicare covers most of the 500,000 or so Americans who need the treatment, regardless of their age, under a government program that has existed since the 1970s and that costs the federal government more than $30 billion a year.

Even with help, people covered by Medicare are left with significant out-of-pocket costs. Most must pay a monthly premium of about $120, as well as a portion of their medical expenses, which can add up to several thousand dollars a year.

Until the late 1990s, the dialysis companies routinely paid these expenses. But a federal law outlawed that practice, out of concern that covering a patient's bills might dissuade that patient from switching to another clinic that might provide better care.

That was when the American Kidney Fund stepped in. In 1995, the charity was relatively small, with a $5 million annual budget and contributions from the dialysis industry that accounted for less than 10 percent of its donations.

The Kidney Fund and the biggest dialysis clinics presented the government with a proposal that would allow the companies to indirectly pay insurance premiums for patients.

The deal, reached with the Office of Inspector General at the Department of Health and Human Services in 1997, has had a profound effect on the charity. In 2015, the Kidney Fund reported revenue of $264 million, making it one of the country's 100 largest nonprofits.

The dialysis industry has also flourished. DaVita and Fresenius in particular have grown quickly, buying smaller chains, consolidating their market share and locking in profits. The Kidney Fund says it got 78 percent of its revenue in 2015 from two companies, which insurers, state regulators and others identified as DaVita and Fresenius.

"There's a long history of recognition of the unique needs of that patient population," said Philipp Stephanus, a senior vice president at DaVita who handles patient support and insurance issues.

The Kidney Fund, DaVita and Fresenius said the federal agreement prohibited them from disclosing what percentage of applications the fund approved from those companies' clinics, or how much the charity paid in insurance aid for patients at those clinics.

But the 1997 deal tried to prevent any preferential treatment, no matter how big the companies became.

Kevin McAnaney, a former government lawyer who helped draft the original agreement, said fairness to patients was at the heart of the deal.

LaVarne A. Burton, the Kidney Fund's chief executive, said the charity treated all patients equally. "It is simply not true that we require any provider to contribute to the program," she said. Mike Coppola/Getty Images, for the American Kidney Fund

Everyone understood that "they were covering free riders who weren't contributing anything," said Mr. McAnaney, a lawyer in private practice who previously worked at the Office of Inspector General.

But if the rules are not followed, the Office of Inspector General has the right to end the agreement, which would profoundly change the relationship of the industry and the charity.

"If all the conditions are not met, the opinion is without force and effect," said Donald White, a spokesman for the agency. In keeping with the agency's policy, he would not confirm or deny whether the agency was investigating the group.

Patients Turned Away

Tracey Dickey works as a social worker for a nonprofit dialysis clinic in rural Missouri with no connection to a big dialysis company, and many of her patients struggle to pay their medical bills, she said. They are exactly the kind of people the Kidney Fund says it is there to help.

In November 2014, Ms. Dickey emailed an executive at the fund. She said she had heard that only clinics that donated to it could apply for

financial aid for patients. Her clinic had not donated, she said — but she still had a patient in need.

“I need to know the facts before I tell her there isn’t premium assistance,” Ms. Dickey wrote in an email to the fund. She provided a copy of the email to The Times.

An executive at the fund wrote back the same day. He was noncommittal, but attached a set of guidelines that he asked her to review. “If your company cannot make fair and equitable contributions,” the guidelines read, “we respectfully request that your organization not refer patients.”

And so she didn’t. The patient, Ms. Dickey said, continues to struggle financially.

This summer, after Ms. Dickey and other social workers shared their experiences in an industry discussion group, the Kidney Fund invited them to contact the charity about their concerns. When she followed up, the charity told Ms. Dickey that she would need some computer training to enroll in the program. She has not pursued it, she said.

Ms. Burton said that Ms. Dickey had apparently misunderstood the exchange with the Kidney Fund employee and that had she applied, her patient would have been approved, assuming the person qualified financially.

But Ms. Brecher and several workers at other nonprofit or independent clinics told similar stories.

An administrator at an independent clinic in a Midwestern city said he had helped a handful of patients maintain their coverage through the fund after they transferred to his clinic from a large chain. He declined to be identified because, he said, he did not want to anger DaVita and Fresenius, who sometimes send him patients.

Each time, he said, the charity’s workers later demanded that the clinic make a donation that at a minimum covered the amount it had paid for the patient’s premium. If he did not pay, he said he had been told, the patient risked losing the financial help from the charity for his insurance.

The administrator said he had refused to donate to the charity. The Kidney Fund continued to help pay for the patients’ insurance, he said, but the aggressive approach angered him.

Ms. Burton said the charity never declined a patient because a clinic did not donate. But she said the Kidney Fund did not hesitate to ask clinics for donations.

“We are a charitable organization,” she said. “We fund-raise for everything that we do.”

She said nearly 40 percent of the 213 dialysis companies whose clinics had successfully helped patients apply to the fund had never donated. She would not say, though, what percentage of the 80,000 patients the fund helps annually comes from clinics that do not donate, or how many of those patients come from the biggest companies, which donate most of their revenue.

Still, some social workers say the assumption at many clinics where they work is that the aid decisions are not always based on financial need.

Jennifer Bruns, now a social worker at the St. John Transplant Specialty Center in Detroit, worked for years in dialysis clinics and said she had many clients who received assistance from the American Kidney Fund. She said sometimes patients would tell her that their insurance premiums — which the Kidney Fund had agreed to pay — had not been paid that month.

Ms. Bruns called the fund to find out why, she said in an interview, “and they would say, ‘Well you haven’t made your contribution this month.’”

Correction: Dec. 27, 2016

An earlier version of a picture caption with this article referred incorrectly to an event being held by the American Kidney Fund. The event was to raise awareness about kidney disease; it was not a fund-raiser.

A version of this article appears in print on , Section A, Page 1 of the New York edition with the headline: Donations Seen Influencing Aid by Kidney Fund

EXHIBIT 13

St. Louis Post Dispatch Article by Samantha Liss, published on October 23, 2016

https://www.stltoday.com/business/local/davita-encouraged-some-low-income-patients-to-enroll-in-commercial-plans/article_ec5dc34e-ca4d-52e0-bc26-a3e56e1e2c85.html

DaVita encouraged some low-income patients to enroll in commercial plans

By Samantha Liss St. Louis Post-Dispatch
Oct 23, 2016

Internal emails from DaVita HealthCare Partners Inc. show the Denver-based company targeted some patients in a campaign to get them to buy insurance they didn't necessarily need, saying their monthly premiums would be paid by a nonprofit foundation.

DaVita, one of the nation's largest dialysis providers, with a major presence in St. Louis, had a financial incentive to get certain Medicaid-eligible dialysis patients to enroll in private insurance. Medicaid, the government-run health insurance program for low-income Americans, pays significantly less than traditional commercial insurance for dialysis treatment.

Emily Bremer, a Clayton-based health insurance broker, said she first heard about kidney failure patients being targeted after one of her clients said he was encouraged by an employee of another dialysis-center company to enroll in a private insurance plan. Bremer said she was concerned because the plan described as best didn't include her client's current BJC HealthCare doctors and also had other limitations.

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Prior to the Affordable Care Act, patients with end-stage renal disease were typically denied commercial insurance because of the high cost of care. Because those patients couldn't get coverage, the federal government decided to allow individuals with failing kidneys to qualify for Medicare — the health insurance plan for the elderly — at any age. Some of those patients also may qualify for Medicaid, the taxpayer-funded health care program for some low-income Americans.

In some cases, however, some patients with failing kidneys have not worked long enough to qualify for Medicare even with the grave diagnosis, leaving them eligible only for Medicaid. This was the population DaVita was targeting for commercial coverage, according to the company's emails, which were provided to the Post-Dispatch by an employee who asked not to be identified.

Private insurers can pay as much as $4,000 per treatment, while government plans such as Medicaid or Medicare pay $300, according to a lawsuit filed in federal court in Florida by the nation's largest health insurer UnitedHealthcare against a separate dialysis chain, American Renal Associates. In Missouri, the Medicaid program pays dialysis centers $122.94 for each treatment, which does not include other monthly payments.

Dialysis filters out toxins from the blood, a normal function of healthy kidneys. Typically, patients receive dialysis treatments up to three times per week and each session can last hours.

There were about 662,000 cases of end-stage renal disease in the country at the end of 2013, according to the U.S. Renal Data System, and treatment costs averaged about $89,000 per patient each year, according to data from the Kidney Project at the University of California San Francisco.

Red flags

Sudden spikes in payments to dialysis centers raised red flags for major health insurers, and they complained to the federal government. It was a significant financial hit they were not expecting.

“This is what’s causing instability, and it’s what’s raising prices for everyone,” a spokeswoman for America’s Health Insurance Plans, an industry group, told the Post-Dispatch.

The effect on the private insurance market, including the exchanges, was obvious to public-policy experts.

“If you suddenly shift these folks into private plans, you’re moving cost increases to marketplace plans,” said Jack Hoadley, a research professor at Georgetown University’s Health Policy Institute.

Bremer, the Clayton insurance agent, agrees.

“I understand the reasoning why different companies would want to manipulate the system,” she said. “But now you’ve basically dumped these catastrophic claims into the pool, and it’s very difficult to offset that with young healthy people.

“It’s a perfect example of one of the unintended consequences of the (Affordable Care Act),” Bremer said.

DaVita adamantly denies that they pushed any patients toward commercial coverage; rather, they characterize their efforts as providing important patient education.

“DaVita does not steer patients toward any particular insurance option or plan. DaVita educates its patients so that they are able to make informed decisions that are in their best interest,” Philipp H. Stephanus, a company senior vice president, said in a statement provided to government officials in September.

A coordinated effort

Based on the company's internal emails, the difference between "steering" and "educating" is a subtle one. Those communications, sent during last year's open enrollment period, outline a systematic approach to "educate" hundreds of area patients — and thousands across the country — about individual health plans.

Those emails show that patients were told by DaVita dialysis center employees — either social workers or insurance counselors — that the American Kidney Fund would pay their monthly health insurance premiums so they could gain coverage that is usually out of reach financially. The DaVita employees were instrumental in helping patients enroll by helping complete applications for the plans and for the American Kidney Fund's health insurance premium assistance program. The initiative was referred to as the "Medicaid Opportunity" in internal emails.

In regulatory filings, DaVita says it contributes to the American Kidney Fund, but doesn't specify how much. In 2015, the fund provided about $255 million worth of patient assistance to 93,000 kidney failure patients, according to its most recent filing with the Internal Revenue Service.

DaVita's dialysis center employees were given information on which patients to target for the program. From there, they were supposed to engage Medicaid patients in a conversation about new coverage options and the employees' progress was closely tracked.

Some advertising and brochure materials listed talking points for dialysis center employees. In bold large print, a brochure asked Medicaid patients: "What could additional coverage do for you?" The brochure went on to explain that the new coverage would improve access to transplants, to doctors that patients were "unable to see today" and to treatment when traveling out of state.

The brochure advertised the coverage as low to no cost and encouraged patients to reach out to social workers and insurance counselors to learn more.

The brochure boasted that patients may have access to an array of specialists if they opted for commercial coverage. The brochure included short testimonials from unnamed patients and workers, and included the statement: “This insurance is excellent. I haven’t been denied anything, and it probably has saved my life.”

The internal emails from last fall’s open enrollment tally each region’s performance. The emails show regions were tracked by how many patients were interested in commercial coverage and the percentage of those that had been talked to by employees about their options.

“Hooray! The Village has completed over 75% of interest conversations, and over 7,200 patients will receive enrollment education on the specific plans available in their market,” an email said. (Village is the company’s term for itself.)

The goal outlined in the emails was to hit 100 percent of “interest conversations” by late October.

However, “disinterested” patients were also tracked and their cases were reviewed by division vice presidents and regional operational directors, according to the emails.

The emails instructed that division leadership teams should conduct weekly or biweekly calls to discuss “validation” for patients who are not interested in this opportunity.

Anne Bailey, group vice president at DaVita, told the Post-Dispatch, “We had to be super organized and systematic.” She explained that employees were instructed to talk to all patients during open enrollment so they could be informed of all their insurance options.

Bailey said of their more than 3,000 patients in Missouri, less than 1 percent — or fewer than 30 — enrolled in commercial plans.

Of those that were interested, the company also tracked who had completed the

health insurance premium program (HIPP) application with the American Kidney Fund.

Continued communications encouraged employees to "close the gap" between the number of patients with a plan selected and those with an AKF check "that has cleared" to "ensure coverage is not delayed because of payment issues."

U.S. expresses concern

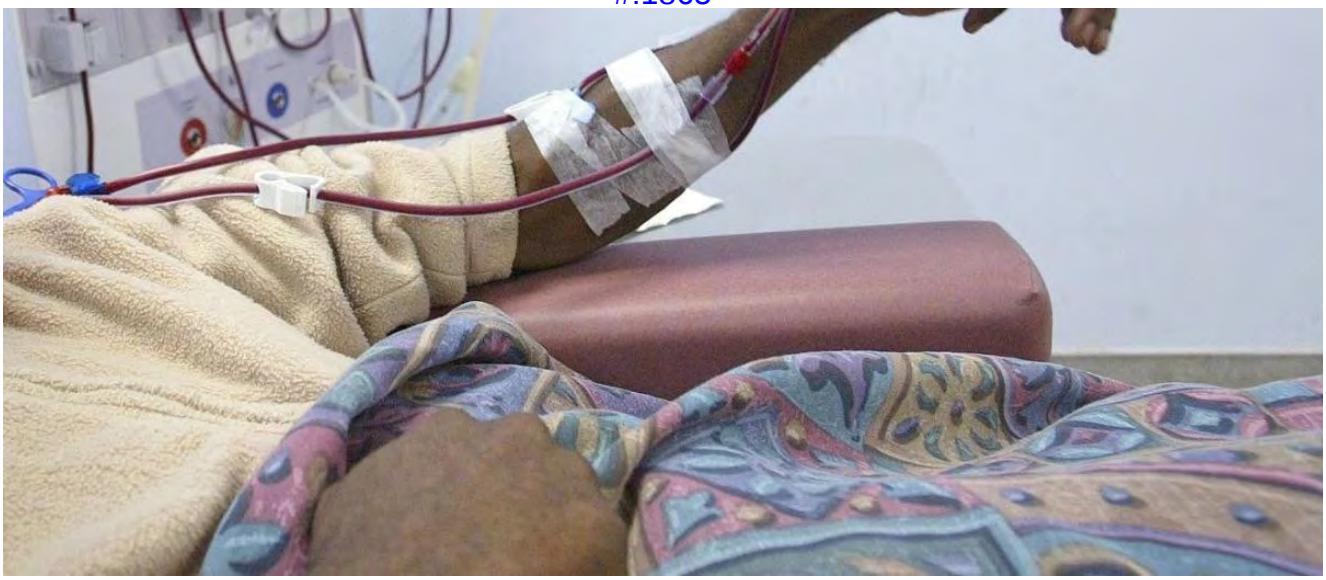
The federal government is concerned about this type of practice. Earlier this year, the government sent out a request for information to gather more information about the practice and its prevalence.

"Enrollment decisions should be made, without influence, by the consumer and based on their individual circumstances and health and financial needs," the letter posted by the Centers for Medicare and Medicaid Services said.

In the letter, CMS warns that patients who are "steered" away from government-run coverage like Medicare and Medicaid could experience a disruption in care, changes in drug benefits, loss of dental care and changes in provider networks.

CMS said it is considering a slew of changes to address these "harms," including imposing financial penalties on individuals and facilities for failing to provide correct coverage information to patients.

***Editor's note**: This story has been updated to clarify that insurance broker Emily Bremer's client was not a DaVita patient.*



Patient receives dialysis treatment. (Post-Dispatch file photo)

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EXHIBIT 14a

Excerpts from transcript of deposition of Corey Danko taken on November 11, 2021, and Exhibit 3

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

FRESENIUS MEDICAL CARE ORANGE COUNTY, LLC; et al.,	)	Case No.
Plaintiffs,	)	8:19-cv-02130 DOC (ADSx)
vs.	)	
XAVIER BECERRA, in his official capacity as Attorney General; et al.,	)	
Defendants.	)	(Pages 1-235)
AND RELATED ACTION.	)	

THIS TRANSCRIPT CONTAINS HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY INFORMATION

VIRTUAL VIDEOCONFERENCE DEPOSITION OF
COREY DANKO
THURSDAY, NOVEMBER 11, 2021
8:32 A.M.

REPORTED BY:
SUSAN NELSON
C.S.R. No. 3202
JOB NO. 4889819

mark as Exhibit 3. And if you could open that up.

(The document referred to was marked as Exhibit 3.)

BY MR. WOODS:

Q. Let me know when you have it in front of you.

A. Okay. I -- well, I'm opening it now.

Okay. I have it.

MR. WOODS: And do you have it, Ari?

MR. HOLTZBLATT: I do. It's 15 pages. Is that right?

MR. WOODS: Yup. I think that's right.

BY MR. WOODS:

Q. Yes, that's right. Okay.

All right. Mr. Danko, have you seen this document before?

A. Let me look through it. Give me one second.

Q. Take your time.

A. I've seen a similar document, but not this exact document.

Q. Okay. You'll see -- well, so this is a document that the state who I represent, the State of California, has produced in this litigation. And you see down at the bottom of page 1, down at the very bottom, there's a -- it says CA, and then 002 -- or

sorry. Strike that. There's CA 0002821.

Do you see that?

A. I do.

Q. Okay. And that's an identifying number that California placed on the document when we produced it to the plaintiffs in this case, including DaVita.

Do you see at the very -- excuse me -- on page 1, at the top of page 1, it looks like an email from sent attachments.

Do you see that?

A. Yes, I do.

Q. Okay. And do you see your name there at the top in the "From" field.

Do you see that?

A. Yes, I do.

Q. Okay. And this is sent August 20 of 2015.

Is that correct?

MR. HOLTZBLATT: Object to form.

THE WITNESS: Yes.

BY MR. WOODS:

Q. Sorry, did you say "yes"?

A. This document shows that it was sent on the 20th of 2015, correct.

Q. August 20th. Correct?

A. That's what this document says, yeah.

Q. Okay. And this would have been when you were manager of operations as it was reflected on your IT -- excuse me -- on your LinkedIn page.

Is that correct?

A. This would be when I was a manager of operations overseeing Polaris.

Q. Got it. Okay. And that subject is, "Recaps: Medicaid Patient Education - Attendance Required."

Did I -- did I read that correctly?

A. That's what I'm reading as well, yes.

Q. Okay. Well, let me ask, first of all, do you have any reason to believe that you did not send this email?

A. No.

Q. Okay. When it says "recaps" there in the subject field, do you have an understanding as to what you meant by that?

A. I likely was just sending this as a follow-up to a caller or something related to a call.

Q. Okay. So you were recapping the call that you might have had previously.

Is that right?

MR. HOLTZBLATT: Object to form.

THE WITNESS: I believe I was just

I'm joined today with Seth Miller the group ROD for Pacific Gold, and Caroline van Oaklin the divisional lead social worker.

"A few housekeeping items before we jump in. We -- this will be a recorded WebEx for those teammates who are not able to join so they can reference it at a later time. Additionally, this conference is on mute so silent until the end of the call. Once we get to the Q and A portion, I will then instruct everyone on how we can unmute your lines and be able to ask questions.

"So I'll go ahead and get started. So thank you, everyone, once again for joining.

"We're here today really to talk about a really exciting opportunity that we're embarking upon for a lot of our patients which really could just be an absolutely amazing opportunity for

some of our patients. So right now what our main opportunity is, is that some of our Medicaid patients may have an opportunity in this upcoming open enrollment period to obtain an individual plan primary and maintain their Medicaid plan secondary. This is just an absolutely really exciting opportunity for our patients because in many cases can really help them to improve their access to care in some cases, as well as potentially their quality of life.

"So one of our goals, as we go through the next few slides and -- and the next few months is that every single appropriate patient who we think may be [beep] the opportunity to get onto an individual plan will have that opportunity to learn about insurance improvements and so" --)

MR. WOODS: Okay. I paused the video for now.

related to this exciting opportunity that you mentioned earlier?

A. Once again, I don't know that I can speak on behalf of all of DaVita, but not to my recollection.

Q. Okay. All right. I'm going to try and play another portion. Unfortunately, and I'm saying this for the record, I can't go -- I have some specific portions that I want to ask questions about, but I might have to hunt around a little bit to get to them, because on my screen I'm not shown the time stamp on the WebEx until I hit play. And so I might have to hunt around a little bit, and I apologize for that. If the court reporter wants, they can go off the record until I'm ready to play.

THE REPORTER: This is the reporter. And I will go off the record until you give me the signal that we can go back on the record. How's that?

MR. WOODS: That would be fine. Thank you.

(Off the record.)

MR. WOODS: Back on the record.

Okay. I'm going to hit play on the WebEx again.

(Video played as follows:

"Overall, this could be a really great win-win for a lot of

our patients in minimizing their costs and allowing them to have better access to care.

"The last year during the open enrollment period we saw in some divisions up to over 90 patients choose to enroll into an individual plan primary and maintain their Medicaid plan secondary. And here's a few patient stories that I would love to share with you to really display how this has been such a life-changing opportunity for some of our patients and could potentially be, you know, a great improvement to the quality of life for additional patients.")

MR. WOODS: Okay. I'm pausing the video now.

BY MR. WOODS:

Q. Mr. Danko, you heard in the video where you described this as a win-win for patients. Do you recall that portion of the video?

A. Yes, I do.

Q. Okay. Then there was also a portion of the

transportation benefits that they currently are utilizing through Medi-Cal. So we can make sure that they continue to have those transportation services while increasing their access to care.

"We'll see if we have any questions on the line. Once again, star 6 to unmute.

"CAROLINE: Corey, this is Caroline, I have a comment.

"COREY: Yeah.

"CAROLINE: So I just wanted to let everyone know, especially the social workers, that there are hours that are additional hours that are available, especially if you have a large number of patients that you're going to be having those interest conversations with. So we're looking at getting support to the social workers so that there's the capacity to do what -- what we're being asked to do.")

BY MR. WOODS:

"I hope you can feel the importance of this opportunity. There are sometimes few opportunities where it's a true win-win situation, and this is -- this is one of those that we get to participate in and we believe that it's a -- it's a true win for those patients who -- who it applies to and who want to pursue this route. And it's a really great opportunity for us to really make an impact on their lives, so thank you" --)

MR. WOODS: Okay. I hit pause at 27:23.

BY MR. WOODS:

Q. Mr. Danko, in the portion that we just played, you identi- -- or you invited a person named Seth to make some comments. Who is Seth?

A. Seth was the group ROD, at the time, of Pacific Gold.

Q. And I believe your testimony earlier was that RODs are directors.

Is that right?

A. Correct. So potentially a senior director for Pacific Gold.

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES) ss.

I, COREY DANKO, hereby declare under the penalties of perjury of the laws of the United States that the foregoing is true and correct.

Executed this _____ day of _____, 2021, at _____, California.

_____

COREY DANKO

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES) ss.

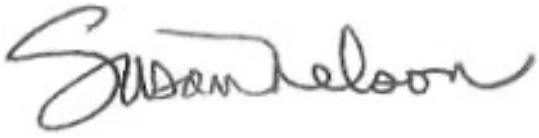
I, SUSAN NELSON, C.S.R. 3202, in and for the State of California, do hereby certify:

That, prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify the truth, the whole truth and nothing but the truth; that said virtual videoconference deposition was taken down by me stenographically at the time and place therein named to the best of my ability, and thereafter transcribed via computer-aided transcription under my direction, and the same is a true, correct and complete transcript of said proceedings;

Before completion of the deposition, review of the transcript [ ] was [X] was not requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

I further certify that I am not interested in the event of the action.

Witness my hand this 8th day of December, 2021.



Susan Nelson, C.S.R. No. 3202
Certified Shorthand Reporter
State of California

From: Corey Danko
Sent: Thursday, August 20, 2015 7:30 AM
Subject: RECAPS: Medicaid Patient Education – Attendance Required
Attachments: Pharmacy Benefits for Individual_Medicaid Coverage.pdf; General Insurance FAQ's.docx; Medicaid Opportunity - Polaris (North Star).pptx

Sent Bcc to North Star AAs, SWs, and FAs to reduce burden of reply all

Good morning, North Star!

Thank you again to all of you attended yesterday's call about the opportunity to educate our Medicaid patients on the potential benefits of obtaining an Individual plan primary while keeping their Medicaid Secondary. As discussed on the call, this could be a huge impact to a patient's access to care and/or quality of life with minimal to no impact to their out of pocket costs.

I have attached some FAQs, the presentation, and the recorded WebEx for all of you to reference. This will be a team effort, so please make sure to reference the materials and clarify any questions you have around the process.

Next Steps:

1. All SWs and AAs will receive training on the AKF HIPP Application process
2. All SWs assisting with interest conversations will receive training on effective conversations
3. ICs will be reaching out to SWs to start reviewing the appropriate patient list
4. All TMs who were not able to attend the call are to review the recorded WebEx – link is listed below

Please reach out to me or Jason Bosh with any questions. Thanks again for your partnership.

Corey Danko
Polaris IMT Manager

Medicaid Patient Education – North Star-20150819 1704-1
Wednesday, August 19, 2015
11:35 am | Mountain Daylight Time (Denver, GMT-06:00)

Play recording (29 min)

DaVita.

Medicaid Patient Education

Opportunity

Some of our Medicaid patients may have the ability to obtain an Individual plan primary to their Medicaid plan this Open Enrollment Period to improve their insurance

Every single appropriate patient will have the opportunity learn more about insurance improvement opportunities

How can this benefit patients?

Potential for better care & QOL

- Transplant
- Access to specialists
- Prescription coverage
- Vision and dental coverage
- Out-of-state travel
- Low to no cost *(w/ MCAID 2nd)*
- Transportation *(w/ MCAID 2nd)*

Patient Success Stories

- *"Not only could my patient now get on the transplant list, he could do it out of state since the local transplant center's list is so long. He just got his transplant in May."*

  – Alabama IC

- *"My patient was so grateful to be able to attend her mother's funeral out of state and continue treatment after purchasing the exchange plan. He wouldn't have been able to do that before."*

  – Florida IC

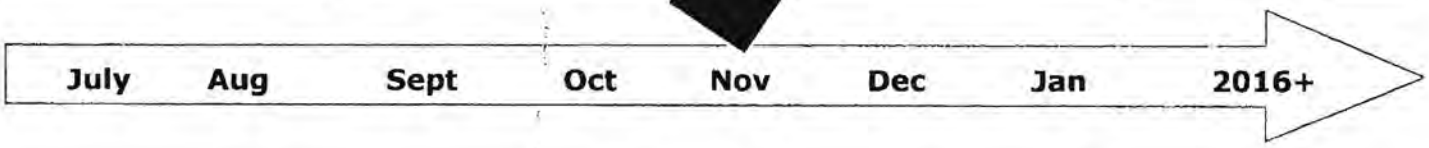
Medicaid Census

- 250 Individual Plan Eligible patients
- Largest census of new patients in: Pasco, Spokane, Yakima, Tacoma

Timeline & Key Milestones

Patient Outreach

Prioritize	Interest	Enroll	Support
• Assess which patients are appropriate for this opportunity • Build schedule to support appropriate patients	• Assess interest of appropriate patients • Research potential regional plans	• Continue to educate and assist interested patients • Support AKF application for all enrolled patients	• Provide ongoing support to new PP Patients



Resourcing Opportunity

Every single appropriate patient will have opportunity learn more about insurance improvement

- SW to date has been primary Medicaid resource
- Team effort in highly successful Divisions
- Increase in IC patient census (10-100%)

Responsibilities of key stakeholders

IMT

- Educate SWs and field on opportunity
- Primary touch-point for interest assessment; almost exclusive touch-point for enrollment
- Document progress in patient tracker

SW

- Partner with IC to make pt introduction
- SWs w/ patient load: Complete interest assessments timely

AA

- HIPP application when patient expresses interest
- Premium assistance request at enrollment

Plan of Action / Next Steps

	When	What	Who
Identify & Prioritize	8/24	*Training*: Interest Conversation and FAQ	SWs w/ pt load
	8/24	*Training*: HIPP Application Process	AAs, SWs
	By 8/31	SWs work through appropriate patient list with ICs and prioritize patient conversations	SWs
Interest	By 9/10	Complete 2-3 AKF submissions in partnership to ensure full training	AAs
	9/1-10/31	1. Perform interest conversations with patients, track conversations 2. Attend SAMs calls with IMT to discuss any updates/questions	SWs w/ pt load
		Submit AKF paperwork with interested patients, track submissions	AAs
Enroll	*Pending Interest Phase Results*		

Frequently Asked Questions

My patients have tried to purchase exchange coverage and the exchange turns patients away if they have Medicaid. Why do we think this is an option?

There are more ways for patients to get non-discriminatory coverage than simply purchasing through an exchange. Many patients directly purchase individual coverage through a payor's website or by directly calling the payor.

The AKF form asks if patients have Medicaid. Can a Medicaid patient qualify?

Application for AKF coverage

Yes, if a patient is eligible given other components of their HIPP application (income, etc). AKF has supported premiums for DaVita patients who will receive expanded coverage (transplant, network) through individual coverage.

Will my patients face any other unexpected costs?

Every state has unique rules for how Medicaid and Individual plans coordinate benefits. We are building a database of regulations.

What would this mean for transportation benefits?

By keeping their Medicaid coverage secondary, patients in most states will be able to keep their transportation benefits.

DaVita.

Appendix

Patient Example 1

Patient: Jane Smith

Has Medicaid primary and is in the process of a transplant work up

1. IC/SW work through patient list and deem Jane as an inappropriate patient to educate due to being in the middle of a transplant work up
2. IC updates tracker with reasoning why patient is not appropriate

Patient Example 2

Commercial insurance has high deductibles + copays, which are out of a Medicaid eligible patient's budget. Why would/ should Medicaid pay high out-of-pocket expenses as the "secondary insurance" Having commercial insurance does not guarantee ability to use specialists.

Patient: John Doe

Has Medicaid primary and is having a hard time accessing specialists

1. IC/SW work through patient list and deem John an appropriate patient to educate
2. IC has an interest conversation with John to see if he has any interest in an individual plan (John mentions that he is interested)
3. AA works with the patient to fill out the AKF application & submits to HIPP Liaison
4. Once 2016 plans become available (late September) IC/SW share plan options with patient
5. Patient applies for an Individual Plan
6. AA assists with submitting AKF premium documents
7. Patient starts new Individual plan primary and keeps Medicaid plan secondary. John starts scheduling appointments with his specialists.

13

Patient Example 3

Some commercial providers do not cover out of state dialysis for travel / personal choice. OR has had Calif Blue Cross deny OR vacation coverage. Kaiser does not cover vaction / travel dialysis.

Patient: Paul Johnson

Has Medicaid primary and has mentioned his desire to travel

1. IC/SW work through patient list and deem Paul is an appropriate patient to educate
2. SW has an interest conversation with Paul to see if he has any interest in an individual plan:
   - Paul mentions he would like travel benefits
   - SW explains that Paul may be able to have greater travel benefits under and individual plan
   - Paul thinks about it and decides he does not want to pursue and individual plan at this time
3. IC updates tracker with reasoning why patient is not interested
4. SW/IC continue to check in with patient and ensure he has the necessary support should he choose to elect an individual plan at a later date

EXHIBIT 14b

Excerpts from transcript of deposition of Steve Dover taken on November 18, 2021

FILED PROVISIONALLY UNDER SEAL

EXHIBIT 14c

Excerpt from transcript of deposition of John Bertko taken on January 13, 2022

UNITED STATES DISTRICT COURT
CENTAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

JANE DOE; STEPHEN ALBRIGHT; AMERICAN KIDNEY FUND, INC.; and DIALYSIS PATIENT CITIZENS, INC.,

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; et al.,

Defendants.

Case No. 8:19-cv-02105-DOC-ADS

(Pages 1-301)

VIRTUAL VIDEOCONFERENCE
VIDEOTAPED DEPOSITION OF
JOHN BERTKO
THURSDAY, JANUARY 13, 2022
10:05 A.M.

REPORTED BY:
SUSAN NELSON
C.S.R. No. 3202
JOB NO. 5014273

(CAPTION CONTINUED)

FRESENIUS MEDICAL CARE ORANGE COUNTY, LLC; DAVITA INC., FRESENIUS MEDICAL CARE HOLDINGS, INC., d/b/a Fresenius Medical Care North America; U.S. RENAL CARE, INC.,	Case No. 8:19-cv-02130-DOC-ADS
Plaintiffs,	
vs.	
ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her Official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,	
Defendants.	

Q. And the 5.3 percent projection is premised on the idea that there are 3,000 more ESRD enrollees. Correct? 14:59:20 14:59:25 14:59:25

A. Over a period of time, yes. 14:59:30

Q. Well, in -- when you prepared this report, you were assuming 3,000 additional ESRD enrollees in 2016. Correct? 14:59:31 14:59:37 14:59:41

A. No. 14:59:42

Q. You compared 2016 to 2015 when you did this report? 14:59:44 14:59:52

A. That's right. I've misstated that in the earlier part. The 3,000 is a projection over time. Midterm. 14:59:52 14:59:55 14:59:59

Q. So the 5.3 percent is based on the 3,000 additional ESRD enrollees. Correct? 15:00:04 15:00:10

A. Yes. 15:00:12

Q. If the number is less than 3,000, then the 5.3 percent would be less? 15:00:13 15:00:16

A. Yes. 15:00:17

Q. Okay. You don't describe how you arrive at the calculation of a risk increase of 5.3 percent in your report. Can you explain it to us? 15:00:19 15:00:24 15:00:28

A. Sure. So when you add in 3,000 people times 38, because that's the risk factor compared to 1.0 for the 1.5 million you have, the percentage increase 15:00:29 15:00:36 15:00:41

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES) ss.

I, JOHN BERTKO, hereby declare under the penalties of perjury of the laws of the United States that the foregoing is true and correct.

Executed this _____ day of _____, 2022, at _____, California.

_____

JOHN BERTKO

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES) ss.

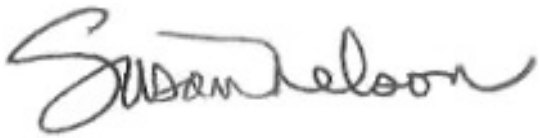
I, SUSAN NELSON, C.S.R. 3202, in and for the State of California, do hereby certify:

That, prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify the truth, the whole truth and nothing but the truth; that said virtual videoconference videotaped deposition was taken down by me stenographically at the time and place therein named to the best of my ability, and thereafter transcribed via computer-aided transcription under my direction, and the same is a true, correct and complete transcript of said proceedings;

Before completion of the deposition, review of the transcript [X] was [ ] was not requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

I further certify that I am not interested in the event of the action.

Witness my hand this 8th day of February, 2022.



Susan Nelson, C.S.R. No. 3202

EXHIBIT 15

Complaint filed in B*lue Cross and Blue Shield of Fla. v. DaVita, Inc.*, No. 3:19-cv-00574 (M.D. Fla.) on May 14, 2019

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

BLUE CROSS AND BLUE SHIELD OF FLORIDA, INC., and HEALTH OPTIONS, INC.

Plaintiffs,

v.

DAVITA, INC. f/k/a DAVITA HEALTHCARE PARTNERS INC.,

Defendant.

CASE NO.: 3:19-cv-_____

COMPLAINT

Plaintiffs Blue Cross and Blue Shield of Florida, Inc. ("BCBSF") and Health Options, Inc. ("HOI") (collectively referred to herein as "Florida Blue") file this Complaint against Defendant DaVita, Inc.[1] ("DaVita") and further state and allege as follows.

I. NATURE OF THE ACTION

1. DaVita has engaged, and continues to engage, in a deceptive and illegal scheme, more specifically set forth below, whereby DaVita donations to a charitable organization, the American Kidney Fund ("AKF"), are used to purchase commercial health insurance coverage for DaVita patients with chronic kidney disease who in turn obtain dialysis services from DaVita, which in turn bills insurance companies, such as Florida Blue, for those services.

[1] Effective September 1, 2016, DaVita HealthCare Partners Inc. changed its name to DaVita Inc.

2. Through this scheme, DaVita has damaged Florida Blue to the tune of tens of millions of dollars over at least the past several years.

3. As one of the country's largest for-profit providers of dialysis services for patients with end stage renal disease ("ESRD"), DaVita used its considerable resources to either steer patients who were eligible for Medicare and/or Medicaid into, or keep those patients enrolled in, Florida Blue commercial health insurance policies, contracts, and/or plans that the patients did not need or could not afford but that DaVita coveted and preferred, so that DaVita could get paid certain rates by Florida Blue for the dialysis services it rendered.

4. Through its efforts, DaVita effectively paid unwitting patients millions of dollars to participate in the scheme—purchasing Florida Blue insurance for its patients and illegally waiving the patients' significant resultant cost-sharing responsibilities (like deductibles and coinsurance obligations) that attached to the dialysis services the patients received, yet leaving the patients responsible for cost-sharing for other areas of care.

5. By paying patients' premiums and eliminating their cost-sharing obligations, DaVita effectively provided patients with free Florida Blue insurance coverage and free dialysis, all so DaVita could reap greater payments and profits from Florida Blue.

6. DaVita's return on investment in the scheme is substantial. For example, in a single year, DaVita illegally invested $120 million—*i.e.*, by "donating" that money to AKF in contravention of applicable DHS regulations to pay for Medicaid patients it was treating to enroll in, or remain enrolled in, commercial health insurance policies, contracts, and/or plans—and

received $450 million in operating income from benefits payments for services it provided to those commercial patients.

7. If those same patients had remained enrolled in government plans, DaVita would have received approximately $300 million *less* in reimbursements for providing the same services to those same patients.

8. Most of DaVita's dialysis patients have or are eligible for Medicare and/or Medicaid insurance. This is because in 1972, Congress passed legislation authorizing the End Stage Renal Disease Program under Medicare, which today extends Medicare coverage to 90% of Americans who require dialysis services from companies like DaVita, regardless of age. Moreover, regardless of whether they qualify for Medicare, many patients with ESRD now qualify to receive health insurance through Medicaid, a healthcare program for families and individuals with low income and limited resources that was created by amendments to Title XIX of the Social Security Act, 42 U.S.C. § 1396, *et seq*. Medicare and Medicaid are often extremely favorable insurance plans for dialysis patients, because they provide free or otherwise affordable coverage of the patients' dialysis and other medical needs.

9. For DaVita, the ready availability of Medicare and/or Medicaid coverage for most of its dialysis patients presents DaVita with a dilemma: accept the Medicare and Medicaid rates of $300 or less per dialysis session, reimbursement rates that substantially reduce DaVita's profits, or actively take steps to enroll those same dialysis patients in commercial health insurance policies, contracts, and/or plans that pay DaVita more for the same services.

10. Commercial health insurance policies, contracts, and/or plans generally reimburse DaVita at rates that are far higher than the rates Medicare and/or Medicaid pay. Accordingly, DaVita prefers dialysis patients with commercial insurance, and, in fact, depends heavily on patients with commercial—not government—insurance for its profits.

11. As DaVita has acknowledged in its SEC filings, the payments it receives "from commercial payors generate nearly all of [its] profits." DaVita 2017 Annual Report at 114. For DaVita to grow its revenues and continue to operate profitably, DaVita actively takes steps to steer patients away from enrolling in Medicare and Medicaid, while promoting and directing their enrollment into private insurance plans so it can provide dialysis services to as many commercially-insured patients as possible and increase its profits.

12. But several barriers sit between DaVita and its ability to move its patients onto, or keep its patients enrolled in, the commercial insurance plans it prefers, and between its ability to earn massive profits from those patients' insurers. *First*, the patients themselves often do not need or want the commercial insurance plans DaVita would prefer them to have, which may not be in the patients' best interests. *Second*, even if the patients want to enroll in, or to remain enrolled in, commercial plans, they must pay the required premiums for those plans, which would be reduced or non-existent if the patients are enrolled in Medicare or Medicaid, rather than commercial insurance. *Third*, even after paying premiums, the patients would still need to pay their "out of pocket" expenses, such as deductibles, copayments, and coinsurance amounts that they would be required to pay under commercial plans, which again would be reduced or non-existent if the patients were to enroll in primary Medicare or

Medicaid. Unfortunately, DaVita's profit-driven incentives to induce its patients to enroll in, or stay enrolled in, commercial insurance plans often conflict with its patients' best interests.

13. To overcome these barriers and inflate its profits, DaVita has orchestrated a multi-faceted scheme designed to aggressively pressure unwitting dialysis patients into enrolling in, or remaining enrolled in, commercial insurance plans offered by Florida Blue (and other insurance providers) while continuing to treat at DaVita clinics in order to get substantially higher payments from Florida Blue for those patients' dialysis treatments than it would have gotten had the patients been covered by Medicare or Medicaid. DaVita's elaborate scheme has consisted of the following components:

14. *First*, DaVita has targeted its own Medicare and Medicaid-eligible patients in order to steer them to, or convince them to remain enrolled in, commercial insurance plans, including those offered by Florida Blue. DaVita has deployed several tactics to push patients into, or keep them enrolled in, the commercial plans it thought would pay the highest reimbursement rates, including directing its insurance counselors and social workers to:

- "Educate" patients that commercial insurance plans are actually in their best interests by providing patients with incomplete, inaccurate, and slanted information and propaganda-like materials about their insurance options and counseling them to enroll in certain commercial plans;
- Promise patients that if they enrolled in commercial insurance plans, they would not have to pay for the coverage (in the form of premiums) or their dialysis treatments (in the form of deductibles and coinsurance payments); and

- In many cases, actually enroll patients into the plans, including Florida Blue plans, that DaVita had hand selected.

DaVita's efforts to steer vulnerable patients into Florida Blue's commercial insurance plans have not been driven by concern for the patients' interests, but rather out of concern for its own bottom line.

15. *Second*, to ensure its patients enrolled in, or remain enrolled in, commercial insurance plans, DaVita paid its patients' premiums. Because paying its own patients' premiums is prohibited by a host of laws, regulations, and other authorities, DaVita works closely with AKF—a registered 501(c)(3) organization—as a financial intermediary through which DaVita effectively paid its patients' premiums and to conceal the fact that DaVita is actually the entity paying the premiums.

16. The DaVita-AKF relationship works, and has worked, as follows: DaVita makes substantial "charitable" "donations" to AKF that are carefully calibrated to cover the amounts in premiums DaVita patients would require for commercial insurance premiums. DaVita and AKF operate under an understanding that AKF will route (or allow DaVita's employees to route) the bulk of the "donations" back to DaVita's patients in amounts calculated to cover their premiums. By funneling money through AKF and back to its patients, DaVita essentially pays its patients to enroll in, or remain enrolled in, commercial insurance plans, including Florida Blue plans, that DaVita believes serves its financial interests and profit goals.

17. *Third*, DaVita by way of pattern and practice routinely waived, eliminated, or otherwise failed to collect its Florida Blue members' deductible, copayment, and coinsurance

obligations. If the patients had maintained Medicare or Medicaid as their primary insurance, many of them would face little to no financial responsibility for any of their dialysis services, other medical treatments, prescription drugs, and services like transportation. Because commercial plans, including Florida Blue plans, generally have higher deductible, copayment, and coinsurance obligations, DaVita eliminates them on its end to ensure that patients will enroll in, or remain enrolled in Florida Blue's plans, and continue treating at DaVita's facilities.

18. By ensuring that patients enrolled in Florida Blue's commercial plans do not have to bear the cost of their dialysis, DaVita keeps treating them at its facilities under conditions most financially beneficial to DaVita. Moreover, although *DaVita* agrees to waive—or to make no meaningful effort to collect—the patients' cost-sharing obligations, it cannot guarantee the patients' *other doctors, pharmacists, medical equipment suppliers, and service providers* will do the same. This means that, by steering patients into Florida Blue's plans, DaVita has caused its patients to incur additional financial burdens, which DaVita intentionally or negligently fails to disclose to patients when trying to convince them to enroll in, or remain enrolled in, commercial insurance plans.

19. *Finally*, DaVita billed Florida Blue tens of millions of dollars for the dialysis services that DaVita rendered to the patients it targeted with its scheme. In billing Florida Blue, DaVita makes material misrepresentations and conceals, and fails to disclose, material facts, including the fact that it is paying the Florida Blue members' premiums and failing to collect their deductible, copayment, and coinsurance obligations—conduct designed to defeat

the cost-sharing features, benefit structure, and function of Florida Blue's commercial benefit plans.

20. DaVita's conduct breaches contractual obligations the company took on when it entered an Ancillary Provider Agreement (the "Provider Agreement") with Florida Blue, most recently in 2014. That Agreement requires DaVita, among other things, to comply with laws that prohibit the exact types of abusive, deceptive, and fraudulent conduct DaVita has engaged in.

21. Because of DaVita's unlawful, tortious, and unfair conduct, Florida Blue paid DaVita (and other providers) millions of dollars more than it would have paid had DaVita acted truthfully, lawfully, and properly. Simply put, DaVita constructed, implemented, and concealed a complex scheme that exploits its own patients and takes advantage of Florida Blue (including Florida Blue's other policyholders and members), all in pursuit of greater profits.

22. Importantly, Florida Blue is not the only victim of DaVita's scheme. As described above, DaVita's conduct exposes patients to cost-sharing obligations (including those related to services received from other providers) that they sometimes cannot afford. And DaVita fails to tell patients that the premium payments they are receiving the benefit of through AKF will only remain available if they s*tay on* dialysis, meaning that if they sought to cure their ESRD with a kidney transplant, they would lose their premium funding and, potentially, their commercial insurance plans.

23. Florida Blue brings this lawsuit to protect all its policyholders and members from further illegal, deceptive, and injurious conduct by DaVita, to bring a stop to the conduct

DaVita has been using to defeat the material provisions of Florida Blue's commercial plans, and to recover the substantial damages it has incurred based on the actions described in this Complaint.

II. PARTIES

24. Blue Cross and Blue Shield of Florida, Inc., a Florida health insurance company, was created in 1980, through the merger of two companies: one that started out as the Florida Hospital Services Corporation (the original name for Blue Cross of Florida, Inc.); and the other that started out as the Florida Medical Service Corporation (the original name for Blue Shield of Florida, Inc.). Following a corporate reorganization in 2014, Blue Cross and Blue Shield of Florida, Inc. d/b/a "Florida Blue" became a wholly-owned subsidiary of GuideWell Mutual Holding Corporation, a Florida not-for-profit corporation, as part of a mutual insurance company holding system including HOI, a licensed Florida Health Maintenance Organization (HMO). Including its predecessor entities, Florida Blue has offered health insurance plans in the state of Florida for at least 74 years. Florida Blue (in its current form) has continuously offered individual health insurance plans in Florida since at least 1980. With respect to its predecessor entities, the Florida Hospital Service Corporation sold its first individual hospital service contract in 1944; the Florida Medical Service Corporation sold its first individual medical service contract in 1946.

25. Plaintiffs BCBSF and HOI offer and provide health coverage and benefits to insured members and plan participants through a variety of benefit plans and policies issued in the State of Florida. BCBSF and HOI are corporations organized under the laws of the State of Florida with their principal place of business located in Jacksonville, Florida. Both

companies operate under certificates of authority issued by the Florida Office of Insurance Regulation.

26. Defendant DaVita is a nationwide provider of dialysis services, and is one of the country's two largest dialysis providers. DaVita is a Delaware corporation with its corporate headquarters located in Denver, Colorado.

27. Various firms and individuals not made defendants in this Complaint, including the AKF, its executives, and employees, participated as co-conspirators with DaVita in the violations alleged in the demand, and performed acts in furtherance of DaVita's violations.

III. RIPENESS OF THIS DISPUTE

28. Many aspects of DaVita's commercial relationship with Florida Blue are governed by, and subject to, the Provider Agreement between the parties effective January 1, 2014 (and amended April 2, 2015 and September 1, 2015). A true and correct copy of the Provider Agreement is attached hereto as **Exhibit A**.[2]

29. All conditions precedent to filing suit have been satisfied.

30. Specifically, Section 5 of the Provider Agreement outlines a dispute resolution process to be completed prior to filing suit. That process is initiated when one party provides written notice of the dispute to the other party. Provider Agreement Section 5.1.1. The contract then goes on to define the "First Level Dispute Process" which requires at least two meetings of a defined Working Group. *Id*. at 5.1.2. The first meeting of the Working Group must be convened within ten business days of receipt of the notice of dispute. *Id*. If the

[2] Florida Blue is contemporaneously filing *Plaintiffs' Motion to Seal Exhibits A and C to the Complaint and Incorporated Memorandum of Law* in accordance with Local Rule 1.09(a).

parties are unable to resolve the dispute through the First Level Dispute Process, they are to engage in the Second Level Dispute Process which requires a meeting of a Senior Working Group comprised of a vice president or senior manager from each party. *Id*. at 5.1.2.1. That Senior Working Group meeting is supposed to occur within thirty business days of receipt of the initial notice. *Id*. The contract goes on to state that if the parties are unable to resolve their dispute through the above described process within 90 days of receipt of the notice of dispute, they agree to participate in non-binding mediation. *Id*. at 5.1.2.2.

31. Florida Blue has made all efforts to meet the conditions precedent set forth in the contract, but DaVita has refused to fully engage in that process and has, thus, waived its right to demand specific performance of those provisions.

32. Specifically, on December 21, 2018, Florida Blue sent written notice of its dispute with DaVita to Robert Badal of DaVita, the individual designated to receive such notice on behalf of DaVita under the Provider Agreement.

33. On January 10, 2019, Brian Stephenson of DaVita sent an e-mail responding to Florida Blue's letter acknowledging receipt of the notice letter and stating that DaVita strongly disagrees with the assertions in that letter. In that correspondence, DaVita did not ask to convene a Working Group and did not offer dates that DaVita representatives were available to meet as part of the First Level Dispute Process.

34. In February 2019, Florida Blue's CEO and CFO met with DaVita's CEO in Jacksonville, Florida to discuss the parties' relationship, and DaVita's treatment of Florida Blue's members, since DaVita's unilateral termination of the Provider Agreement in September 2018. After that meeting, DaVita sent a settlement agreement and release to

Florida Blue that expressly sought to resolve all issues raised in the December 21, 2018 notice of dispute.

35. The parties did not execute the proposed agreement and were otherwise unable to resolve the dispute. On April 5, 2019, more than 90 days after it sent the dispute letter, Florida Blue sent an e-mail to DaVita for purposes of initiating the non-binding mediation contemplated in the dispute resolution provision of the Provider Agreement. Specifically, Florida Blue requested that DaVita identify potential mediators by April 12, 2019.

36. On April 12, 2019, DaVita responded and insisted that, despite the fact that more than 90 days had passed since Florida Blue provided initial notice of the dispute, and the fact that the parties most senior executives had already met, the parties started the dispute resolution process all over with the First Level Dispute Process.

37. Florida Blue responded to that letter on April 19, 2019 explaining why the parties had substantially complied with the pre-mediation dispute resolution process or alternatively, waived the dispute resolution conditions precedent in the Provider Agreement. Notwithstanding, in an effort to avoid unnecessary back-and-forth and without waiver of its rights, Florida Blue identified the persons comprising its Working Group and Senior Working Group and provided dates that Florida Blue's Working Group and Senior Working Group were available to meet. Florida Blue also identified potential mediators and dates that those mediators are available for mediation. Florida Blue asked for a response by April 23, 2019 and noted that "if DaVita fails to respond by identifying its respective representatives

and the dates they are available, we will accept such further evidence of DaVita's waiver of the conditions precedent outlined in the Agreement."

38. To date, DaVita has never responded to Florida Blue's April 19, 2019 letter.

IV. JURISDICTION AND VENUE

39. Personal jurisdiction is proper before this Court pursuant to Fla. Stat. § 48.193(1)(a)(1) and (2) because DaVita operates, conducts, engages in, and carries on business in this district in Florida, has offices in this state, and has committed tortious acts within this state targeted towards Florida businesses and residents, as described in this Complaint. Personal jurisdiction is also proper before this Court pursuant to Fla Stat. § 48.193(2) because DaVita is engaged in substantial and not isolated activity within this district in Florida.

40. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs, and is between citizens of different states.

41. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims in this action have occurred in this district. Many individuals who have Florida Blue insurance plans are located in this district, many activities giving rise to this action have taken place in and through DaVita's dialysis centers located in this district, and harm resulting from DaVita's conduct has been felt and incurred in this district. Florida Blue also made certain commercial plans at issue in this case available in this district at all relevant times by offering them through the federal

marketplace. And Florida Blue and DaVita entered into the Provider Agreement that governs the parties' relationship in this district.

V. FACTUAL BACKGROUND

A. Treatment of Chronic Kidney Disease

42. The kidneys play a critical role in the body's effort to excrete waste produced by metabolism. Kidneys filter blood and remove water-soluble wastes, such as urea and ammonium. Every day, the kidneys filter about 200 quarts of blood to produce about 1 to 2 quarts of urine, which is composed of wastes and extra fluid.

43. The kidneys are important because they keep the composition of the blood stable, which lets the body function properly. Among other things, kidneys prevent the buildup of wastes and extra fluid in the body and help stabilize electrolyte levels, such as sodium, potassium, and phosphate.

44. Chronic kidney disease ("CKD") is a condition characterized by a gradual loss of kidney function over time. There are five stages of CKD, which generally track the functionality of the kidneys. When kidney function drops to 10-15% of normal capacity, a patient is said to have stage five CKD. This stage is also referred to as end-stage renal disease ("ESRD"). ESRD is an irreversible condition.

45. Patients with ESRD are commonly treated with dialysis, which is a process for removing waste and excess water from the blood. ESRD patients typically receive dialysis treatments three times per week for the rest of their lives.

46. Unfortunately, dialysis does not correct the compromised functions of the kidneys. It simply replaces some of the kidneys' functions through diffusion (waste removal) and ultrafiltration (fluid removal). The only way to cure ESRD is with a kidney transplant.

B. Insurance Coverage for People with ESRD

47. Various types of insurance coverage are offered for people with ESRD.

1. Medicaid

48. Many patients with ESRD qualify to receive health insurance through Medicaid. Medicaid is a government insurance program available for families and individuals with low income or limited resources that was created by amendments to Title XIX to the Social Security Act, 42 U.S.C. § 1396, *et seq*. Medicaid is a means-tested program that is jointly funded by the state and federal governments and managed by the states. Under the program, the federal government provides matching funds to states to enable them to provide medical assistance to residents who meet certain eligibility requirements. Within the last several years, 31 states and Washington D.C. have expanded Medicaid to be available for individuals who make more than the national poverty rate.

49. Medicaid pays for ESRD patients' dialysis and kidney transplants. Although patient responsibility amounts for healthcare services vary by state, ESRD patients who have Medicaid are 100% covered for dialysis and have very low out-of-pocket expenses for other medical care and prescriptions. Medicaid also pays for other essential non-medical services such as medical transportation and home assistance.

50. Medicaid reimburses DaVita at a rate of less than $300 per dialysis treatment.

51. Upon information and belief, many of the patients DaVita steered and induced onto Florida Blue's commercial plans were insured by Medicaid at the time of the steering. In other words, at the time of the steering, those patients' dialysis services were covered in full by Medicaid at virtually no cost to the patients. Moreover, many of the patients who were not fully insured by Medicaid at the time of DaVita's steering, presumably would have qualified for comprehensive, low-cost coverage under Medicaid and likely would have selected Medicaid coverage had they been given an opportunity to make an informed, objective decision about the insurance options available to them.

2. Medicare

52. Today, 90% of U.S. citizens who require dialysis also qualify for Medicare. Since 1973, under the law, people with ESRD have qualified for Medicare, regardless of their age, so long as they (or their spouses) have sufficient working credits. Qualifying citizens may enroll in Medicare Parts A and B, and Medicare coverage of dialysis services generally commences three months after enrollment.

53. Medicare is an affordable means of covering dialysis and other medical services. Medicare Part B premiums are generally just over $100 per month, and the annual deductibles are also generally in the $100-$150 range. Medicare can also be much less if patients qualify for low-income assistance, and can be free for patients who qualify for Supplemental Security Income. Medicare enrollees are also responsible for a cost-sharing obligation amounting to 20% of the applicable Medicare fee schedule. The Centers for Medicare and Medicaid Services ("CMS") has set a reimbursement rate of less than $300 per treatment for dialysis services.

54. Patients who become eligible for Medicare, including those who develop and progress to ESRD, need to enroll in Medicare in a timely fashion or they risk possibly incurring financial penalties for late enrollment. Moreover, if patients do not have Medicare when they receive a kidney transplant, Medicare Part B will not cover the cost of the necessary immunosuppressant medications patients require following a transplant.

55. Upon information and belief, many of the patients that DaVita steered onto Florida Blue's commercial plans were eligible for Medicare at the time of the steering.

3. Private Commercial Insurance

56. Patients with ESRD may also have or seek insurance coverage from private individual and group commercial plans offered or administered by companies like Florida Blue. Commercial plans vary in terms of the services they cover, the facilities and providers they consider to be in-network, and the other benefits they offer. Commercial plans also generally require patients who want to be enrolled in them to purchase the coverage (by paying specific premiums), and bear some portion of the cost of the healthcare services they use (by paying some combination of deductibles, copays, and coinsurance). These requirements ensure that patients consider, and purchase, the coverage that they believe is right for them, and then remain sensitive the cost of services they receive from the providers they choose.

57. Many patients with ESRD who are working have private commercial coverage through employer group health plans ("EGHPs"). These patients generally pay the premiums for their EGHPs by having those amounts automatically deducted from their paychecks.

58. Private individual commercial plans are also offered by insurers pursuant to the Patient Protection and Affordable Care Act ("ACA"), as well as other non-ACA governed commercial insurance plans. The ACA created exchanges run by states and the federal government where insurance companies offer various health insurance plans for individuals to compare and purchase for themselves or their families. Plans offered through the exchanges are called Qualified Health Plans ("QHPs") and must meet certain requirements in terms of the benefits they offer, as required by the ACA.

59. Under the Affordable Care Act, low-income individuals and families whose incomes are between 100% and 400% of the federal poverty guidelines will receive federal subsidies on a sliding scale if they purchase insurance via an exchange. These subsidies are not available for plans purchased off-exchange.

60. Florida Blue offers a variety of commercial insurance plans, including individual plans offered on- or off-exchange, as well as fully-funded and employer self-funded group insurance plans. All of Florida Blue's commercial plans provide coverage for dialysis services, though the rates vary by type of commercial plan.

4. COBRA

61. The Consolidated Omnibus Budget Reconciliation Act, 29 U.S.C. § 1161, *et seq.*, ("COBRA") was enacted by the federal government in 1986 to provide, among other things, continuation of group commercial health coverage that otherwise might be terminated.

62. At some point, many patients with ESRD can no longer work. When this happens, they often qualify for Medicare and/or Medicaid.

63. Patients with ESRD who cannot continue to work can also sometimes keep their EGHPs under COBRA, which requires employers with more than 20 employees to allow individuals to keep their EGHP coverage for a temporary amount of time when coverage is lost due to certain qualifying events, including voluntary or involuntary termination of employment due to ESRD.

64. COBRA plans provide the same benefits that the individual received prior to the loss of group coverage – *i.e.*, the same coverage for dialysis services that the individual previously had under his or her commercial group plan.

65. The maximum period of continuation coverage is between 18 and 36 months, though it can be extended for beneficiaries with a qualifying disability. Also, COBRA enrollees are responsible for premium payments to maintain their coverage. These premium payments range from 102% to 150% of the monthly premiums associated with their previous group coverage. If payments are made in a timely fashion following the qualifying event, individuals are entitled to COBRA coverage as a matter of right.

C. Florida Blue's Commercial Insurance Plans

66. Florida Blue offers and/or administers a variety of types of commercial health insurance policies, contracts, and/or plans, including those offered on or off the health insurance exchanges pursuant to the ACA ("ACA plans"), EGHPs, and COBRA plans.

67. In its capacity as an insurer and as a claims administrator, Florida Blue processes hundreds of thousands of health care claims per day, and is responsible for processing and administering tens of millions of health care claims per year.

68. All of Florida Blue's commercial plans provide coverage for dialysis services, though the specific benefits relating to dialysis services vary by plan.

69. Florida Blue's commercial plans function in accordance with insurance policies, contracts, and/or plan documents, which establish, among other things, the rights and responsibilities of the payor entities and of the individuals who have enrolled in the policies, contracts, and/or plans. Florida Blue refers to its enrollees as "members."

70. The terms of the plans set forth several requirements designed to ensure that members pay for some portion of (a) the insurance coverage they want to purchase and (b) the cost of the healthcare services they receive from healthcare providers.

71. Florida Blue's commercial plans require members to purchase the plan coverage and benefits by paying the required plan premiums.

72. For example, Florida Blue's BlueChoice, PPO Family Physician Plan defines "premium" as "the total amount that [member] must pay BCBSF periodically for coverage under this Contract." The plan also states that "to be eligible to be a [member], a person must: . . . pay the required premiums."

73. Florida Blue's commercial plans also require members to pay for all or some portion of the charges submitted by their medical providers for the services the members receive. These member payment responsibilities are referred to as "cost-sharing obligations" and generally consist of a few components.

74. *First*, Florida Blue's plans generally require members to pay a deductible. A deductible is a dollar amount a member must pay each calendar year for the healthcare services they receive before their insurance company begins to pay for certain health

services. Until a deductible is met, a member's plan benefits and their insurer's obligation to pay for healthcare services are generally not triggered.

75. For example, Florida Blue's BlueChoice, PPO Family Physician Plan, defines "deductible" as "the amount of charges, up to the Allowed Amount, for Covered Services which an Insured must actually pay to an appropriate licensed health care Provider, who is recognized for payment under this Contract, before BCBSF's payment for Covered Services begins."

76. *Second*, assuming members have paid their deductibles, Florida Blue's plans generally also require members to pay coinsurance for the healthcare services they receive, until they meet the annual "out of pocket" maximum set forth in the plans. Coinsurance is the percentage of costs of a covered health care service members pay (e.g., 20% of allowed amounts) after they have paid their deductible.

77. For example, Florida Blue's BlueChoice, PPO Family Physician Plan defines "coinsurance" as the "sharing of health care expenses for Covered Services between BCBSF and the Insured. After the Insured's Deductible requirement is met, BCBSF will pay a percentage of the Allowed Amount for Covered Services, as set forth in the Schedule of Benefits."

78. *Third*, Florida Blue's plans sometimes require members to pay modest, fixed dollar amounts called "copays" at the time they receive certain healthcare services after their deductible is paid.

79. For example, Florida Blue's BlueChoice, PPO Family Physician Plan defines "copayment" as "the dollar amount established solely by BCBSF which is required to be paid

to a health care Provider by an Insured at the time certain Covered services are rendered by that Provider."

80. These Florida Blue plans' requirements provide structure to the insurance markets, help control the cost of healthcare, and serve as important checks on fraud, waste, and abuse. Since Florida Blue's members (not Florida Blue) control which healthcare services they receive, Florida Blue's plan requirements regarding member payment responsibilities ensure that members only enroll in coverage they are willing to pay for and remain sensitized to some portion of the cost of the healthcare services they receive from the providers they choose to patronize. This results in more affordable healthcare for all Florida Blue members, as well as members of the public more broadly.

D. Florida Blue's Provider Agreement with DaVita

81. As discussed above, Florida Blue and DaVita were parties to the Provider Agreement. In the fall of 2018, DaVita terminated the Provider Agreement. That Provider Agreement governs certain aspects of the parties' business relationship while it was in place. For example, the Provider Agreement addresses many aspects of the process by which DaVita provides dialysis services to Florida Blue members, and that Florida Blue pays DaVita for those services. As is discussed in greater detail below, DaVita's conduct has continued since its termination of the Provider Agreement. Florida Blue's breach of contract claims apply only to conduct that occurred while the Provider Agreement was in effect. The non-contract based causes of action cover both DaVita's past conduct and post-contract termination conduct.

82. Before entering into the January 1, 2014 Provider Agreement, Florida Blue and DaVita entered into a Traditional Dialysis Center Services Agreement effective June 1, 2004.

83. As a means of controlling costs to their members and improving quality of care, most commercial insurers, including Florida Blue, create provider networks for their plans. Providers who join a network enjoy the benefit of increased patient volume, as plan members are financially incentivized to seek medical treatment from in-network providers. In exchange, providers agree to certain terms set forth in a provider agreement. Providers further agree to a fee schedule that sets out the rates they will receive for the various services provided to each plan's members.

84. The Provider Agreement contains a material provision that requires DaVita to comply with a host of laws and regulations designed to prevent deceptive and abusive conduct.

85. Specifically, Section 2.1.1.2 of the Provider Agreement requires DaVita and each of its dialysis clinics to, throughout the term of the Agreement, "render Services in compliance with all Laws, this Agreement, the Manual for Physicians and Providers, and [Florida Blue's] policies and procedures."

86. Schedule A to the contract states that DaVita "shall not waive, discount or rebate any such deductible, coinsurance, and/or copayment amounts without the prior written consent of Florida Blue except for demonstrated hardship and following a documented process to collect applicable deductibles, coinsurance and copayments."

E. The American Kidney Fund and its Relationship with DaVita

87. AKF is registered as a tax-exempt, non-profit organization under Section 501(c)(3) of the Internal Revenue Code. 26 U.S.C. § 501(c)(3). AKF is based in Rockville, Maryland.

88. Publicly, AKF states that its mission is to "help people fight kidney disease and live healthier lives." (*See* AKF 2016 Form 990).

89. Privately, AKF has become an arm of its for-profit dialysis donors, serving as a conduit dialysis providers use to make and conceal premium payments to their own patients, to induce those patients to enroll in or stay enrolled in insurance plans that pay the dialysis providers the highest reimbursement rates and continue treating at the providers' clinics.

90. AKF did not always operate substantially or primarily for the private benefit of for-profit dialysis companies, nor was it exclusively organized to operate for the private benefit of for-profit dialysis companies. AKF was founded in 1971, and by 1995—twenty-five years after its founding—it was still a relatively small, independent charity, receiving less than $5 million a year in donations, with less than $500,000 of those donations coming from for-profit dialysis providers.

91. That began to change in 1997, when AKF and several for-profit dialysis companies, including DaVita, asked the Office of Inspector General ("OIG") to issue an advisory opinion allowing AKF to start operating and expanding a program called the Health Insurance Premium Payment ("HIPP") program where it would take donations from the for-profit dialysis companies and use them to pay the Supplementary Medical Insurance Program

("Medicare Part B") or Medicare Supplementary Health Insurance ("Medigap") premiums of financially needy patients who were enrolled in Medicare and being treated by the donating dialysis companies.

92. AKF sought the OIG advisory opinion because it did not want to be subject to civil monetary penalties under Section 231(h) of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which authorized the OIG to impose those penalties against entities who offer remuneration to Medicare or Medicaid beneficiaries that they know or should know will influence the beneficiary's decision to order or receive covered items or services from a particular medical provider.

93. In the request to the OIG, AKF stated that dialysis company donors "will be free to determine whether to make contributions to the AKF and, if so, how much to contribute." It stated further that "[c]ontributions will be made without any restrictions or conditions placed on the donation," and that AKF's "discretion as to the uses of the contributions will be absolute, independent, and autonomous."

94. Moreover, neither AKF nor DaVita then, or since, disclosed any intention to use the contributions of donating dialysis companies to pay those patients' EGHP, COBRA, or Affordable Care Act plan premiums, nor did they disclose how paying those premiums could impact donating companies' profits.

95. Ultimately, the OIG issued Advisory Opinion 97-1 which set forth guidelines that AKF and its donating companies would need to follow for AKF's HIPP program to avoid being subject to civil monetary penalties. In that Opinion, the OIG stated that AKF could not "earmark" "[c]ontributions . . . for the use of particular beneficiaries or groups of

beneficiaries," "take into account the identity of the referring provider or the amount of any donation to AKF by such provider," "assure" providers "that the amount of HIPP assistance their patients receive bears any relationship to the amount of their donations," or "guarantee[] that beneficiaries [donating companies] refer to HIPP will receive any assistance at all." The OIG stated that AKF assistance should be "available to any financially needy ESRD patient regardless of provider" and should not be "limited to patients of the [donating] companies."

96. The OIG also stated that providers could not "track the amounts that AKF pays on behalf of patients dialyzing at their facilities in order to calculate amounts of future contributions," and prohibited providers from "advertis[ing] the availability of possible financial assistance to the public[.]" The OIG also stated that Advisory Opinion 97-1 was "limited in scope to the specific arrangement described in this letter," had "no applicability to other arrangements, even those which appear similar in nature or scope[.]"

97. Thus, subject to the restrictions and limitations of Advisory Opinion 97-1, AKF's HIPP program came into being.

98. Today, 20 years later, AKF's HIPP program has evolved into a *de facto* profit-maximizing arm of AKF's dialysis company donors—something far different than the modest Medicare Part B and Medigap premium assistance program that AKF and DaVita pitched to the OIG in 1997.

99. In fact, AKF and a handful of large dialysis providers (including DaVita) have turned AKF's HIPP program into a lucrative investment vehicle, wherein the dialysis providers use AKF as a conduit to pay (and conceal the fact that they are paying) the commercial insurance premiums of patients dialyzing at their facilities, to induce them to

enroll in or stay enrolled in the insurance plans that in turn pay lucrative reimbursement rates to the dialysis providers.

100. By routing massive sums of money to their patients through a "charity," DaVita and other providers are able to mask the apparent source of the funds, and conceal the fact that they are paying their patients' premiums from insurers.

101. Crucially, AKF has made it clear that if providers it distribute funds sufficient to pay providers' patients' premiums, the providers need to "donate" corresponding sums of money to AKF's HIPP program.

102. Indeed, AKF has instructed and required providers to calculate and contribute sums to AKF that correspond to the amount of money those providers want or expect their patients to receive from AKF's HIPP program.

103. This "pay-to-play" requirement is embodied in what AKF has called its "fair share" requirement and "Honor System."

104. As recently as 2016, AKF had posted its HIPP Guidelines, which included a section describing the "HIPP Honor System," on its website. In that section, AKF set forth its requirement that "each referring dialysis provider should make equitable contributions to the HIPP pool" and that each provider should "reasonably determine its 'fair share' contribution to the pool [i.e., the funds available for premium assistance] by considering the number of patients it refers to HIPP." (*See* **Exhibit B**.) AKF emphasized that all providers had an "ethical obligation to contribute their respective 'fair share' to ensure that the HIPP pool is adequately funded." (*Id.*) And AKF instructed providers that "[i]f your company cannot

make fair and equitable contributions, we respectfully request that your organization not refer patients to the HIPP program . . . ." (*Id.*)

105. The message from AKF could not have been clearer: if providers wanted AKF to use their "donations" to pay their patients' premiums, the providers needed to calculate and contribute amounts of money commensurate with the amount of money their patients would require for premium payments. And if providers did not contribute their "fair share" to AKF, they should not expect their patients to receive HIPP funding.

106. AKF's Form 990 tax filings show that it is now operating substantially and primarily for the private benefit of the nation's large for-profit dialysis providers, including DaVita. In 2014, AKF collected cash contributions of $236,848,398 primarily from a handful of private donors and paid out $221,389,802 in premium assistance. In 2015, AKF collected cash contributions of $264,353,872 primarily from a handful of private donors and paid out $251,193,896 in premium assistance. In 2016, AKF collected cash contributions of $308,829,440 primarily from just five private donors and paid out $285,525,417 in premium assistance. And in 2017, AKF collected cash contributions of $297,553,398 from a small number of private donors and paid out $273,273,359 in premium assistance. Public sources report that the bulk of AKF's payouts during these years have been to patients receiving dialysis services at clinics owned by AKF's private donors, including DaVita.

107. Upon information and belief, based on AKF's Form 990 tax filings, its 2014 single-donor cash contributions of approximately $88 and $100 million, its 2015 single-donor cash contributions of approximately $98 and $108 million, its 2016 single-donor cash contributions of approximately $119 and $123 million, and its 2017 single-donor cash

contributions of approximately $120 and $126 million came from DaVita, Inc. and Fresenius Medical Care—the two largest for-profit dialysis providers in the country.

108. Recently, disparate pieces of information about how AKF's HIPP program actually works have started to leak out.

109. For example, on December 25, 2016, *The New York Times* published an exposé on AKF and its relationship with dialysis providers, entitled "Kidney Fund Seen Insisting on Donations, Contrary to Government Deal." (*See* Katie Thomas & Reed Abelson, *Kidney Fund Seen Insisting on Donations, Contrary to Government Deal*, THE NEW YORK TIMES (Dec. 25, 2016), https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html.)

110. The article stated that "For years, . . . the Kidney Fund's preference for patients at the biggest clinics has been an open secret among many social workers," and noted that 78 percent of AKF's 2015 reported revenue of $264 million came from two dialysis providers – DaVita and Fresenius. The article also reported that AKF "has resisted giving aid to patients at clinics that do not donate money to the fund" and that those "actions have limited crucial help for needy patients at these clinics." Pointing out that "[t]he agreement governing the relationship between the group and [dialysis providers] forbids choosing patients based on their clinic," the article nonetheless reported that "[i]n multiple cases, the charity pushed back on workers at clinics that had not donated money, discouraging them from signing up their patients for assistance." The article also observed that, "[u]ntil recently, the Kidney Fund's guidelines even said clinics should not apply for patient aid if the company had not donated to the charity," quoting the guidelines as stating

"[i]f your company cannot make fair and equitable contributions, we respectfully request that your organization not refer patients." And the article cited multiple examples of AKF demanding that dialysis providers "make a donation that at a minimum covered the amount [AKF] had paid for [a] patient's premium," threatening to cut off assistance for patients if such donations were not made, and, in some instances, refusing to pay patients' monthly premiums until those patients' dialysis providers made their monthly contributions to the HIPP fund.

111. Other information suggesting that AKF's HIPP program has also not been operating solely as a "last resort" source of assistance, as its own guidelines say it must, has also come to light. According to AKF's guidelines, HIPP is supposed to be "a 'last resort' source of assistance" wherein its funds are "restricted to patients who ha[d] limited means of paying health insurance premiums … and who would forego coverage without the benefit of HIPP." (**Exhibit B** at 6.) As the guidelines make clear, "[a]lternative programs that pay for primary or secondary health coverage . . . such as Medicaid . . . **must** be utilized first." (*Id.*) (emphasis in original). In other words, patients whose dialysis services could be covered by Medicaid, Medicare, or another public-assistance program were not supposed to be receiving AKF HIPP funding to pay for the premiums of commercial plan coverage when they could have used Medicaid to cover their dialysis services at no cost.

112. Florida Blue has recently discovered that many of its commercial insurance plan members treating at DaVita facilities have been receiving AKF HIPP funding to pay their premiums, despite being eligible for or enrolled in Medicaid, and despite the fact that they would not forego that coverage without the benefit of HIPP.

113. Separately, DaVita social workers have also been anonymously disclosing how DaVita actually uses AKF. As discussed below, toward the end of 2016, CMS put out a Request for Information ("RFI") to the dialysis community, asking for information about how dialysis providers were steering Medicare and Medicaid-eligible patients into ACA plans. Several current and former DaVita social workers responded anonymously by publicly submitting pieces of information suggesting that AKF is not acting as an independent entity for charitable purposes. For example:

- One former DaVita social worker explained that "corporate launched an individual market plan initiative, "tasked the social workers with identifying out patients who were insured with [a certain Medicaid plan] only[,]" "asked [the social workers] to 'educate' the patients with marketing material DaVita designed specifically to entice the patient into enrolling in a secondary private payer plan. . . ." and "assured our most vulnerable population of patients that they would not have to worry about paying their health insurance premium because our Insurance Counselors would preapprove them for the AKF HIPP grant."
- A kidney transplant social worker stated, "In my experience, DaVita Dialysis has inappropriately steered all pts on medical assistance to individual market plans" and that "[t]he dialysis co provides contributions to American Kidney Fund to pay the premiums and then dialysis gets reimbursed at a higher rate."
- A former DaVita insurance counselor confirmed that DaVita was involved in rampant patient steering, and disclosed that DaVita closely tracked "their

AKF enrollees and how much money goes for each person that receives assistance."

- And a nephrology social worker who had worked with various dialysis companies for over two decades stated, "Unfortunately over the years, the practice of steering patients to commercial insurances and paying for their coverage through donations to the American Kidney Fund (AKF) has become akin to money laundering. I implore you to **dig deeply** into the accounting practices of . . . DaVita, to discern the practice of linking patients with the amount of donations made to AKF. Many social workers have been concerned about this practice for several years." (emphasis in original).

114. Upon information and belief, DaVita has been calculating its "donations" to AKF's HIPP program to correspond as close as possible to the amount of premium payment money DaVita expects its patients will need to draw from the HIPP fund, and because DaVita does so, AKF ensures that those funds get distributed back to DaVita's designated patients. Moreover, upon information and belief, DaVita has taken on administering certain aspects of AKF's HIPP program, and is able to determine when and in what amounts premium payment checks are sent to its own patients.

115. DaVita has also openly advertised the availability of HIPP funds, violating the OIG's prohibition of exactly that practice. The availability of HIPP assistance was a regular component of DaVita's steering "pitch" to its patients and DaVita even prominently displayed information about the program on its own website for years.

116. Pieced together, different pieces of information show HIPP has not been operating legally, or the way AKF and DaVita told HHS-OIG it would operate.

117. Upon information and belief, AKF has been operating in violation of the restrictions set forth in Advisory Opinion 97-1 by earmarking DaVita's contributions for the use of DaVita's patients, taking into account DaVita's identity and the amount of DaVita's "donations" to AKF in deciding whether to distribute funds to DaVita's patients, assuring DaVita that the amount of HIPP assistance its patients will receive bears a relationship to the amount of DaVita's donations, and restricting HIPP funds to patients of donating providers like DaVita.

118. Upon information and belief, AKF has also failed to maintain independence and autonomy from DaVita, by allowing DaVita to use HIPP as a conduit through which to pay its own patients, and by allowing DaVita to access its HIPP program and take actions to cause premium payment checks to be sent to DaVita patients.

119. In sum, AKF is now being used by large dialysis providers like DaVita to pay their own patients' premiums to induce them to enroll or stay enrolled in commercial insurance plans that pay the providers the highest reimbursement rates, and to reward them for receiving, dialysis services from providers on terms that are in the providers' financial interest. AKF is also being used and operated, by design, to conceal from insurers like Florida Blue the fact that DaVita is funding and paying for its own patients' insurance premiums to serve its own financial interests.

120. AKF knows that DaVita uses AKF to conceal and route money for insurance premiums to its dialysis patients.

121. Simply put, AKF is not operating as an independent, autonomous, 501(c)(3) charity. Rather, it is operating for the private benefit of a small number of large for-profit dialysis companies like DaVita who influence, control, and administer many aspects of AKF's HIPP program.

122. DaVita's own public disclosures suggest it is not donating massive sums of cash to AKF to be charitable, but rather is doing so in order to serve DaVita's own financial interests and maximize its potential return on its "charitable" investment. For example, in a supplemental 8-K filing dated October 31, 2016 DaVita announced to its investors that "a policy change that prevents patients with minimum essential Medicaid coverage from accessing charitable premium assistance to enroll in ACA Plans would result in a reduction in its annualized operating income of up to approximately $140 million before any offsets. If CMS were to issue a broader ruling that made access to charitable premium assistance unavailable to all ESRD patients on ACA Plans, the estimated financial impact would increase by up to $90 million."

123. Likewise, in its 10-K filing dated February 24, 2017, DaVita disclosed that "if any . . . challenges to kidney patients' use of premium assistance are successful or regulators impose restrictions on the use of financial assistance from such charitable organizations such that these patients are unable to obtain, or continue to receive or receive for a limited duration, such financial assistance, ***our revenues, earnings, and cash flow could be substantially reduced***."

124. Relatedly, on October 9, 2017, AKF disclosed for the first time that it had been providing premium payment money to 21,000 non-ACA commercial plan members.

That disclosure prompted J.P. Morgan to issue a report downgrading DaVita's stock, having used AKF's numbers to estimate that "60-80% plus of [DaVita's] earning power is derived from its AKF relationship[.]" J.P. Morgan also questioned the "legal legitimacy" of DaVita's financial relationship with AKF.

125. These events forced DaVita to start disclosing some of its conduct. Thus, in a press release dated October 10, 2017, DaVita disclosed that approximately 25,000 of its patients were receiving premium payment money from AKF, including 1,800 patients who were enrolled in ACA plans and another 4,000 who were enrolled in EGHP and COBRA plans.

126. Collectively, DaVita estimated that the aggregate operating income it was deriving from reimbursement payments received from these two AKF-funded sub-groups of patients ranged between $495 million and $540 million. These disclosures confirmed that *the majority of DaVita's annual profits* were dependent on its financial relationship with AKF.

127. On information and belief, the relationship between AKF and DaVita is now currently the subject of an ongoing criminal investigation. On January 6, 2017, *The Wall Street Journal* reported that the U.S. Department of Justice had commenced a probe into DaVita's relationship with the AKF and, as part of the investigation, the U.S. Attorney's Office for the District of Massachusetts had issued a subpoena seeking information relating to DaVita's AKF donations. AKF has also reportedly been served with Department of Justice subpoenas.

F. DaVita's Scheme Harms Florida Blue, Florida Blue Members, and the Health Insurance Market

1. DaVita Targeted and Steered Patients in Florida into Florida Blue's Commercial Plans

128. DaVita provides dialysis services to Florida residents suffering from ESRD through the more than 250 dialysis centers that it owns, operates, and manages across the State of Florida.

129. Pursuant to the Provider Agreement, DaVita is paid for providing dialysis services to Florida Blue's members through a combination of payments received from Florida Blue and from the members themselves in the form of the deductible, copay, and coinsurance obligations required by the members' insurance plans, as described above.

130. Although the *services* DaVita provides to a patient do not vary depending on the patient's insurance plan, the "benefit" payment DaVita receives from the patient's insurer for those services varies greatly depending on the patient's coverage.

131. For example, if a patient is covered by Medicaid, then DaVita would receive the State Medicaid reimbursement rate, which on average amounts to $230 per visit for dialysis treatments in Florida. But if the patient is covered by a Florida Blue private commercial plan, then DaVita could receive a higher reimbursement rate for the same services.

132. Therefore, for DaVita to maximize the reimbursement rates it received for dialysis services, DaVita first needed to come up with a way to convince its patients to enroll in, or stay enrolled in, the commercial insurance plans DaVita coveted, even though they were eligible for Medicare or Medicaid.

133. In order to "steer" its patients into commercial insurance plans, or to keep them enrolled in commercial insurance plans, including Florida Blue plans, DaVita formulated and deployed a corporate-wide strategy that is outlined below.

134. *First*, DaVita scoured its rosters of patients and identified those who were eligible for, or enrolled only in, Medicaid or Medicare. Upon information and belief, DaVita also identified those of its patients who might soon be eligible to transition from an EGHP to Medicaid or Medicare, who DaVita wanted to keep on their EGHPs through COBRA.

135. DaVita then used its insurance counselors and social workers, who had a relationship of trust with their patients—many of whom lacked a sophisticated understanding of health insurance, and many others who were not native English speakers—to do its bidding.

136. DaVita armed its insurance counselors and social workers with marketing materials DaVita had prepared and strict directives regarding how to convince as many patients as possible to become enrolled in commercial insurance plans.

137. DaVita and its employees:

- Selected specific commercial insurance plans they wanted their patient "targets" to become enrolled in;
- Told the patients that commercial insurance plans were in their best interest, and counseled patients to enroll in them (or allow DaVita to enroll them);
- Provided patients with inaccurate, misleading, and incomplete information about the features and benefits of commercial insurance plans;

- Promised patients that if they enrolled or stayed enrolled in commercial insurance plans, they would not have to pay the plan premiums for the coverage or the cost-sharing obligations for their dialysis treatments;
- Ignored or denigrated Medicaid and Medicare as insurance options; and
- In many cases, enrolled the unwitting patients into DaVita's preferred commercial insurance plans.

138. DaVita directed this conduct at patients who it caused to become or stay enrolled in commercial plans offered by many insurers, including commercial insurance plans offered by Florida Blue, to serve its own financial interests.

139. Recently, DaVita's investors filed a class action complaint against DaVita in the District of Colorado alleging that DaVita violated federal securities laws by engaging in the conduct described herein and then lying about it. The case is captioned *Peace Officers' Annuity and Benefit Fund of Georgia, et al. v. DaVita Inc., et al.*, Case No. 1:17-cv-00304-WJM-CBS (D. Col. 2017). The investors amended that complaint on January 12, 2018, and included, for the first time, detailed allegations based on their counsel's independent investigation and review of internal DaVita documents and interviews with high-ranking former DaVita employees, as well as other sources.

140. Although too voluminous to repeat here, the *Peace Officers'* Amended Class Action Complaint revealed that DaVita had been engaging in the aggressive behavior described herein as a matter of nationwide corporate strategy, formulated at and directed by employees and executives at its Denver, Colorado headquarters.

141. Among other things, the *Peace Officers*' Amended Class Action Complaint demonstrated that:

- Internal DaVita documents and statements from former employees confirmed that DaVita's officers, mangers, and executives developed a plan and directed DaVita facilities across the country to steer patients off government plans and into AKF-backed commercial insurance plans.
- This directive was disseminated in the form of "Village Announcements" informing employees that getting increased numbers of patients into commercial insurance plans was a top priority. DaVita implemented company-wide "Private Pay Incentive Programs" in 2014 that offered bonuses to employees that converted the most patients to commercial insurance. DaVita developed and rolled out a company-wide initiative in the summer of 2015 called the "Medicaid Opportunity." DaVita then disseminated materials regarding this initiative to all employees to show that its singular purpose was to steer all of its government-insured dialysis patients onto AKF-funded plans.
- DaVita executives conducted training programs where they instructed attendees to "get [the] American Kidney Fund to pay for exchange plans," taught attendees steering techniques, instructed insurance counselors to promote commercial insurance over Medicare, and told insurance counselors that it was "important for us to get [the patients] onto private insurance. Even if they qualified for Medicare or Medicaid, you were

encouraged to get them on private insurance." These training programs included "80-hour two-week training program[s] at the Company's headquarters in Denver in August 2015 about steering patients off of Medicaid and into commercial plans."

- As part of this training program, DaVita prepared propaganda-like materials for employees to use with patients that promoted commercial plans and either ignored or disparaged Medicare and Medicaid, often with unsubstantiated, misleading, or false claims. DaVita management was also "very hungry" to make sure DaVita employees got patients into COBRA plans as well as ACA plans.
- DaVita frequently wrote off deductible obligations that patients who had been enrolled in commercial policies owed for their dialysis services, in order to make sure those patients were not discouraged from enrolling or staying enrolled.

142. Shortly before the *Peace Officers*' case was filed, CMS publicly expressed its significant concerns that dialysis providers like DaVita were engaging in inappropriate conduct designed to steer people eligible for or receiving Medicare and/or Medicaid benefits into private ACA plans for the purpose of obtaining higher reimbursement rates. Accordingly, as discussed above, on August 18, 2016, CMS released an RFI regarding the existence and nature of the practice.

143. In the RFI, CSM identified the type of behavior DaVita has engaged in as being dangerous, harmful, inappropriate, and unlawful.

144. CMS stated that it had learned of "reports that individuals who are eligible for Medicare and/or Medicaid benefits are receiving premium and other cost-sharing assistance from a third party so that the individual can enroll in individual market plans for the provider's financial benefit. In some cases, a health care provider may estimate that the higher payment rate from an individual market plan compared to Medicare or Medicaid is sufficient to allow it to pay a patient's premiums and still financially gain from the higher reimbursement rates." CMS also emphasized that insurance "[e]nrollment decisions should be made, without influence, by the individual based on their specific circumstances, and health and financial needs."

145. CMS explained that "when health care providers or provider-affiliated organizations steer or influence people eligible for or receiving Medicare and/or Medicaid benefits, it may not be in the best interests of the individual, it may have deleterious effects on the insurance market, including disruptions to the individual market risk pool, and it is likely to raise overall healthcare costs." And CMS further explained that "there is potential for financial harm to a consumer when a health care provider or provider-affiliated organization (including a non-profit organization affiliated with the provider) steers people who could receive or are receiving benefits under Medicare and/or Medicaid to enroll in an individual market plan. The potential harm is particularly acute when the steering occurs for the financial gain of the health care provider through higher payment rates without taking into account the needs of these beneficiaries. People who are steered from Medicare and Medicaid to the individual market may also experience a disruption in the continuity and coordination of their care as a result of changes in access to their network of providers,

changes in prescription drug benefits, and loss of dental care for certain Medicaid beneficiaries." CMS also made clear that "it is unlawful to enroll an individual in individual market coverage if they are known to be entitled to benefits under Medicare Part A, enrolled in Medicare Part B, or receiving Medicaid benefits."

146. Finally, CMS emphasized that "offering premium and cost-sharing assistance in order to steer people eligible for or receiving Medicare and/or Medicaid benefits to individual market plans for a provider's financial gain is an inappropriate action that may have negative impacts on patients" and "strongly encourage[d] any provider or provider-affiliated organization that may be currently engaged in such a practice to end the practice."

147. In response to the RFI, several current and former DaVita social workers responded by anonymously disclosing information suggesting that DaVita was engaged in the corporate-wide practice of inappropriate and unlawful steering and patient inducements.

148. For example, one social worker stated that, "In my experience, DaVita Dialysis has inappropriately steered all pts on medical assistance to individual market plans." Another social worker stated that, while he or she was employed at DaVita "corporate launched an individual market plan initiative and tasked the social workers with identifying our patients who were insured with '[a certain Medicaid plan] only.' They asked us to 'educate' the patients with marketing material DaVita designed specifically to entice the patient into enrolling in a secondary private payer plan . . . I knew this was an unethical practice[.]" And yet another DaVita employee described multiple instances in which DaVita insurance counselors instructed Medicare-eligible patients to not enroll in Medicare, and to instead enroll in private ACA and COBRA plans.

149. Florida Blue has interviewed members with ESRD who were enrolled in its commercial insurance plans, and many of them reported that DaVita had steered them into those plans, and away from primary Medicaid or Medicare coverage, using the tactics described herein.

150. DaVita's conduct has pushed large numbers of dialysis patients eligible for Medicare or Medicaid into Florida Blue commercial plans, or kept them on those plans even though they were eligible for Medicare or Medicaid, and has caused millions of dollars in damages to Florida Blue.

2. DaVita Used AKF as a Conduit to Pay Its Patients' Premiums

151. DaVita understood that in order for its scheme to succeed, it needed to induce the patients it targeted to enroll or stay enrolled in the Florida Blue commercial insurance plans DaVita preferred. DaVita specifically understood that if the patients had to purchase the plans themselves by paying the premiums the plans required, its scheme would fail, as many or all of them would opt to have Medicaid or Medicare as their primary insurer instead.

152. Thus, to defeat the premium payment requirements and provisions of patients' Florida Blue plans, DaVita funneled millions of dollars through AKF and back to its patients to pay their insurance plan premiums. Upon information and belief, DaVita employees also accessed and logged into the administrative system AKF set up for HIPP and used it to cause premium payment checks to be sent to DaVita patients. AKF administers its HIPP program through what it calls its "Grants Management System" ("GMS"), which is an online portal. Though the mechanics of how this system works are not publicly available, publicly-

available materials suggests that DaVita employees could be able to use the system to cause premium payments to go to DaVita's own patients.

153. For example, the current version of AKF's HIPP Guidelines acknowledge that dialysis company employees can register to gain access to and use GMS, and AKF's website links to a GMS login page designed to allow just that. AKF's HIPP Guidelines also state that "patients must work with their renal professional (or their assigned AKF contact) to ensure that subsequent grant installments are released for payment within GMS." This suggests that DaVita professionals who have access to GMS are capable of taking some action within GMS that sends or causes premium payments to go to DaVita patients.

154. As described above, DaVita's arrangement with AKF was a "pay-to-play" relationship, where substantial payments from DaVita to AKF were required if DaVita wanted AKF to route, or allow DaVita to route, the money back to DaVita's patients under the guise of "charitable" grants. AKF made it clear that if DaVita wanted AKF to make premium assistance "grant" money available to DaVita's patients, DaVita had to pay AKF substantial sums to fund those "grants" on a regular basis. In other words, DaVita had to pay AKF to route DaVita's "donations" back to DaVita's patients, for DaVita's financial benefit. DaVita calculated its "donations" to AKF to correspond with the amount of premium payment money it wanted and expected its patients to receive, and AKF and DaVita then distributed those "donations" back to DaVita's designated patients.

155. DaVita also concealed and failed to disclose the fact that it was engaging in this routine and systemic practice of paying patient premiums from Florida Blue.

156. Florida Blue has interviewed members with ESRD who were enrolled in its commercial insurance plans, and many of them reported that DaVita had connected them with AKF money and that some or all of their premiums were being paid for with money coming from AKF/DaVita.

157. DaVita's premium payment scheme with AKF induced patients to (a) enroll or remain enrolled in Florida Blue's commercial plans and (b) continue receiving dialysis at DaVita clinics under circumstances most financially favorable to DaVita. It also interfered with, undermined, and defeated the provisions of Florida Blue's plans that required enrolled members to pay their own premiums. This scheme allowed DaVita to bill Florida Blue for millions of dollars for dialysis and other services that otherwise would never have been billable to Florida Blue. The scheme also resulted in Florida Blue paying millions of dollars for non-dialysis services for members that were only enrolled in (or only remained enrolled in) Florida Blue plans as a result of DaVita's impermissible conduct and funding of the plan premiums.

158. DaVita's "donations" to AKF and subsequent premium payments to patients are kickbacks, bribes, and illegal remuneration designed to generate business, patronage, and a private financial benefit for DaVita, and are not charitable by any measure.

159. DaVita's relationship with AKF is also inconsistent with and not sanctioned by Advisory Opinion 97-1, and violates several of the restrictions set forth in that Opinion.

160. Florida Blue has been duped into paying millions of dollars for dialysis services rendered by DaVita on claims tainted by DaVita's plan interference and improper financial inducements.

3. DaVita Waived or Eliminated Patients' Cost-Sharing Obligations

161. Even though DaVita was paying Florida Blue's members' premiums (using AKF to conceal as much), DaVita knew that its overall scheme would still fail if it held the patients it had steered into Florida Blue's plans financially responsible for any portion of the cost of the frequent dialysis services they received at DaVita clinics. Specifically, DaVita knew that the patients it had steered would not want to pay the significant deductibles Florida Blue's plans required them to pay in order for their plan benefits to be triggered, or the significant cost-sharing amounts Florida Blue's plans required them to pay for their dialysis services. DaVita also knew that the patients might choose to drop their Florida Blue coverage and revert to Medicare or Medicaid if they had to pay for any portion of the cost of their DaVita dialysis treatments.

162. Thus, to interfere with, undermine, and defeat the cost-sharing provisions of Florida Blue's plans, and to induce its patients to continue treating at its clinics while remaining enrolled in Florida Blue's plans, DaVita systematically promised to waive and/or not collect the Florida Blue members' cost-sharing obligations – including deductibles, copayments, and coinsurance.

163. DaVita also promised Florida Blue members that they would not be responsible for paying DaVita for any out-of-pocket costs associated with their DaVita dialysis treatments, and that DaVita would accept as payment in full whatever amounts it could cause Florida Blue to pay.

164. This was not done to ease an otherwise unavoidable financial burden for these patients. Rather, DaVita decided to waive the cost-sharing obligations believing that the

money it forewent from these patients would pale in comparison to the additional dollars DaVita would extract from Florida Blue by keeping them on Florida Blue plans.

165. Upon information and belief, at the beginning of each plan year, DaVita also instructed Florida Blue members to refrain from seeking treatment from other medical providers, including specialists, until after those patients had hit their entire deductible at DaVita clinics. DaVita did this to ensure that it could control whether the members were ever asked to pay their required deductibles, and to ensure it would start getting paid by Florida Blue after Florida Blue assumed that the members had satisfied those deductible obligations.

166. DaVita did in fact waive and fail to collect these amounts from the Florida Blue members, effectively providing them with free dialysis.

167. DaVita also concealed and failed to disclose the fact that it was engaging in this routine and systemic practice from Florida Blue.

168. Florida Blue interviewed members with ESRD who were enrolled in its commercial insurance plans and many of them reported that they had not made any out-of-pocket payments to DaVita, and that DaVita had told them not to worry about making any of those payments.

169. Through this conduct, DaVita induced Florida Blue members to receive dialysis services from DaVita under conditions that were in DaVita's financial self-interest. DaVita also induced Florida Blue members to remain on commercial insurance plans instead of enrolling in more affordable Medicare and/or Medicaid plans for which they were eligible.

170. The systematic and routine waiver of patients' cost-sharing obligations is widely recognized to be a fraudulent, abusive, inappropriate, unethical, and unlawful practice

within the healthcare industry. Indeed, many states have recognized that schemes like the one DaVita has employed victimize health insurers and their insurance plans, including the members who are enrolled in them, and exponentially increase the cost of healthcare to the entire population.

171. For example, Florida law provides that it is insurance fraud for any services provider, other than a hospital, to engage in a general business practice of billing amounts as its usual and customary charge, if the provider has agreed with the insured or intends to waive deductibles or copayments or does not intend to collect the total amount of the charge. Fla. Stat. § 817.234(7).

172. Moreover, as early as 1994, the Department of Health and Human Services Office of Inspector General issued a special fraud alert noting that the "[r]outine waiver of deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare." *See* Office of the Inspector General, OIG Special Fraud Alert (May 1991), *Routine Waiver of Copayments and Deductibles under Medicare Part B*, *reprinted in* 59 Fed. Reg. 65372, at *65374 (Dec. 19, 1994). These same concepts apply in the commercial insurance context.

173. As a result of DaVita's actions, Florida Blue has paid out millions of dollars for dialysis services that it otherwise would not have paid.

4. Interviews with Florida Blue Members Confirm DaVita's Scheme

174. In an effort to determine how Florida Blue members who are receiving treatment at DaVita's dialysis centers ended up enrolled in Florida Blue's commercial insurance plans, Florida Blue interviewed a small subset of these members and their family.

175. The interviewees consistently reported that DaVita had employed some combination of the tactics described herein. Specifically, the members reported that DaVita handled enrolling them in Florida Blue commercial insurance plans, that their plan premiums were being paid with money coming through AKF, and that they had not paid DaVita for any costs associated with their dialysis treatments.

176. For example, "Member 1", a non-native English speaker, confirmed that a DaVita employee told him to enroll in Florida Blue's MyBlue Silver Plan. He confirmed that the DaVita employee did not tell him about any other insurance options available to him. Member 1 confirmed that he brings his premium bills to the dialysis center which then facilitates their payment using a check card that is sent to Member 1 every three months. Member 1 reported that he does not pay co-pays or co-insurance to DaVita.

177. Similarly, "Member 2," another non-English speaker, confirmed that a DaVita social worker helped enroll Member 2 in his Florida Blue insurance plan. The DaVita social worker did not tell him about any other insurance options available to him. Member 2 was told that his premiums would be paid by the AKF. AKF sent him a bank card to pay his premiums. Member 2 recently got a kidney transplant and now, AKF no longer pays his insurance premiums.

178. Attached as **Exhibit C** are exemplary claims that DaVita billed Florida Blue for dialysis services provided to Member 1 and Member 2.

5. DaVita Submitted Deceptive and Fraudulent Claims to Florida Blue

179. As a final step in its scheme, DaVita endeavored to bill Florida Blue in a misleading and deceptive way for the dialysis services rendered to Florida Blue's members, in order to cause Florida Blue to pay DaVita the sums it desired.

180. Florida Blue receives hundreds of thousands of healthcare claims per day and works hard to adjudicate, process, and pay them expeditiously. Because of this extraordinary volume, Florida Blue reasonably relies on the truth, accuracy, and completeness of the claims submitted by providers like DaVita for services rendered to Florida Blue's members. Florida Blue also assumes that its members have enrolled in their Florida Blue plans without undue influence by their providers and that the members—not their providers—are paying for their insurance coverage and their portion of the costs of their care.

181. DaVita knows this, and has taken advantage of it, submitting claims that have misrepresented, concealed, and failed to disclose material facts in an effort to mislead and induce Florida Blue into approving and making payments that it otherwise would not approve. Specifically, DaVita does this to mislead Florida Blue about its role in enrolling patients into Florida Blue's plans, its systemic payment of Florida Blue members' premiums, and its routine waiver of the members' cost-sharing obligations associated with the dialysis services DaVita has rendered.

182. DaVita submits claims to Florida Blue using standard forms and their electronic equivalents, in accordance with the terms of the Provider Agreement. (*See* **Exhibit**

A at Section 4.2.) These forms are approved and generated in connection with the federal Medicare program, and it is common in the healthcare industry for these same forms to be used in connection with other governmental and commercial insurance. The forms require providers to describe the services provided and the procedures performed using certain mandated coding regimes. The forms also require providers to set forth their "Charges" for each service or procedure and to list the "balance due" or "est. amount due."

183. The UB-04 form, which DaVita has utilized to submit the vast majority of claims to Florida Blue, also contains certifications to which DaVita affirmatively attests every time it uses the form to bill Florida Blue for dialysis services. Specifically, the UB-04 form states that: "Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete" and that "the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts."

184. This statement on the UB-04 form, among other things, obligates DaVita to accurately represent all information on its claim and to refrain from disregarding, concealing, misrepresenting, or failing to disclose material information from Florida Blue that DaVita knows bears on Florida Blue's ability to determine whether the claims being submitted should be paid and, if so, in what amount.

185. DaVita thus understands that when it uses claim forms (or their equivalents) to submit charges to Florida Blue, it is representing that its charges are accurate and payable and that no material information bearing on Florida Blue's payment decision has been disregarded, withheld, or concealed. DaVita also understands that Florida Blue relies on the

information and certifications in the claims DaVita submits in deciding whether, and in what amount, to pay the claims.

186. Nevertheless, the claims DaVita submits to Florida Blue contain material misrepresentations.

187. In each claim, DaVita set forth charges and told Florida Blue that it was entitled to be paid on those charges, even though it was in fact not entitled to be paid on those charges, due to its conduct described herein.

188. For example, because DaVita did not collect required patient obligations like deductibles and coinsurance obligations, charges contained in the claims DaVita submitted are not payable. Nevertheless, DaVita submitted charges to Florida Blue for its patients representing that it was entitled to be paid on the charges for purposes of causing Florida Blue to pay the claims based on the charges set forth therein.

189. DaVita's claims are also tainted by multiple other forms of unlawful remuneration, as described herein, rendering them not payable. In each claim, DaVita also untruthfully represented and certified that the claims were true, accurate, and complete, and that it had not knowingly or recklessly disregarded, misrepresented, or concealed material facts. In reality, DaVita billed Florida Blue charges having knowingly and/or recklessly disregarded and concealed the material facts that it had been providing the relevant Florida Blue members with free Florida Blue insurance (by using AKF to systematically pay their premiums and disguise as much) and free dialysis (by waiving and failing to collect their cost-sharing obligations).

190. Separate from its false certifications, DaVita made misrepresentations in connection with the claims it submitted by concealing and failing to disclose material facts that it was paying Florida Blue member premiums and waiving member cost-sharing obligations. Indeed, as described above, DaVita used AKF as an intermediary specifically to hide the fact that DaVita was paying its patients premiums.

191. DaVita's concealment and failure to disclose these material facts were calculated to induce and deceive Florida Blue into falsely believe that its members were paying their plan premiums and the cost-sharing obligations associated with the DaVita dialysis services they ostensibly chose to receive, as required, so that Florida Blue would continue paying the claims DaVita submitted.

192. DaVita had special, unique possession and knowledge of these material facts which it actively concealed and failed to disclose, which Florida Blue had no access to and could not discover by ordinary observation.

193. As a result of DaVita's conduct and deceptive billing, Florida Blue has paid out tens of millions of dollars for dialysis services for which Florida Blue would not have paid had it known of the material facts DaVita misrepresented and concealed.

6. DaVita's Conduct Harms the Health Insurance Markets

194. Importantly, DaVita's conduct harms not only private payers like Florida Blue, but also individual people enrolled in or looking to enroll in health benefit plans, the health insurance markets, legitimate business, and the American public at large.

195. Indeed, by misleading, steering, and using remuneration to induce unwitting people into the insurance plans it desires, a provider can generate the following harms,

among others: subordinating individual consumers' best interests to their providers' financial interests, increasing the actual financial burdens individual consumers must bear for their care, disrupting consumers' insurance coverage and network of treating physicians, negatively impacting consumers' eligibility for and ability to access other healthcare benefits (including those potentially available during the present or future under Medicare), negatively skewing the individual insurance market risk pools, and adding artificial and unnecessary costs onto the healthcare system thereby raising costs for everyone. Indeed, undetected healthcare fraud and abuse adds massive costs to the healthcare system every year—costs which everyone bears.

196. CMS has stated as much, by recognizing that "there is potential for financial harm to a consumer when a health care provider or provider-affiliated organization (including a non-profit organization affiliated with the provider) steers people who could receive or are receiving benefits under Medicare and/or Medicaid to enroll in an individual market plan. The potential harm is particularly acute when the steering occurs for the financial gain of the health care provider through higher payment rates without taking into account the needs of these beneficiaries."

197. The practice of routinely waiving or eliminating patient cost-share obligations only amplifies these harms. Indeed, because members are more likely to complain to their insurers, or alert them to issues regarding the provision of the health care services they are receiving, when they are having to bear the cost of some of their care, eliminating member cost-share obligations is one of the most common tactics adopted by providers to mask and keep members from alerting insurers to larger fraud and abuse schemes the providers are

perpetuating and allow those schemes to proliferate undetected. The systematic elimination of member cost share obligations also disrupts the behavioral incentives inherent in benefit plans designed to control healthcare costs, and can cause costs to increase for everyone.

198. The widespread harm that can flow from the type of conduct DaVita has been engaged in only makes it more important that DaVita's conduct be remedied and stopped.

VI. COUNTS AGAINST DAVITA

A. Count I – Breach of Contract

199. Florida Blue incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

200. Florida Blue has a contract with DaVita consisting of the Provider Agreement and the policies referenced and incorporated therein.

201. Florida Blue has performed its obligations under the Provider Agreement.

202. DaVita has breached the Provider Agreement in material ways.

203. Section 2.1.1.2 of the Provider Agreement requires DaVita and each of its dialysis clinics to, throughout the term of the Agreement, "render Services in compliance with all Laws, this Agreement, the Manual for Physicians and Providers, and [Florida Blue's] policies and procedures."

204. Section 5.4 of the Provider Agreement states: "The validity of this Agreement and of any of its terms and provisions, as well as the rights and duties of the parties hereunder, shall be interpreted and enforced pursuant to and in accordance with the Laws of the State of Florida," making Florida's healthcare fraud and abuse laws applicable to DaVita's conduct at issue here.

205. *First*, DaVita has breached Section 2.1.1.2 of the Provider Agreement by violating Florida's Insurance Fraud Statute, Fla. Stat. § 817.234(1)(a)(1)-(2), (3), (7)(a).

206. Under Florida's Insurance Fraud Statute, a person commits insurance fraud if that person, with the intent to injure, defraud, or deceive any insurer presents or causes to be presented any written or oral statement as part of, or in support of, a claim for payment or other benefit pursuant to an insurance policy, knowing that such statement contains any false, incomplete, or misleading information concerning any fact or thing material to such claim. Fla. Stat. § 817.234(1)(a)(1).

207. A person also commits insurance fraud if that person, with the intent to injure, defraud, or deceive any insurer prepares or makes any written or oral statement that is intended to be presented to any insurer in connection with, or in support of, any claim for payment or other benefit pursuant to an insurance policy, knowing that such statement contains any false, incomplete, or misleading information concerning any fact or thing material to such claim. Fla. Stat. § 817.234(1)(a)(2).

208. Further, a person commits insurance fraud if that person knowingly presents, causes to be presented, or prepares or makes with knowledge or belief that it will be presented to any insurer, any false, incomplete, or misleading information or written or oral statement as part of, or in support of, an application for the issuance of, or the rating of, any insurance policy, or knowingly conceals information concerning any fact material to such application. Fla. Stat. § 817.234(1)(a)(3).

209. Finally, Florida's Insurance Fraud Statute also states that it shall constitute a material omission and insurance fraud for any service provider, other than a hospital, to

engage in a general business practice of billing amounts as its usual and customary charge, if such provider has agreed with the insured or intends to waive deductibles or copayments, *or does not for any other reason intend to collect the total amount of such charge.* Fla. Stat. § 817.234(7)(a).

210. Thus, Fla. Stat. § 817.234(7)(a) applies to any instance where a provider, like DaVita, intends to not collect the deductible, copayment, and/or coinsurance owed by a patient pursuant to his commercial insurance plan. The business practices, actions, and deceptive billing conduct described above which DaVita engaged in intending to injure, defraud, and deceive Florida Blue, including: (a) DaVita's use of AKF to fund and pay its patients' Florida Blue premiums (and conceal as much), (b) its billing of Florida Blue coupled with its routine waiver of and decision to not collect Florida Blue members' payment responsibilities, (c) its role in presenting, preparing, and causing to be presented to Florida Blue false, incomplete, or misleading statements or information associated with Florida Blue members' insurance policy applications, and (d) its role in causing insurance claims containing misrepresented, incomplete, and misleading information concerning material facts to be prepared and submitted to Florida Blue, directly violate the provisions of Florida's Insurance Fraud Statute set forth above.

211. By failing to render services in compliance with Florida's Insurance Fraud Statute, DaVita has breached Section 2.1.1.2 of the Provider Agreement.

212. *Second,* DaVita has breached Section 2.1.1.2 of the Provider Agreement by violating Florida's Patient Brokering Statute, Fla. Stat. § 817.505 *et seq*. Florida's Patient Brokering Statute prohibits "any person, including any health care provider or health care

facility," from offering or paying "any commission, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind, or engage in any split-fee arrangement, in any form whatsoever, to induce the referral of patients or patronage to or from a health care provider or health care facility[.]" Fla. Stat. § 817.505(1)(a).

213. It is also unlawful for any person to solicit or receive any commission, bonus, rebate, kickback, or bribe, directly or indirectly, in return for referring patients or patronage to or from a health care provider or health care facility. Fla. Stat. § 817.505(1)(b). It is unlawful for any person to solicit or receive any commission, bonus, rebate, kickback, or bribe, directly or indirectly, in return for the acceptance or acknowledgement of treatment from a health care provider or health care facility. Fla. Stat. § 817.505(1)(c). And it is also unlawful for any health care provider or facility to aid, abet, advise, or otherwise participate in the conduct prohibited under Fla. Stat. § 817.505(a), (b), or (c). Fla. Stat. § 817.505(1)(d).

214. In violation of Fla. Stat. § 817.505(1)(a), DaVita has offered to pay and has paid remuneration, directly or indirectly, to induce the referral of patients or patronage by (a) agreeing to waive patients' cost-sharing obligations to induce them to enroll in Florida Blue's commercial plans and choose to receive dialysis treatments from DaVita under those conditions, (b) using AKF to provide remuneration to Florida Blue members for their insurance premiums to induce them to enroll in Florida Blue commercial plans and choose to receive dialysis treatments from DaVita under those conditions. DaVita has orchestrated these payments to cover patients' premiums and cost-share obligations to induce patronage by Florida Blue members and create the opportunity to bill Florida Blue at higher and more profitable rates for their dialysis services, to enrich itself.

215. In violation of Fla. Stat. § 817.505(1)(b), AKF has solicited or received remuneration in return for referring patients and patronage to DaVita by accepting "donations" on behalf of DaVita and then using those "donations" to pay the insurance premiums of patients who enrolled in Florida Blue's commercial plans, ensuring that these members would receive dialysis services at DaVita facilities and become enrolled in, or remain enrolled in, commercial insurance coverage that would allow DaVita to extract higher and more profitable rates for the same services. DaVita has violated Fla. Stat. § 817.505(1)(d) by aiding, abetting, advising, and otherwise participating in AKF's aforementioned prohibited conduct.

216. DaVita has also violated Fla. Stat. § 817.505(1)(d) by aiding, abetting, advising, directing, controlling, and otherwise participating in conduct described above that violates Fla. Stat. § 817.505(a), (b), and (c).

217. *Third,* DaVita has breached Section 2.1.1.2 of the Provider Agreement by violating Florida's Anti-Kickback Statute, Fla. Stat. § 456.054.

218. Florida's Anti-Kickback Statute makes it "unlawful for any health care provider or any provider of health care services to offer, pay, solicit, or receive a kickback, directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients." Fla. Stat. § 456.054(2). A kickback is remuneration or payment, by or on behalf of a provider of health care services or items, to any person as an incentive or inducement to refer patients for past or future services or items. Fla. Stat. § 456.054(1). "Violations of [section 456.054] shall be considered patient brokering and shall be punishable as provided in [Florida's Patient Brokering Act, Fla. Stat. § 817.505]." Fla. Stat. § 456.054(4).

219. As described above, DaVita has violated Florida's Anti-Kickback Statute through its actions described above, including its practice of waiving copays and of making payments to and through AKF to pay the insurance premiums of patients eligible for benefits under Medicare or Medicaid. DaVita has done this to solicit and obtain the referral of patients, knowing the payments were likely to influence the patients to purchase, order, arrange for, receive, or continue receiving, dialysis services from DaVita, and to enroll in, or remain enrolled in, the insurance plans DaVita coveted that pay DaVita higher rates.

220. By failing to render services in compliance with Florida's Anti-Kickback Statute, DaVita has also violated Florida's Patient Brokering Statute, and has independently breached Section 2.1.1.2 of the Provider Agreement.

221. *Fourth,* DaVita has separately breached Section 2.1.1.2 of the Provider Agreement by violating Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.201, *et seq.*, by engaging in the host of unfair, deceptive, and abusive practices described herein and in more detail below.

222. *Fifth,* DaVita has also breached Schedule A of the Provider Agreement which states that DaVita "shall not waive, discount or rebate any such deductible, coinsurance, and/or copayment amounts without the prior written consent of Florida Blue except for demonstrated hardship and following a documented process to collect applicable deductibles, coinsurance and copayments." As discussed above, DaVita routinely waived Florida Blue members' deductibles, coinsurance and copayment requirements in furtherance of its scheme.

223. As a direct and proximate consequence of DaVita's conduct and material breaches of the Provider Agreement, Florida Blue has been harmed by paying DaVita amounts it would not have paid but for DaVita's breaches.

224. By virtue of the foregoing, Florida Blue is entitled to compensatory damages.

B. Count II – Breach of the Implied Covenant of Good Faith and Fair Dealing

225. Florida Blue incorporates by reference paragraphs 1-223 (specifically including the allegations contained in Count I) as if fully set forth herein and further alleges as follows.

226. Every contract, including the Provider Agreement, contains in it an implied covenant of good faith and fair dealing.

227. Under the Provider Agreement, Florida Blue reasonably expected to receive certain benefits, including to have DaVita's services made available to (and only have to pay benefits for) Florida Blue members who enrolled or chose to stay enrolled in Florida Blue's plans through their own volition and satisfied their plan obligations, not members who DaVita improperly manipulated, steered, and induced to enroll (or stay enrolled) in the plans, including by paying their premiums and/or eliminating their cost-sharing obligations, and by utilizing other methods to manipulate and steer patients described above.

228. DaVita breached the implied covenant of good faith and fair dealing by engaging in conduct designed to interfere with Florida Blue's right to receive those benefits and take advantage of its contractual relationship with Florida Blue so it could get paid greater sums. DaVita specifically breached the implied covenant of good faith and fair dealing by engaging in misconduct designed to steer and induce members to stay off of

Medicare or Medicaid as primary insurance and enroll or stay enrolled in Florida Blue's plans, so DaVita could reap more payments under the Provider Agreement from DaVita than it otherwise would have received.

229. In engaging in this misconduct, DaVita acted consciously, deliberately, and in bad faith, frustrating the purpose of the Provider Agreement and Florida Blue's reasonable expectations.

230. As a direct and proximate consequence of DaVita's breaches, Florida Blue has been harmed, by paying DaVita amounts it would not have paid but for DaVita's breaches.

231. By virtue of the foregoing, Florida Blue is entitled to compensatory damages.

C. Count III – Tortious Interference with Contract

232. Florida Blue incorporates by reference paragraphs 1-198 as if fully set forth herein and further alleges as follows.

233. DaVita's conduct constitutes wrongful interference with Florida Blue's contractual relationships.

234. Each of the Florida Blue members for whom DaVita submitted claims and received payment from, Florida Blue received healthcare benefits pursuant to a benefit plan insured and/or administered by Florida Blue.

235. The terms of members' benefit plans were set forth in individual contracts between the members and Florida Blue.

236. Many of these contracts contained provisions that explicitly required that members to pay their premiums in order to obtain and maintain their insurance coverage.

237. These contracts also contained provisions that required members to satisfy their cost-sharing obligations associated with healthcare services they received, including their deductibles, coinsurance obligations, and any copayments, by making those payments to their providers.

238. Having counseled its patients to enroll in, or remain enrolled in, Florida Blue's commercial plans, DaVita knew, or reasonably should have known, that those plans required Florida Blue members to pay their own premiums as well as their cost-sharing responsibilities.

239. Despite this knowledge, DaVita intentionally interfered with, attempted to defeat, and procured the breach of members' contracts by waiving or failing to collect their required payment responsibilities and by coordinating with and using AKF to pay members' required premiums.

240. DaVita's interference and procurement of these breaches was without justification or privilege.

241. The breaches DaVita caused have resulted in significant damages to Florida Blue in the form of unnecessary payments Florida Blue made to DaVita subsequent to and as a result of those breaches.

242. By virtue of the foregoing, Florida Blue is entitled to an award of compensatory damages together with interest and costs, injunctive relief, and any other relief the Court deems just and proper.

D. Count IV – Fraud

243. Florida Blue incorporates by reference paragraphs 1-198 as if fully set forth herein and further alleges as follows.

244. DaVita knowingly and willfully executed a scheme to defraud Florida Blue by submitting fraudulent claims for dialysis services rendered to Florida Blue members.

245. DaVita had an independent duty to submit honest, accurate, and complete claims that did not misrepresent, disregard, or conceal any facts material to Florida Blue's decision about whether the claims were payable, and, if so, in what amount.

246. DaVita also had an independent state law duty to disclose certain material facts relating to the claims it was submitting to Florida Blue, including the facts that it was secretly and systematically funding Florida Blue's members' premiums (using AKF as a conduit to do so), and that it was secretly and systematically waiving or choosing to not collect Florida Blue's members' cost-sharing obligations. This duty is not only imposed by Fla. Stat. § 817.234, it also arises from the facts that: (a) as one party to the claims transactions, DaVita could have disclosed material facts that would have prevented its claims submissions from misleading Florida Blue, and (b) DaVita had special, unique possession and knowledge of these material facts, which Florida Blue had no access to and could not discover by ordinary observation.

247. In submitting and causing to be submitted claims to Florida Blue, DaVita misrepresented material facts in several respects.

248. *First*, in submitting the claims, DaVita told Florida Blue to reimburse it for the charges contained in the claims and represented that it was entitled to be paid on those

charges, knowing that it was not entitled to be paid on those charges, and that the claims were also tainted by conduct that violated the Florida healthcare fraud and abuse statutes described above.

249. *Second*, in submitting the claims, DaVita untruthfully represented and certified that the claims were true, accurate, and complete, and that it had not knowingly or recklessly disregarded, misrepresented, or concealed material facts. In reality, DaVita billed Florida Blue charges that it knew were not payable while knowingly or recklessly disregarding and concealing the material facts that it had been providing Florida Blue members with free Florida Blue insurance (by systematically paying their premiums) and free dialysis (by failing to collect their cost-sharing obligations).

250. *Third,* in submitting the claims, DaVita affirmatively concealed and failed to disclose the fact that it was paying the Florida Blue members' insurance premiums. As described above, DaVita used the AKF as a conduit through which to pay its patients' premiums, and specifically to *conceal* the fact that DaVita itself was paying those premiums from insurers like Florida Blue. DaVita used AKF as a pass-through intermediary to "wash" itself off as the apparent source of its patients' premium payments, when in fact DaVita was funneling massive, proportional sums through AKF to correspond to the amounts of premium payments it believed its patients would need.

251. Upon information and belief, and based on publicly available information, DaVita employees appear to have been able to log into and use AKF's online Grants Management System to take actions that would cause premium payment checks to go out to DaVita's own patients. DaVita then submitted claims to Florida Blue while fraudulently

concealing and failing to disclose that it was paying Florida Blue members' premiums, or the true nature of its financial arrangement with AKF.

252. *Fourth*, in submitting the claims, DaVita failed to disclose that it was systematically waiving and failing to collect Florida Blue's members' cost-sharing obligations.

253. The information DaVita misrepresented and concealed was material to Florida Blue's determination of whether to pay the claims and, if so, in what amount.

254. At the time DaVita made its misrepresentations, DaVita knew they were misleading and false.

255. DaVita also knew that it was concealing and omitting material information, that the material information should be disclosed and not concealed, and that its conduct would induce Florida Blue to make payments on the claims to DaVita.

256. DaVita submitted and caused to be submitted the claims to Florida Blue with the intent to defraud Florida Blue by inducing Florida Blue to rely on the misrepresented and concealed material facts and pay the claims based on the charges contained therein.

257. In so doing, DaVita acted in bad faith.

258. Florida Blue reasonably and justifiably relied on DaVita's material misrepresentations, concealments, and omissions in paying the false, inaccurate, incomplete, and misleading claims, and, as a direct and proximate result of DaVita's conduct, suffered compensable injury. Florida Blue has been harmed by paying DaVita amounts that would not have been paid had Florida Blue known of DaVita's misrepresentations, and that are far in excess of what should have been paid.

259. By virtue of the foregoing, Florida Blue is entitled to injunctive relief, compensatory damages, including consequential damages, punitive damages, interest and costs, and any other relief the Court deems just and proper.

E. Count V – Negligent Misrepresentation

260. Florida Blue incorporates by reference paragraphs 1-198 as if fully set forth herein and further alleges as follows.

261. DaVita misrepresented material facts in connection with the claims it submitted to Florida Blue.

262. DaVita either knew the misrepresentations it made were false, made them without knowledge of their truth or falsity, or made them under circumstances in which DaVita ought to have known of their falsity.

263. Specifically, DaVita misrepresented that the charges contained in the claims were payable, that the claims were true, accurate, and complete, and that it had not knowingly or recklessly disregarded, misrepresented, or concealed material facts, as described above.

264. DaVita intended to induce Florida Blue to act on these misrepresentations and pay amounts on the charges contained in the claims DaVita submitted. Florida Blue justifiably relied on DaVita's misrepresentations in processing and paying the claims, and suffered pecuniary loss as a result.

265. By virtue of the foregoing, Florida Blue is entitled to compensatory damages and injunctive relief.

F. Count VI – Civil Conspiracy

266. Florida Blue incorporates by reference paragraphs 1-198 as if fully set forth herein and further alleges as follows.

267. DaVita has conspired with AKF to unlawfully procure funds from Florida Blue through fraud, negligent misrepresentation, and tortious interference with Florida Blue's plan provisions.

268. In order to accomplish these unlawful acts, DaVita and AKF have conspired to calculate, and have DaVita make, large "charitable donations" to AKF, which AKF would then direct, or allow DaVita to direct, to pay DaVita's patients' insurance premiums so those patients would enroll or remain enrolled in Florida Blue commercial plans. This was done so DaVita could collect increased payments from those plans and so that AKF could receive larger additional "charitable donations" from DaVita. DaVita and AKF understood that by acting in concert, they could both benefit: DaVita would be able to increase revenues and profits, and AKF would be able to maintain or increase the massive "donations" it was receiving, to further perpetrate the scheme.

269. The overt acts DaVita and AKF have taken to perpetuate the scheme are described above and in the Counts for fraud and tortious interference. They include: (a) DaVita and AKF working together to concoct core elements of the scheme and then calculating and making massive "donations" to AKF that corresponded to DaVita's understanding of how much premium payment money its patients would need, (b) DaVita "steering" patients into, or keeping patients on, Florida Blue commercial plans by telling them AKF would pay their premiums, (c) DaVita employees filling out and submitting

patient "grant" applications to AKF, (d) AKF approving these applications, oftentimes in violation of AKF's own policies, (e) AKF allocating sums that had been "donated" by DaVita to be distributed back to DaVita's patients in amounts necessary to pay their premiums, (f) DaVita and AKF taking action within AKF's GMS system and other actions to cause premium payments to go to DaVita's patients, (g) DaVita and AKF engaging in this conduct despite knowing that Florida Blue's plans required members to pay their own premiums, and (h) DaVita submitting claims to Florida Blue while concealing and without disclosing that it, through AKF, was paying the premiums of Florida Blue's members and while concealing and without disclosing that it was not collecting Florida Blue member cost-sharing obligations.

270. DaVita and AKF also possess a peculiar power of coercion when acting in unison that they would not have had they acted alone. Specifically, by acting in unison, DaVita and AKF are able to facilitate DaVita's payments of its patients' insurance premiums all while concealing the mechanics of that payment system and DaVita's involvement in it from Florida Blue. This allows them to defeat the provisions of Florida Blue's plans, bill Florida Blue, and extract substantial payments from Florida Blue, while evading detection.

271. The concerted actions of DaVita and AKF have proximately caused Florida Blue to suffer significant damages.

272. Accordingly, Florida Blue is entitled to compensatory damages, interest and costs, and an injunction prohibiting Florida Blue from continuing to engage in the conduct described herein.

G. Count VII – Violation of Florida Unfair and Deceptive Trade Practices Act, Fla. Stat. § 501.201, *et seq.*

273. Florida Blue incorporates by reference paragraphs 1-198 as if fully set forth herein and further alleges as follows.

274. DaVita is, and has been, engaged in trade and commerce in the State of Florida.

275. DaVita has sought to specifically harm Florida consumers in the execution of their deceptive and fraudulent scheme.

276. Florida Blue and its members are consumers under FDUTPA. *See* Fla. Stat. § 501.203(7).

277. Florida Blue has been injured by DaVita's unfair or deceptive practices in the course of buying and paying for medical services that DaVita rendered unlawfully and sold in the State of Florida.

278. DaVita's business practices constitute both *per se* and traditional violations of FDUTPA.

279. DaVita's acts and practices constitute *per se* FDUTPA violations because they violate statutes that proscribe unfair methods of competition and unfair, deceptive, or unconscionable acts or practices, including Fla. Stat. § 817.234 (prohibiting false and fraudulent insurance claims), Fla. Stat. § 817.505 (prohibiting patient brokering), and Fla. Stat. § 456.054 (prohibiting kickbacks), as described above.

280. DaVita's unlawful acts and practices affected many claims for services rendered in Florida and have caused significant economic harm to Florida Blue because they

have caused Florida Blue to make substantial benefits payments to, and inuring to the benefit of, DaVita, that Florida Blue was not obligated to make.

281. DaVita's acts and practices also constitute traditional violations of FDUTPA.

282. DaVita engaged in unfair methods of competition, unconscionable, unfair, and deceptive acts and practices in the conduct of trade or commerce when it used the misconduct described herein to target, steer, induce, and enroll vulnerable patients into the plans it coveted and deceive Florida Blue in connection with those efforts and the unlawful and unpayable claims it submitted for dialysis services rendered to the Florida Blue members.

283. As described herein, after using a host of unfair and deceptive methods to steer, induce, and enroll vulnerable patients into treat at DaVita while enrolled in the plans DaVita coveted, DaVita continued to deceive Florida Blue in connection with the claims it submitted or caused to be submitted in order to extract maximum sums. DaVita falsely represented that the charges it submitted were payable and due and that it had not knowingly or recklessly disregarded, misrepresented, or concealed material facts, when it had. DaVita also concealed and failed to disclose the fact that it had targeted, steered, and often enrolled patients into Florida Blue's plans for its own financial gain, the nature and operation of the premium payment and financial arrangement DaVita had with the AKF, and the fact that it was funneling premium payment money to its Florida Blue member patients through and in cooperation with the AKF, and waiving or otherwise eliminating patients' deductibles, coinsurance, and other cost-sharing obligations. DaVita concealed and failed to disclose this

material information despite having special, unique possession of and access to it, and despite having a duty to do so to prevent Florida Blue from being misled.

284. DaVita engaged in the conduct described above, concealed material facts, and billed Florida Blue in a deceptive, false, and misleading way to deceive Florida Blue into making payments it otherwise would not have made.

285. DaVita's unfair trade practices and deceptive acts that comprised its inappropriate steering and billing scheme misled Florida Blue to its detriment and caused Florida Blue to make substantial payments to, and that directly benefitted, DaVita that, unbeknownst to Florida Blue, were not owed and would not have been paid but for DaVita's conduct. Florida Blue has retained the undersigned firm to represent it in this action and is entitled to recover its attorney's fees pursuant to the provisions of Fla. Stat. § 501.2105 and Fla. Stat. § 501.211(2).

286. In addition to authorizing damages, FDUTPA authorizes declaratory and injunctive relief for violations of its provisions. *See* Fla. Stat § 501.211(1).

287. By virtue of the foregoing, and consistent with the provisions of Fla. Stat. § 501.211, Florida Blue seeks damages for benefits paid on the unlawful and deceptive claims DaVita submitted to Florida Blue, plus attorney's fees, costs, and interest; a declaratory judgment declaring that DaVita's acts and practices are unfair and deceptive and in violation of FDUTPA; an order enjoining DaVita from continuing to engage in such unfair and deceptive acts and practices; and any other relief the Court deems just and proper.

H. Count VIII – Unjust Enrichment

288. Florida Blue incorporates by reference paragraphs 1-198 as if fully set forth herein and further alleges as follows.

289. Florida Blue has conferred direct benefits on DaVita in the form of significant payments based on claims DaVita submitted for dialysis services rendered to patients enrolled in Florida Blue plans, to which DaVita was not entitled, and DaVita has knowledge of those benefits.

290. DaVita has received a direct benefit from those payments.

291. DaVita has voluntarily accepted and retained the payments it has received and other associated benefits conveyed by Florida Blue.

292. Under the circumstances of this case, as set forth herein, it would be unjust and inequitable for DaVita to retain those payments and benefits that it received.

293. The money DaVita has received from Florida Blue belongs in equity and good conscience to Florida Blue.

294. By virtue of the foregoing, Florida Blue is entitled to recover the substantial amount of payments DaVita has improperly retained, which Florida Blue estimates to be to the tune of tens of millions of dollars.

VII. PRAYER FOR RELIEF

WHEREFORE, Florida Blue respectfully requests an award in its favor and granting the following relief:

a. An award of compensatory damages, including actual damages, as requested herein;

b. An award of punitive damages as requested herein;

c. Declaratory and injunctive relief as requested herein;

d. An award of attorneys' fees and costs as requested herein;

a. Prejudgment and post-judgment interest; and

b. An award of any other relief the Court deems just and proper.

Dated: May 14, 2019

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[3] In accordance with Local Rule 2.02, Jeffrey S. Gleason, Jamie R. Kurtz, William Borstein and Chelsea A. Walcker will be filing a written motion, as well as a designation and consent to act with fourteen (14) days.

Exhibit A

[Subject to *Plaintiffs' Motion to Seal Exhibits A and C to the Complaint and Incorporated Memorandum of Law*]

Exhibit B

American Kidney Fund®

HIPP

Health Insurance Premium Program

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HEALTH INSURANCE PREMIUM PROGRAM (HIPP)

GUIDELINES, RULES AND PROCEDURES

INTRODUCTION

The mission of the American Kidney Fund is to fight kidney disease through direct financial support to patients in need; health education; and prevention efforts. The American Kidney Fund leads the nation in providing charitable assistance to dialysis patients who need help with the costs associated with treating kidney failure. Last year, more than 87,000 people—1 out of every 5 dialysis patients in the United States—received assistance from the American Kidney Fund for health insurance premiums and other treatment-related expenses. Millions of people nationwide benefit annually from the American Kidney Fund's efforts to fight kidney disease through health education and prevention efforts. The American Kidney Fund offers free kidney health screenings in communities nationwide, as well as extensive online health education materials and courses and a toll-free health information HelpLine (866.300.2900).

As a 12-time recipient of the top "Four Star" rating from Charity Navigator, the American Kidney Fund is ranked among the top 1 percent of charities nationwide for fiscal accountability. In addition, the American Kidney Fund holds an A+ rating from the American Institute of Philanthropy; adheres to the National Health Council Standards of Excellence; and is a member of the Better Business Bureau Wise Giving Alliance. For more information, visit www.KidneyFund.org.

SECTION 1: HIPP BASICS

WHAT IS HIPP?

In 1997, AKF collaborated with the renal community to establish and administer the Health Insurance Premium Program (HIPP). HIPP is 100% funded by voluntary contributions from the dialysis community. Today, through HIPP, AKF provides assistance to more than 60,000 dialysis patients annually. AKF pays Part B Medicare, Medigap, commercial, EGHP, and COBRA premiums for dialysis patients who lack the resources to pay for them. The financial assistance provided by HIPP enables patients to maintain their health insurance coverage, thus providing continued access to vital health care. HIPP serves as a "last resort" for financial assistance to dialysis patients who have no other means or other sources of financial assistance to pay health insurance premiums.

Assistance is available to all eligible patients on an equal basis. In general, eligibility for participation in HIPP requires a signed grant application by a social worker employed by or an administrator of a dialysis provider. The grant application requires the patient to provide detailed financial information for his or her entire household. Applications must be submitted on the patient's behalf by a social worker employed by or an administrator of a dialysis provider.

Following receipt by AKF of the patient's application, an AKF employee assigned to HIPP reviews the application, gathers additional information, if necessary, and makes an evaluation as to the disposition of the application based upon AKF's needs assessment and eligibility criteria. All determinations are made by AKF employees who have no financial interests in dialysis providers. Such determinations are solely based upon AKF's assessment that the applicant is in financial need and meets HIPP eligibility criteria.

Because of limited financial resources, HIPP insurance premium assistance is provided only for a specific time period. Upon expiration of the period, the patient must submit another grant application for assistance. Grant requests are reviewed on a "first-come, first-served" basis, subject to the availability of funds in the HIPP "pool."

HOW HIPP WORKS

In 1997, the U.S. Department of Health and Human Services Office of Inspector General issued a written opinion (Advisory Opinion 97-1) that enabled AKF to establish HIPP. AKF operates HIPP strictly in accordance with the guidelines set forth in Advisory Opinion 97-1. A hallmark of HIPP is that AKF carefully evaluates each patient's application and provides assistance based solely on the patient's financial need, without regard to the facility where the patient is receiving dialysis. Another hallmark of HIPP is that dialysis providers make voluntary contributions (including an AKF programmatic fee) to the HIPP pool. Such voluntary contributions make it possible for AKF to have the resources to pay premiums that keep in force health insurance for the neediest patients. Providers which contribute are conclusively deemed to have knowledge of these Guidelines and Procedures, including, but not limited to, that AKF invariably will ignore any "earmarking" of any funds for the patients of any provider. All contributions to AKF are subject to these Guidelines and Procedures.

THE HIPP HONOR SYSTEM

In order for this program to work for patients and dialysis providers, each referring dialysis provider should make equitable contributions to the HIPP pool. A facility can reasonably determine its “fair share” contribution to the pool by considering the number of patients it refers to HIPP. Without an effort on the part of all providers to contribute equitably to the program, HIPP cannot continue to help existing and newly qualified patients who need assistance. We believe all facilities share a common ethical obligation to contribute their respective “fair share” to ensure that the HIPP pool is adequately funded. This is essential in order for AKF to have the resources to help dialysis patients who need premium assistance in order to keep in force their health insurance. We regard this as a mutual honor system. It is the only way in which HIPP can continue to help patients in need.

We know that your focus, like ours, is on assisting patients. Working together and with your company making its fair and equitable share to the HIPP pool, we can assure that patients in need continue to receive the assistance that they need to obtain and maintain health insurance. Please discuss this with your management and finance staff and contact us immediately if you require additional information.

All contributions are, of course, voluntary and there is no "earmarking" of contributions to specific patients within the HIPP pool. As you should be aware, AKF operates the HIPP program under the auspices of the Office of Inspector General's Opinion 97-1 and AKF focuses solely on patients' needs without considering the facility where they are receiving dialysis (reference the enclosed Guidelines). Nonetheless, it should be obvious to all facilities that if each one does not contribute its fair share, the HIPP pool cannot continue to help all patients who need assistance.

If your company cannot make fair and equitable contributions, we respectfully request that your organization not refer patients to the HIPP program in order that we may preserve this important program for the tens of thousands of patients nationwide who are currently enrolled in HIPP to maintain their insurance coverage.

THE VALUE OF HIPP

1. HIPP ensures that dialysis patients maintain coverage under the spectrum of insurance modalities: Medicare Part B, Medigap, COBRA and commercial (including policies purchased via the ACA marketplace exchanges) and EGHP plans.
2. AKF provides a quick turnaround (10 to 14 business days, on average) for HIPP applications that are fully and correctly completed and provides expedited handling for urgent requests that meet HIPP guidelines.
3. AKF provides “troubleshooting” with Medicare and private insurance carriers.
4. Through HIPP, patients maintain health insurance coverage and have access to comprehensive medical care.
5. AKF helps patients maintain continued access to comprehensive quality dialysis and healthcare which enhances treatment outcomes and reduces hospitalizations.

PROVIDER UTILIZATION RULES AND BEST PRACTICES

1. Provider must assign a corporate representative to be the principal HIPP liaison.
2. Provider must assign a corporate Finance Administrator (separate from HIPP liaison) to be the financial contact to AKF. The corporate Finance Administrator must have the financial authority from the Provider to make contributions to AKF's HIPP program.
3. Complete required training orientation in order to activate / sustain an account:
    - Both the HIPP liaison and the corporate Finance Administrator **must complete** orientation and/or additional training with AKF prior to submitting any grant application. Follow-up / additional training may be required, if deemed necessary by AKF. AKF reserves the right to require providers to complete training before submitting applications via GMS for new patients. AKF reserves the right to deny access for failure to complete required training and/or a failure to follow guidelines.
    - HIPP liaison and corporate Finance Administrator completes online course in GMS (training tab) within 90 days of account activation.
    - Corporate Finance Liaison: completes a "phone call" orientation with AKF's Director of Financial Analysis (301-984-6633) prior to the HIPP liaison account activation / sustainment.
4. Provider must use AKF's Grants Management System (GMS) at www.gms.kidneyfund.org for application submission.
5. Encourage your facility to make equitable contributions to AKF.

PROGRAM ELIGIBILITY

1. Applicants must reside and dialyze in the United States or its territories.
2. Applicants must meet the eligibility qualifications of the insurance policy for which premium assistance is being requested.
3. Transplant patients are not eligible for HIPP. Due to limited funding, HIPP enrollees are not eligible for premium assistance after they receive a kidney transplant.
4. Applicants must be verified and referred to AKF by a renal professional assigned to a Medicare certified dialysis provider/center. Patients are not permitted to apply directly to AKF for a grant. A renal professional must apply on their behalf.
5. HIPP is a "last resort" source of assistance. It is restricted to patients who have limited means of paying health insurance premiums (based on income-to-debt ratio) and who would forego coverage in the absence of assistance from HIPP. Alternative programs that pay for primary or secondary health coverage or provide financial assistance grants, and for which the patient is eligible, such as Medicaid, state renal programs, other organizations, etc. **must** be utilized first. Premiums deducted from income sources such as Social Security checks cannot be reimbursed.
6. AKF does not represent that a properly completed application will be approved or, if approved, that insurance premium assistance from HIPP will be ongoing. To the contrary, the decision to provide assistance in response to any given application or request is at all times subject to the sole and absolute

discretion of AKF. HIPP is not an entitlement program. There is no "right" to a grant or financial assistance, either initially or for any given period. AKF reserves the right to modify or withdraw at any time any commitment as to any grant or financial assistance. Without limiting the foregoing, a finding of eligibility does not give rise to entitlement to financial assistance which, upon other variables, depends on available funds in the HIPP pool. AKF reserves the right, exercisable in its sole and absolute discretion, to revise eligibility criteria, from time to time, and make such changes effective as of any date selected by AKF. AKF neither warrants nor represent that applications will be reviewed within any certain period of time. If an application is approved, AKF neither warrants nor represents that a HIPP grant or payment will be made within any certain period of time. AKF is not responsible for errors or delays, irrespective of the cause, either in the review of properly completed applications or issuance of checks or other forms of payments. Under no event shall AKF be liable for damages alleged to have been caused by denials of applications, errors or delays in the review of applications, errors or delays in the issuance of checks or other forms of payments or delays in the U.S. postal system or commercial delivery services. All applications to HIPP are irrevocably deemed submitted with the full acceptance of the foregoing both by the Provider and by the dialysis patient.

7. Applicants must demonstrate that they cannot afford health coverage. Monthly household income may not exceed reasonable monthly expenses by more than $600. If there is no income at the time of application, you will be required to provide an explanation. Total liquid assets, such as savings accounts and stocks/bonds may not exceed $7,000. (IRAs and other retirement accounts are excluded and will not be counted toward this amount.) AKF reserves the right to request additional information and documentation, as it relates to reported income, expenditures and all reported application information.

8. Savings up to $1,500 formally set aside for burial expenses in a bank account, other financial instrument or prepaid burial arrangement will be exempted as an asset. (This criterion was adopted from the Social Security Administration, which uses it for the purpose of Supplemental Security Income eligibility.)

9. HIPP only provides premium assistance in connection with primary and secondary insurance coverage. HIPP does not assist with tertiary coverage of any kind.

10. In some situations, AKF may choose to institute a premium cap. AKF currently has a cap on Medigap premiums at $550 per month. Before submitting an application, please contact AKF directly to obtain specific capped amounts and possible exceptions, due to transplant list status. AKF reserves the right to institute changes to grant maximums. Proper advance notice will be provided.

SECTION 2: APPLICATION PROCESS

APPLICATION SUBMISSION

1. AKF will **ONLY** accept applications submitted **ONLINE** via the Grants Management System (GMS). Online applications may be submitted either as a "one-time" request or as recurring request.

2. AKF reserves the right to request additional backup documentation to validate application information.

3. AKF reserves the right to require new annual applications for all enrollees to ensure system accuracy and applicant eligibility.

4. All new applicants to HIPP shall be provided a copy of *HIPP Procedures and Guidelines,* along with the application. Confirmation of guideline receipt is included as a part of the patient's consent form. Copies are available through AKF's Grant Management System, our website at www.KidneyFund.org or by calling AKF.

   This procedure is intended to ensure that all prospective recipients of assistance from HIPP understand the benefits, responsibilities **and** limitations of "enrollment" in HIPP. Most importantly, patients need to be informed that HIPP assistance is limited to those receiving dialysis treatment. It is especially critical that HIPP enrollees who may be candidates for a kidney transplant understand this aspect of HIPP.

5. Once the patient is enrolled in the program through an online GMS submission and the premium amount and payee remain the same you **will not** have to provide another premium bill to AKF until the beginning of the next calendar year. Payments will automatically be issued by AKF through the end of the calendar year. **Note:** HIPP liaisons are required to approve and release all subsequent payments before AKF issues a grant check. This will help mitigate the possibility of making payments that are not needed.

6. You must submit a new online request and bill if your patient has **any** changes in insurance coverage or premium amount. This will update the automated payment information. Please also notify AKF immediately if your patient dies, transfers or receives a transplant, so that his or her record can be updated.

7. A new online application is required if your patient changes dialysis providers.

8. HIPP payment requests must be accompanied by an insurance bill or coupon when applying initially or if the request is modified thereafter. Please follow the following guidelines for bill submission:

   - Only bills/coupons from the current year will be accepted for the initial request. Subsequent requests may not be older than three (3) months from the payment request submission date.

   - All bills/invoices must reference the insured's name, policy number and coverage period. This information must match the payment request.

   - Original bills are always the best choice, but due to time constraints, you may change the dates and/or amounts to match your payment request. However, **do not** "white out" the original information. Simply draw one line through it and add your new information.

- Insurance bills showing a "zero balance" or a credit balance will be accepted as long as you have verified the patient's current coverage is up-to-date. You must indicate the date through which the policy is paid.

- When requesting the reinstatement of a policy, or as a last resort, you may submit a letter signed by an authorized agent of the insurer. The letter must be on the letterhead stationery of the insurer. Also acceptable are letters from insurance agents and brokers. These letters similarly must be signed and printed on the letterhead stationery of the signer's company. In all cases, the letter must reference the insured's name, policy amount and coverage period. You must provide an actual current bill for the next payment request year.

- If the request is for assistance in connection with a new insurance policy, a copy of the application for the insurance is required.

9. Payments will be issued, based upon the billing schedule (monthly, bi-monthly, quarterly, semi-annual and annual) of the patient's insurer. AKF prefers to issue payments on a quarterly basis, ideally on the basis of the calendar quarters (i.e., Jan thru Mar; Apr thru June, etc.) Do not, however, attempt to force a payment request to conform to a calendar quarter, if it is not normally billed in this manner. Some insurance companies bill bi-monthly. In this case, please request either a 2- or 4-month payment.

10. All applications must be signed by the patient on whose behalf HIPP assistance is requested. If the patient is unable to sign the Consent Form, it is permissible for a legally authorized representative of the patient (e.g., a person who has a power-of-attorney) to sign on behalf of the patient. The signed Consent Form cannot be older than 60 days of the application submission date.

- If the employer is deducting from the patient's paycheck, annuity or retirement check an amount equal to the premium paid to the insurer, it is permissible to request that the check be made payable to the patient (instead of to the insurer). However, in such case, the following procedures must be followed: The patient must request his or her employer to bill the patient directly. If the employer is not willing to do so, the employer must so state in writing. This written statement must be provided to HIPP.

- This written communication from the employer should accompany the most current pay stubs for the current period requested, and indicate the individual medical portion of that patient's insurance that is being deducted.

- A rate sheet may be included to confirm the amount, but will not be considered as a bill individually. This information is needed when initially requesting assistance through HIPP. If a rate sheet is not available, you may submit a letter from the employer's H.R. department indicating the individual premium amount on company letterhead.

- It is also advisable to submit a copy of the insurance application when requesting assistance with a new policy for which a premium invoice has not yet been issued.

- New HIPP applicants requesting assistance with policies where payment must be made payable to the patient, may only request assistance for the current calendar month and subsequent months. Requests for previous months will be denied.

11. **The policy holder is solely responsible for paying his or her insurance premiums** in a timely manner. While HIPP makes every effort to pay premiums on or before due dates, AKF is not liable if insurance coverage is terminated. (Please see #6 under Program Eligibility)

12. Urgent requests will be considered, based on the following rules:

    - Have a termination date that will occur within 10-14 days of the request date **AND/OR**
    - Have no grace period **AND** are within 5-7 days of the due date. AKF reserves the right to verify all information.

13. It is important that all HIPP enrollees be informed that any refund check from a health insurance policy paid from HIPP fund is the property of AKF and promptly must be returned to AKF. These refunds are deposited in the HIPP "funding pool" to support the program. When a HIPP enrollee expires, the insurance company should be notified and a request made by the patient and/or provider to refund any unused portion of the premium payment to AKF. Some companies refund checks directly to the patient's estate. In this case, please notify the patient's family or estate representative that the funds belong to the HIPP Program and should be returned to AKF

GRANT PREMIUM PAYMENT PROCESSING

1. Please allow AKF at least 2 weeks to process and mail premium payments. Most requests, if correctly submitted, are processed within 10-14 days. You may track its progress through GMS. Patients whose payment requests are submitted online and are approved will have their premiums automatically paid through the end of the calendar year, subject to available funds in the HIPP pool and the other criteria set forth above. Reoccurring payments must be approved and released to AKF by the HIPP liaison in order for any subsequent (reoccurring) payment to be issued by AKF.

2. To have payments made for the following year, the applicant must submit a new payment request for such year with appropriate documentation, as set forth above.

3. Most premium payments are paid directly to patients' insurance carriers. There are some insurance companies that do not accept third-party checks. In these situations premiums will be mailed payable to the patient in care of their dialysis center's social workers to ensure the grant is used for its intended purpose. A list of insurance companies which do not accept third party payment directly from AKF is available for download on the GMS messages board.

4. If the insurance company **does** accept third party payments and the patient is having the premium deducted from their bank account, AKF requires that the patient arrange for direct billing prior to requesting assistance from HIPP so that the payment can be paid directly to the insurance carrier.

5. HIPP payments cannot be requested to cover Medicaid spend downs or Share of Cost.

6. Vision, "smoker's surcharges," and dental premiums cannot be requested unless they are a part of a "bundled" insurance premium that cannot be itemized. Prescription coverage premiums that are a part of policy will be considered, as long as they are not a Medicare Part D plan.

7. Premiums that have been paid by the patient prior to requesting assistance from HIPP cannot be reimbursed.

8. No payments from HIPP will be made in connection with the premiums of a deceased patient, even if the invoice for the premium predates the death of the patient. Renal professionals should notify AKF and/or update GMS (upon change occurrence) to indicate the death of a patient who was enrolled in HIPP. If a dialysis provider is in receipt of a HIPP grant for a patient who has died, the grant should be returned promptly to AKF. The same is true with respect to any refund from an insurance company for a deceased patient who was enrolled in HIPP. These funds are added back to the HIPP pool.

CHECKING THE STATUS OF A REQUEST

You must register to use AKF's Grants Management System (GMS) to check the "real-time" status of pending, incomplete and approved requests. Patient grant histories are also available. Information may also be obtained by contacting your HIPP liaison or AKF associate.

Please allow at least two (2) weeks after submitting a premium request before checking its payment status. To avoid the possibility of duplicate payment, do not resubmit a payment request without first checking online or speaking to your HIPP liaison (or AKF associate, if you do not have a HIPP liaison).

REQUESTING A CHECK REISSUE OR COPY

- To avoid incurring bank fees, AKF generally will not reissue checks unless at least 45 days has elapsed from the date of issuance.
- Your GMS online dashboard will indicate the check number, mailing address, status of the check sent to the insurance company, whether it has been cashed and the date it was cleared. This information is also available by contacting your AKF representative.
- In the event a check has not been cashed, you should contact your AKF representative for further assistance. Please do not reenter a new/duplicate payment request to request a reissue, unless it is requested by an AKF representative.
- AKF does not automatically reissue un-cashed checks. Reissues must be specifically requested. Be sure to return the check to AKF or your HIPP liaison, if it has been returned to you. Un-cashed checks are automatically voided after 180 days.
- If you find that the insurance company has not properly credited the account and the check has been cashed, AKF can provide a copy of the cancelled check. Please allow at least 10 business days from the date of issuance of the check before requesting a copy.

SECTION 3: AKF'S ONLINE GRANTS MANAGEMENT SYSTEM (GMS)

WHAT IS GMS?

This online portal allows renal professionals to log in to submit grant requests, obtain real-time grant application status updates and patient grant histories, and upload required HIPP back-up documents. GMS also will generate automated e-mails to registered renal professionals and alert them when a grant application is incomplete or requires attention.

WHO MAY REGISTER TO USE GMS?

GMS may be used by both renal professionals and patients.

AKF is empowering patients by allowing them to register as a GMS user so they can track their own grant requests online. However, in keeping with longstanding AKF policy, patients are not permitted to apply directly for a grant. As noted above, a renal professional must apply on behalf of the patient. GMS will enable patients to view "real-time" status updates, make sure their applications are complete and obtain grant history information.

In order to use this service, renal professionals must have a valid individual corporate email account. Email accounts associated with publicly available Internet access (such as, but not limited to Yahoo, AOL, Gmail, etc.) may **not** be used in connection with GMS. Corporate email accounts are email accounts that are restricted only to users (e.g., employees) authorized by your company and usually end in some form of your company name. They may not be shared universal accounts. This rule is designed to help protect the confidentiality of patient information.

HOW TO OBTAIN A CORPORATE EMAIL ACCOUNT

First check to see if your company offers a corporate email account you can use. If it does not, there are several hosted email providers available to choose from. Either your office manager or your company's IT staff should be able to set up one of these hosted email providers for you to use.

At the link below is one email provider who offers corporate email at a nominal price:
http://www.microsoft.com/exchange/en-us/exchange-online-hosted-email.aspx

AKF is not partial nor do we endorse any specific email provider.

If you have any questions please feel free to contact our support staff at helpdesk@kidneyfund.org

SECTION 4: ADDITIONAL INFORMATION

CONTACT INFORMATION

For more information or to learn about GMS, log onto AKF's website at www.KidneyFund.org.

You may contact AKF's HIPP Team at 1-800-795-3226 or email us at patientservice@kidneyfund.org.

For assistance with GMS, please contact GMS Support by calling 1-800-795-3226 or email: GMSSupport@kidneyfund.org.

If you are a new company applying to utilize HIPP, you need to complete orientation training by contacting the AKF Director of Financial Analysis by calling 301-984-6633.

FREQUENTLY ASKED QUESTIONS ABOUT HIPP:

Q. What OIG opinion governs the administration of HIPP?

A: AKF operates HIPP strictly in accordance with the guidelines set forth in Advisory Opinion 97-1.

Q. Why does AKF require that insurance bills be no more than three months old and from the submission date of the request?

A: This requirement is intended to protect the HIPP program and the continuation of health insurance coverage of enrollees. AKF wants to make sure the amount paid is the correct premium amount, in order that coverage is not cancelled by the insurer. This is why it requires "current" premium invoices, which AKF defines as not more than three months old. Original billing statements are always the best choice, when possible. If the enrollee becomes aware of any change in the premium amount within the three month "window," you must provide this information promptly to AKF.

Q. Who are HIPP liaisons and what is their role?

A: HIPP liaisons are employees of dialysis providers who coordinate HIPP communications between the company's social workers, financial caseworkers and insurance coordinators and AKF. HIPP liaisons track the progress of each patient's grant request from the time it is submitted to AKF to the time a grant payment is issued so that patients and their social workers are kept informed. They also help educate social workers about the HIPP program and "trouble-shoot" problems that arise.

Q. Why doesn't AKF reimburse patients who have their health insurance premiums deducted from Social Security checks or have already paid the premium?

A: HIPP is not intended to be an insurance premium reimbursement program. Eligibility is restricted to financially qualified patients who have no alternative means for paying their health insurance premiums and who would not have insurance coverage unless HIPP provided financial assistance. Individuals whose Medicare premiums are deducted automatically from their Social Security checks have a mechanism for guaranteeing premium payment. Patients (or family members) who have already paid an insurance premium are also considered to be a source of assistance.

Q. What should I do if the patient (or patient's estate) receives a refund check?

A: It is important that all HIPP enrollees be informed that any refund check from a health insurance policy paid from HIPP funds is the property of AKF and promptly must be returned to AKF. These refunds are deposited into the HIPP "funding pool" to support the program. When a HIPP enrollee dies, the insurance company should be notified and a request made to refund any unused portion of the premium payment to AKF. Some companies refund checks directly to the patient's estate. In this case, please notify the patient's family or estate representative that the funds belong to the HIPP Program and should be returned to AKF.

Q. Why does AKF generally pay only one quarter at a time?

A: There are several reasons. First, the contributions necessary to fund premium payments are made on a quarterly basis. Second, most insurance companies discourage premium payments for future quarters and many will refund advance payments to patients. And, third, should your patient change dialysis providers, receive a kidney transplant or die, there will be a larger refund at risk for retrieval.

Q. Does AKF prioritize premium requests by their due date?

A: According to its Advisory Opinion (97-1), the American Kidney Fund is obliged to handle premium requests on a first-come, first-served basis. Your best assurance of timely payment is timely submission. Please pay close attention to the billing cycles, coverage, grace periods and termination policies of the health insurers of patients enrolled in HIPP.

In addition, AKF strongly recommends that you submit your premium requests early and that you prioritize them according to "time-sensitivity." COBRA policies usually are most time-sensitive; if you have a choice, submit them first. Generally speaking, Medigap premiums are less time-sensitive than COBRA and Medicare premiums are the least time-sensitive. However, many insurers do not provide grace periods or do not provide benefits during the grace period. Please inform AKF of any policy changes by the insurance company. In most situations changes in policy are usually sent directly to the insured.

Q. What types of insurance policies are paid for by HIPP?

A: HIPP pays for Medicare Part B, COBRA, Medigap, EGHP and commercial policies.

Q. Why won't HIPP pay for tertiary coverage, if the patient is eligible for Medicaid?

A: AKF will not pay for **duplicative** tertiary coverage. HIPP's purpose is to ensure that eligible dialysis patients have a mechanism for paying for dialysis treatment. Eligibility for Medicaid usually means that patients have a mechanism for paying the Medicare allowable balance due of 20% when Medicare is their primary insurer. In circumstances where this is not the case, AKF will request additional documentation to explain a patient's individual Medicaid benefits.

Q. My records show that AKF made a payment for my patient, but the insurance company has no record of it. What should I do?

A: Insurance companies sometimes cash HIPP premium checks through their lock boxes, but for various reasons are unable to properly credit the patient's policy. Check online through GMS or contact AKF to find out if the check has been cashed. If it has, a copy of the cancelled check can be provided for you to give to the insurance company. If it has not, a reissue can be requested if the check is over 45 days old. You should also verify the mailing address.

Q. Why aren't transplant patients eligible for HIPP assistance?

A: The American Kidney Fund has supported dialysis patients since its inception in 1971. AKF has limited resources and cannot cover every need. HIPP is a very expensive program, currently serving over 66,000 dialysis patients nationwide on an ongoing basis. The program is 100% funded by voluntary contributions.

Q. What happens if the patient receives a kidney transplant while receiving premium assistance through HIPP?

A: Dialysis patients enrolled in HIPP are not eligible to continue receiving assistance once they receive a kidney transplant. However, HIPP will provide assistance for one month post-transplant.

Q. What if a patient has had his Medicare Part B policy terminated or no bill has been received?

A: If no bill has been received they may contact 1-800-Medicare to confirm their current status and billing address or go to their local Social Security (SSA) Field Office and request a copy of a CMS500 or SSA 2458, provided their Medicare Part B is still active.

If the Part B Medicare plan has been terminated for more than 1 month, they should bring a letter of "good cause" (SSA 795) to be filed at the SSA field office requesting reinstatement. Per CMS, once filed, the patient will **not** receive automatic reinstatement of their Part B.

They will have a wait of approximately 4-6 weeks for a decision on their status in the form of the Medicare Award Letter or a new CMS500 premium bill. A request for assistance through HIPP should not be filed until written notification of reinstatement has been received. Contact you AKF HIPP Representative for further assistance.

Q. What if current HIPP payments are coming to the patient but he or she is now on a Leave of Absence or on FMLA?

A: A letter from the company on its letterhead explaining the date that the patient begins a Leave of Absence (LOA) or FMLA is required. You may alternatively submit the approved H.R. form(s) with the patient's signature indicated on the document. This should be entered as a one-time request in GMS, due to the uncertainty of the length of the patient's FMLA or LOA.

Q. Can a letter from the insurance company or agent be accepted in place of a premium bill?

A: A current premium bill is the preferred choice for all requests, but due to time constraints, a letter from the insurance company will be accepted as a one-time request only. The letter must be written on letterhead, include the name of the patient/insured requesting assistance, policy number, current premium amount for medical portion only, and payment remittance address. A new premium bill must be submitted when requesting future recurring payment requests.

Q. I currently have Medicare as my primary insurance, but do not have a secondary insurance, can AKF get insurance for me?

A: AKF is not a referral agency for insurers and does not offer advice as to insurance policies. You should contact your social worker or renal professional, the insurance commission in your state, and/or an independent insurance broker.

Q. Are health insurance policies purchased through the Affordable Care Act (ACA) marketplace exchanges eligible for HIPP grant assistance with respect to premiums?

A. Yes, health insurance policies purchased through ACA exchanges are eligible for HIPP assistance in connection with premiums.

HAVE QUESTIONS? NEED ASSISTANCE?

PLEASE CONTACT THE AMERICAN KIDNEY FUND:

1.800.638.8299

OR BY EMAIL:

patientservice@kidneyfund.org

American Kidney Fund®

11921 Rockville Pike | Suite 300 | Rockville, MD 20852

www.**KidneyFund**.org

Exhibit C

[Subject to *Plaintiffs' Motion to Seal Exhibits A and C to the Complaint and Incorporated Memorandum of Law*]

JS 44 (Rev. 02/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

BLUE CROSS AND BLUE SHIELD OF FLORIDA, INC. and HEALTH OPTIONS, INC.

(b) County of Residence of First Listed Plaintiff Duval
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Michael A. Abel
Abel Bean Law P.A., 50 N. Laura St., Suite 2500, Jacksonville, FL 32202
(904) 516-5486

DEFENDANTS

DAVITA, INC. f/k/a DAVITA HEALTHCARE PARTNERS INC.

County of Residence of First Listed Defendant Out of District
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	☒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ☒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 485 Telephone Consumer Protection Act
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. Section 1332(a)(1)

Brief description of cause:
Breach of contract, breach of implied covenant of good faith, tortious interference, other

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 10,000,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ❒ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 05/14/2019

SIGNATURE OF ATTORNEY OF RECORD s/ Michael A. Abel

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Florida

BLUE CROSS AND BLUE SHIELD OF FLORIDA, INC. and HEALTH OPTIONS, INC.

Plaintiff(s)

v.

DAVITA INC. f/k/a DAVITA HEALTHCARE PARTNERS, INC.

Defendant(s)

Civil Action No. 3:19-cv-574

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* DAVITA INC. f/k/a DAVITA HEALTHCARE PARTNERS, INC

c/o Registered Agent:

Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Michael A. Abel
Abel Bean Law P.A.
50 N. Laura St., Suite 2500
Jacksonville, FL 32202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No. 3:19-cv-574

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

EXHIBIT 16

qui tam Complaint Filed Under Seal Pursuant to 31 U.S.C. §3730(b)(2) in _United States, ex. rel. Gonzalez v. DaVita Health Care Partners,_ No. 1:16-cv-11840-NMG (D. Mass) on September 8, 2016.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.*, STATE OF CALIFORNIA, *ex rel.*, STATE OF COLORADO, *ex rel.*, STATE OF CONNECTICUT, *ex rel.*, STATE OF DELAWARE, *ex rel.*, DISTRICT OF COLUMBIA, *ex rel.*, STATE OF GEORGIA, *ex rel.*, STATE OF HAWAII, *ex rel.*, STATE OF ILLINOIS, *ex rel.*, STATE OF INDIANA, *ex rel.*, STATE OF IOWA, *ex rel.*, STATE OF LOUISIANA, *ex rel.*, STATE OF MARYLAND, *ex rel.*, COMMONWEALTH OF MASSACHUSETTS, *ex rel.*, STATE OF MICHIGAN, *ex rel.*, STATE OF MINNESOTA, *ex rel.*, STATE OF MONTANA, *ex rel.*, STATE OF NEVADA, *ex rel.*, STATE OF NEW JERSEY, *ex rel.*, STATE OF NEW MEXICO, *ex rel.*, STATE OF NEW YORK, *ex rel.*, STATE OF NORTH CAROLINA, *ex rel.*, STATE OF OKLAHOMA, *ex rel.*, STATE OF RHODE ISLAND, *ex rel.*, STATE OF TENNESSEE, *ex rel.*, STATE OF TEXAS, *ex rel.*, STATE OF VERMONT *ex rel.*, COMMONWEALTH OF VIRGINIA, *ex rel.*, and STATE OF WASHINGTON, *ex rel.*, DAVID GONZALEZ 11700 Old Columbia Pike, #709 Silver Spring, MD 20904 Plaintiff-Relator, BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN,	CASE NO.:_____ **COMPLAINT** **FILED UNDER SEAL** PURSUANT TO 31 U.S.C. §3730(b)(2) **JURY TRIAL** **DEMANDED**

MINNESOTA, MONTANA, NEVADA,
NEW JERSEY, NEW MEXICO, NEW YORK,
NORTH CAROLINA, OKLAHOMA,
RHODE ISLAND, TENNESSEE, TEXAS, VERMONT
WASHINGTON,
THE COMMONWEALTH OF MASSACHUSETTS,
THE COMMONWEALTH OF VIRGINIA, and
THE DISTRICT OF COLUMBIA

c/o
UNITED STATES ATTORNEY
JOHN JOSEPH MOAKLEY
UNITED STATES COURTHOUSE
1 COURTHOUSE WAY, SUITE 2300
BOSTON, MA,02210

ATTORNEY GENERAL OF
THE UNITED STATES
U.S. Department of Justice
10th and Constitution Avenue, N.W.
Washington, DC 20530

ATTORNEY GENERAL FOR THE STATE OF
CALIFORNIA
P.O. Box 944255
Sacramento, CA 94244-2250

ATTORNEY GENERAL FOR THE STATE OF
COLORADO
1300 Broadway 9th Floor
Denver, CO 80203

ATTORNEY GENERAL FOR THE STATE OF
CONNECTICUT
55 Elm Street
Hartford, CT 06106

ATTORNEY GENERAL FOR THE STATE OF
DELAWARE
820 N. French Street
Wilmington, DE 19801

ATTORNEY GENERAL FOR THE
DISTRICT OF COLUMBIA
441 4th Street NW, Suite 1060 N
Washington, DC 20001

ATTORNEY GENERAL FOR THE STATE OF GEORGIA
40 Capitol Square, SW
Atlanta, GA 30334

ATTORNEY GENERAL FOR THE STATE OF HAWAII
425 Queen Street
Honolulu, HI 96813

ATTORNEY GENERAL FOR THE STATE OF ILLINOIS
100 West Randolph Street
Chicago, IL 60601

ATTORNEY GENERAL FOR THE STATE OF INDIANA
Indiana Government Center South
302 W. Washington St., 5th Floor
Indianapolis, IN 46204

INSPECTOR GENERAL FOR THE STATE OF INDIANA
315 WEST OHIO STREET
Indianapolis, IN 46202

ATTORNEY GENERAL FOR THE STATE OF IOWA
1305 E. Walnut Street, 2nd Floor
Des Moines, IA 50319

ATTORNEY GENERAL FOR THE STATE OF LOUISIANA
1885 North 3rd St
Baton Rouge, LA 70802

ATTORNEY GENERAL FOR THE STATE OF MARYLAND
200 St. Paul Place
Baltimore, MD 212202

ATTORNEY GENERAL FOR THE COMMONWEALTH OF MASSACHUSETTS
One Ashburton Place
Boston, MA 02108-1518

ATTORNEY GENERAL FOR THE STATE OF MICHIGAN
G. Mennen Williams Building, 7th Floor
525 W. Ottawa St.
P.O. Box 30212
Lansing, MI 48909

ATTORNEY GENERAL FOR THE STATE OF MINNESOTA
1400 Bremer Tower
445 Minnesota Street
St. Paul, MN 55101

ATTORNEY GENERAL FOR THE STATE OF MONTANA
Justice Building, Third Floor
215 North Sanders
P.O. Box 201401
Helena, MT 59620-1401

ATTORNEY GENERAL FOR THE STATE OF NEVADA
100 North Carson Street
Carson City, NV 89701

ATTORNEY GENERAL FOR THE STATE OF NEW JERSEY
Richard J. Hughes Justice Complex
8th Floor, West Wing
25 Market Street
Trenton, NJ 08625-0080

ATTORNEY GENERAL FOR THE STATE OF NEW MEXICO
PO Box 1508
Santa Fe, NM 87504-1508

ATTORNEY GENERAL FOR THE STATE OF NEW YORK
120 Broadway, 24th Floor
New York, NY 10271

ATTORNEY GENERAL FOR THE STATE OF NORTH CAROLINA

9001 Mail Service Center
Raleigh, NC 27699-9001

ATTORNEY GENERAL FOR THE STATE OF OKLAHOMA
313 NW 21st St
Oklahoma City, OK 73105

ATTORNEY GENERAL FOR THE STATE OF RHODE ISLAND
150 South Main Street
Providence, RI 02903

ATTORNEY GENERAL AND REPORTER FOR THE STATE OF TENNESSEE
425 5TH Avenue
Nashville, TN 37243

ATTORNEY GENERAL FOR THE STATE OF TEXAS
PO Box 12548
Austin, TX 78711-2548

ATTORNEY GENERAL FOR THE COMMONWEALTH OF VERMONT
109 State Street
Montpelier, Vermont 05609

ATTORNEY GENERAL FOR THE COMMONWEALTH OF VIRGINIA
Office of the Attorney General
900 East Main Street
Richmond, Virginia 23219

ATTORNEY GENERAL FOR THE STATE OF WASHINGTON
1125 Washington Street, SE
P.O. Box 40100
Olympia, WA 98504

v.

DAVITA HEALTH CARE PARTNERS
DAVITA KIDNEY CARE
2000 16th Street
Denver, Colorado 80202

FRESENIUS MEDICAL CARE NORTH AMERICA
FRESENIUS KIDNEY CARE
920 Winter Street
Waltham, MA 02451

AMERICAN KIDNEY FUND
11921 Rockville Pike #300,
Rockville, MD 20852

JOHN DOE 1-100

DEFENDANTS.

1. This is an action filed under the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. Sec. 3729, *et seq*., by Plaintiff-Relator David Gonzalez, in the name of the United States and the governments of California, Colorado, Connecticut, Delaware, the District of Columbia, Georgia Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington and himself to recover penalties and damages arising from the Defendants knowing direction of payments for End Stage Renal Services in a manner, which creates illegal remuneration and kickbacks and thereby false claims to the above listed governments.

2. Accordingly, Plaintiff-Relator files this action to recover penalties and damages on behalf of himself and the above-listed governments.

I. JURISDICTION AND VENUE

3. This action arises under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.*

4. This Court maintains subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331, and supplemental and pendant jurisdiction.

5. Plaintiff-Relator also brings this action on behalf of the governments of California, Colorado, Connecticut, Delaware, the District of Columbia, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia and Washington, hereinafter referred to collectively as "the States."

6. Plaintiff-Relator brings this action on behalf of the States for the Defendant's violations of Cal. Gov't Code §§ 12650 *et seq.;* Colo. Rev. Stat. §§ 25.4-4-303.4 *et seq.*; Conn. Gen. Stat. §§17b-301a--17b-301p (2010 supplement)*;* Del. Code Ann. Tit.6. §§ 1201 *et seq.*; D.C. Code §§ 2-381.01 *et seq.;* Ga. Code. Ann. §§ 49-4-168 *et seq.;* Haw. Rev. Stat. Ann. §§ 661-21 *et seq.;* 740 Ill. Comp. Stat. Ann. 175/1 *et seq.*; Ind. Code §§ 5-11-5.5 *et seq.;* Iowa Code § 685.1 *et seq.*; La. Rev. Stat. Ann. §§ 6:438.1 *et seq.;* Md. Code Ann. Health-Gen. §§ 2-601 *et seq.;* Md. Code Ann. Gen. Prov. §§ 8-101 *et seq.;* Mass. Ann. Laws ch.12, §§ 5 *et seq.;* Mich. Comp. Laws. Serv. §§ 400.601 *et seq.;* Minn. Stat. §§ 15C.01 *et seq.;* Mont. Code Ann. §§ 17-8-401 *et seq.;* Nev. Rev. Stat. Ann. §§ 357.010 *et seq.;* N.J. Stat. Ann. §§ 2A: 32C-1 *et seq.*; N.M. Stat. Ann. §§ 27-14-1 *et seq.;* N.M. Stat. Ann. §§ 44-9-1 *et seq.* N.Y. State Fin. Law §§ 188 *et seq.;* N.C. Gen. Stat. §§ 1-605 *et seq.;* Okla. Stat. tit. 63, §§ 5053 *et seq.;* R.I. Gen. Laws §§ 9-1.1-1 *et seq.;* Tenn. Code Ann. §§ 4-18-101 *et seq.;* Tenn. Code Ann. §§ 71-5-181 *et seq.* 1993; Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.;* Va. Code Ann. §§ 8.01-216.1 *et seq.;* 32 VSA §§ 630 *et seq.;* RCW 74.66.005 *et seq.*

7. These laws hereinafter are collectively referred to as the "State False Claims Acts."

8. Jurisdiction over claims arising under the State False Claims Acts is also conferred by 31 U.S.C. § 3732(b) in that the transactions and or occurrences described, which violate the State False Claims Acts involve a common nucleus of facts as, and are related to, those that violate the Federal False Claims Act.

9. Venue is proper in this jurisdiction pursuant to 31 U.S.C. § 3732(a) because at least one Defendant maintains an office in this district, and regularly transacts business in this district and did so at all times relevant to this Complaint. The False Claims Act confers nationwide jurisdiction and at least one of the Defendants resides or regularly transacts business in this district.

II. PARTIES

10. Plaintiff-Relator David Gonzalez, of 11700 Old Columbia Pike, #709, Silver Spring, MD 20904, worked for the American Kidney Fund for twelve years, until October 20, 2015, when he was forced out of the organization for questioning the practices detailed herein. He served as an "HIPP" or Health Insurance Premium Program, Patient Services Coordinator.

11. There have been no prior public disclosures of allegations or transactions that are the subject of this Complaint as defined by the term "publicly disclosed" under 31 U.S.C. § 3730(e)(4)(A).

12. Mr. Gonzalez is an original source of all the allegations contained in this Complaint within the meaning of 31 U.S.C. § 3730(e)(4)(B). Mr. Gonzalez has independent knowledge of all the information contained herein, and voluntarily provided such

information to the United States and the above listed States prior to filing an action in Court.

13. Defendant DaVita Health Care Partners is a fortune 500 health care company traded on the New York Stock Exchange and the parent company of DaVita Kidney Care (hereinafter collectively "DaVita"). The company maintains headquarters at 2000 16th Street Denver, Colorado 80202. DaVita provides End Stage Renal Services including dialysis treatment. Its website includes a service whereby a patient seeking dialysis treatment can search by zip code and find a DaVita provider in any state in the United States as well as in Washington, DC. DaVita claims to operate or provide administrative services at more than two thousand outpatient dialysis centers in the United States and DaVita regularly conducts business and has caused to be submitted some of the false claims at issue in this case in this district.

14. Defendant Fresenius Medical Care provides Dialysis to almost three hundred thousand patients worldwide. International Headquarters are at 61346 Bad Homburg v.d. H. Germany, with subsidiaries including Fresenius Medical Care North America and Fresenius Kidney Care (hereinafter all referred to as "Fresenius") headquartered at 920 Winter Street Waltham, MA 02451. Fresenius also operates in all 50 states and the District of Columbia. Fresenius regularly conducts business and has caused to be submitted some of the false claims at issue in this case in this district.

15. Defendant, American Kidney Fund ("AKF") of 11921 Rockville Pike #300, Rockville, MD, 20852 is a non-profit "501(c)(3)" corporation. The AKF raises money and provides public services including providing free screenings for kidney disease, education and advocacy on kidney related issues. The majority of funds raised by the AKF, however, go

to provide payment assistance for patients who need dialysis treatment for kidney conditions. The AKF's latest IRS Form 900 disclosure shows it obtained gross receipts of more than $275,000,000 in 2015. The AKF caused to be submitted some of the false claims at issue in this case in this district.

16. In addition, the Plaintiff-Relator brings these claims against John Doe Defendants 1-100 which include, but are not limited to, six companies listed anonymously as Company A, Company B, Company C, Company D, Company E and Company F who along with the AKF are referred to as the "Requestors," in the 1997 Advisory Opinion 97-1 discussed fully below. The AKF 2015 IRS form 990 lists anonymous contributions from its six largest contributors, each such contributor providing a minimum of $6,000,000 with the largest contribution exceeding $100,000,000.

III. FACTUAL ALLEGATIONS

A. Introduction

17. The allegations in the above paragraphs are hereby re-alleged and set forth fully as above.

18. The Plaintiff-Relator worked for the American Kidney Fund ("AKF") for twelve years as a "HIPP" or Health Insurance Premium Program, Patient Services Coordinator. He discovered, that while the organization was set up to be a charity and certainly did provide funds on behalf of needy dialysis patients, the Defendants knowingly violated requirements that had been in place to ensure funds provided to the AKF and used to secure government health insurance and make copayments, did not become illegal remuneration and kickbacks.

19. The intentional violations were committed in concert between the two largest dialysis providers in the world (i.e., Fresenius and DaVita) and AKF, thereby creating illegal

referrals and payments under the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

B. OIG Requirements to create a fair payment structure and avoid kickbacks.

20. The allegations in the above paragraphs are hereby re-alleged and set forth fully as above.

21. In 1997, AKF and several anonymous providers made certain representations to obtain an advisory opinion from the Department of Health and Human Services, Office of Inspector General ("OIG") on how to manage funds so as to avoid creating illegal incentives to any party in the process. It was plain that paying money to those who choose which dialysis treatment provider to use would otherwise be considered illegal remuneration.

22. The AKF and several anonymous dialysis providers made specific material representations about how they would conduct themselves to the OIG, and the OIG relied on those representations in rendering its advisory opinion.

23. The representations made by the AKF and several providers were stated in an advisory opinion issued in 1997 by the U.S. Department of Health and Human Services, Office of Inspector General ("OIG") which, based on those representations, placed specific conditions on the conduct of the AKF and any of the providers who made donations for the purpose of providing patient assistance.

24. The 1997 OIG advisory opinion made clear its purpose was to determine if there was a structure under which such payments would not create kickbacks:

> We are writing in response to your request for an advisory opinion, which we accepted pursuant to 42 C.F.R. § 1008.41 on April 11, 1997. Your request asks whether donations by renal dialysis providers to an independent 501(c)(3) charitable organization for the purpose of funding a program to pay for Supplementary Medical Insurance Program ("Medicare Part B") or Medicare Supplementary Health Insurance ("Medigap") premiums for financially needy Medicare beneficiaries with end-stage renal disease, where such beneficiaries may be receiving treatment from

> the donor-dialysis providers (The "Proposed Arrangement") would constitute grounds for the imposition of a civil monetary penalty under Section 231 (h) of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

OIG, Advisory Opinion 97-1, p. 1.

25. The AKF and the other six so called "Requestors" listed as Company A, Company B, Company C, Company D, Company E and Company F in the OIG Advisory Opinion 97-1 made representations to the Office of Inspector General, which are recounted in the opinion.

26. Defendants DaVita and Fresenius are believed to have been among the providers that anonymously also sought the opinion.

27. Additionally, Defendants DaVita and Fresenius each have been major contributors to the AKF and are aware of OIG Advisory Opinion 97-1 going forward.

28. Each Defendant that provided funding to AKF was required to ensure that the OIG Advisory Opinion 97-1 and other requirements to prevent illegal kickbacks were followed and to be sure that any funds paid to AKF and subsequently received by patients from the AKF were not illegal remuneration.

29. The OIG Advisory Opinion discussed the makeup of board members and committees within the AKF and how that was done to insulate the AKF from any specific companies who were also requestors of the opinion, or donors to the AKF, but who had former executives serving with the AKF. In addition, the OIG noted:

> AKF's Health Insurance Premium Program ("HIPP") provides financial assistance to financially needed ESRD [End Stage Renal Dialysis] patients for the costs of medicine, transportation, and health insurance premiums, including Medicare Part B and Medigap Premiums. Assistance is available to all eligible patients on an equal basis. In general, eligibility for participation in AKF's assistance programs requires a physician certification, a referral letter signed by a social worker or administrator at

> a dialysis provider, and an individual Patient Grant Application. The Patient Grant Application requires patients to provide detailed financial information for their entire household.
>
> While a patient can apply directly to AKF for a grant, most applications are submitted on the patient's behalf by dialysis providers or social workers employed by a dialysis provider.
> ...
> All determinations are made by AKF employees who have no financial interest in the companies or other dialysis providers and are based on their good faith assessment that the applicant is in financial need and eligible for assistance.
> ...
> Because of AKF's limited financial resources, an AKF patient assistance grant is provided for a specific time period. Upon expiration of the period, the patient must submit another grant application. Grant requests are reviewed on a first-come, first served basis to the extent funding is available.

OIG, Advisory Opinion 97-1, pp. 3-4 [emphasis added].

30. This was the status of the program according to the OIG as stated by the requestors prior to acceptance of their proposal to the Office of Inspector General.

31. The Requesters including the AKF and the unnamed companies wanted to expand the program and the OIG reported in a section of the report entitled "The Proposed Agreement" that:

> AKF proposes to expand significantly its patient assistance grants to financially needy ESRD [End Stage Renal Dialysis] patients for payment of medical insurance premiums through HIPP. Additional funding will be donated primarily by the companies.

OIG, Advisory Opinion 97-1, p.4.

32. While medical social workers could assist patients in identifying "all available sources of assistance..." that still precluded the companies from advertising the availability of the possibility of financial assistance to the public or disclosing to individual patients they refer that such members contributed to the AKF to fund these grants. *See* OIG, Advisory

Opinion 97-1, p.4.

33. Specific promises to keep the AKF decision-making and the funders separate were made part of the requirements of this opinion, including:

> AKF will continue to use its current procedures in assessing the financial need and eligibility of all patients, whether self referred or referred by the Companies, or other non-donor dialysis providers. Determination will be made solely on AKF's good faith assessment of a patient's financial need. AKF staff involved in awarding patient grants will not take the identity of the referring facility or the amount of any provider's donation into consideration when assessing patient applications or making grant determinations.
>
> Under the Proposed Agreement, the Companies will be free to determine whether to make contributions to AKF and, if so, how much to contribute. All the Companies have certified that they will not track the amount that AKF pays on behalf of patients dialyzing at their facilities in order to calculate future contributions. However, in calculating their contributions to AKF, the Companies have indicated that they may consider what they would have otherwise paid on behalf of financially needy patients utilizing their facilities…The Companies will not disclose to each other, or other dialysis providers, the amount or method of calculating their respective contributions to AKF, and AKF will not disclose one Company's contribution to another company or to other dialysis providers.
>
> Contributions will be made without any restrictions or conditions placed on the donation. The Companies have acknowledged that "contributions …will be gifts without any guarantee or promise on the part of AKF that patients referred to AKF for possible financial assistance with their insurance premiums will receive such assistance. AKF's discretion as to the uses of contributions will be absolute, independent, and autonomous."

OIG, Advisory Opinion 97-1, pp. 4-5.

34. Not surprisingly, based upon, and explicitly subject to, these representations by the AKF and the providers, the OIG determined that the proposed scheme would not constitute illegal remuneration:

> …while the premium payments by AKF may constitute remuneration to beneficiaries, they are not likely to influence patients to order or receive services from particular providers. To the contrary, the insurance coverage purchased by AKF will follow a patient regardless of which provider the

> patient selects, thereby enhancing patient freedom of choice in health care providers.

OIG, Advisory Opinion 97-1, p.5.

35. In addition in 1998, the OIG issued an advisory opinion following similar reasoning forming the basis for an unnamed dialysis provider and an unnamed charity to provide assistance to patients. The charity could receive funds and the provider could donate, but such payments to patients and donations could not be tracked to the provider. *See* OIG, Advisory Opinion, 98-17.

36. In 2002, the OIG considered whether to change this structure and whether an exception to the requirement should be allowed for dialysis providers to support premium payments for patients directly. *See* 67 Fed. Reg. 236 (Dec. 9, 2002).

37. Although the proposed exception purported to limit such payments to those patients whom the providers could determine to be needy and to providers that did not regularly partake in such payments, the OIG rejected this proposed rule stating:

> First the direct payment of supplemental premiums by ESRD providers for financially needy patients carries the same potential for abuse as the provision of free or below market rate goods or services by any other health care provider…In short, the exception would promote the very conduct the statute prohibits: the offering of remuneration to influence the selection of a provider. Moreover, patients would not only be influenced to select ESRD facilities that buy them supplemental health insurance, but would be "locked in" to those facilities, since changing facilities would jeopardize their supplemental insurance for all services, including substantial non-ESRD services.
>
> Second, creating an exception for direct premium payments by ESRD providers would create demands for additional exceptions for comparable payments by other health care providers and would potentially increase federal expenditures and Medigap premiums. We can discern no rational basis--and Congress has provided no guidance--for distinguishing between providers paying premiums for ESRD patients and providers paying premiums for other chronically ill, financially needy patients, such as patients with cancer, diabetes, or congestive heart disease. Nor can we

> discern any rational bases for distinguishing among types of benefits provided to Medicare and Medicaid beneficiaries or among categories of sick beneficiaries. Absent congressional guidance, attempting to draw such distinctions would necessarily result in arbitrary standards and would undermine the statute.
>
> It is to a provider's financial advantage (i) to pay the Medigap premium whenever the premium is less than the expected copayments and (ii) to pay the Part B premium whenever the premium is less than the expected Part B payments. Thus, the insurer will always lose money on these policies, as the amount paid out to the provider will always exceed the premiums received. This phenomenon-adverse selection-will likely cause insurers to raise premiums for all other enrollees to cover the losses. For this reason, the health insurance industry objected to the proposed exception.

67 Fed. Reg. 236, pp. 72897-8 (Dec. 9, 2002).

38. Notably, in rejecting this proposed rule the OIG relied on the representations of AKF and Companies A-F, who submitted the request that resulted in OIG Advisory Opinion 97-1, that the arrangements between these providers and the AKF were independent and operating lawfully, when the OIG concluded:

> Finally, we are not persuaded that a special exception for ESRD premium payments is needed. Financially needy dialysis patients are already receiving, and will continue to receive, supplemental health insurance support through funding arrangements with AKF or comparable independent nonprofit organizations. These arrangements are lawful, are apparently efficient, and minimize the potential for abuse.

Id.

39. In 1997, when the opinion sought by the AKF, was issued, the charity reported assisting 12,000 patients with End Stage Renal Dialysis and receiving some $5,000,000 in donations. It has been almost twenty years since then, and the AKF has grown considerably, to an entity with $275,000,000 in gross receipts in 2015.

40. The AKF provided funds to support treatment for 93,000 patients in 2015, a large portion of those funds were used to pay for Medicare Part B payments or Medigap payments or

to participate in some form of insurance to cover co-payments with public health plans of some kind thereby facilitating government payments to the providers.

C. Defendants Willfully Violated the OIG's Requirements and Used Kickbacks.

41. The allegations in the above paragraphs are hereby re-alleged and set forth fully as above.

42. The Plaintiff-Relator learned that the Defendants eventually violated virtually every material representation made to obtain the OIG advisory opinion, which thereby became essential requirements to avoid liability for paying kickbacks.

43. Plaintiff-Relator learned that specific providers were involved in the process with the AKF as well, in direct violation of the requirements of the Advisory Opinion, thereby creating a scheme, which provided illegal remuneration to patients and created incentives for, if not conditions requiring, those patients to use only those providers who contributed to the fund rather than those who do not.

44. Indeed, the coverage did not follow the patient, but was subject to the provider's donations, which were tracked by the AKF.

45. In fact, the improper processes put into place, which violate the OIG Opinion came as a result of complaints by Fresenius and DaVita to the AKF.

46. These facts demonstrate that Defendants are knowingly violating the restrictions imposed by the OIG to avoid kickbacks.

47. The Plaintiff-Relator's position put him into regular and direct contact with many officials of the AKF. For example, Dennis Cooper was the Relator's direct supervisor and was the HIPP manager. Mr. Cooper reported to Jeremy Abundy, Director of Patient Services.

48. Gwen Dewberry was Mr. Abundy's boss and served as Senior Director of Patient Services. Jack Cunningham was the Director of Financial Analysis. David Frazer was the Vice President of Patient Services during the majority of the Relator's experience at AKF. Mike Spigler became involved in the process when David Frazer left the AKF in mid-2015, and quickly became aware of the operation.

49. Plaintiff-Relator observed that all of these AKF officials acted contrary to the restrictions made by the OIG.

50. Many of the practices became more blatant as time went on, but as early as 2008 and 2009 the AKF was pressed for funds.

51. As a result, the AKF would have to suspend sending funding for patients. Officials of the AKF including Dennis Cooper and Gwen Dewberry had conversations in front of the Plaintiff-Relator when they discussed Fresenius's and DaVita's reaction to this situation.

52. Defendants Fresenius and DaVita asked the AKF why it was running out of funding as early as 2007.

53. The AKF consistently went to these market leaders to obtain additional funding. According to these conversations, DaVita and Fresenius were asking why the AKF was letting all the providers use the program, when they were the ones providing most of the funds.

54. The issue of DaVita and Fresenius being upset that they had to pay when other providers were not was a regular topic of discussions between Gwen Dewberry and Dennis Cooper.

55. The Plaintiff-Relator overheard Dennis Cooper and Gwen Dewberry openly discussing that Fresenius and DaVita were questioning why AKF was running out of funding for Fresenius' and DaVita's patients, when they were making contributions at least 10 times

between 2007 and 2009. Mr. Cooper twice mentioned this issue to Mr. Gonzalez directly in 2007.

56. Mr. Gonzalez was responsible for issuing checks to pay for patients' premium payments, so when the AKF was out of funding, Cooper and Dewberry would instruct him not to issue checks. Once Fresenius or DaVita or both would wire money for funding, the Plaintiff-Relator would then be instructed that he could resume issuing checks.

57. Contrary to the conditions set forth on page 5 of the Advisory Opinion 97-1, the AKF has been taking into account the identity of the contributors by tracking, which provider was paying them and how much, for several years.

58. Mr. Cunningham started formally tracking usage of the program in 2009.

59. Prior to this, Gwen Dewberry ordered the Plaintiff-Relator to record every contribution submitted by providers on a spreadsheet as well as record every patient's name and amount of the grant. With this information, she would label some providers as "Free Riders" because if the dollar amount of their patients' grant usage exceeded the contributions, then the spreadsheet would show that they were in the negative.

60. The AKF acted to restrict grants only to patients whose providers paid contributions, which is also in violation of the OIG's conditions. *Cf.,* Advisory Opinion 97-1, p. 5.

61. Methodist Hospital in Texas confronted the then VP of patient services Carol Lynn Halal in a conference phone call in 2007 with Dennis Cooper in which David Gonzalez also participated. The lawyers for Methodist Hospital told the AKF that they were not required to fund the program and were not going to fund the program.

62. After this phone call Mr. Cooper told Mr. Gonzalez to make Methodist Hospital's applications disappear and said that Mr. Gonzalez should not process them.

63. That meant any patients seeking dialysis treatment from Methodist Hospital would not be able to obtain AKF support for insurance payments. At the time, the applications were made via facsimile transmission and AKF officials had no difficulty in making applications for providers who did not donate "disappear."

64. Of course, this is in direct contradiction of the requirement for the AKF to treat each application blindly and based on need on a first come first served basis, and not on whether the provider made a donation to AKF.

65. In 2010, the AKF started a new grant management system which intensified this *qui pro quo* of patient support in exchange for donations. They created an online portal to accept applications for patients to receive funding.

66. However, they did not stop discriminating against certain providers as a result. If anything, the Internet application made it much easier to aggregate information about what providers were donating and how to implement a more stringent system to approve financial support of patients whose providers made donations to AKF.

67. The process of demanding funds from providers continued to intensify. AKF officials would tell new smaller providers who did not want to contribute or the patients who went to such facilities that it would be best for the patients to go to Fresenius and DaVita.

68. Thus, AKF began driving business to its large provider funders instead of exercising autonomy as an independent charity.

69. Notably, Gwen Dewberry specifically used the term "pay to play" regarding this process in front of the Plaintiff-Relator on a regular basis between 2014 and 2015.

70. To further implement this scheme, the AKF set up a "blocked" list, which meant that any application from a patient using that provider would not receive funds until such time as the provider contributed to the program.

71. The "blocked" list was referred to as such until 2015, when an AKF employee named Lynthia Williams, a Call Center Associate, took a call from a provider who had learned the provider was on this blocked provider list. The provider discovered they had been blocked and protested the action. The AKF's response was not to stop the practice, but to call the same list a "Training List" instead of the "blocked" list.

72. The so-called "training" involved a call scheduled regularly for Tuesdays in which AKF officials would make it plain to the provider that they had to contribute to the AKF in order to have any of their patients receive funding. The substance of the training (which was really a *quid pro quo* solicitation of a donation in exchange for patient support) was the same regardless of whether the provider had been on a "blocked list" or a "training list."

73. These "training calls" started in approximately 2012 and this program was also referred to internally as the "Recoupment Effort." The providers on the list were also commonly referred to as the "inequitables."

74. Dealing with such providers was systematized into a collection schedule. Every Tuesday the AKF would have a call for up to two providers on the new or on the blocked list. The purpose of the call was to obtain funds from the provider that had not contributed.

75. This was all conducted with specific amounts required to be paid as donations by the providers. David Frazer, AKF Vice President of Patient Services and Kidney Education,

would use terms such as "you owe (a certain amount) for this year and you have not paid for last year."

76. The internal Grants Management System (GMS) had a report function so AKF officials could run a report by specific provider name that would tell them how much funding they had used based on all patient records associated with their facility name and amount of premium payments made on behalf of their patients.

77. Mr. Cunningham would often use the following analogy in the training calls in explaining to providers on the "blocked" list what they were required to do as far as the AKF was concerned: if you take out buckets of water from a pool and don't replenish it, then the well runs dry. Therefore, Mr. Cunningham would tell providers that AKF needed them to replenish 100% of what they take out, plus five and three quarters for overhead expenses.

78. The AKF also did not comply with the OIG Advisory Option No. 97-1 requirements to allow the coverage to follow the patient. As a specific example, in 2014 the AKF initially blocked funds to a patient who had previously been receiving them while that patient had been treated by a Fresenius branch in Florida because the new provider had not made a donation to AKF. The patient had been transferred from the Fresenius branch to Indiana University Health Adult Dialysis Center in Indianapolis, IN, and the social worker wrote:

> We recently had a patient transfer to us from a Fresenius unit in Florida. This patient had been receiving AKF funding for her Medicare supplement, which she was completely unable to pay on her own. Now that she is our patient, will she have to lose this assistance? Since she is not a new AKF patient, can we get her into the system as a patient at our unit now and allow her to keep receiving AKF funding? She will definitely lose the policy without AKF assistance, so I just wanted to see what we are able to do. Just let me know what you think. Thank you!
>
> Heather Kenjorski

Patient Transfer Email correspondence with the Plaintiff-Relator.

79. Initially, Mr. Gonzalez replied by requesting patient information and telling Ms. Kenjorski to enter a new application. This is when she found her facility was not able to receive the funds for the patient. The social worker wrote back as follows:

> I am trying to input [patient name redacted] HIPP application on the AKF site and it won't allow me to do it. I have gotten the following message:
>
> "Your dialysis facility has not completed the proper GMS training which includes training of a financial representative. Please contact your dialysis administrator and/or financial representative to have this training completed."
>
> What should I do about this? Is this training that I need to complete?
>
> Thank you,
>
> Heather Kenjorski

Id.

80. Given that part of the rationale in the OIG Advisory Opinion was that funding would not influence the patient's decision as to which provider to use, and that the funding was supposed to follow the patient and not the provider, this is a direct example that the AKF was not following the requirements of that opinion. *See* OIG, Advisory Opinion 97-1, p. 5.

81. When that patient transferred from Fresenius to Indiana University Health the funding for the patient was denied so AKF could conduct "training" of the provider's "financial representative," which is how AKF characterized its demand that providers make donations in exchange for providing funding to the provider's patients.

82. The Plaintiff-Relator was particularly sensitive to the rough treatment the AKF provided Kaiser Permanente.

83. In 2015, the AKF blocked Kaiser Permanente and Jack Cunningham would not take a conference call with them until he was assured somebody on the call had authority to provide funds to the AKF. This was a particularly protracted collection that went on the entire last year the Plaintiff-Relator was working for the AKF.

84. The AKF also knowingly favored DaVita and Fresenius in violation of the OIG's Advisory Opinion's restrictions beyond using the training calls to obtain funds from competitors. The Plaintiff-Relator heard Jack Cunningham and Dennis Cooper on phone calls directing social workers and patients to use Fresenius and DaVita if the provider had not contributed to the AKF. He specifically heard them say this to providers several times between 2014 and 2015.

D. Implications of Defendants' Knowing Violations.

85. The allegations in the above paragraphs are hereby re-alleged and set forth fully as above.

86. Any inducement to favor one provider over another by the AKF would become illegal remuneration pursuant to OIG Advisory Opinion No. 97-1. Knowledge and participation by DaVita, Fresenius and any of the John Doe Defendants in any such step implicates them in the scheme as well.

87. These providers were prohibited from pressuring the AKF to obtain funds from competitors, or contribute on any such basis without destroying the structure created in 1997 to make the entire program effectively a safe harbor from the Anti-Kickback Statute, pursuant to the terms of the OIG Advisory Opinion No. 97-1. However, both DaVita and Fresenius knowingly violated these restrictions.

88. Indeed, given the size of the two companies (i.e., DaVita and Fresenius) who are leaders in the field, and who are major contributors to the AKF, it is not an exaggeration to say

that unrestrained, the Defendants could exert control over virtually the entire ESRD provider market.

89. Defendants' adherence to the restrictions imposed by the OIG upon the AKF and providers regarding the operation of the fund was necessary to prevent such funds from being illegal inducements in violation of the Anti-Kickback Statute. Such knowing violations by Defendants can also be violations of the False Claims Act as well.

90. Money given to patients under the AKF triggers vast amounts of payments to the providers charged for treatment through government programs. The AKF may provide support for a Medicare part B premium of $104.90 per month as well as support for supplemental insurance to cover the 20% co-payment under Part B. That will cover a patient for the entire cost of ESRD treatment, which is generally 80% paid for by Medicare, for example.

91. It is fair to say that $104.90 per month does not come close to paying the amount that the government ends up paying for ESRD treatment to the average recipient of AKF funds.

92. It therefore makes economic sense for providers to participate in the program. Even if they spend 105.75% of what their patients receive in funds to the AKF, the providers are able to charge the vast majority of their dialysis treatments to government programs. That 105.75% is essentially a fractional cost of doing business for the providers to send some money to the patient so that the patient can obtain government funding for dialysis treatment to be spent on the providers.

93. At the time Defendants submitted or caused to be submitted these false and fraudulent claims the Defendants knew that the government insurance programs would refuse

payment for these claims if the requirements of OIG Advisory Opinion No. 97-1 were not followed.

94. This implicates the treatment of thousands of government-funded dialysis patients in a kickback scheme thereby creating excessive damages and extensive numbers of individual false claims paid by the government.

IV. FEDERAL AND STATE FALSE CLAIMS ACT VIOLATIONS

COUNT I
Violations of 31 U.S.C. § 3729(a)(1)(A)
Submission of False Claims

95. The allegations in the above paragraphs are hereby re-alleged and set forth fully as above.

96. Solicitations made by the AKF and or paid by DaVita and Fresenius and any of the John Doe Defendants, based on any knowledge of patient funding violates the structure set forth in the OIG Advisory Opinion 97-1. Such solicitations and payments are done knowingly in violation of that structure and affect the decision by the patient as to which provider of End Stage Renal Disease treatments they use. Each such payment therefore, creates illegal remuneration and violations of the Anti-Kickback Statute, which punishes both the payer and the solicitor of such funds:

> **(1)** Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> **(A)** in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> **(B)** in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

> **(2)** Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> **(A)** to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> **(B)** to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both..

42 U.S.C. § 1320a–7b(b).

97. Each such payment or solicitation made by the Defendants creates liability under the False Claims Act as the Anti-Kickback Statute provides:

> In addition to the penalties provided for in this section or section 1320a–7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31.

42 U.S.C. § 1320a–7b(g).

98. These practices by Defendants DaVita, Fresenius, the John Doe Defendants and the AKF make a mockery of the OIG Advisory Opinion that was designed to separate the provision of charitable grant funding to patients from the financial influence of the providers. This kickback scheme creates a circle of a *quid pro quo* solicitation of donations in exchange for payments and incentives, which has been continually creating false claims in violation of the False Claims Act 31 U.S.C. § 3729(a)(1)(A) at the expense of government programs.

99. Defendants knowingly violated the requirements of OIG Advisory Opinion No. 97-1, and Defendants were aware that compliance with those requirements was material to the

government's decision to pay claims submitted or caused to be submitted by Defendants.

100. As a direct and proximate result of Defendants' knowing violations of the False Claims Act, the Defendants are liable to the United States for three times the amount of damages they have created to the United States as a result of submitting, or causing to submit, these false claims.

101. Each and every such violation of the Federal False Claims Act is also subject to a civil fine under the False Claims Act of between $5,500-$11,000, for conduct occurring prior to November 2, 2015, and a civil fine of between $10,781 and $21,563, for conduct occurring after November 2, 2015. *See* 81 Fed. Reg. 42491 (June 30, 2016). In addition Defendants are liable for any increase as specified by the Federal Civil Penalties Inflation Adjustment Act of 1990. Defendants are also liable for similar penalties for each violation of the State False Claims Acts.

COUNT II
Violations of 31 U.S.C. § 3729(a)(1)(B)
Use of False Statements or Records

102. The allegations in the above paragraphs are hereby re-alleged and set forth fully as above.

103. In submitting or causing to submit false claims the Defendants necessarily created false records and false statements including, but not limited to submitting bills to government programs, which require adherence to the Anti-Kickback Statute and by maintaining that they were in compliance with laws and regulations regarding the provision of ESRD services.

104. Defendants therefore violated the False Claims Act prohibition against using false records and statements under 31 U.S.C. § 3729(a)(1)(B).

105. The Defendants are liable to the United States for three times the amount of damages they have created to the United States as a result of using false records and statements.

106. Each and every such violation of the Federal False Claims Act is also subject to a civil fine under the False Claims Act of between $5,500-$11,000, for conduct occurring prior to November 2, 2015, and a civil fine of between $10,781 and $21,563, for conduct occurring after November 2, 2015. *See* 81 Fed. Reg. 42491 (June 30, 2016). In addition, Defendants are liable for any increase as specified by the Federal Civil Penalties Inflation Adjustment Act of 1990. Defendants are also liable for similar penalties for each violation of the State False Claims Acts.

COUNT III
Violations of Cal. Gov't Code §§ 12650 *et seq.*
The California False Claims Act

107. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

108. This is a claim for treble damages and civil penalties under the Cal. Gov't Code §§12650 *et seq*.

109. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services.

110. As a result, Defendants knowingly presented or caused to be presented false claims to the California Medicaid program (Medi-Cal), as well as programs funded by California and its political subdivisions, as defined under the California False Claims Act for health care plans of their employees.

111. Defendants knowingly accomplished these unlawful acts by making, using or causing false records or statements to be used in support of false claims.

112. The California Medicaid Program and any additional program paying for ESRD services with California State funds or funds from the political subdivisions of California were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been paid.

113. By reason of these payments California has been damaged and continues to be damaged in an amount to be determined at trial.

COUNT IV
Violations of Colo. Rev. Stat. §§ 25.4-4-303.4 *et seq.*
The Colorado False Claims Act

114. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

115. This is an action for treble damages and civil penalties for violations of The Colorado False Claims Act, Colo. Rev. Stat. §§ 25.4-4-303.4 *et seq*.

116. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services.

117. As a result Defendants knowingly presented or caused to be presented false claims to the Colorado Medicaid program, and to programs funded by Colorado and its political subdivisions, to cover health care costs for their employees.

118. Defendants knowingly accomplished these unlawful acts by making, using or causing the use of false records or statements.

119. The Colorado Medicaid Program and any additional program paying for ESRD services with funds from the state of Colorado or its subdivisions were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been paid.

120. By reason of these payments Colorado has been damaged and continues to be damaged in an amount to be determined at trial.

COUNT V
Violations of Conn. Gen. Stat. §§ 17b-301a--17b-301p (2010 Supplement)
The Connecticut False Claims Act

121. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

122. This is an action for treble damages and civil penalties for violations of the Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-301a--17b-301p (2010 Supplement).

123. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services.

124. As a result Defendants knowingly presented or caused to be presented false claims to the Connecticut Medicaid program, and to programs funded by the state of Connecticut as well as its political subdivisions, to support the health care of their employees.

125. Defendants knowingly accomplished these unlawful acts by making using or causing to the use of false records or statements.

126. The Connecticut Medicaid Program and any additional program paying for ESRD Services with Connecticut State funds, or funds from a political subdivision of the State, were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been paid.

127. By reason of these payments Connecticut has been damaged and continues to be damaged in an amount to be determined at trial.

COUNT VI
Violations of DC Code, §§ 2-381.01 *et seq.*
The District of Columbia False Claims Act

128. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

129. This is an action for treble damages and civil penalties for violations of District of Columbia False Claims Act, DC Code §§ 2-381.01 *et seq*.

130. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services.

131. As a result Defendants knowingly presented or caused to be presented false claims to the District of Columbia's Medicaid program, and to programs paying for health care costs employees of the District of Columbia.

132. Defendants knowingly accomplished these unlawful acts by making using or causing the use of false records or statements.

133. The District of Columbia's Medicaid Program, and any additional program paying for ESRD services with District of Columbia funds, were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid.

134. By reason of these payments the District of Columbia has been damaged and continues to be damaged in an amount to be determined at trial.

COUNT VII
Violations of Del. Code Ann. tit. 6, §§ 1201 *et seq*.
The Delaware False Claims and Reporting Act

135. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

136. This is an action for treble damages and civil penalties for violations of Section 1201(a) of the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201 *et seq*.

137. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services.

138. As a result Defendants knowingly presented or caused to be presented false claims to Delaware's Medicaid program, and to programs funded by the Government of Delaware as defined under the Delaware False Claims and Reporting Act to include all political subdivisions and all Government organizations.

139. Defendants knowingly accomplished these unlawful acts by making, using or causing the use of false records or statements.

140. The State of Delaware's Medicaid Program, and any additional program paying for ESRD services with funds from political subdivisions of the State of Delaware or from the State of Delaware, were unaware of the falsity or fraudulent nature of these claims.

141. Such claims otherwise would not have been paid.

142. By reason of these payments the State of Delaware has been damaged and continues to be damaged in an amount to be determined at trial.

COUNT VIII
Violations of O.C.G.A. § 23-3-120 (2012), *et seq.*
The Georgia Taxpayer Protection False Claims Act

143. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

144. This is an action for treble damages and civil penalties for violations of The Georgia Taxpayer Protection False Claims Act, O.C.G.A. § 23-3-120 (2012), *et seq.*

145. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

146. Defendants therefore knowingly presented or caused to be presented false claims to the Georgia's Medicaid program.

147. The Georgia Medicaid Program was unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been allowed.

148. By reason of these payments the State of Georgia has been damaged and continues to be damaged in a substantial amount to be determined at trial in an amount to be determined at trial.

COUNT IX
Violations of Haw. Rev. Stat. Ann. §§ 661-21 *et seq.*
The Hawaii False Claims Act

149. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

150. This is an action for treble damages and civil penalties for violations of the Hawaii False Claims Act, Haw. Rev. Stat. Ann. §§ 661-21 *et seq.*

151. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

152. As a result Defendants knowingly presented or caused to be presented false claims to Hawaii's Medicaid program and to programs funded by Hawaii, and its political subdivisions, to pay health care costs for their employees.

153. Defendants knowingly accomplished these unlawful acts by making, using or causing to the used of false records or statements.

154. The Hawaii Medicaid Program, and any additional program paying for ESRD services with funds from Hawaii, or one of the political subdivisions of the State, were unaware of

the falsity or fraudulent nature of the claims paid. Such claims otherwise would not have been allowed.

155. By reason of these payments the State of Hawaii has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT X
Violations of 740 Ill. Comp. Stat. Ann. 175/1 *et seq.*
The Illinois False Claims Act

156. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

157. This is an action for treble damages and civil penalties for violations of The Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. 175/1 *et seq*.

158. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

159. As a result Defendants knowingly presented or caused to be presented false claims to the Illinois' Medicaid program, and to programs funded by the State of Illinois as defined under the Illinois False Claims Act including, but not limited to, political subdivisions and Municipalities.

160. Defendants knowingly accomplished these unlawful acts by making, using or causing the use of false records or statements.

161. The Illinois Medicaid Program, and any additional program using Illinois Funds, or funds from any subdivision of the State of Illinois were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been allowed.

162. By reason of these payments the State of Illinois has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XI
Violations of Ind. Code §§ 5-11-5.5 *et seq.*
The Indiana False Claims and Whistleblower Protection Act

163. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

164. This is an action for treble damages and civil penalties for violations of The Indiana False Claims Act, Ind. Code §§ 5-11-5.5 *et seq*.

165. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

166. As a result Defendants knowingly presented or caused to be presented false claims to the Indiana Medicaid program and to other programs funded by the state of Indiana.

167. Defendants knowingly accomplished these unlawful acts by making, using or causing the use of false records or statements.

168. The Indiana Medicaid Program and any additional Indiana programs paying for ESRD Services, were unaware of the falsity or fraudulent nature of the claims and paid those claims. Such claims otherwise would not have been allowed.

169. By reason of these payments the State of Indiana has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XII
Violations of Iowa Code § 685.1 *et seq.*
The Iowa False Claims Act

170. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

171. This is an action for treble damages and civil penalties for violations of The Iowa False Claims Act Iowa Code § 685.1 *et seq*.

172. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

173. As a result Defendants knowingly presented or caused to be presented false claims to the Iowa Medicaid program.

174. Defendants knowingly accomplished these unlawful acts by making, using or causing the use of false records or statements.

175. The Iowa Medicaid Program was unaware of the falsity or fraudulent nature of the claims, and paid the claims. Such claims otherwise would not have been allowed.

176. By reason of these payments the State of Iowa has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XIII
Violations of La. Rev. Stat. Ann. §§ 6:438.1 *et seq*.
The Louisiana Medical Assistance Program Integrity Law

177. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

178. This is an action for treble damages and civil penalties for violations of the Louisiana Medical Assistance Program Integrity Law, La. Rev. Stat. Ann. §§ 6:438.1 *et seq*.

179. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

180. As a result Defendants knowingly presented or caused to be presented false claims to the Louisiana Medicaid program.

181. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

182. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims paid for claims. Such claims would otherwise not have been allowed.

183. By reason of these payments the State of Louisiana has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XIV
Violations of Md. Code Ann. Health-Gen. §§ 2-601 *et seq.*
The Maryland False Health Claims Act of 2010 and
Md. Code Ann. Gen. Prov. §§ 8-101 *et seq.*
The Maryland False Claims Act

184. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

185. This is an action for treble damages and civil penalties for violations of the Maryland False Health Claims Act, Md. Code Ann. Health-Gen. §§ 2-601 *et seq.*, and the Maryland False claims Act Md. Code Ann. Gen. Prov. §§ 8-101 *et seq.*

186. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

187. As a result Defendants knowingly presented or caused to be presented false claims to Maryland state health plans or programs, the State of Maryland and Counties of the State of Maryland.

188. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

189. Maryland state health plan or programs, the State and Counties, unaware of the falsity or fraudulent nature of the claims, paid these ESRD related claims. Such claims otherwise would not have been allowed.

190. By reason of these payments the State of Maryland and Counties have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT XV
Violations of Mass. Ann. Laws ch.12, §§ 5 *et seq.*
The Massachusetts False Claims Act

191. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

192. This is an action for treble damages and civil penalties for violations of the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, §§ 5 *et seq*.

193. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

194. As a result Defendant knowingly presented or caused to be presented false claims to the Massachusetts Medicaid program, as well as other programs funded by Massachusetts and its subdivisions.

195. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

196. The Massachusetts Medicaid Program and any additional program funded by Massachusetts and its subdivisions were unaware of the falsity or fraudulent nature of the claims. Those programs paid for claims that otherwise would not have been allowed.

197. By reason of these payments the Commonwealth of Massachusetts and its political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT XVI
Violations of Mich. Comp. Laws. Serv. §§ 400.601 *et seq.*
The Michigan Medicaid False Claims Act

198. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

199. This is an action for treble damages and civil penalties for violations of the Michigan Medicaid False Claims Act, Mich. Comp. Laws. Serv. §§ 400.601 *et seq*.

200. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

201. As a result Defendants knowingly presented or caused to be presented false claims to the Michigan Medicaid program and or the Michigan Department of Community Health.

202. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

203. The Michigan Medicaid Program and Department of Community Health, were unaware of the falsity or fraudulent nature of the claims, and paid for claims. Such claims otherwise would not have been allowed.

204. By reason of these payments the State of Michigan has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XVII
Violations of Minn. Stat. §§ 15C.01 *et seq.*
The Minnesota False Claims Act

205. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

206. This is an action for treble damages and civil penalties for violations of the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq*.

207. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

208. As a result Defendants knowingly presented or caused to be presented false claims to the state of Minnesota, political subdivisions of the State of Minnesota and programs funded by Minnesota and its subdivisions.

209. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used a false record or statement.

210. The State of Minnesota and any program funded by Minnesota or its subdivisions were unaware of the falsity or fraudulent nature of the claims. These programs therefore paid for claims that otherwise would not have been allowed.

211. By reason of these payments the State of Minnesota and its political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT XVIII
Violations of Mont. Code Ann. §§ 17-8-401 *et seq.*
The Montana False Claims Act

212. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

213. This is an Action for treble damages and civil penalties for violations of the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq*.

214. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

215. As a result Defendants knowingly presented or caused to be presented false claims to Montana, and "Government entities" of the State of Montana as defined in the Montana False Claims Act.

216. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

217. The State of Montana and Montana Government entities were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been allowed.

218. By reason of these payments the State of Montana and its Government entities have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT XIX
Violations of Nev. Rev. Stat. Ann. §§357.010 *et seq.*
The Nevada Submission of False Claims to State or Local Government Act

219. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

220. This is an action for treble damages and civil fines for violations of the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 *et seq*.

221. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

222. As a result Defendants knowingly presented or caused to be presented false claims to the state of Nevada, as well as programs funded by Nevada and its Political Subdivisions as defined under the Nevada False Claims to State and Local Government Act.

223. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

224. The state of Nevada and its political subdivisions were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been allowed.

225. By reason of these payments the State of Nevada and its political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT XX
Violations of N.J. Stat. Ann. § 2A:32C-1 *et seq*.
The New Jersey False Claims Act

226. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

227. This is an action for treble damages and civil fines under the Section 2A:32C-3 of the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 *et seq*.

228. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

229. As a result Defendants knowingly presented or caused to be presented false claims to the State of New Jersey and programs funded by the State of New Jersey as "State" is defined under the New Jersey False Claims Act.

230. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

231. The State of New Jersey and programs funded by the State of New Jersey were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been allowed.

232. By reason of these payments the State of New Jersey has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXI
Violations of N.M. Stat. Ann. §§ 27-14-1 *et seq.*
The New Mexico Medicaid False Claims Act and
N.M. Stat. Ann. §§ 44-9-1 *et seq.*
The New Mexico Fraud Against Taxpayers Act

233. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

234. This is an action for treble damages and civil fines under The New Mexico Medicaid False Claims Act and New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann. §§ 27-14-1 *et seq.*

235. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

236. As a result Defendants knowingly presented or caused to be presented false claims to the New Mexico Medicaid program, as well as programs funded by The State of New Mexico as defined under the New Mexico Fraud Against Taxpayers Act.

237. Defendants knowingly accomplished these unlawful acts by making, using or causing the use of false records or statements.

238. The New Mexico Medicaid Program and other programs funded by the State of New Mexico were unaware of the falsity or fraudulent nature of the claims. They therefore paid for claims that otherwise would not have been allowed.

239. By reason of these payments the State of New Mexico has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXII
Violations of N.Y. State Fin. Law §§ 188 *et seq.*
The New York False Claims Act

240. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

241. This is an action for treble damages and civil fines under the New York False Claims Act. N.Y. State Fin. Law §§ 188 *et seq*.

242. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

243. As a result Defendants knowingly presented or caused to be presented false claims to the New York Medicaid program, as well as programs funded by the State of New York and programs funded by Local Governments of the State as defined under the New York False Claims Act.

244. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

245. The New York Medicaid Program and other programs funded by New York State and New York Local Governments were unaware of the falsity or fraudulent nature of the claims. They therefore paid for claims that otherwise would not have been allowed.

246. By reason of these payments the State of New York and Local Governments have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT XXIII
Violations of N.C. Gen. Stat. §§ 1-605 *et seq.*
The North Carolina False Claims Act

247. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

248. This is an action for treble damages and civil fines against the Defendants under The North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq*.

249. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

250. As a result Defendants knowingly presented or caused to be presented false claims to North Carolina and programs funded by the State of North Carolina.

251. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

252. The State of North Carolina and programs funded by the State of North Carolina were unaware of the falsity or fraudulent nature of the claims. They therefore paid for claims that otherwise would not have been allowed.

253. By reason of these payments the State of North Carolina has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXIV
Violations of Okla. Stat. tit. 63, §§ 5053 *et seq.*
The Oklahoma Medicaid False Claims Act

254. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

255. This is an action for treble damages and civil fines against the Defendants under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053 *et seq*.

256. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

257. As a result Defendants knowingly presented or caused to be presented false claims to Oklahoma and programs funded by the State of Oklahoma.

258. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

259. The State of Oklahoma and programs funded by the State of Oklahoma were unaware of the falsity or fraudulent nature of the claims. They therefore paid for claims that otherwise would not have been allowed.

260. By reason of these payments the State of Oklahoma has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXV
Violations of R.I. Gen. Laws §§ 9-1.1-1 *et seq.*
The Rhode Island False Claims Act

261. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

262. This is an action for treble damages and civil fines against Defendants under The Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq.*

263. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

264. As a result Defendants knowingly presented or caused to be presented false claims to the State of Rhode, as well as programs funded by the State of Rhode Island as defined under the Rhode Island False Claims Act to include all Rhode Island agencies, government entities, cities, towns.

265. Defendants also knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

266. The State of Rhode Island and programs funded by the State of Rhode Island were unaware of the falsity or fraudulent nature of the claims. They therefore paid for claims that otherwise would not have been allowed.

267. By reason of these payments the State of Rhode Island has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXVI
Violations of T.C.A. §§ 4-18-101 et seq.
The Tennessee False Claims Act
and T.C.A. §§ 71-5-181 *et seq.*
and Tennessee Medicaid False Claims Act

268. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

269. This is an action for treble damages and civil fines against the Defendants under T.C.A §§ 4-18-101 *et seq*., the Tennessee False Claims Act and T.C.A. §§ 71-5-181 *et seq*. the Tennessee Medicaid False Claims Act.

270. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

271. As a result Defendants knowingly presented or caused to be presented false claims to the Tennessee Medicaid program, as well as programs funded by Tennessee and its political subdivisions as defined under the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act.

272. Defendants knowingly accomplished these unlawful acts by making, using. or causing the use of false records or statements.

273. The Tennessee Medicaid Program and other programs funded by Tennessee and its political subdivisions were unaware of the falsity or fraudulent nature of the claims. They therefore paid for claims that otherwise would not have been allowed.

274. By reason of these payments the State of Tennessee and its political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT XXVII
Violations of Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*
The Texas Medicaid Fraud Prevention Act

275. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

276. This is an action for treble damages and civil fines against the Defendants under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. §§ 36.001 *et seq*.

277. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

278. As a result Defendants knowingly presented or caused to be presented false claims to the Texas Medicaid program, and or knowingly accomplished these unlawful acts by making using or causing to be used a false record or statement.

279. The Texas Medicaid Program was unaware of the falsity or fraudulent nature of the claims. Texas therefore paid for claims that otherwise would not have been allowed.

280. By reason of these payments the State of Texas has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXVIII
Violations of 32 VSA §§ 630 *et seq.*
The Vermont False Claims Act

281. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

282. Plaintiff-Relator seeks relief against Defendants under the Vermont False Claims Act, 32 VSA §§ 630 *et seq*.

283. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

284. As a result Defendants knowingly presented or caused to be presented false claims to the Vermont Medicaid program, as well as programs funded by the State of Vermont as defined under the Vermont False Claims Act to include, any agency of state government, and any political subdivision.

285. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

286. The Vermont Medicaid Program and other Vermont programs were unaware of the falsity or fraudulent nature of the claims. They therefore paid for claims that otherwise would not have been allowed.

287. By reason of these payments the State of Vermont and its political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT XXIX
Violations of Va. Code Ann. §§ 8.01-216.1 *et seq.*
The Virginia Fraud Against Taxpayers Act

288. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

289. Plaintiff-Relator seeks relief against Defendants under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq*.

290. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

291. As a result Defendants knowingly presented or caused to be presented false claims to the Virginia Medicaid program, as well as programs funded by the Commonwealth of Virginia as defined under the Virginia Fraud Against Taxpayers Act to include, any agency of state government, and any political subdivision.

292. Defendants knowingly accomplished these unlawful acts by making, using, or causing to the use of false records or statements.

293. The Virginia Medicaid Program and other Commonwealth of Virginia programs were unaware of the falsity or fraudulent nature of the claims. They therefore paid for claims that otherwise would not have been allowed.

294. By reason of these payments the Commonwealth of Virginia has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXX
Violations of RCW 74.66.005 *et seq.*
The Washington Medicaid Fraud Act

295. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

296. This is an action for treble damages and civil fines against the Defendants under The Washington Medicaid Fraud Act RCW 74.66.005 *et seq.*

297. Defendants engaged in a kickback scheme to direct payments of insurance and copayments for End Stage Renal Dialysis ("ESRD") services thereby creating false claims.

298. As a result Defendants knowingly presented or caused to be presented false claims to the Washington Medicaid program.

299. Defendants knowingly accomplished these unlawful acts by making, using, or causing the use of false records or statements.

300. The State of Washington was unaware of the falsity or fraudulent nature of the claims. The State therefore paid for claims that otherwise would not have been allowed.

301. By reason of these payments the State of Washington has been damaged and continues to be damaged in a substantial amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff-Relator, on behalf of himself, the United States, and all States listed herein request that judgment be entered in his favor and against Defendants as follows:

(a) That Defendants cease and desist from violating 31 U.S.C. § 3729, *et seq.*, and the counterpart provisions of the State False Claims Acts set forth above;

(b) Plaintiff-Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act and the maximum amount allowed pursuant to the State False Claims Act statutes;

(c) That in the event the United States Government continues to proceed with this action, the Plaintiff-Relator be awarded an amount for bringing this action of at least 15% but not more than 25% of the proceeds of any award or the settlement of the claims;

(d) That in the event the United States Government does not proceed with this action, the Plaintiff-Relator be awarded an amount that the Court decides is reasonable for collecting the civil penalty and damages, which shall be not less than 25% nor more than 30% of the proceeds of any award or settlement;

(e) That this Court enter judgment against all Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 of between $5,500-$11,000, for each violation of 31 U.S.C. § 3729 occurring prior to November 2, 2015, and a civil fine of between $10,781 and $21,563, for such conduct occurring after November 2, 2015. *See* 81 Fed. Reg. 42491 (June 30, 2016). In addition Defendants are liable for any increase in civil fines as specified by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus the appropriate amount to the States for damages and civil fines as determined under the above listed State False Claims Acts;

(f) That Plaintiff-Relator be awarded an amount that the Court decides is reasonable, which shall not be less than 15% of the proceeds or settlement of any related administrative, criminal, or civil actions, including the monetary value of any equitable relief, fines, restitution, or disgorgement to the United States and/or third parties;

(g) That Plaintiff-Relator be granted a trial by jury;

(h) That Plaintiff-Relator, the United States, and the States listed herein be awarded pre-judgment interest;

(i) That the Plaintiff-Relator, be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. §§ 3730(d) and similar provisions of the Sate False Claims Acts listed herein.

(j) The United States, the States, sub-divisions or municipalities and the Plaintiff-Relator recover such other relief as the Court deems just and proper

JURY TRIAL DEMANDED

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE; STEPHEN ALBRIGHT; AMERICAN KIDNEY FUND, INC.; and DIALYSIS PATIENT CITIZENS, INC.,

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

Case No. 8:19-cv-2105-DOC-ADS

REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Date:	May 2, 2022
Time:	8:30 a.m.
Courtroom:	9D
Judge:	The Honorable David O. Carter
Trial Date:	July 12, 2022
Action Filed:	November 1, 2019

REQUEST FOR JUDICIAL NOTICE

Pursuant to Federal Rule of Evidence 201, Defendants ROB BONTA, RICARDO LARA, SHELLY ROUILLARD, and TOMÁS J. ARAGÓN, sued in their official capacities (Defendants), respectfully request that the Court take judicial notice of the following materials submitted in support of their concurrently filed Motion for Summary Judgment in this action.

1. Attached hereto as **Exhibit 1** is a true and correct copy of an excerpt (pages 1-2 and 18-19) from the certified transcript of the testimony of AKF President and CEO LaVarne Burton at the July 3, 2019 California Senate Health Committee hearing.

2. Attached hereto as **Exhibit 2** is a true and correct copy of a comparison between AB 290 as introduced on January 28, 2019, and AB 290 as enacted on October 13, 2019, available at https://leginfo.legislature.ca.gov/faces /billVersionsCompareClient.xhtml?bill_id=201920200AB290&cversion=20190AB 29099INT (last accessed February 24, 2022).

DISCUSSION

Federal Rule of Evidence 201(b) provides that a judicially noticed fact must be one "not subject to reasonable dispute" because it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot readily be questioned. Fed. R. Evid. 201(b).

"Legislative history is properly a subject of judicial notice." *Anderson v. Holder*, 673 F.3d 1089, 1094, n.1 (9th Cir. 2012); *Chaker v. Crogan*, 428 F.3d 1215, 1223 n. 8 (9th Cir. 2005); *see also Ramos v. Capital One, N.A.*, No. 17-CV-00435-BLF, 2017 WL 3232488, at *3 (N.D. Cal. July 27, 2017) (taking judicial notice of Senate Committee hearing notes).

In addition, a court may take judicial notice of matters of public record. *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001) (citing *Mack v. South Bay*

Beer Distrib., 798 F.2d 1279, 1282 (9th Cir. 1986)). Government documents that are public records are appropriate subjects for judicial notice. *See, e.g.*, *Cachil Dehe Band of Wintun Indians of the Colusa Indian Cmty. v. California*, 547 F.3d 962, 968 n. 4 (9th Cir. 2008). Courts regularly take judicial notice of government documents posted on government websites. *Anderson*, 673 F.3d at 1094 n.1 (the Court may take judicial notice of records and reports of government entities, including when that information is posted on a government webpage); *Daniels-Hall v. National Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010) (taking judicial notice of information made publicly available by a government entity on its website).

Based on the above authorities, Defendants request that this Court take judicial notice of Exhibit 1, the excerpted California Senate Health Committee testimony of LaVarne Burton, on the ground that it is a legislative record and a public record of a government agency. *Anderson*, 673 F.3d at 1094 n.1. Defendants also request that this Court take judicial notice of Exhibit 2, a comparison between AB 290 as introduced on January 28, 2019, and AB 290 as enacted on October 13, 2019, that is posted and available on a government website, specifically at https://leginfo.legislature.ca.gov/faces/billVersionsCompareClient.xhtml?bill_id=201920200AB290&cversion=20190AB29099INT, on the ground that it is likewise a legislative record and a public record of a government agency.

Dated: February 25, 2022

Respectfully submitted,

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MARK R. BECKINGTON
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Supervising Deputy Attorneys General
S. CLINTON WOODS
Deputy Attorney General

/s/ Lisa J. Plank

LISA J. PLANK
Deputy Attorney General
Attorneys for Defendants Rob Bonta, et al.

EXHIBIT 1

Fresenius Medical v. Xavier Becerra

Hearing of the Senate Committee on Health

AB 290

CHAIR RICHARD PAN: So, let's move to Item Number 2, AB 290.

ASSEMBLYMEMBER JIM WOOD: Good afternoon, once again, Dr. Chair and Members. The proposal before you is not a new one. AB 290 is very similar to SP 1156 of last year, carried by my co-author and your colleague, Senator Leyva.

Senator Leyva's bill made it to the Governor's desk but was vetoed. In my bill, I have included language to address the very concerns expressed by then Governor Braun.

Additionally, my office, the sponsors, and the Senate Health Committee staff, have been working diligently to address the Chair's concerns and that of the California Medical Association regarding rate setting. And I would like to thank everyone for their hard work addressing this issue.

I've agreed to take amendments that provide arbitration as an option to the default of Medicare rates so there is an opportunity for providers to make a case for an alternative higher rate.

I believe this process will provide an

In the State of California, last year, we provided to assistance to almost 4,000 people who dependent upon our grants to help pay their health insurance premiums.

For these people about half were helped with Medicare and Medigap policies. We've always operated the American Kidney Fund with the highest standards -- ethical standards and efficiency.

For this we've been rewarded the -- with the highest ratings from organizations that review Charity Navigator. We're a 17-year running recipient of 4-star charity, placing us among the top 10 charities in the country.

We do all of this with a staff of 80 people. Despite our great work and commitment to patients, our lawyers have determined that we will be forced to shut down in California if AB 290 is enacted. My general counsel is here today.

First, I know that there are different legal opinions about whether we can safely continue operations under AB 290. But the advisory opinion for our premium assistance program is from the Inspector General at the

Department of Health and Human Services and legally binding. And it requires that we act in good faith to comply with its arrangements. Should we not do so, we, AKF, are liable to the IG for sanctions.

Your own general counsel, on Page 6 of its letter to Chairman Wood, confirms AKF's conclusion that AB 290 would take us outside the protection of our advisory opinion.

Why would we, an organization that has always played by the rules, step out on a limb, when our best judgement and that of your own legal counsel, says that AB 290 takes us outside the protections of the IG.

When the HIPAA law, that enables the IG opinion was written, I was the presidential appointee in the Clinton administration and I co-led an effort in the department to develop this legislation.

I can tell you that our chief concern was protecting against this closure so that patient could make unfeathered choices of their own as to their healthcare providers.

Now, AKF is -- if AKF is forced to shut down in California, here's what happens to

EXHIBIT 2

AB-290 Health care service plans and health insurance: third-party payments. (2019-2020)

Current Version: 10/13/19 - Chaptered **Compared to Version:** 01/28/19 - Introduced Compare Versions

~~SEC. 3.~~ ***SECTION 1.*** *The Legislature finds and declares as follows:*

(a) There has been a rapid increase in the practice of certain health care providers and provider-funded groups paying health insurance premiums in California's individual and group health insurance markets on behalf of consumers with very high-cost conditions such as end stage renal disease and addiction to alcohol or drugs.

(b) These third-party payment arrangements have proliferated in recent years as a result of health care providers that have demonstrated a willingness to exploit the Affordable Care Act's guaranteed issue rules for their own financial benefit.

(c) Encouraging patients to enroll in commercial insurance coverage for the financial benefit of the provider may result in an unjust enrichment of the financially interested provider at the expense of consumers purchasing health insurance. This practice can also expose patients to direct harm.

(d) According to the federal Centers for Medicare and Medicaid Services, patients caught up in these schemes may face higher out-of-pocket costs and mid-year disruptions in coverage, and may have a more difficult time obtaining critical care such as kidney transplants.

(e) Consumers also pay higher health insurance premiums due to the distortion of the insurance risk pool caused when providers steer patients into particular health insurance plans with the promise of having the patients' premiums paid. Nationally, this problem has added billions of dollars of costs to the individual and group health insurance markets.

(f) Certain residential substance use disorder treatment facilities have induced patients to enroll in health insurance with assurances that the treatment center will pay the patients' health insurance premiums. In some cases, patients were not even informed that health insurance was being purchased on their behalf. According to news reports, at the end of their treatment benefit, patients are sometimes stranded far from home and enter a cycle of homelessness.

(g) Large dialysis organizations control 77 percent of California's dialysis clinics, and this market concentration has risen dramatically in recent years. Nationally, the two largest dialysis companies account for 92 percent of all dialysis industry revenue. These companies systematically exert their market dominance to command commercial reimbursement rates that are many times the cost associated with providing care.

(h) Large dialysis companies contribute more than 80 percent of the revenue to a nonprofit that pays health insurance premiums for patients on dialysis for kidney failure. In turn, this nonprofit generates hundreds of millions of dollars for large dialysis organizations by artificially increasing the number of their patients who have commercial insurance coverage.

~~No~~ *(i)* ~~reimbursement is required by this act pursuant to Section 6 of Article XIII~~ *It is the intent* ~~B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII~~ *of the Legislature in enacting this act to protect the sustainability of risk pools within the individual and group health insurance markets, shield patients from potential harm caused by being steered into coverage options that may not be in their best interest and to correct a market failure that has allowed large dialysis organizations to use* ~~B of the California Constitution.~~ *their*

oligopoly power to inflate commercial reimbursement rates and unjustly drive up the cost of care.

(j) It is the intent of the Legislature that the delayed implementation and conditional nature of certain provisions of this act will allow the American Kidney Fund to request an updated advisory opinion from the United States Department of Health and Human Services Office of Inspector General for the purposes of protecting patients in California.

SEC. 2. *Section 1210 is added to the Health and Safety Code, to read:*

1210. *(a) A chronic dialysis clinic shall not steer, direct, or advise a patient regarding any specific coverage program option or health care service plan contract.*

(b) A chronic dialysis clinic shall post a notice in a prominent location visible to all patients displayed in large font type that questions about Medicare coverage for patients with end stage renal disease should be directed to the Health Insurance Counseling and Advocacy Program or HICAP at 1-800-434-0222.

~~**SECTION 1.**~~ ***SEC. 3.*** Section 1367.016 is added to the Health and Safety Code, to read:

1367.016. (a) A health care service plan shall accept premium payments from the following third-party entities without the need to comply with subdivision (c):

(1) A Ryan White HIV/AIDS Program under Title XXVI of the federal Public Health Service Act.

(2) An Indian tribe, tribal organization, or urban Indian organization.

(3) A local, state, or federal government program, including a grantee directed by a government program to make payments on its behalf.

(4) A member of the individual's family, defined for purposes of this section to include the individual's spouse, domestic partner, child, parent, grandparent, and siblings, unless the true source of funds used to make the premium payment originates with a financially interested entity.

(b) A financially interested entity that is not specified in subdivision (a) and is making third-party premium payments shall comply with all of the following requirements:

(1) It shall provide assistance for the full plan year and notify the enrollee prior to an open enrollment period, if applicable, if financial assistance will be discontinued. *Notification shall include information regarding alternative coverage options, including, but not limited to, Medicare, Medicaid, individual market plans, and employer plans, if applicable.* Assistance may be discontinued at the request of an enrollee who obtains other health coverage, or if the enrollee dies during the plan year.

(2) ~~If the entity provides coverage for an enrollee with end stage renal disease, the entity~~ *It* shall agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug, or device.

(3) It shall inform an applicant of financial assistance, and shall inform a recipient annually, of all available health coverage options, including, but not limited to, Medicare, Medicaid, individual market plans, and employer plans, if applicable.

(4) It shall agree not to steer, direct, or advise the patient into or away from a specific coverage program option or health care service plan contract.

(5) It shall agree that financial assistance shall not be conditioned on the use of a specific ~~facility or healthcare provider.~~ *facility, health care provider, or coverage type.*

(6) It shall agree that financial assistance shall be based on financial need in accordance with criteria that are uniformly applied and publicly available.

(c) ~~An entity described in subdivision (b)~~ *A financially interested entity* shall not make a third-party premium payment unless the entity complies with both of the following requirements:

(1) Annually provides a statement to the health care service plan that it meets the requirements set forth in subdivision (b), as applicable.

(2) Discloses to the health care service plan, prior to making the initial payment, the name of the enrollee for each health care service plan contract on whose behalf a third-party premium payment described in this section will be made.

(d) (1) Reimbursement for enrollees for whom a nonprofit financially interested entity described in paragraph (2) of subdivision (h) that was already making premium payments to a health care service plan on the enrollee's behalf prior to October 1, 2019, is not subject to subdivisions (e) and (f) and the financially interested entity is not required to comply with the disclosure requirements described in subdivision (c) for those enrollees.

(2) Notwithstanding paragraph (1), a financially interested entity shall comply with the disclosure requirements of subdivision (c) for an enrollee on whose behalf the financially interested entity was making premium payments to a health care service plan on the enrollee's behalf prior to October 1, 2019, if the enrollee changes health care service plans on or after March 1, 2020.

(3) The amount of reimbursement for services paid to a financially interested provider shall be governed by the terms of the enrollee's health care service plan contract, except for an enrollee who has changed health care service plans pursuant to paragraph (2), in which case, commencing January 1, 2022, the reimbursement amount shall be determined in accordance with subdivisions (e) and (f).

~~(d)~~ *(e)* ~~If~~ *Commencing January 1, 2022, if* a financially interested entity makes a third-party premium payment to a health care service plan on behalf of an enrollee, reimbursement to a provider who is also a financially interested entity for covered services provided shall be determined by the following:

(1) For a contracted financially interested provider that makes a third-party premium payment or has a financial relationship with the entity making the third-party premium payment, the amount of reimbursement for covered services that shall be paid to the financially interested provider on behalf of the enrollee shall be ~~governed by the terms and conditions of the enrollee's health care service plan contract or the Medicare reimbursement rate, whichever is lower.~~ *the higher of the Medicare reimbursement or the rate determined pursuant to the process described in this subdivision, if a rate determination pursuant to that process is sought by either the provider or the health care service plan.* Financially interested providers shall ~~not~~ *neither* bill the enrollee nor seek reimbursement from the enrollee for services provided, except for cost sharing pursuant to the terms and conditions of the enrollee's health care service plan contract. If an enrollee's contract imposes a coinsurance payment for a claim that is subject to this paragraph, the coinsurance payment shall be based on the amount paid by the health care service plan pursuant to this paragraph.

(2) For a noncontracting financially interested provider that makes a third-party premium payment or has a financial relationship with the entity making the third-party premium payment, the amount of reimbursement for covered services that shall be paid to the financially interested provider on behalf of the enrollee shall be governed by the terms and conditions of the enrollee's health care service plan contract or the ~~Medicare reimbursement rate, whichever is lower.~~ *rate determined pursuant to the process described in this subdivision, whichever is lower, if a rate determination pursuant to that process is sought by either the provider or the health care service plan.* Financially interested providers shall neither bill the enrollee nor seek reimbursement from the enrollee for services provided, except for cost sharing pursuant to the terms and conditions of the enrollee's health care service plan contract. If an enrollee's contract imposes a coinsurance payment for a claim that is subject to this paragraph, the coinsurance payment shall be based on the amount paid by the health care service plan pursuant to this paragraph. A claim submitted to a health care service plan by a noncontracting financially interested provider may be considered an incomplete claim and contested by the health care service plan pursuant to Section 1371 or 1371.35 if the financially interested provider has not provided the information as required in subdivision (c).

(f) (1) By October 1, 2021, the department shall establish an independent dispute resolution process for the purpose of determining if the amount required to be reimbursed by subdivision (e) is appropriate.

(2) If either the provider or health care service plan submits a claim to the department's independent dispute resolution process, the other party shall participate in the independent dispute resolution process.

(3) In making its determination, the independent organization shall consider information submitted by either party regarding the actual cost to provide services, patient eligibility for Medicare or Medi-Cal, and the rate that would be paid by Medicare or Medi-Cal for patients eligible for those programs.

(4) The health care service plan shall implement the determination obtained through the independent dispute resolution process. The independent organization's determination of the amount required to be reimbursed shall apply for the duration of the plan year for that enrollee. If dissatisfied, either party may pursue any right, remedy, or penalty established under any other applicable law.

(5) In establishing the independent dispute resolution process, the department shall permit the bundling of claims submitted to the same plan or the same delegated entity for the same or similar services. The department shall

permit claims on behalf of multiple enrollees from the same provider to the same health care service plan to be combined into a single independent dispute resolution process.

(6) The department shall establish uniform written procedures for the submission, receipt, processing, and resolution of claim payment disputes pursuant to this section and any other guidelines for implementing this section.

(7) The department shall establish reasonable and necessary fees not to exceed the reasonable costs of administering this subdivision.

(8) The department may contract with one or more independent organizations to conduct the proceedings. The independent organization handling a dispute shall be independent of either party to the dispute.

(9) The department shall use conflict-of-interest standards consistent with the standards pursuant to subdivisions (c) and (d) of Section 1374.32.

(10) The department may contract with the same independent organization or organizations as the Department of Insurance.

(11) The independent organization retained to conduct proceedings shall be deemed to be consultants for purposes of Section 43.98 of the Civil Code.

(12) Contracts entered into pursuant to the authority in this subdivision shall be exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code, Section 19130 of the Government Code, and Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code, and shall be exempt from the review or approval of any division of the Department of General Services.

(13) This subdivision does not alter a health care service plan's obligations under Section 1371.

(14) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section by means of all-plan letters or similar instructions, without taking regulatory action, until regulations are adopted.

~~(e)~~ *(g)* For the purposes of this section, third-party premium payments only include health care service plan premium payments made directly by a provider or other third party, made indirectly through payments to the individual for the purpose of making health care service plan premium payments, or provided to one or more intermediaries with the intention that the funds be used to make health care service plan premium payments for the individuals.

~~(f)~~ *(h)* The following definitions apply for purposes of this section:

(1) "Enrollee" means an individual whose health care service plan premiums are paid by a financially interested entity.

(2) "Financially interested" ~~means an entity or provider described by either~~ *includes any* of the following ~~criteria:~~ *entities:*

(A) A provider of ~~healthcare~~ *health care* services that receives a direct or indirect financial benefit from a third-party premium payment.

(B) An entity that receives the majority of its funding from one or more financially interested providers of ~~healthcare~~ *health care* services, parent companies of providers of ~~healthcare~~ *health care* services, subsidiaries of ~~healthcare~~ *health care* service providers, or related entities.

(C) A chronic dialysis clinic that is operated, owned, or controlled by a parent entity or related entity that meets the definition of a large dialysis clinic organization (LDO) under the federal Centers for Medicare and Medicaid Services Comprehensive ESRD Care Model as of January 1, 2019. A chronic dialysis clinic that does not meet the definition of an LDO or has no more than 10 percent of California's market share of licensed chronic dialysis clinics shall not be considered financially interested for purposes of this section.

(3) "Health care service ~~plan"~~ *plan contract"* means an individual or group health care service plan contract that provides medical, hospital, and surgical benefits, except a specialized health care service plan contract. The term does not include coverage of Medicare services pursuant to contracts with the United States government, Medicare supplement coverage, long-term care insurance, coverage issued as a supplement to liability insurance, insurance arising out of workers' compensation law or similar law, automobile medical payment insurance, or insurance under which benefits are payable with or without regard to fault and that is statutorily required to be

contained in any liability insurance policy or equivalent self-insurance.

(4) "Provider" means a professional person, organization, health facility, or other person or institution that delivers or furnishes ~~healthcare~~ *health care* services.

~~(g)~~ *(i)* The following shall occur if a health care service plan subsequently discovers that a financially interested entity fails to provide disclosure pursuant to subdivision (c):

(1) The health care service plan shall be entitled to recover 120 percent of the difference between a payment made to a provider and the payment to which the provider would have been entitled pursuant to subdivision ~~(d),~~ *(e),* including interest on that difference.

(2) The health care service plan shall notify the department of the amount by which the provider was overpaid and shall remit to the department any amount exceeding the difference between the payment made to the provider and the payment to which the provider would have been entitled pursuant to subdivision ~~(d),~~ *(e),* including interest on that difference that was recovered pursuant to paragraph (1).

~~(h)~~ *(j)* ~~Each~~ *Commencing January 1, 2022, each* health care service plan licensed by the department and subject to this section shall provide to the department information regarding premium payments by financially interested entities and reimbursement for services to providers under subdivision ~~(d).~~ *(e).* The information shall be provided at least annually at the discretion of the department and shall include, to the best of the health care service plan's knowledge, the number of enrollees whose premiums were paid by financially interested entities, disclosures provided to the plan pursuant to subdivision (c), the identities of any providers whose reimbursement rate was governed by subdivision ~~(d),~~ *(e),* the identities of any providers who failed to provide disclosure as described in subdivision (c), and, at the discretion of the department, additional information necessary for the implementation of this section.

~~(i)~~ *(k)* This section does not limit the authority of the Attorney General to take action to enforce this section.

~~(j)~~ *(l)* This section does not affect a contracted payment rate for a provider who is not financially interested.

~~(k)~~ *(m)* This section ~~shall not be construed to authorize~~ *does not alter any of* a health care service ~~plan to refuse to accept premium payments, nor cancel nor refuse to renew an existing enrollment or subscription, irrespective of the source of payment.~~ *plan's obligations and requirements under this chapter, including, but not limited to, the following:*

(1) The obligation of a health care service plan to fairly and affirmatively offer, market, sell, and issue a health benefit plan to any individual, consistent with Article 11.8 (commencing with Section 1399.845), or small employer, consistent with Article 3.1 (commencing with Section 1357).

(2) The obligations of a health care service plan with respect to cancellation or nonrenewal as provided in this chapter, including, but not limited to, Section 1365.

(3) A health care service plan may not deny coverage to an enrollee whose premiums are paid by a third party.

(n) This section does not supersede or modify any privacy and information security requirements and protections in federal and state law regarding protected health information or personally identifiable information, including, but not limited to, the federal Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Sec. 300gg).

(o) Notwithstanding clause (iii) of subparagraph (A) of paragraph (1) of subdivision (d) of Section 1399.849, an enrollee's loss of coverage due to a financially interested entity's failure to pay premiums on a timely basis shall be deemed a triggering event for special enrollment pursuant to subparagraph (A) of paragraph (1) of subdivision (d) of Section 1399.849.

SEC. 4. *Section 1385.09 is added to the Health and Safety Code, to read:*

1385.09. *A health care service plan contract subject to Section 1385.03 or 1385.04 shall file a separate schedule documenting the cost savings associated with Section 1367.016 and the impact on rates.*

SEC. ~~2.~~ *5.* Section 10176.11 is added to the Insurance Code, to read:

10176.11. (a) An insurer that provides a policy of health insurance shall accept premium payments from the following third-party entities without the need to comply with subdivision (c):

(1) A Ryan White HIV/AIDS Program under Title XXVI of the federal Public Health Service Act.

(2) An Indian tribe, tribal organization, or urban Indian organization.

(3) A local, state, or federal government program, including a grantee directed by a government program to make payments on its behalf.

(4) A member of the individual's family, defined for purposes of this section to include the individual's spouse, domestic partner, child, parent, grandparent, and siblings, unless the true source of funds used to make the premium payment originates with a financially interested entity.

(b) A financially interested entity that is not specified in subdivision (a) and is making third-party premium payments shall comply with all of the following requirements:

(1) It shall provide assistance for the full policy year and notify the insured prior to an open enrollment period, if applicable, if financial assistance will be discontinued. *Notification shall include information regarding alternative coverage options, including, but not limited to, Medicare, Medicaid, individual market policies, and employer policies, if applicable.* Assistance may be discontinued at the request of an insured who obtains other health insurance coverage, or if the insured dies during the policy year.

(2) ~~If the entity provides coverage for an insured with end stage renal disease, the entity~~ *It* shall agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug, or device.

(3) It shall inform an applicant of financial assistance, and shall inform an insured annually, of all available health coverage options, including, but not limited to, Medicare, Medicaid, individual market plans, and employer plans, if applicable.

(4) It shall agree not to steer, direct, or advise the insured into or away from a specific coverage program option or health coverage.

(5) It shall agree that financial assistance shall not be conditioned on the use of a specific ~~facility or healthcare provider.~~ *facility, health care provider, or coverage type.*

(6) It shall agree that financial assistance shall be based on financial need in accordance with criteria that are uniformly applied and publicly available.

(c) ~~An entity described in subdivision (b)~~ *A financially interested entity* shall not make a third-party premium payment unless the entity complies with both of the following requirements:

(1) Annually provides a statement to the health insurer that it meets the requirements set forth in subdivision (b), as applicable.

(2) Discloses to the health insurer, prior to making the initial payment, the name of the insured for each policy on whose behalf a third-party premium payment described in this section will be made.

(d) (1) Reimbursement for insureds for whom a nonprofit financially interested entity described in paragraph (2) of subdivision (h) that was already making premium payments to a health insurer on the insured's behalf prior to October 1, 2019, is not subject to subdivisions (e) and (f) and the financially interested entity is not required to comply with the disclosure requirements described in subdivision (c) for those insureds.

(2) Notwithstanding paragraph (1), a financially interested entity shall comply with the disclosure requirements of subdivision (c) for an insured on whose behalf the financially interested entity was making premium payments to a health insurer on the insured's behalf prior to October 1, 2019, if the insured changes health insurers on or after March 1, 2020.

(3) The amount of reimbursement for services paid to a financially interested provider shall be governed by the terms of the insured's health insurance policy contract, except for an insured who has changed health insurers pursuant to paragraph (2), in which case, commencing January 1, 2022, the reimbursement amount shall be determined in accordance with subdivisions (e) and (f).

~~(d)~~ *(e)* ~~If~~ *Commencing January 1, 2022, if* a financially interested entity makes a third-party premium payment to a health insurer on behalf of an insured, reimbursement to a financially interested provider for covered services shall be determined by the following:

(1) For a contracted financially interested provider that makes a third-party premium payment or has a financial relationship with the entity making the third-party premium payment, the amount of reimbursement for covered services that shall be paid to the financially interested provider on behalf of the insured shall be governed by the ~~terms and conditions~~ *higher* of the ~~insured's health insurance policy or the Medicare reimbursement rate,~~

~~whichever is lower.~~ *Medicare reimbursement or the rate determined pursuant to the process described in this subdivision, if a rate determination pursuant to that process is sought by either the provider or the health insurer.* Financially interested providers shall neither bill the insured nor seek reimbursement from the insured for services provided, except for cost sharing pursuant to the terms and conditions of the insured's health insurance policy. If an insured's policy imposes a coinsurance payment for a claim that is subject to this paragraph, the coinsurance payment shall be based on the amount paid by the health insurer pursuant to this paragraph.

(2) For a noncontracting financially interested provider that makes a third-party premium payment or has a financial relationship with the entity making the third-party premium payment, the amount of reimbursement for covered services that shall be paid to the financially interested provider on behalf of the insured shall be governed by the terms and conditions of the insured's health insurance policy or the ~~Medicare reimbursement rate, whichever is lower.~~ *rate determined pursuant to the process described in this subdivision, whichever is lower, if a rate determination pursuant to that process is sought by either the provider or the health insurer.* Financially interested providers shall not bill the insured nor seek reimbursement from the insured for services provided, except for cost sharing pursuant to the terms and conditions of the insured's health insurance policy. If the insured's policy imposes a coinsurance payment for a claim that is subject to this paragraph, the coinsurance payment shall be based on the amount paid by the health insurer pursuant to this paragraph. A claim submitted to a health insurer by a noncontracting financially interested provider may be considered an incomplete claim and contested by the health insurer pursuant to Section 10123.13 or 10123.147 if the financially interested provider has not provided the information as required in subdivision (c).

(f) (1) By October 1, 2021, the department shall establish an independent dispute resolution process for the purpose of determining if the amount required to be reimbursed by subdivision (e) is appropriate.

(2) If either the provider or health insurer submits a claim to the department's independent dispute resolution process, the other party shall participate in the independent dispute resolution process.

(3) In making its determination, the independent organization shall consider information submitted by either party regarding the actual cost to provide services, patient eligibility for Medicare or Medi-Cal, and the rate that would be paid by Medicare or Medi-Cal for patients eligible for those programs.

(4) The health insurer shall implement the determination obtained through the independent dispute resolution process. The independent organization's determination of the amount required to be reimbursed shall apply for the duration of the policy year for that insured. If dissatisfied, either party may pursue any right, remedy, or penalty established under any other applicable law.

(5) In establishing the independent dispute resolution process, the department shall permit the bundling of claims submitted to the same insurer or the same delegated entity for the same or similar services. The department shall permit claims on behalf of multiple insureds from the same provider to the same health insurer to be combined into a single independent dispute resolution process.

(6) The department shall establish uniform written procedures for the submission, receipt, processing, and resolution of claim payment disputes pursuant to this section and any other guidelines for implementing this section.

(7) The department shall establish reasonable and necessary fees not to exceed the reasonable costs of administering this subdivision.

(8) The department may contract with one or more independent organizations to conduct the proceedings. The independent organization handling a dispute shall be independent of either party to the dispute.

(9) The department shall use conflict-of-interest standards consistent with the standards pursuant to subdivisions (c) and (d) of Section 10169.2.

(10) The department may contract with the same independent organization or organizations as the Department of Managed Health Care.

(11) The independent organization retained to conduct proceedings shall be deemed to be consultants for purposes of Section 43.98 of the Civil Code.

(12) Contracts entered into pursuant to the authority in this subdivision shall be exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code, Section 19130 of the Government Code, and Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code, and shall be exempt from the review or approval of any division of the Department of General Services.

(13) This subdivision does not alter a health insurer's obligations under Section 10123.13.

(14) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section by issuing guidance, without taking regulatory action, until regulations are adopted.

~~(e)~~ *(g)* For the purposes of this section, third-party premium payments only include health insurance premium payments made directly by a provider or other third party, made indirectly through payments to the individual for the purpose of making health insurance premium payments, or provided to one or more intermediaries with the intention that the funds be used to make health insurance premium payments for the individuals.

~~(f)~~ *(h)* The following definitions apply for purposes of this section:

(1) "Financially interested" ~~means an entity or provider described by either~~ *includes any* of the following ~~criteria:~~ *entities:*

(A) A provider of ~~healthcare~~ *health care* services that receives a direct or indirect financial benefit from a third-party premium payment.

(B) An entity that receives the majority of its funding from one or more financially interested providers of ~~healthcare~~ *health care* services, parent companies of providers of ~~healthcare~~ *health care* services, subsidiaries of ~~healthcare~~ *health care* service providers, or related entities.

(C) A chronic dialysis clinic that is operated, owned, or controlled by a parent entity or related entity that meets the definition of a large dialysis clinic organization (LDO) under the federal Centers for Medicare and Medicaid Services Comprehensive ESRD Care Model as of January 1, 2019. A chronic dialysis clinic that does not meet the definition of an LDO or has no more than 10 percent of California's market share of licensed chronic dialysis clinics shall not be considered financially interested for purposes of this section.

(2) "Health insurance" means an individual or group health insurance policy as defined in subdivision (b) of Section 106. The term does not include coverage of Medicare services pursuant to contracts with the United States government, Medicare supplement coverage, or specialized health insurance coverage as described in subdivision (c) of Section 106.

(3) "Insured" means an individual whose health insurance premiums are paid by a financially interested entity.

(4) "Provider" means a professional person, organization, health facility, or other person or institution that delivers or furnishes ~~healthcare~~ *health care* services.

~~(g)~~ *(i)* The following shall occur if a health insurer subsequently discovers that a financially interested entity fails to provide disclosure pursuant to subdivision (c):

(1) The health insurer shall be entitled to recover 120 percent of the difference between payment made to a provider and the payment to which the provider would have been entitled pursuant to subdivision ~~(d),~~ *(e),* including interest on that difference.

(2) The health insurer shall notify the department of the amount by which the provider was overpaid and shall remit to the department any amount exceeding the difference between the payment made to the provider and the payment to which the provider would have been entitled pursuant to subdivision ~~(d),~~ *(e),* including interest on that difference that was recovered pursuant to paragraph (1).

~~(h)~~ *(j)* ~~Each~~ *Commencing January 1, 2022, each* health insurer licensed by the department and subject to this section shall provide to the department information regarding premium payments by financially interested entities and reimbursement for services to providers under subdivision (d). The information shall be provided at least annually at the discretion of the department and shall include, to the best of the health insurer's knowledge, the number of insureds whose premiums were paid by financially interested entities, disclosures provided to the insurer pursuant to subdivision (c), the identities of any providers whose reimbursement rate was governed by subdivision ~~(d),~~ *(e),* the identities of any providers who failed to provide disclosure as described in subdivision (c), and, at the discretion of the department, additional information necessary for the implementation of this section.

~~(i)~~ *(k)* This section does not limit the authority of the Attorney General to take action to enforce this section.

~~(j)~~ *(l)* This section does not affect a contracted payment rate for a provider who is not financially interested.

~~(k)~~ *(m)* This section ~~shall not be construed to authorize an insurer to refuse to accept premium payments, nor~~

~~cancel nor refuse to renew an existing enrollment or subscription, irrespective of the source of payment.~~ *does not alter any of a health insurer's obligations and requirements under this part, including, but not limited to, the following:*

(1) The obligation of a health insurer to fairly and affirmatively offer, market, sell, and issue a health benefit plan to any individual, consistent with Chapter 9.9 (commencing with Section 10965), or small employer, consistent with Chapter 8 (commencing with Section 10700).

(2) The obligations of a health insurer with respect to cancellation or nonrenewal as provided in this part, including, but not limited to, Sections 10273.4, 10273.6, and 10273.7.

(3) A health insurer may not deny coverage to an insured whose premiums are paid by a third party.

(n) This section does not supersede or modify any privacy and information security requirements and protections in federal and state law regarding protected health information or personally identifiable information, including, but not limited to, the federal Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Sec. 300gg).

(o) Notwithstanding clause (iii) of subparagraph (A) of paragraph (1) of subdivision (d) of Section 10965.3, an insured's loss of coverage due to a financially interested entity's failure to pay premiums on a timely basis shall be deemed a triggering event for special enrollment pursuant to subparagraph (A) of paragraph (1) of subdivision (d) of Section 10965.3.

SEC. 6. *Section 10181.8 is added to the Insurance Code, to read:*

10181.8. *A health insurance policy subject to Section 10181.3 or 10181.4 shall file a separate schedule documenting the cost savings associated with Section 10176.11 and the impact on rates.*

SEC. 7. *For financially interested entities covered by Advisory Opinion No. 97-1 issued by the United States Department of Health and Human Services Office of Inspector General, Sections 3 to 6, inclusive, of this act shall become operative on July 1, 2020, unless one or more parties to Advisory Opinion 97-1 requests an updated opinion from the United States Department of Health and Human Services Office of Inspector General and notifies the Department of Managed Health Care and the Department of Insurance of that request, in writing, including a copy of the request. If the notification and copy of the request are received by the departments prior to July 1, 2020, Sections 3 to 6, inclusive, of this act shall become operative with respect to those entities upon a finding by the United States Department of Health and Human Services Office of Inspector General, in accordance with Section 1128D(b) of the federal Social Security Act (42 U.S.C. Sec. 1320a-7d(b)) and Part 1008 (commencing with Section 1008.1) of Subchapter B of Chapter V of Title 42 of the Code of Federal Regulations, that compliance with those sections by a financially interested entity does not violate the federal laws addressed by Advisory Opinion 97-1 or a successor agreement. Each department shall post any notice received pursuant to this section and a copy of the request on its internet website.*

SEC. 8. *No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE; STEPHEN ALBRIGHT; AMERICAN KIDNEY FUND, INC.; and DIALYSIS PATIENT CITIZENS, INC.,

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

8:19-cv-2105-DOC-(ADSx)

DEFENDANTS' STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

PROVISIONALLY REDACTED PURSUANT TO PENDING APPLICATION FOR LEAVE TO FILE UNDER SEAL

Date: May 2, 2022
Time: 8:30 a.m.
Courtroom: 9D
Judge: The Honorable David O. Carter
Trial Date: July 12, 2022
Action Filed: November 1, 2019

TO PLAINTIFFS AND THEIR ATTORNEYS OF RECORD:

Pursuant to C.D. Cal. Local Rule 56-1, Defendants ROB BONTA, RICARDO LARA, SHELLY ROUILLARD, and TOMÁS J. ARAGÓN (Defendants) submit the following statement of uncontroverted facts and conclusions of law in support of their concurrently filed Motions for Summary Judgment in this action.

DEFENDANTS' STATEMENT OF UNCONTROVERTED FACTS

NO.	UNCONTROVERTED FACTS	SUPPORTING EVIDENCE
1.	End-stage renal disease "is irreversible and permanent."	Plank Decl., ¶ 2, Ex. 1c (CA1759).
2.	ESRD patients require a kidney transplant or regular dialysis to survive.	*Id.*
3.	Recognizing the necessity and high costs of treatment, Congress permitted ESRD patients, regardless of age, to obtain Medicare coverage when it enacted the Social Security Amendments of 1972.	*Id.*
4.	Medicare covers a range of services to treat kidney failure, including transplant and dialysis services, along with other health care needs.	*Id.*

5.	Some patients may qualify for and receive coverage through both Medicare and Medi-Cal, California's Medicaid system.	*See* Plank Decl., ¶ 2, Ex. 1c (CA1760).
6.	In 2010, the Patient Protection and Affordable Care Act (ACA) enacted a set of reforms "to make health insurance more affordable and accessible to millions of Americans." One such reform, which took effect on January 1, 2014, "prohibited insurers . . . from imposing pre-existing condition exclusions" and required them "to guarantee the availability and renewability of non-grandfathered health plans to any applicant." Under this "guaranteed issue" provision, among other ACA provisions, ESRD patients can no longer be denied coverage or charged higher premiums based on their health status.	*Id*.
7.	These provisions of the ACA, together with the "higher reimbursement rates available	Plank Decl., ¶ 8, Ex. 6 (Expert Report of Randolph Wayne Pate, JD, MPH (Pate Report), p. 5).

	through private coverage when compared to Medicare," "in effect created a financial incentive for dialysis facilities to leverage [the higher rates] by providing premium assistance to ESRD patients"—primarily through a third party entity, Plaintiff AKF—"and inappropriately steering them to purchase coverage in the individual market."	
8.	HHS became concerned that health care providers were "encouraging individuals to make coverage decisions based on the financial interest of the health care provider, rather than the best interests of the individual patients."	Plank Decl., ¶ 2, Ex. 1c (CA1761).
9.	Based on this concern, the Centers for Medicare & Medicaid Services (CMS), a subdivision of HHS, issued a Request for Information on August 23, 2016, seeking public comment "about health care providers and	Plank Decl., ¶ 2, Ex. 1c (CA1753).

	provider-affiliated organizations steering people eligible for or receiving Medicare and/or Medicaid benefits to an individual market plan for the purpose of obtaining higher payment rates."	
10.	In response, CMS received over 800 public comments from patients, providers, and other stakeholders, which "documented a range of concerning practices, with providers and suppliers"—such as DaVita and Fresenius—"influencing enrollment decisions in ways that put the financial interest of the supplier above the needs of patients."	Plank Decl., ¶ 2, Ex. 1c (CA1761).
11.	In particular, commenters noted that patients "are sometimes specifically discouraged from pursuing Medicare or Medicaid" and "are unaware that a dialysis facility is seeking to enroll them in the individual market," and that facilities "retaliate against social workers who attempt to	Plank Decl., ¶ 2, Ex. 1c (CA1765).

	disclose additional information to consumers."	
12.	Commenters agreed that these practices are fueled by a powerful incentive—the considerably higher rates that commercial coverage reimburses dialysis providers as compared to public coverage.	Plank Decl., ¶ 2, Ex. 1c (CA1761), Ex. 1d (CA2109).
13.	HHS's own data and the comments "suggest[ed] that this inappropriate steering of patients may be accelerating over time."	Plank Decl., ¶ 2, Ex. 1c (CA1765).
14.	The comments also reflected three types of possible harms to patients: "[n]egatively impacting patients' determination of readiness for a kidney transplant, potentially exposing patients to additional costs for health care services, and putting individuals at significant risk of a mid-year disruption in health care coverage."	Plank Decl., ¶ 1c (CA1762).
15.	Comments also "indicat[ed] that inappropriate steering practices"—which add ESRD	Plank Decl., ¶ 2, Ex. 1c (CA1773).

	patients to the individual market—"could have the effect of skewing the insurance risk pool."	
16.	In the face of such harms, "which go to essential patient safety and care in life-threatening circumstances," CMS issued an interim final rule establishing new standards for Medicare-certified dialysis facilities that pay premiums for individual market health plans, whether directly or through another entity.	Plank Decl., ¶ 2, Ex. 1c (CA1765).
17.	Shortly after that rule was issued, it was enjoined for alleged failure to comply with Administrative Procedures Act requirements. That decision was not appealed.	*See Dialysis Patient Citizens v. Burwell*, No. 4:17-cv-00016-ALM, 2017 WL 365271 (E.D. Tex. Jan. 25, 2017).
18.	In the absence of federal regulations addressing inappropriate steering of dialysis patients, states across the country, such as California, Delaware, Idaho, Louisiana, Minnesota, New Mexico, North	Plank Decl., ¶ 2, Ex. 1d (CA2595-2596).

	Carolina, Oregon, and Washington, took action.	
19.	In 2018, the California Legislature passed Senate Bill 1156, a predecessor to AB 290.	Plank Decl., ¶ 2, Ex. 1d (CA2482).
20.	Governor Brown vetoed SB 1156 because it "would permit health plans and insurers to refuse premium assistance and to choose which patients they will cover."	Plank Decl., ¶ 2, Ex. 1d (CA2585).
21.	Given that third party entities such as AKF often provide patients with debit cards that patients then use to pay their premiums, prohibiting providers from directly billing enrollees facilitates the identification of patients receiving premium assistance.	Plank Decl., ¶ 2, Ex. 1b (CA595).
22.	After AB 290 was signed by Governor Newsom in October of 2019, AKF planned to leave California at the end of 2019, despite a concerted effort by the Legislature to amend AB 290 to address AKF's concerns.	Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-807).

23.	The steering prohibition in AB 290 primarily regulates patient interactions with dialysis social workers and insurance counselors, who are tasked with helping patients "obtain insurance and apply for financial assistance," and who "may face a perceived or actual conflict of interest in doing so, since they may recommend insurance options that help patients remain on dialysis and maximize profits for the dialysis centers in which they work."	Plank Decl., ¶ 10, Ex. 8 (Supplemental Expert Report of Amy D. Waterman, PhD (Waterman Supp. Report), p. 1); *see also* ¶ 8, Ex. 6 (Pate Report, p. 12).
24.	Documents in the legislative record, including J.P. Morgan research reports, detail how critical commercial patients are to Plaintiffs' bottom line.	Plank Decl., ¶ 2, Ex. 1d (CA2091, CA2101, CA2104); *see also id.*, ¶ 9, Ex. 7 (Expert Report of Amy D. Waterman, PhD (Waterman Report), pp. 3-4).
25.	Plaintiffs' communications with shareholders also indicate that commercial patients are critical to Plaintiffs' bottom line.	Plank Decl., ¶ 6, Ex. 4a (FMC3049-3050).
26.	[redacted]	*See*, *e.g.*, Plank Decl., ¶ 6, Ex. 4b (FMC4931).

	[redacted]	
27.	The SB 1156 legislative record refers to a Washington Office of the Insurance Commissioner (OIC) order requiring DaVita "to immediately stop engaging in the business of unauthorized insurance via steering dialysis patients into higher reimbursing plans by offering to pay premiums."	Plank Decl., ¶ 2, Ex. 1d (CA2596).
28.	Washington OIC took enforcement action after learning that DaVita insurance coordinator Cary Ancheta had attempted "to sign up approximately 30 kidney dialysis patients, most of whom [we]re receiving Medicaid," onto commercial insurance.	Plank Decl., ¶ 2, Ex. 1e (CA3072-3074, CA3171-3173 (transcript of Ancheta call)).
29.	The Washington OIC order was rescinded by stipulation of the parties on the condition, among other requirements, that DaVita counselors "not ask or urge	Plank Decl., ¶ 2, Ex. 1e (CA3097-3100).

	dialysis patients to enroll in any particular kind of insurance from any particular insurer" for a period of two years.	
30.	That investigation also uncovered evidence provided by a former DaVita social worker of a DaVita PowerPoint presentation directing insurance counselors and social workers "to 'target' Medicaid eligible patients to get them to purchase commercial insurance."	Plank Decl., ¶ 2, Ex. 1e (CA3072).
31.	Known as "Medicaid Opportunity," this program, which began in 2015, was designed to increase the number of Medicaid patients enrolled in an individual market plan (paid for with HIPP assistance) as primary coverage.	Plank Decl., ¶ 7, Ex. 5b (DAV14359 (WebEx presentation about Medicaid Opportunity program, and transcription presentation for the Court's convenience)); *id*., ¶ 16, Ex. 14a (Deposition of Corey Danko taken on November 11, 2021 (Danko Dep.) 111:15-113:15; Danko Dep. Ex. 3).
32.	DaVita set about to discuss this "absolutely amazing opportunity" with "every single" patient on Medicaid.	Plank Decl., ¶ 16, Ex. 14a (Danko Dep. 177:20-178:23).

33.	DaVita considered this program a "true win-win situation" for patients and DaVita.	Plank Decl., ¶ 16, Ex. 14a (Danko Dep. 182:24-183:3, 214:1-25).
34.	DaVita's efforts to enroll patients in HIPP to facilitate the move to private primary insurance were meticulously tracked, and staff were urged to use "additional hours" to ensure that every patient was "educated" on HIPP availability.	*Id.*, ¶ 16, Ex. 14a (Danko Dep. 207:13-24, Ex. 3, pp. 3-9).
35.	[redacted]	Plank Decl., ¶ 16, Ex. 14b (Deposition of Steve Dover taken on November 18, 2021 (Dover Dep.) 119:11-120:1); *id.*, ¶ 6, Ex. 4b (FMC4926); *see also id.*, ¶ 16, Ex. 14b (Dover Dep. 148:5-9).
36.	[redacted]	Plank Decl., ¶ 16, Ex. 14b (Dover Dep. 47:2-8, 48:6-18, 50:10-51:19, 63:6-24, 64:5-65:24, 66:1-67:4); *id.*, ¶ 6, Ex. 4b (FMC4940, FMC4941-4943); *see also id.*, ¶ 16, Ex. 14b (Dover Dep. 69:8-25, 70:5-14, 72:11-23).

	[redacted]	
37.	One federal court, observing that DaVita's "own definition of 'steering' [] as legal communications with ESRD patients" was "a weak plausible alternative explanation as to the meaning of the statement that it 'does not steer,'" concluded that there was a "strong inference that [DaVita] made statements about steering and the source of [DaVita's] financial success with the intent to manipulate, deceive, or defraud."	*Peace Officers' Annuity and Benefit Fund of Ga. v. DaVita Inc.*, 372 F. Supp. 3d 1139, 1143, 1147, 1155 (D. Colo. 2019).
38.	Another federal court determined that it was "reasonable to infer . . . that the Medicaid Opportunity initiative was part of a larger, systematic plan by DaVita's management to drive revenues and profitability through [DaVita's] AKF donations."	*In re DaVita Inc. v. Stockholder Derivative Litig.*, No. 17-152-MPT, 2019 WL 1855445, *14 (D. Del. Apr. 25, 2019); *id.* at *1, *12.
39.	This industry scheme to steer patients into private insurance has also been the focus of	Plank Decl., ¶ 2, Ex. 1d (CA2328-2329).

	countless news articles and investigative journalism.	
40.	Patients steered into commercial insurance who would have been eligible for a kidney transplant under Medicare may be unable to demonstrate the financial means to care for a new kidney, given that HIPP assistance ends within months to a year of transplant.	Plank Decl., ¶ 9, Ex. 7 (Waterman Report, pp. 4-5); *id*., ¶ 2, Ex. 1c (CA1826-1829 (Browne letter)).
41.	This "threat of cessation of health insurance benefits" not only impairs transplant eligibility but "may induce some patients to remain on dialysis and never pursue transplant."	Plank Decl., ¶ 10, Ex. 8 (Waterman Supp. Report, pp. 3-4).
42.	Patents steered into commercial insurance are saddled with high out-of-pocket expenses post-transplant when HIPP assistance ends, which may lead them to stop taking their immunosuppressant drugs, causing their transplant to fail.	Plank Decl., ¶ 9, Ex. 7 (Waterman Report, p. 5); *id*., ¶ 8, Ex. 6 (Pate Report, p. 16); *id*., ¶ 2, Ex. 1c (CA1826-1829).
43.	Patients who are unable to "make other arrangements" face mid-year disruptions in coverage,	Plank Decl., ¶ 9, Ex. 7 (Waterman Report, p. 5).

	leading to similarly bad outcomes.	
44.	Various researchers and other groups have examined the potential scope of the distortion to the insurance market caused by the scheme to steer patients into commercial insurance.	Plank Decl., ¶ 11, Ex. 9 (Expert Report of John Bertko, F.S.A., M.A.A.A. (Bertko Report), p. 7); *id*., ¶ 16, Ex. 14c (Deposition of John Bertko taken on January 13, 2022, 175:1-13); *id*., ¶ 12, Ex. 10 (Supplemental Expert Report of John Bertko, F.S.A., M.A.A.A. (Bertko Supp. Report), pp. 2-3); *id*., ¶ 2, Ex. 1c (CA1917-1938 (AHIP letter)), *id*., ¶ 4, Ex. 2c (AKF-DOE-10132).
45.	Placing guardrails on staff communications with patients by banning steering would alleviate these harms by "remov[ing] a potential conflict of interest" from staff-patient interactions, providing the space for independent advocacy organizations, such as the Health Insurance Counseling and Advocacy Program (HICAP), to step in to "help patients navigate the complexities of their different insurance options."	Plank Decl., ¶ 10, Ex. 8 (Waterman Supp. Report, p. 4); *id*., ¶ 9, Ex. 7 (Waterman Report, p. 6).

46.	Together with the disclosure requirements, the steering prohibition "[i]ncrease[]s transparency regarding coverage options and third-party premium payments," which "is important for patients to be able to make informed decisions and minimize their potential exposure to financial liabilities."	Plank Decl., ¶ 8, Ex. 6 (Pate Report, p. 23).
47.	Reimbursement rates for commercial coverage are considerably higher than for public coverage, and evidence in the CMS record shows that providers "therefore have much to gain financially (on the order of tens or even hundreds of thousands of dollars per patient) by making a relatively small outlay to pay an individual's premium to enroll in commercial coverage so as to receive a much larger payment for providing an identical set of health care services."	Plank Decl., ¶ 2, Ex. 1c (CA1761).

48.	Evidence in the CMS record also shows that Plaintiffs "[s]upport[] premium payments to facilitate enrollment of their patients in individual market coverage."	*Id.*
49.	The "only way" in which AKF can afford to pay the premiums of commercially-insured patients is for providers to pay their "fair share."	Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-805); *see also id.,* ¶ 4, Ex. 2b (AKF-DOE-10060), *id.,* ¶ 2, Ex. 1c (CA1782-1806 (Blue Cross letter), CA1964-1972 (UHC letter)).
50.	For a time, AKF "request[ed] that [an] organization not refer [] patients to the HIPP program" "if [the] company [could] not make fair share contributions."	Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-806), Ex. 2b (AKF-DOE-10060); *see also id.,* ¶ 4, Ex. 2c (AKF-DOE-10078), Ex. 2d (AKF-DOE-10097).
51.	[redacted]	Plank Decl., ¶ 4, Ex. 2f (AKF-DOE-10136).
52.	[redacted]	*Id.*

53.	[redacted]	*Id*.
54.	In November 2018, DaVita sent a letter informing AKF that it anticipated contributing [redacted] during the period of February 1, 2019, through January 31, 2020.	Plank Decl., ¶ 7, Ex. 5a (DAV8275).
55.	In June 2019, DaVita sent an "[a]djustment [l]etter" modifying its contribution to [redacted].	Plank Decl., ¶ 7, Ex. 5a (DAV8274).
56.	Later, in November 2019, DaVita sent a second adjustment letter further modifying its contribution to [redacted]	Plank Decl., ¶ 7, Ex. 5a (DAV8273).
57.	The very precise amounts of each contribution, as well as the periodic "adjustments," underscore the direct connection between Plaintiffs' annual "fair share" contribution amount and the premium assistance that AKF provides to their patients.	*See* Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-805).

58.	The arrangement between AKF and the providers is "a business strategy rather than a form of charity."	Plank Decl., ¶ 8, Ex. 6 (Pate Report, p. 8).
59.	By "eliminat[ing] preferentially high reimbursement rates for privately insured dialysis patients," the reimbursement cap removes an "incentive to keep patients on dialysis," and serves California's interest in "provid[ing] needed protections for kidney patients."	Plank Decl., ¶ 10, Ex. 8 (Waterman Supp. Report, p. 4).
60.	The provision in AB 290 that prohibits a financially interested entity like AKF from making a third-party premium payment unless it discloses to a health insurer the name of each insured patient who will receive premium assistance "supports transparency for ESRD patients" and "assist[s] [patients] in making informed decisions about how to finance their own care by removing potentially ethically compromising dynamics between	*Id.*

	AKF, dialysis providers, and private insurance companies."	
61.	Plaintiffs' interests do not align with those of their patients.	*See, e.g.*, Plank Decl., ¶ 10, Ex. 8 (Waterman Supp. Report, pp. 1, 2 (citing Paul J. Eliason, *How Acquisitions Affect Firm Behavior and Performance: Evidence From the Dialysis Industry*, Quarterly Journal of Economics (February 2020), https://doi.org/10.1093/qje/qjz034), 3-4).
62.	AKF not only opposed AB 290, but notified the Legislature that it would "be forced to shut down in California if AB 290 is enacted" because, as AKF President and CEO LaVarne Burton stated, "AB 290 would take us outside of the protections of our Advisory Opinion."	Request for Judicial Notice, Ex. 1 (excerpt from testimony of AKF President and CEO LaVarne Burton at July 3, 2019 California Senate Health Committee meeting).
63.	Advisory Opinion 97-1, issued by HHS's OIG in 1997 at AKF's request, concluded that AKF's practice of paying Medicare Part B and Medigap premiums for ESRD patients in financial need did not violate the federal	Plank Decl., ¶ 2, Ex. 1a (CA92).

	prohibition against providing remuneration to Medicare-eligible individuals if such remuneration is likely to influence the individual's health care choices.	
64.	OIG found it significant that AKF, rather than dialysis providers, determined which patients would receive AKF's Health Insurance Premium Program (HIPP) assistance and that HIPP assistance was available regardless of the patient's provider.	Plank Decl., ¶ 2, Ex. 1a (CA97).
65.	Advisory Opinion 97-1 specifies that it is "case specific" and "is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope."	Plank Decl., ¶ 2, Ex. 1a (CA99).
66.	California's Legislative Counsel concluded that based on the available facts, AKF "would remain in compliance with the	Plank Decl., ¶ 2, Ex. 1a (CA42).

	arrangement approved in Advisory Opinion 97-1" if AB 290 is enacted and AKF "complies with the changes enacted by that bill."	
67.	Much has changed since Advisory Opinion 97-1 was issued, as back then ESRD patients generally lacked access to commercial insurance, and "less than ten percent" of donations to AKF were from companies that owned dialysis providers.	Plank Decl., ¶ 2, Ex. 1a (CA94).
68.	At the time the Advisory Opinion was issued, patients with ESRD were usually unable to obtain commercial insurance because ESRD was an expensive pre-existing condition.	Plank Decl., ¶ 8, Ex. 6 (Pate Report, pp. 4-5).
69.	After the ACA was enacted in 2010, many more patients with ESRD were able to access commercial insurance because the ACA prohibits insurance companies from discriminating	*Id*.

	against patients with pre-existing conditions.	
70.	Reforms under the ACA have led to the expansion of AKF's HIPP assistance to pay the premiums of commercially-insured patients, and the contributions of "[l]arge dialysis companies" have grown to "more than 80 percent" of AKF's revenue.	AB 290, § 1(h); *see also* Plank Decl., Ex. 3 (AKF RFP Response 11).
71.	AKF maintained its plans to leave California at the end of 2019, despite amendments largely delaying AB 290's implementation.	Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-807).
72.	The fact that other types of coverage options have been created since 1997 does not shift the scope of Advisory Opinion 97-1 because the Opinion is by its own terms limited to federal health care programs, and thereby expressly excludes programs such as Qualified Health Care Programs, Covered California, employer group plans, or private insurance.	Plank Decl., ¶ 2, Ex. 1a (CA96-98); *id*., ¶ 8, Ex. 6 (Pate Report, pp. 6-7).

73.	AB 290 and Advisory Opinion 97-1 both require that financial assistance not be conditioned on the use of a specific facility or health care provider.	Plank Decl., ¶ 2, Ex. 1a (CA96-98); AB 290, §§ 3(b)(2) & 5(b)(2).
74.	If AB 290 were to go into effect, a HIPP recipient would be highly unlikely to learn of their dialysis providers' donor status through the disclosure of information required of AKF by AB 290.	Plank Decl., ¶ 8, Ex. 6 (Pate Report, pp. 19-22).

CONCLUSIONS OF LAW

1. Summary judgment is proper where no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). While the Court must draw all reasonable inferences in favor of the nonmoving party, *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), Rule 56(c) "mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

2. Under the governing test from *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983), speech may be "characterized as commercial when (1) the speech is admittedly advertising, (2) the speech references a specific product, and (3) the speaker has an economic motive for engaging in the speech." *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1106 (9th Cir. 2004) (citing *Bolger*, 463 U.S. at 66-67). While the combination of all of these characteristics strengthens the conclusion that the speech at issue is "properly characterized as commercial

speech," it is not necessary for "each of the characteristics" to "be present in order for speech to be commercial." *Bolger*, 463 U.S. at 67 n.14. The steering prohibition meets the latter two *Bolger* factors, and thus implicates commercial speech.

3. Because commercial speech is at issue, intermediate scrutiny applies: AB 290 must directly advance a substantial governmental interest and do so in a manner that is not more extensive than necessary. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). Put another way, AB 290 must tackle harms that are "real" and must "in fact alleviate them to a material degree." *See Edenfield v. Fane*, 507 U.S. 761, 771 (1993). AB 290 meets this standard because it tackles harms that are real and alleviates them to a material degree. *Id*.

4. A statute will generally survive a vagueness challenge so long as the speaker is not "compelled to steer too far clear of any forbidden area" of speech. *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 588 (1998) (internal quotation marks omitted). Indeed, "perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity." *Edge v. City of Everitt*, 929 F.3d 657, 664 (9th Cir. 2019) (quoting *United States v. Williams*, 553 U.S. 285, 304 (2008)).

5. AB 290's steering prohibition is sufficiently definite to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Edge v. City of Everitt*, 929 F.3d at 664 (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)). Here, the terms "steer," "direct," and "advise" are not difficult to understand, particularly "when read in context with the entire provision." *Hunt v. City of Los Angeles*, 638 F.3d 703, 714 (9th Cir. 2011). The steering prohibition addresses the concerning practice of "[e]ncouraging patients to enroll in commercial insurance coverage for the financial benefit of the provider." AB 290, § 1(c). Its purpose is thus to "shield patients

from potential harm caused by being steered into coverage options that may not be in their best interest." *Id.*, § 1(i). Taken together, the phrase "steer, direct, or advise" covers, in a comprehensive manner, the forms of encouragement prohibited by the statute. When "used in combination," these terms "provide sufficient clarity." *Edge*, 929 F.3d at 665 (quoting *Gammoh v. City of La Habra*, 395 F.3d 1114, 1120 (9th Cir. 2005)). Providing factual information or answering questions about plan options is permissible; telling or prompting a patient to choose a certain option is not. These terms are "reasonably ascertainable to a person of ordinary intelligence." *Id*. at 666.

6. AB 290's reimbursement cap does not burden Plaintiffs' right of association. As the Court posited at the outset of the case, it is merely "a restriction on economic activity or nonexpressive conduct" because Plaintiffs' donations are not an "expressive avenue by which providers join and support AKF's mission," but a quid pro quo arrangement that "secure[s] a later 'return on investment' in the form of higher private insurance reimbursements." *See* ECF No. 58 at 10-11; *cf. Lair v. Motl*, 873 F.3d 1170, 1172 (9th Cir. 2017) (upholding state law that regulated campaign contributions for the purpose of "combating quid pro quo corruption or its appearance"). Rather than burden Plaintiffs' expressive interests, the reimbursement cap regulates conduct that is not "actually under the aegis of the First Amendment." *See id.* at 11; *see also Interpipe Contracting, Inc. v. Becerra*, 898 F.3d 879, 892 n.11 (9th Cir. 2018) (observing that plaintiff bringing expressive association claim must show that the challenged law "regulates speech, not just conduct")

7. In *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626(1985), the Supreme Court held that Ohio could require lawyers advertising contingency arrangements to disclose that clients might be liable for litigation costs if their cases were unsuccessful. *Id.* at 650-53. Noting the "material differences between disclosure requirements and outright prohibitions on speech,"

the Court recognized that there is only a "minimal" constitutionally protected interest in not providing "factual and uncontroversial information" to a consumer. *Id.* at 650, 651. The Court concluded that such disclosure requirements do not implicate First Amendment concerns as long as they "are reasonably related to the State's interest in preventing deception of consumers." *Id*. at 651.

8. Consistent with *Zauderer*, the Court has repeatedly acknowledged the government's authority to require disclosures of factual information that promote transparency. The Court has made clear that a requirement for fundraisers to "disclose unambiguously" their paid status "would withstand First Amendment scrutiny," *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 799 n.11 (1988); has upheld a federal statute requiring attorneys advertising debt relief assistance to disclose that such relief would likely involve filing for bankruptcy, *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010); and has observed that a statutorily mandated disclosure of a film's connection to a federally registered agent of a foreign government would "better enable the public to evaluate the [film's] import," *Meese v. Keene*, 481 U.S. 465, 480 (1987). The Court has also long recognized that requiring entities—including charitable organizations—to "report certain information" on a routine basis does not offend First Amendment interests. *Village of Schaumburg v. Citizens for a Better Env't*, 444 U.S. 620, 637-38 n.12 (1980); *Riley*, 487 U.S. at 800 (same).

9. The Court's decision in *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (*NIFLA*) did not undermine this precedent. There, the Court held that the *Zauderer* standard applies only if the compelled disclosure involves "purely factual and uncontroversial" information. *Id.* at 2372. In so holding, the Court "d[id] not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *Id.* at 2376. Thus, "[u]nder *Zauderer*, compelled disclosure of commercial speech complies with the First Amendment if the information in the

disclosure is reasonably related to a substantial governmental interest and is purely factual and uncontroversial." *CTIA – The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 845 (9th Cir. 2019).

10. AB 290 requires a financially interested entity like Plaintiff AKF to inform HIPP recipients of "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and employer plans." AB 290, §§ 3(b)(3) & 5(b)(3). AB 290 similarly prohibits a financially interested entity from making a third-party premium payment unless it provides an annual statement of compliance with the law and discloses to a health insurer the name of each insured patient who will receive premium assistance. *Id.*, § 3(c).

11. AB 290's disclosure provisions meet the *Zauderer* standard: they implicate commercial speech, are reasonably related to a substantial governmental interest, and are purely factual and uncontroversial. Like the steering prohibition, the disclosure provisions regulate the discussion of a specific commercial product—in particular, commercial insurance products—which Plaintiffs have an economic motive to promote. The disclosed information is also "purely factual and uncontroversial," as that requirement was further defined in NIFLA. There, the Court specified that a purely factual statement was not uncontroversial where the statement "took sides in a heated political controversy." *CTIA*, 928 F.3d at 845 (citing *NIFLA*, 138 S. Ct. at 2372). The Court further required that the statement "relate to the product or service that is provided by an entity subject to the requirement." *Id.* (citing *NIFLA*, 138 S. Ct. at 2372). Here, the disclosure provisions require a financially interested entity to make truthful and neutral statements about a patient's health coverage options and receipt of premium assistance, *see* AB 290, §§ 3(b)(3), 3(c)—subjects that relate directly to the HIPP assistance that AKF provides patients. These "purely factual and uncontroversial" statements meet the *Zauderer* standard, and thus, permissibly regulate speech.

12. AB 290 does not abridge the right to petition. Plaintiffs allege that Section 7

of AB 290, which allows AKF to request an updated advisory opinion, abridges its freedom to petition "by compelling AKF to file a petition it actually opposes." Compl. ¶ 105. This argument mischaracterizes Section 7. That section is not a "mandate," *see id.*; it merely provides AKF the *option* to request an updated advisory opinion. Without "a coerced nexus between the individual and the specific expressive activity," there is no First Amendment violation. *See Cal-Almond, Inc. v. U.S. Dep't of Agric.*, 14 F.3d 429, 435 (9th Cir. 1993).

13. AB 290 is not preempted by federal law. "[B]ecause the States are independent sovereigns in our federal system," preemption analysis must begin "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Plaintiffs have not demonstrated any actual conflict between a federal regulation and the steering prohibition. AB 290 can and should be interpreted in a manner consistent with federal law. *Cal. Ins. Guarantee Ass'n v. Azar*, 940 F.3d 1061, 1071 (9th Cir. 2019) ("Well-established preemption principles favor upholding state law if it can plausibly coexist with the federal statute.")

14.*Doe* Plaintiffs' arguments regarding the preemptive effect of Advisory Opinion 97-1 fail because it is black letter law that "[i]nterpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all . . . lack the force of law[.]" *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); *see also Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 643 (2013) (agency memorandum and letter approving of state statutory scheme for Medicaid reimbursement were "opinion letters, not regulations with the force of law"); *United States v. Mead Corp.*, 533 U.S. 218, 233 (2001) (federal agency's "classification ruling" letters did not have the force of law when agency did not engage in notice-and-comment, and did not bind third parties). Although "an agency regulation with the force of law can pre-empt conflicting state

requirements," an agency action that was not the product of notice-and-comment rulemaking does not have the force of law and thus cannot, by itself, have preemptive effect. *Wyeth v. Levine*, 555 U.S. 555, 576, 580 (2009) (cleaned up); *see also Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) (Ninth Circuit "declin[es] to afford preemptive effect to agency actions that do not carry the force of law under *Mead* and its progeny"). Accordingly, Advisory Opinion 97-1 does not have the force of federal law or regulation and cannot preempt AB 290.

15. *Doe* Plaintiffs' argument regarding the preemptive effect of Advisory Opinion 97-1 fail because there is no conflict between the Opinion and AB 290. The Advisory Opinion does not discuss premium payments for commercial insurance or group health coverage. Thus, the Opinion's restrictions would apply only to payments for Medicare Part B or Medigap premiums, neither which fall within the scope of AB 290. *See* AB 290, §§ 3(h)(3) & 5(h)(2) (no application to "coverage of Medicare services pursuant to contracts with the United States government [or] Medicare supplement coverage").

16. AB 290 does not conflict with the "take into account" provision or the "non-differentiation" provisions of the Medicare Secondary Payer Act. The "take into account" provision prohibits group health plans from "tak[ing] into account that an individual [with ESRD] is entitled to or eligible for [Medicare] benefits" for the first thirty months of eligibility. 42 U.S.C. § 1395y(b)(1)(C)(i). Similarly, the "nondifferentiation" requirement provides that group health plans "may not differentiate in the benefits [they] provide[] between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner" during the first thirty months of Medicare eligibility. *Id.* § 1395y(b)(1)(C)(ii). Prohibited "differentiation" includes "[i]mposing on persons who have ESRD, but not on others enrolled in the plan, benefit limitations" and "[p]aying providers and suppliers less for services furnished to individuals who

have ESRD than for the same services furnished to those who do not have ESRD . . . ." 42 C.F.R. §§ 411.161(b)(ii), (iv). The "pertinent inquiry' is "whether the plan's provisions 'result' in *different benefits for persons with ESRD*, not whether the plan's provisions disproportionately affect persons with ESRD or otherwise 'discriminate' against persons with ESRD." *DaVita Inc. v. Amy's Kitchen, Inc.*, 981 F.3d 664, 674-75 (9th Cir. 2020). Plaintiffs do not—and cannot—show that AB 290 requires health plans to treat patients differently based on their Medicare eligibility or their ESRD status. Although treatments provided to HIPP recipients may be reimbursed at a lower rate, that is not a result of a patient's eligibility or non-eligibility for Medicare. The statute makes no distinction among patients based on their Medicare eligibility; a plan can "ignore[]" this factor. *Amy's Kitchen*, 981 F.3d at 670. Nor does the statute require differentiation between patients based on their ESRD status; a plan can "provide[] identical benefits to someone with ESRD as to someone without ESRD" and thus "not 'differentiate' between those two classes." *Id.* at 678. AB 290 comports with the MSPA.

17. *Fresenius* Plaintiffs' obstacle preemption argument assumes a conflict, not with a specific federal statutory provision or requirement, but with an alleged federal policy that Plaintiffs contend is broadly reflected in the Medicare Act, the Medicare Secondary Payer Act, and the ACA. Compl. ¶¶ 35, 130-133. These statutes purportedly embody a general federal policy of "ensuring ESRD patient access to care; protecting patient choice in insurance; and safeguarding the stability of the dialysis system by spreading the high costs of dialysis treatment among private and public insurers." Compl. ¶¶ 130-133. This argument fails because preemption cannot be based on an amorphous federal policy, even if such a policy existed. "Invoking some brooding federal interest or appealing to a judicial policy preference should never be enough to win preemption of a state law; a litigant must point specifically to 'a constitutional text or a federal statute' that does the displacing or conflicts with state law," or that authorizes an agency to do so. *Va.*

Uranium, Inc. v. Warren, 139 S. Ct. 1894, 1901 (2019) (lead opinion of Gorsuch, J) (cleaned up). Here, although the policy goals that Plaintiffs rely on might be consistent with various federal statutes, that does not mean that those goals have the *force* of any of those statutes. A federal policy, by itself, cannot preempt. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019) ("The Supremacy Clause grants 'supreme' status only to the 'the *Laws* of the United States.'") (citing U. S. Const., Art. VI, cl. 2., emphasis in opinion); *Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 357 (1986) (rejecting a federal agency's attempt to preempt based solely on its own determination that preemption would "best effectuate a federal policy").

18. *Fresenius* Plaintiffs' Contract Clause cause of action fails because the reimbursement cap does not "operate[] as a substantial impairment of a contractual relationship." *Gen. Motors Corp. v. Romein*, 503 U.S. 181, 186 (1992). The Contracts Clause does not trump the police power of a state to protect the general welfare of its citizens, a power which is paramount to any rights under contracts between individuals. *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 241 (1978). Plaintiffs have not shown impairment of any specific contractual right held by the providers that would not under normal circumstances be subject to regulation by the State.

19. No contract between a medical provider and an insurer can avoid the application of state law to the reimbursement rates provided. *See Campanelli v. Allstate Life Ins. Co.*, 322 F.3d 1086, 1098 (9th Cir. 2003) ("One whose rights, such as they are, are subject to state restriction, cannot remove them from the power of the State by making a contract about them.") That the insurance market is already heavily regulated by state and federal law weighs against any finding of impairment, much less substantial impairment. "In determining the extent of the impairment, a court must consider 'whether the industry the complaining party has entered has been regulated in the past." *Id*. at 1098. If the answer is yes, "then the

impairment is less severe because '[o]ne whose rights, such as they are, are subject to state restriction, cannot remove them from the power of the State by making a contract about them." *Id*.

20. Article III standing requires a party to show that (1) it has suffered a concrete and particularized "injury in fact" that is "actual or imminent" and not hypothetical; (2) the injury is "fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court;" and (3) it is likely the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *Clapper v. Amnesty Intern. USA*, 568 U.S. 398, 409 (2013) ("possible future injuries that depend on a speculative chain of possibilities that may not occur are not sufficient").

21. *Fresenius* Plaintiffs' substantive due process claim fails because they cannot establish standing. Plaintiffs do not set forth specific facts demonstrating a concrete injury that is non-speculative or fairly traceable to AB 290 because their alleged injury stems from third-party AKF's threatened cessation of operations in California, not AB 290's provisions. *See, e.g.*, Compl. ¶¶ 106, 147-48. AB 290 does not compel AKF to stop providing assistance to ESRD patients in California. *Id*. ¶¶ 95, 98. Yet all of the alleged injuries are contingent on AKF's threatened departure from the state. *Id*. ¶¶ 106, 147. They depend on a "speculative chain of possibilities," and thus do not confer standing. *Clapper*, 568 U.S. at 411-12. Nor can Plaintiffs meet prudential standing requirements, *see Powers v. Ohio*, 499 U.S. 400, 410-413 (1991)—in particular, that their interests align with those of their patients.

22. *Fresenius* Plaintiffs' substantive due process claim also fails because the challenged provisions do not infringe on any fundamental right. Plaintiffs' assertion (Compl. ¶¶ 146, 149) that AB 290 interferes with a "fundamental right to lifesaving treatment"—a theory that is based on a dissenting opinion in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d

695 (D.C. Cir. 2007)—is incorrect as a matter of law. The range of liberty interests that substantive due process protects is narrow; "only those aspects of liberty that we as a society traditionally have protected as fundamental are included within the substantive protection of the Due Process Clause." *Mullins v. Oregon*, 57 F. 3d 789, 793 (9th Cir. 1995). The novel right asserted by Plaintiffs has never been recognized. Only "a clear showing of arbitrariness and irrationality" can overcome the presumption of legislative acts that do not impinge on fundamental rights. *Hodel v. Indiana*, 452 U.S. 314, 331-32 (1981).

23. *Fresenius* Plaintiffs' claim that AB 290 Section 3(i) violates their due process rights also fails, because the regulation does not penalize Plaintiffs for "the independent acts of others" and conduct they "had no ability to control." Compl. ¶¶ 158, 160. Instead, that section only allows for recovery of overpayments when a provider accepts a health plan's payment that exceeds the Medicare rate (or other applicable rate). All a provider would need to do to stay in compliance with this provision is decline to accept any overpayments from health plans for services to premium assistance recipients. Plaintiffs fail to establish a comprehensible basis for a claim their due process rights are denied by Section 3(i). *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976).

24. The Supreme Court has recognized that a per se taking occurs when an owner is deprived of "*all* economically beneficial uses" of the property, *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1019 (1992), and when "a regulation results in a physical appropriation of property," *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021). All other regulations of private property are governed by *Penn Central*'s balancing test, which considers (1) the character of the government action, (2) the economic impact of the regulation, and (3) the regulation's interference with reasonable investment-backed expectations. *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

25. *Fresenius* Plaintiffs' Takings Clause claim fails because none of the

Plaintiffs' purported harms constitute a taking. Any contention that the reimbursement cap—which has never taken effect—could be to blame for the closure of certain clinics or could "impos[e] significant economic losses" on Plaintiffs is highly speculative. This is not the sort of "'extraordinary case' in which a regulation permanently deprives property of all use." *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 303 (2002). Nor does the reimbursement cap "seize a sum of money from a specific fund." *Ballinger v. City of Oakland*, __ F. 4th __, 2022 WL 289180, *4 (9th Cir. 2022). Plaintiffs' takings claim is thus subject to the *Penn Central* framework—which "aims to determine whether a regulatory action is functionally equivalent to the classic taking." *Bridge Aina Le'a, LLC v. Land Use Comm'n*, 950 F.3d 610, 630 (9th Cir. 2020) (internal quotation marks omitted). Absent evidence of such injury—which Plaintiffs have yet to produce—this claim rests on "speculative possibilities" that do not rise to the level of a taking. *See id.* at 634.

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