XAVIER BECERRA
Attorney General of California
MARK R. BECKINGTON
Supervising Deputy Attorney General
P. PATTY LI
Deputy Attorney General
MARTINE D'AGOSTINO
Deputy Attorney General
KETAKEE KANE
Deputy Attorney General
KARLI EISENBERG
Deputy Attorney General
AMIE L. MEDLEY
Deputy Attorney General
State Bar No. 266586
300 South Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6226
Fax: (916) 731-2124
E-mail: Amie.Medley@doj.ca.gov
Attorneys for Defendants Xavier Becerra, Ricardo Lara, Shelly Rouillard, and Sonia Angell, in their official capacities

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.

XAVIER BECERRA, 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 SUSAN FANELLI, in her Official Capacity as Acting Director of the California Department of Public Health,

Defendants.

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

DEFENDANTS' OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

Date: December 16, 2019
Time: 8:30 a.m.
Dept: 9D
Judge: The Honorable David O. Carter
Trial Date: n/a
Action Filed: 11/5/2019

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

STATUTES

CONSTITUTIONAL PROVISIONS

OTHER AUTHORITIES

INTRODUCTION

The harms that Plaintiffs claim will flow from the California Legislature's passage of AB 290 are not harms inherent in the statute. Instead they flow entirely from an arbitrary decision by the American Kidney Fund (AKF)—backed by large dialysis companies that provide 80 percent of its funding—to cease supporting California patients with premium contribution payments effective January 1, 2020. AKF has made this decision even though AB 290 requires no action until July 1, 2020 at the earliest to ensure patient continuity of care; provides AKF with the option of tolling AB 290 after that date by seeking a revised opinion letter from the federal government; and includes other safe harbors designed by the Legislature to alleviate AKF's concerns. Whatever else Plaintiffs' papers show, one thing is clear: this is a self-manufactured dispute, one created entirely by the large dialysis providers and AKF, for reasons that remain elusive from the face of their complaints. This Court should decline Plaintiffs' invitation to enjoin an important state law, one designed to protect patients and reduce soaring health care costs, based on alleged injuries generated entirely by self-interested parties.

In enacting AB 290, the Legislature sought to protect patients on dialysis from higher out-of-pocket costs, mid-year disruptions in coverage, and difficulty in obtaining life-saving kidney transplants while also protecting the sustainability of risk pools in commercial insurance markets.[1] AB 290 contains provisions that prohibit organizations offering premium payment assistance to patients on dialysis (mainly AKF) from steering those patients toward a specific healthcare plan—particularly from steering patients eligible for Medicare or Medi-Cal (California's

[1] Plaintiffs are two individuals—Jane Doe and Stephen Albright—and two nonprofit corporations—the American Kidney Fund and Dialysis Patient Citizens, Inc. Plaintiffs have filed their motion in conjunction with the motion for preliminary injunction filed by the provider plaintiffs in *Fresenius Medical Care Orange County LLC v. Xavier Becerra*, case no. 8:19-cv-02130. Because much of plaintiffs' argument in these cases overlaps, the points made in this brief will also apply to the *Fresenius* motion and vice versa.

Medicaid) toward commercial premiums that might not be the best fit for their care needs.

Plaintiffs are not likely to succeed on the merits of their claims challenging AB 290. Plaintiffs assert that AB 290 is preempted by federal law. They contend that an Advisory Opinion issued in 1997 by the Department of Health and Human Services (HHS) Office of the Inspector General preempts AB 290. But that Advisory Opinion does not conflict with AB 290 and, in any event, it does not have the force of law for preemption purposes. Plaintiffs also contend that they cannot comply with both AB 290 and the Medicare Secondary Payer Act; they can. Plaintiffs' First Amendment claims are equally unlikely to succeed. They contend that AB 290's disclosure requirements violate their right to freedom of expression and association. But those disclosure provisions are economic regulations with only incidental burdens on speech. Plaintiffs also assert that the provision allowing AKF a grace period to seek an updated advisory opinion should it choose to do so violates AKF's right to petition by compelling it to request an opinion. AB 290 clearly makes requesting an updated opinion optional, not compulsory.

Plaintiffs attempt to demonstrate irreparable harm by attributing all of the negative effects that will result from AKF's decision to leave California to AB 290 itself. But the statute does not require AKF to leave the state. Furthermore, because AB 290 is not effective as to AKF until at least July 1, 2020, and longer if AKF seeks an updated Advisory Opinion, any irreparable harm that could truly be attributed to the state lacks the immediacy necessary for a preliminary injunction and is speculative, at best.

Aside from the lack of success on the merits and the failure to demonstrate irreparable harm attributable to the statute, the public interest weighs against preliminary injunctive relief because enjoining the statute would allow harms to patients across California to continue. Plaintiffs' request for a preliminary injunction should be denied.

BACKGROUND

I. THE AMERICAN KIDNEY FUND

The California Legislature passed AB 290 in response to the increased payment of health insurance premiums by healthcare providers and provider-funded groups for end-stage renal disease patients (ESRD). Assem. B. 290, Reg. Sess. (Cal. 2019-2020). The bill will impose requirements on "financially interested providers and entities that make third-party premium payments on behalf of health plan enrollees and insureds." Sen. Com. on Health, Analysis of Assem. Bill. No. 290 (2019-2020 Reg. Sess.) July 2, 2019 (Sen. Com. on Health Analysis) at 1. One such third-party payment provider is plaintiff AKF, a non-profit organization that pays insurance premiums for patients on dialysis that could not otherwise afford them. Complaint, Dkt. 1 at 4, 15. AKF receives roughly 80 percent of its funding from the two largest dialysis providers, DaVita and Fresenius. Declaration of Amie L. Medley (Medley Decl.), Ex. 1. Large dialysis providers such as DaVita, Fresenius, and U.S. Renal Care make up 77 percent of California's dialysis clinics. AB 290, Stats. 2019, ch. 862 (AB 290), § 1(h).

AKF reported to the Senate Health Committee that in 2018, AKF provided premium payment assistance to 3,756 patients through a total of 4,367 policies. Sen. Com. on Health Analysis at 7. Of those policies, 1,447 were for commercial employer or COBRA coverage, 311 policies were other commercial policies, 1,154 policies were Medicare Part B (outpatient coverage and physician visits), 880 policies were Medigap (extra health insurance from a private company to pay health care costs not covered by Original Medicare), and 224 policies were Medicare Advantage (privately administered plans covering Medicare Part A (hospital coverage) and Medicare Part B). *Id*. AKF claims to operates under a 1997 Advisory Opinion from HHS's Office of Inspector General (OIG). *Id*. That Advisory Opinion found that AKF's practice of paying insurance premiums for Medicare Part B and Medigap policies for ESRD patients who could not afford

them did not violate HIPAA's prohibition on providing remuneration to individuals who are eligible for federal health care coverage such as Medicare or Medicaid if such remuneration is likely to influence the individual's health care choices. Plaintiff's Request for Judicial Notice (Plaintiff's RJN), Dkt. 29, Ex. 2. In that Advisory Opinion, the OIG found that AKF's arrangement did not constitute prohibited remuneration under the statute because the premiums were paid by AKF rather than directly by a dialysis provider. *Id.* at 6. The Advisory Opinion also found it significant that AKF, not the dialysis providers themselves, determined which patients would receive premium assistance and that AKF did not limit its charitable contributions only to premiums paid for patients treated by its donor companies. *Id.* Further, the Advisory Opinion concluded that AKF's arrangement did not influence a patient's provider choice, because patients applying for HIPP often already had selected a provider. *Id.* at 6-7. As an additional safeguard, dialysis providers would not advertise the availability of HIPP. *Id.*

II. PROBLEMS ADDRESSED BY AB 290

AB 290 was enacted against a backdrop of nationwide concern over dialysis providers and third-party payers inappropriately steering patients onto commercial insurance plans for their own—not the patient's—benefit. As noted in the legislative history of AB 290, in 2016, "the federal Department of Health and Human Services (HHS) had become concerned about the inappropriate steering of dialysis patients eligible for, or entitled to, Medicare or Medicaid into private plans by providers because of significantly higher reimbursement." Sen. Com. on Health Analysis at 5. The Centers for Medicare & Medicaid Services (CMS), a subdivision of HHS, issued a Request for Information (RFI) titled "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans," which was published in the Federal Register on

August 23, 2016. 81 Fed. Reg. 57554, 57555 (Aug. 23, 2016).[2] In response, CMS received 800 public comments from patients, providers, health insurance companies, social workers and other stakeholders.[3] 81 Fed. Reg. 90214.

Based on these public comments, CMS found 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" and that "these non-profits will not continue to provide financial assistance once a patient receives a successful kidney transplant." 81 Fed. Reg. 90215. This can "cause significant issues for patients that cannot afford their coverage without financial support" and "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."[4] *Id.* A New York Times investigation in 2016 reached the same conclusion, reporting that "the charity has resisted giving aid to patients at clinics that do not donate money to the fund." Medley Decl., Ex. 1.[5] According to that investigation, a previous version of AKF's guidelines even said "clinics should not apply for patient aid if the company had not donated to the charity."[6] *Id.*

[2] Cited portions of the Federal Register are attached to Defendants' Request for Judicial Notice as Exhibits 2 & 3.

[3] Available at https://www.regulations.gov/docket?D=CMS-2016-0145.

[4] CMS promulgated guidance and a final interim rule, but the rule was invalidated by the United States District Court for the Eastern District of Texas, Case No. 4:17-cv-00016-ALM for failure to comply with the Administrative Procedures Act.

[5] Katie Thomas and Reed Abelson, *Kidney Fund Seen Insisting on Donations, Contrary to Government Deal*, N.Y. Times, Dec. 25, 2016, available at https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html.

[6] Although news articles are generally hearsay, "[t]he urgency of obtaining a preliminary injunction necessitates a prompt determination" and so "[t]he trial court may give even inadmissible evidence some weight, when to do so serves the purpose of preventing irreparable harm before trial." *Flynt Distrib. Co. v. Harvey*, 734 F.2d 1389, 1394 (9th Cir. 1984); *see also Ticketmaster L.L.C. v. RMG Techs., Inc.*, 507 F. Supp. 2d 1096, 1114 (C.D. Cal. 2007) ("[T]o the extent some of the newspaper articles may be offered for a hearsay purpose, the Court has wide latitude to consider such evidence in the preliminary injunction context.").

III. WHAT AB 290 DOES

Under AB 290, a financially interested entity making third-party premium payments must comply with several requirements, including "agree[ing] not to steer, direct, or advise the patient into or away from a specific coverage program option or health care service plan contract." AB 290, § 3, Cal. Health & Safety Code § 1367.016(b)(4). The law requires financially interested entities, including organizations providing premium payment assistance, to provide that assistance for the full plan year and to notify the patient before an open enrollment period if that assistance is to be discontinued. *Id.* at (b)(1). It provides that financial assistance shall not be conditioned on eligibility for any particular surgery, procedure or device, or on use of any particular facility, healthcare provider, or coverage type. *Id.* at (b)(3) & (5). And it requires covered entities to inform applicants for premium assistance about all available health coverage options, including Medicare, Medicaid, individual market plans, and employer plans. *Id.* at (b)(3).

During the legislative process, AKF commented on AB 290. On July 3, 2019, AKF President and CEO, LaVarne Burton, testified before the Senate Health Committee that AB 290 would take AKF outside the protections of Advisory Opinion 97-1.[7] Medley Decl., Ex. 2. This concern is also reflected in the Senate Health Committee bill analysis comments, which note that "AKF operates under OIG guidance issued in 1997, which indicates that, as described by AKF, the arrangement does not constitute a violation of HIPAA." Sen. Com. on Health Analysis at 7. In order to rectify and mitigate AKF's expressed concerns, the Senate proposed four amendments to either address compliance with Advisory Opinion 97-1 or delay AKF's timeframe for compliance to provide them additional time to adjust to AB 290's requirements.

[7] https://www.kidneyfund.org/news/news-releases/akf-president-testimony-to-senate-health-committee-on-california-ab-290.html

First, the Senate amended section 1 of the bill to state that legislative intent was to grant "delayed implementation" to 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." *Compare* Assem. Bill No. 290 (2019-2020 Reg. Sess.) as introduced Jan. 28, 2019 (Jan. 28 Bill), *with* AB 290 at § 7.[8]

Second, the Senate amended the bill to state that if a financially interested entity covered by Advisory Opinion No. 97-1—like AKF—requested an updated advisory opinion before July 1, 2020, the effective date of AB 290 as to that entity would be tolled until OIG issues an advisory opinion stating that AB 290 does not conflict with federal law. *Compare* Jan. 28 Bill, *with* AB 290, § 7.

Third, to ensure continuity of care for patients on dialysis, the Senate amended the bill to ensure AKF could continue providing premium payment assistance for its existing patients under its existing arrangement. The amended bill exempts AKF from complying with AB 290 for those patients whose health insurance premiums were being paid by AKF or a similar nonprofit as of October 1, 2019. *Compare* Jan. 28 Bill, *with* AB 290, § 3, Cal. Health & Safety Code § 1367.016 (d)(1), § 5, Cal. Ins. Code § 10176.11(d)(1). This ensures that dialysis providers would continue to receive commercial reimbursement rates for those patients and AKF does not have to report information about these exempt patients to health insurance companies or health plans. *Id*.

Finally, the Senate amended the bill to delay implementation of the Medicare-linked reimbursement cap until January 1, 2022, giving providers and other financially interested entities around two years to adjust to the different reimbursement rates. *Compare* Jan. 28 Bill, *with* AB 290, § 3, Cal. Health & Safety Code § 1367.016 (d)(2); § 5, Cal. Ins. Code § 10176.11(d)(2).

[8] A comparison between AB 290 as introduced on January 28, 2019, and AB 290 as enacted on October 13, 2019 is attached to Defendants' Request for Judicial Notice as Exhibit 4.

IV. BACKGROUND OF THE CURRENT CASE

Plaintiffs filed the current case on November 5, 2019. The Complaint includes claims under the First and Fourteenth Amendments and the Supremacy Clause. Dkt. 1. Plaintiffs filed their motion for preliminary injunction, seeking to enjoin the implementation of AB 290 in its entirety, on November 8, 2019. Dkt. 30.

LEGAL STANDARD

To succeed in their motion for preliminary injunction, Plaintiffs must establish that they are likely to succeed on the merits, that they are likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in their favor, and that an injunction would be in the public interest. *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). Injunctive relief is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id*. at 22.

Plaintiffs seek to invalidate the enforcement of the entirety of AB 290 across California. Facial challenges to statutes are disfavored for a variety of reasons. They "often rest on speculation" resulting in a risk of "premature interpretation of statutes on the basis of factually barebones records." *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 450 (2008) (citations omitted). Facial challenges also contradict the principle of judicial restraint that "courts should neither 'anticipate a question of constitutional law in advance of the necessity of deciding it' nor formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied.'" *Id.* Last, but not least, "facial challenges threaten to short circuit the democratic process by preventing laws embodying the will of the people from being implemented in a manner consistent with the Constitution." *Id*.

In light of all of the potential problems posed by facial challenges, "a plaintiff can only succeed in a facial challenge by 'establish[ing] that no set of circumstances exists under which the Act would be valid,' i.e., that the law is

unconstitutional in all of its applications." *Washington State Grange*, 552 U.S. at 449 (citing *U.S. v. Salerno*, 481 U.S. 739, 745 (1987)); *Morrison v. Peterson*, 809 F.3d 1059, 1064 (9th Cir. 2015). In considering a facial challenge to a statute, a court must "be careful not to go beyond the statute's facial requirements and speculate about 'hypothetical' or 'imaginary' cases." *Washington State Grange*, at 450. Although Plaintiffs challenge the statute on its face, the Court cannot consider such challenges in the abstract.

ARGUMENT

I. PLAINTIFFS ARE NOT LIKELY TO SUCCEED ON THE MERITS OF THEIR CONSTITUTIONAL CLAIMS

A. AB 290 Is Not Preempted By Federal Law

Plaintiffs assert conflict preemption, under which "state laws are preempted when they conflict with federal law. This includes cases where 'compliance with both federal and state regulations is a physical impossibility,' and those instances where the challenged state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (*Arizona II*) (citations omitted). "In preemption analysis, courts should assume that 'the historic police powers of the States' are not superseded 'unless that was the clear and manifest purpose of Congress.'" *Id*. at 400 (citations omitted).

1. The Advisory Opinion Does Not Preempt AB 290

Plaintiffs contend that the Advisory Opinion preempts AB 290, because it is impossible to comply with both. This argument fails because the Advisory Opinion (1) does not have the force of federal law, and (2) does not conflict with AB 290.

a. The Advisory Opinion Does Not Impose a Requirement With the Force of Federal Law

The Advisory Opinion examines AKF's practice, in 1997, of paying premiums for Medicare Part B and Medigap policies, using funds that were donated in large

part by dialysis companies, concluding that the arrangement as described did *not* fall within the HIPAA remuneration prohibition.[9] Plaintiff's RJN, Dkt. 29, Ex. 2.

The Advisory Opinion 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.[10] 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 provide no authority for the proposition that a finding that a particular course of action is consistent with federal law thus transforms the parameters of that course of action into affirmative requirements of federal law.

Plaintiffs are thus incorrect to ascribe to the Advisory Opinion the mandate of federal law. "Interpretations 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-

[9] In 1995, "less than ten percent" of donations received by AKF were from companies that own dialysis facilities. Plaintiff's RJN, Dkt. 29, Ex. 2. Currently, as stated in the AB 290's legislative findings, "[l]arge dialysis companies contribute more than 80 percent of the revenue to [AKF]." AB 290, § 1(h).

[10] 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. Medley Decl., Ex. 5 at 3. Thus, AKF paid Medigap and Medicare Part B premiums for patients on dialysis. After the Affordable Care Act (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. *Id*.; 42 U.S.C. § 18001.

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) (citations omitted); *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"). The Advisory Opinion does not have the force of federal law or regulation and cannot preempt AB 290.

b. The Advisory Opinion Does Not Conflict with AB 290

Even if the Advisory Opinion had the force of a federal statute or regulation, it still does not preempt AB 290 because there simply is no conflict between the Advisory Opinion and the statute. The Advisory Opinion only considers payments for Medicare Part B or Medigap premiums. Plaintiffs' RJN, Dkt. 29, Ex. 2. The Advisory Opinion does not discuss premium payments for commercial insurance or group health coverage. Even if the Advisory Opinion had the force of federal law, its requirements restrictions would apply only to payments for Medicare Part B or Medigap premiums, which do not fall within the scope of AB 290. *See* AB 290, § 3, Cal. Health & Safety Code § 1367.016(f)(3); Cal. Ins. Code § 10176.11(f)(2) (no application to "coverage of Medicare services pursuant to contracts with the United States government, Medicare supplement coverage").

And, even if the Advisory Opinion could be construed to apply to premium payments for commercial health insurance and group health plans, there is still no conflict with AB 290. Nothing in AB 290 prevents AKF from using its funds in accordance with its charitable mission and it does not restrict the kinds of patients AKF may help. AB 290 and the Advisory Opinion also both require that financial assistance may not be conditioned on the use of a specific facility or health care provider. Plaintiffs' RJN, Ex. 2 at 5-7; AB 290, § 3, Cal. Health & Safety Code § 1367.016(b)(2); § 5, Cal. Ins. Code § 10176.11(b)(2). Further, the Advisory Opinion is 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 Advisory Opinion.

Plaintiffs also claim that AB 290 requires AKF to disclose patients' identities to the "insurers of those patients for whom it provides premium assistance," which will lead to HIPP participants determining that their provider is a donor and feeling bound to stay with their provider, contrary to the Advisory Opinion. Mem., Dkt. 28, at 10. Under Plaintiffs' theory, HIPP participants would only *potentially* learn that their provider is a HIPP donor *after* a patient picks a provider, applies for and receives HIPP, obtains dialysis, and then receives a benefits statement. By then, the patient has already picked a provider without undue influence, as required by the Advisory Opinion. In addition, this concern is purely speculative, as Plaintiffs have not provided any evidence that HIPP participants are likely to examine their billing statements in order to determine whether their provider is a donor.[11]

c. The Court Should Not Presume a Conflict When AKF Can Forestall AB 290

Where there is "a basic uncertainty about what the law means and how it will be enforced," it would be "inappropriate to assume" that a state law "will be construed in a way that creates a conflict with federal law." *Arizona II*, 567 U.S. at 415 (citation omitted). Here, AB 290 explicitly provides a mechanism for regulated entities to receive a finding that compliance with AB 290 is consistent with federal law, before AB 290 will apply to those entities. AB 290, § 7.

[11] Plaintiffs also argue that AB 290 creates different classes of patients contending that it requires HIPP to treat California patients differently, as well as those patients in grandfathered plans, which would contradict the Advisory Opinion. Mem., Dkt. 28, at 10-11. It is not clear what portion of the Advisory Opinion Plaintiffs believe conflicts with AB 290 in this respect. To the extent Plaintiffs' contention is that the grandfathering provisions require differential treatment that is alleged to violate non-discrimination requirements in the Medicare Secondary Payer Act, that argument fails for the reasons discussed below.

Thus, "the nature and timing of this case counsel caution in evaluating the validity of" AB 290. *Id.* (citing *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960) ("To hold otherwise would be to ignore the teaching of this Court's decisions which enjoin seeking out conflicts between state and federal regulation where none clearly exists")). "Well-established preemption principles favor upholding state law if it can plausibly coexist with the federal statute." *California Ins. Guarantee Ass'n v. Azar*, 940 F.3d 1061, 1071 (9th Cir. 2019) (citing *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)). Because the provisions of AB 290 that relate to the Advisory Opinion need not take effect, with respect to AKF or other entities covered by the Advisory Opinion, unless and until a federal agency has determined that compliance with AB 290 is consistent with federal law, there is no need to presume an irreconcilable conflict between the Advisory Opinion and AB 290.

2. AB 290 Does Not Conflict with the Medicare Secondary Payer Act

Plaintiffs 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]. Mem., Dkt. 28, at 14.

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). However, "a health plan only violates this provision through disparate treatment based on Medicare eligibility—that is, when a group health plan treats those eligible for Medicare differently than those who are not." *DaVita, Inc. v. Marietta*

Mem'l Hosp. Employee Health Benefit Plan ("*Marietta Mem'l Hosp.*"), No. 2:18-CV-1739, 2019 WL 4574500, at *3 (S.D. Ohio Sept. 20, 2019).[12]

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. 42 U.S.C. § 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). Thus, "a health plan only violates this provision when it treats those with ESRD differently than those who do not have ESRD . . ." (i.e., disparate treatment). *Marietta Mem'l Hosp.*, 2019 WL 4574500, at *3–5.[13]

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

[12] *See also DaVita, Inc. v. Amy's Kitchen, Inc.*, 379 F. Supp. 3d 960, 973 (N.D. Cal. 2019) (finding that because those receiving dialysis treatment who are Medicare-eligible and those who are not are subject to the same provisions, the benefit plan did not violate the "take into account" provision); *Dialysis of Des Moines, LLC v. Smithfield Foods Healthcare Plan*, No. 2:18-CV-653, slip op. at 11–12 (E.D. Va. Aug. 5, 2019) ("[A] limitation on services is permitted so long as it is uniform, meaning that it applies to all plan enrollees regardless of Medicare eligibility or ESRD diagnosis."); *Nat'l Renal All., LLC v. Blue Cross & Blue Shield of Ga, Inc.*, 598 F. Supp. 2d 1344, 1354 (N.D. Ga. 2009) ("Plaintiffs have not demonstrated that Blue Cross's decision to lower reimbursement rates on dialysis treatment . . . constitutes 'taking into account' or 'differentiating' a level of coverage provided to those suffering from ESRD and those not.").

[13] *See also Dialysis of Des Moines*, slip op. at 11–12; *Amy's Kitchen*, 379 F. Supp. 3d at 973 ("[T]he applicable rates in Amy's Plan are set based on the fact of dialysis treatment, not the existence of ESRD."); *Nat'l Renal All.*, 598 F. Supp. 2d at 1354. ("Significant to the court's finding is the fact that there is no allegation that Blue Cross pays a different amount for dialysis treatment of non-ESRD patients than ESRD patients.").

necessarily have ESRD) and another amount for everyone else." Mem., Dkt. 28, at 14. But Plaintiffs do not—and cannot—allege 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. Nor does the statute differentiate between patients based on their ESRD status. AB 290 treats all patients with ESRD equally. Thus, consistent with the findings of numerous other federal courts in analogous cases, AB 290 does not violate the "take account" or "nondifferentiation" provisions of the MSPA. *See Marietta Mem'l Hosp.*, 2019 WL 4574500, at *3–5; *Amy's Kitchen, Inc.*, 379 F. Supp. 3d at 973; *Dialysis of Des Moines, LLC*, No. 2:18-CV-653, slip op. at 11–12; *Nat'l Renal All., LLC*, 598 F. Supp. 2d at 1354.

B. AB 290 Does Not Violate Plaintiffs' First Amendment Rights

1. The Requirement that AKF Inform Patients About Available Healthcare Plan Options Does Not Violate Its Free Speech Rights

AB 290 requires that financially interested entities like AKF inform the recipients of premium payment assistance of "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and employer plans." AB 290, § 3, Cal. Health & Safety Code § 1367.016(b)(3), § 5, Cal. Ins. Code § 10176.11(b)(3). The Supreme Court has held that a speaker's First Amendment rights are "adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Milavetz, Gallop & Milavetz v. U.S.*, 559 U.S. 229, 250 (2010). That is the case here. In *Milavetz*, the Court considered a law that required attorneys advertising debt relief assistance to disclose that such relief would likely involve filing for bankruptcy. *Id.* The Court found that the required disclosures were "intended to combat the problem of inherently misleading commercial advertisements—

specifically, the promise of debt relief without any reference to the possibility of filing for bankruptcy, which has inherent costs." *Id*. Simliarly, AB 290's requirement that AKF and other financially interested entities provide information to patients about their insurance options protects against patient steering by insuring that patients are informed about all of their options, not just the commercial insurance options that result in higher reimbursement rates for dialysis providers. Additionally, it is difficult to see how this requirement places a burden on AKF. Although AKF asserts that "[b]y policy and practice, AKF does not discuss coverage options with patients" but "simply pays for coverage submitted by the patients" (Mem., Dkt. 28, at 16), it does provide a list of the types of health care plans for which they offer premium payment assistance. Medley Decl. at Ex. 3 at 2.

Plaintiffs rely on *Nat'l Institute of Family and Life Advocates v. Becerra*, 138 S.Ct. 2361 (2018) (*NIFLA*), arguing that the disclosures required by AB 290 trigger the same level of First Amendment scrutiny as the required disclosure in that case. But the Court specifically explained in *NIFLA* that the required disclosure—the availability of publicly-funded reproductive healthcare services, including abortion—was not the type of "notice limited to purely factual and uncontroversial information" that it had previously upheld as a reasonable regulation of commercial speech. *Id*. at 2372 (citing *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985).) Furthermore, the Court in *NIFLA*, found it significant that the state could inform the target audience about available services "without burdening a speaker with unwanted speech." *Id*. at 2376. However, in the present case, the State has no way to identify patients receiving premium payment assistance from AKF because AKF often provides patients with debit cards that the patients then use to pay their premiums. Medley Decl., Ex. 4 at 15. Thus, the State cannot simply provide the information directly to patients who need it. AB 290's required disclosure of information about "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and

employer plans" is much more akin to the disclosures at issue in *Zauderer* and *Milavetz* than those at issue in *NIFLA*. As such, the State must only show that the requirements are "reasonably related to the State's interest in preventing deception of consumers." The State has already done so. *Supra* pp. 4-5.

2. AB 290's Prohibition on Steering, Directing, or Advising Patients Regarding Insurance Options Is Not Unconstitutionally Vague

As discussed in further detail in Defendants' opposition to the preliminary injunction motion filed in *Fresenius, et al. v. Becerra, et al.*, 8:19-cv-02130, the meaning of AB 290's prohibition on steering, directing, or advising patients "into or away from a specific coverage program option or health care service plan contract" is sufficiently definite to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited" and will not compel speakers "to steer too far clear of any forbidden area" of speech. *Edge v. City of Everett*, 929 F.3d 657, 665 (9th Cir. 2019). The phrase "steer, direct, or advise" in the context of AB 290 is not difficult to ascertain—the Legislative findings highlight concerns over "[e]ncouraging patients to enroll in commercial insurance coverage for the financial benefit of the provider." AB 290, § 1(c). Plaintiffs rely on *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), arguing that AB 290's prohibition on steering, directing, or advising patients toward or away from a particular insurance option has the effect of preventing one type of speaker from communicating with a particular audience "in an effective and informative manner." Mem., Dkt. 28, at 18. It does not; nothing in AB 290 prohibits a financially interested entity from communicating factual information to its patients.

AKF's argument that the steering provision "restricts AKF's freedom to inform patients, for example, of Medicare costs and deductibles, or to state its view that particular types may better fit a patient than other plan types, or to "advise patients about the availability of better, more appropriate, or less expensive coverage" undercuts their statement on the previous page of their brief that "[b]y

policy and practice, AKF does not discuss coverage options with patients" but "simply pays for coverage submitted by the patients." Mem., Dkt. 28, at 16. It also undercuts AKF's claim that "HIPP patients . . . come to the program only *after* they have qualified for and obtained health insurance of their choosing." Compl., Dkt. 1, at 16. Furthermore, curtailing the ability of financially interested entities to tell patients they should choose one insurance option over another is precisely the point of the statute, in light of documented concerns that these entities are inappropriately steering patients toward insurance options that benefit their major donors—the dialysis providers. AB 290, § 1(h); 81 Fed. Reg. 90217.

3. AB 290's Requirement of an Annual Statement Certifying Compliance Does Not Violate the First Amendment

AB 290 requires that a financially interested entity "shall not make a third-party premium payment" unless it "[a]nnually provides a statement to the health care service plan that it meets the requirements set forth in subdivision (b)" and "[d]iscloses 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." AB 290, § 3, Cal. Health & Safety Code § 1367.016(c)(1); Cal. Ins. Code § 10176.11(c)(1). Plaintiffs contend that each of these requirements violates their First Amendment right to be free from compelled speech.

It is not unusual for charitable organizations to be subject to reporting or certification requirements. *See, e.g.*, *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620, 637-38 n.12 (2019) (noting that "Illinois law . . . requires charitable organizations to register with the State Attorney General's Office and to report certain information about their structure and fundraising activities"); *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 800 (1988) (noting that the State may "publish the detailed financial disclosure forms it requires professional fundraisers to file."). AB 290's required compliance

statement is just such a requirement. It does not force AKF "to endorse a pledge or motto contrary to their deeply-held beliefs," a sign of impermissible compelled speech. *Beeman v. Anthem Prescription Mgmt., Inc.*, No. EDCV 04-407-VAP (SFLx), 2007 WL 8433882 at *5 (C.D. Cal. May 7, 2007). It is simply a mechanism to ensure compliance with the statutory requirements of AB 290.

Likewise, the requirement that financially interested entities disclose to insurers the names of patient enrollees receiving premium payment assistance does not violate the First Amendment. Plaintiffs offer no authority for the proposition that a statutory requirement that a financially interested entity paying premiums on a patient's behalf has a constitutional right not to disclose the identities of those patients to the insurer.[14] But like the required compliance statement, the disclosure of patient names does not involve any compelled message. The disclosure of patient names is necessary to the functioning of the statute; health plans will only know whether the reimbursement cap applies if they know which patients are receiving premium payment assistance. The provision will also help ensure that patients receive complete information about their insurance options and can choose the best insurance for their care needs.

Plaintiffs also assert that the compliance statement and patient disclosure requirements are content-based regulations subject to strict scrutiny because the regulations apply only to financially interested entities as defined by statute. The logical extension of this argument is that states could not regulate any specific industry or group of economic actors if any kind of reporting or disclosure were required. That is obviously not the case. *See, e.g., SEC v. Tex. Gulf Sulphur Co.*, 401 F.2d 833 (2d Cir. 1968) (regulating the exchange of information about

[14] AB 290 specifies that its provisions do 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. § 300gg)." AB 290, § 3, Cal. Health & Safety Code § 1367.016(n); § 5, Ins. Code § 10176.11(n).

securities); *Mills v. Elec. Auto-Lite Co.*, 396 U.S. 375 (1970) (requirements relating to corporate proxy statements).

4. AB 290 Does Not Violate AKF's Right of Association

AB 290 requires financially interested entities such as AKF to "agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug or device." AB 290, § 3, Cal. Health & Safety Code § 1367.016(b)(2); § 5, Cal. Ins. Code § 10176.11(b)(2). AKF argues that this restriction would prevent it from providing HIPP assistance limited to patients on dialysis or those who within the past year have received a kidney transplant. Mem., Dkt. 28, at 19. But AB 290 does not prohibit AKF from limiting its assistance to those patients diagnosed with ESRD. Instead, it is designed to prevent harmful practices such as withdrawing premium payment assistance when a patient receives a kidney transplant. AB 290, § 1(c) and (d); *see also* 81 Fed. Reg. 90215 ("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"). The statute would require organizations who offer premium payment assistance to pay those premiums no matter which course of treatment is best for a patient suffering from ESRD, not only when the insurance purchased with those premiums is used to cover dialysis treatment to the benefit of AKF's major donors.

Plaintiffs assert that AB 290 "burdens AKF's right to associate with patients by imposing mandatory and prohibitory speech restrictions on how AKF communicates with them, and by requiring AKF to disclose their identities, along with their medical and financial status, to the insurance companies." Mem., Dkt. 28, at 20. And Plaintiffs argue that "the Act burdens the right of patients to associate with the dialysis providers of their choice" by "allowing more generous reimbursement for providers who do not donate to AKF than for providers that do."

Id. But the cases out of which the right to expressive association grew "protect[ed] 'freedom of association *for the purpose of advancing ideas and airing grievances*.'" *Whalen v. Roe*, 429 U.S. 589, 604 (1977) (emphasis added); and *Nat'l Ass'n for Advancement of Colored People v. State of Ala. ex rel. Patterson*, 357 U.S. 449, 462 (1958). In fact, courts have held that "the relationship between an individual patient and doctor is not the kind of association whose communications are protected by the First Amendment right to freedom of association." *Conant v. McCoffey*, No. C 97-0139 FMS, 1998 WL 164946, at *3 (N.D. Cal. Mar. 16, 1998); *see also Behar v. Pa. Dep't of Transp.*, 791 F. Supp. 2d 383 (M.D. Pa. 2011) (doctor's "association with a patient is an association in the broadest sense [but] it is not the type of association protected by the First Amendment.") A different conclusion is not warranted as to the association between AKF and patients, which facilitates the association between patients and dialysis providers through the payment of money to fund insurance premiums.

As discussed in further detail in the opposition to the preliminary injunction motion filed in *Fresenius v. Becerra*, Plaintiffs' argument that AB 290 permits more generous reimbursement for providers who do not donate to AKF than for providers that do is incorrect. AB 290's reimbursement limit is not a penalty imposed on dialysis providers because of their financial support of AKF. Instead, it is a cap on commercial insurance reimbursement rates for dialysis care provided to patients who receive premium payment assistance from an entity in which the dialysis provider has a financial stake.

5. AB 290 Does Not Violate AKF's Right to Petition by Compelling It to Seek an Updated Advisory Opinion

In response to AKF's expressed concerns that compliance with AB 290 would require it to run afoul of Advisory Opinion 97-1, the Legislature added a provision to the bill specifically to "allow the American Kidney Fund to request an updated advisory opinion" from the OIG. AB 290, § 1(j). That provision not only allows a

grace period until July 1, 2010 for AKF to request an updated advisory opinion, but also states that if AKF does so, the sections of AB 290 that would impose requirements on AKF, including offering HIPP assistance for an entire plan year and disclosing the identities of patients to the patients' insurers, will only become operative relative to AKF "upon a finding by the [OIG] that compliance with those sections by a financially interested entity does not violate the federal laws addressed by Advisory Opinion 97-1." AB 290, § 7. In other words, if AKF requests an updated OIG advisory opinion, certain provisions of AB 290 will not go into effect for AKF until the OIG issues an opinion, and if that opinion says that AKF cannot comply with both AB 290 and federal law, those provisions will never go into effect as to AKF at all.

AKF asserts a novel argument that the provision allowing them to seek an updated advisory opinion from the OIG violates its First Amendment rights by compelling it to exercise its right to petition. As an initial matter, AKF offers no authority demonstrating that the courts have ever found a cognizable cause of action for forced or compelled petition under similar circumstances, or recognized the theory at all under the First Amendment. Instead, AKF cites *Wayte v. United States*, 470 U.S. 598, 610 n.11 (1985) for the general proposition that "the right to petition and the right to free speech . . . are related and generally subject to the same constitutional analysis." Mem., Dkt. 28, at 21. Even assuming that a theory of compelled petition is cognizable, it is not the case that AB 290 compels AKF to seek an updated advisory opinion. AKF argues that AB 290 "attempts to force AKF to submit a petition advocating a result it vigorously opposes." Mem., Dkt. 28 at 21. AB 290 does no such thing. It provides the option for AKF to request an updated advisory opinion on the question of whether, by complying with AB 290's requirements, it would be violating federal law. It does not mandate that AKF do so. "Both the right to be free from compelled expressive activity and the right to be free from compelled affirmation of belief presuppose a coerced nexus between the

individual and the specific expressive activity." *Cal-Almond, Inc. v. U.S. Dept. of Agric.*, 14 F.3d 429, 435 (9th Cir. 1993). No such coercion is at issue here.

Neither does AB 290 force AKF to convey any specific message if it requests an updated advisory opinion. AKF could phrase the request as seeking a finding that "complying with the requirements of AB 290 would require it to violate federal law." Compelled speech occurs when "an individual is obliged personally to express a message he disagrees with, imposed by the government." *Johanns v. Livestock Mktg. Ass'n*, 544 U.S. 550, 557 (2005). That is not the case here.

II. PLAINTIFFS FAIL TO DEMONSTRATE ANY IRREPARABLE HARM CAUSED BY AB 290 RATHER THAN BY THE PROVIDERS AND AKF'S DECISIONS

Plaintiffs paint a dire picture in their brief and declarations of the effects that will result if AB 290 goes into effect on January 1, 2020, including the loss of premium payment assistance, due to AKF's decision to leave the State of California. But most provisions of the statute—including the cap on reimbursements to private insurers or health care plans for treatments provided to patients receiving premium assistance from a financially interested entity—will not go into effect until at least January 1, 2022, and may be delayed further if AKF seeks an updated opinion from the OIG by July 1, 2020. AB 290, § 7. In fact, the only provision that will go into effect as of January 1, 2020 is the patient steering prohibition. Furthermore, patients who were receiving HIPP assistance before October 1, 2019 are grandfathered such that AKF may continue paying their premiums and the dialysis providers may continue receiving reimbursement at the non-Medicare rate. AB 290, § 3, Cal. Health & Safety Code § 1367.016(d)(1) & (2); Cal. Ins. Code § 10176.11(d)(1) & (2). The alleged harms Plaintiffs assert are not so imminent to support a preliminary injunction, or AKF's decision to vacate the California market. Additionally, nothing in AB 290 requires AKF to cease making premium payments on behalf of patients on dialysis it has already been serving effective January 1, 2020. AB 290 does not apply to third-party premium

payments for Medigap coverage or for Medicare coinsurance costs at all. AB 290 only applies when commercial insurance is involved. AKF has articulated no rational reason connected to AB 290 to withdraw funding from those patients it serves who are enrolled in government insurance programs.

Despite all of these mechanisms built into AB 290 to encourage AKF to continue providing premium assistance in California, AKF has stated that it will be leaving the state entirely—cutting off all funding to patients it currently serves in California—as of January 1, 2020. Leaving the state rather than taking advantage of provisions is a decision AKF is making to the detriment of the patients it serves. The harm AKF asserts is of its own making, not a result of AB 290.

AKF makes much of the harm it will suffer from losing the "safe harbor" provided by Advisory Opinion 97-1. But circumstances have changed drastically since the 1997 Advisory Opinion, which stated that it was "[b]ased on the information provided" and was "limited to the facts presented." *Id*. at 1. In 1995, "less than ten percent" of donations received by AKF were from companies that own dialysis facilities. Plaintiff's RJN, Ex. 2 at 3. Currently, as stated in the AB 290's legislative findings, "[l]arge dialysis companies contribute more than 80 percent of the revenue to [AKF]." AB 290, § 1(h). At the time the opinion was issued, most ESRD patients were only able to obtain coverage through Medicare, and as such, would rely on AKF for Medicare Part B (outpatient coverage and physician visits) and Medigap coverage (extra health insurance from a private company to pay health care costs not covered by Original Medicare). Upon implementation of the Affordable Care Act, many ESRD patients were able to enroll in private insurance plans, since insurance companies could no longer deny coverage based on preexisting conditions. 42 U.S.C. § 18001.

The irreparable harms described in Plaintiffs brief will result from AKF's own decision to exit the State of California—a decision that is in no way required by

AB 290. AKF should not be permitted to obtain an injunction of an important state statute by threatening the dialysis care of vulnerable patients within the state.

III. ENJOINING AB 290 WOULD NOT BE IN THE PUBLIC INTEREST

The last two preliminary injunction factors under the *Winter* test—the balance of hardships and the public interest—weigh in favor of denying Plaintiff's request for a preliminary injunction. *Winter*, 555 U.S. at 20. "When the government is a party, these last two factors merge." *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014) (citing *Nken v. Holder*, 556 U.S. 418 (2009)).

The State of California and its citizens have an interest in laws that protect California patients and to ensure that commercial insurance remains affordable. AB 290 is designed to "shield patients from potential harm caused by being steered into coverage options that may not be in their best interest." AB 290, § 1(i). Furthermore, "any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1301 (2012). As both the California Legislature and CMS have found, the proliferation of third-party payment arrangements since the enactment of the Affordable Care Act has exposed patients on dialysis to direct harm and caused health care and insurance premium costs to escalate. AB 290, § 1(c)-(e); 81 Fed. Reg. 90214, *et seq*. If AB 290 is enjoined, these practices will continue and patients will continue to have their care compromised and costs increased. It is squarely within California's traditional police powers to regulate arrangements between dialysis providers and third-party premium payers in order to protect its citizens from these ill effects. *See Cal. Ins. Guarantee Ass'n v. Azar*, 940 F.3d 1061, 1064 (9th Cir. 2019).

CONCLUSION

For the foregoing reasons, Plaintiffs' motion for preliminary injunction should be denied.

Dated: November 25, 2019

Respectfully Submitted,

XAVIER BECERRA
Attorney General of California
MARK R. BECKINGTON
Supervising Deputy Attorney General

/s/ Amie L. Medley
AMIE L. MEDLEY
Deputy Attorney General
Attorneys for Defendants Xavier Becerra, Ricardo Lara, Shelly Rouillard, and Sonia Angell, in their official capacities

CERTIFICATE OF SERVICE

Case Name: **Jane Doe, et al v. Xavier Becerra, et al.** Case No.: **8:19-cv-2105-DOC-(ADSx)**

I hereby certify that on November 25, 2019, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

DEFENDANTS' OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

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 the foregoing is true and correct and that this declaration was executed on November 25, 2019, at Los Angeles, California.

Colby Luong	/s/ Colby Luong
Declarant	Signature

SA2019106023
53924910.docx

XAVIER BECERRA
Attorney General of California
MARK R. BECKINGTON
Supervising Deputy Attorney General
P. PATTY LI
Deputy Attorney General
MARTINE D'AGOSTINO
Deputy Attorney General
KETAKEE KANE
Deputy Attorney General
KARLI EISENBERG
Deputy Attorney General
AMIE L. MEDLEY
Deputy Attorney General
State Bar No. 266586
300 South Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6226
E-mail: Amie.Medley@doj.ca.gov
Attorneys for Defendants Xavier Becerra, Ricardo Lara, Shelly Rouillard, and Sonia Angell, in their official capacities

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.

XAVIER BECERRA, 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 SUSAN FANELLI, in her Official Capacity as Acting Director of the California Department of Public Health,

Defendants.

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

DECLARATION OF AMIE L. MEDLEY IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

Date: December 16, 2019
Time: 8:30 a.m.
Courtroom: 9D
Judge: The Honorable David O. Carter
Trial Date: n/a
Action Filed: 11/5/2019

I, Amie L. Medley declare as follows:

1. I am an attorney licensed to practice law in California. I am a deputy attorney general in the Office of the California Attorney General in Los Angeles, California and one of the attorney of record for Defendants Xavier Becerra, 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 Susan Fanelli, in her Official Capacity as Acting Director of the California Department of Public Health ("Defendants") in this matter.

2. I have personal knowledge of the following facts and, if called as a witness in a relevant proceeding, I could and would testify competently to them.

3. Attached hereto as Exhibit 1 is a true and correct copy of an article by Katie Thomas and Reed Abelson and published in *The New York Times* on December 25, 2016, entitled "Kidney Fund Seen Insisting on Donations, Contrary to Government Deal." This article is also , available at https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html (last accessed November 23, 2019).

4. Attached hereto as Exhibit 2 is a true and correct copy of a news release dated July 3, 2019, and posted on the website of the American Kidney Fund at https://www.kidneyfund.org/news/news-releases/akf-president-testimony-to-senate-health-committee-on-california-ab-290.html (last accessed November 23, 2019).

5. Attached hereto as Exhibit 3 is a true and correct copy of an excerpt from the American Kidney Fund's website, available at https://www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/ (last accessed November 23, 2019).

6. Attached hereto as Exhibit 4 is a true and correct copy of the American Kidney Fund's Patient Handbook for its Health Insurance Premium Program, also

available at https://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-patient-handbook.pdf (last accessed November 24, 2019).

7. Attached hereto as Exhibit 5 is a true and correct copy of a letter from Representative Katie Porter to Joanne Chiedi, Acting Inspector General at the Department of Health and Human Services, dated July 23, 2019. This letter is also available at https://porter.house.gov/sites/porter.house.gov/files/Porter%20Letter%20to%20HHS%20OIG%20re%20Dialysis.pdf (last accessed November 25, 2019.)

I declare under penalty of perjury that the foregoing is true and correct, and that I signed this declaration on November 25, 2019, at Los Angeles, California.

Amie L Medley

EXHIBIT 1

The New York Times

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.

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.

"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.

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.’”

EXHIBIT 2

Donate Now

News Releases

American Kidney Fund President Testimony to Senate Health Committee on California AB 290

FOR IMMEDIATE RELEASE

SACRAMENTO, Calif. (July 3, 2019)—The American Kidney Fund (AKF) president and CEO LaVarne A. Burton delivered the following testimony today at hearing held by the California State Senate Health Committee on AB 290 (Wood), a bill that will harm thousands of low-income dialysis and transplant patients throughout California. The bill was opposed by 70 organizations and numerous individuals representing a diverse cross section of consumer interests.

In reaction to the bill passing committee, Burton added: “I am extremely concerned that thousands of dialysis and transplant patients who depend on AKF in California are closer to losing an essential financial lifeline that gives them access to lifesaving medical care. All of our State Senators have to understand the gravity of the consequences if AB 290 becomes law and AKF is forced to discontinue its charitable premium assistance program in California.”

Testimony:

My name is LaVarne Burton. I’m President and CEO of the American Kidney Fund. I want to talk about who we are and why we oppose AB 290.

AKF is a servant organization helping people fight kidney disease at every stage—from prevention to dialysis and transplant.

We've done this work for almost 50 years. Last year, almost 4,000 Californians depended on us to help pay their health insurance premiums. We paid Medicare and Medigap premiums for just over half of them.

We have always operated with the highest ethical standards and efficiency. Charity Navigator

has given us a 4-Star rating for 17 years running and we are on their Top 10 charities list. We do this with fewer than 80 staff 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 legal opinions differ about whether we can safely continue operations under AB 290. But, the advisory opinion for our premium assistance program from the Inspector General at the U.S. Department of Health and Human Services is legally binding, and it requires that we act in good faith to comply. Should we not do so, we become liable to IG sanctions.

Your own Legal Counsel, on page 6 of its letter, confirms AKF's conclusion that AB 290 would take us outside of the protections of our Advisory Opinion.

Why would we, an organization that has always played by the rules, step out on a limb when our best judgment and that of your own Legal Counsel says that AB 290 takes us outside our protections?

When the HIPAA law that enables the IG opinion was written, I was a Presidential Appointee in the Clinton Administration working at HHS. I co-chaired efforts in the department to develop this legislation. Our chief concern was protecting against disclosure so that patients could have true freedom of choice in selecting health care professionals. AB 290 undermines that.

Now, if AKF is forced to shut down in California, here's what happens to thousands of Californians if they cannot find another way to pay their premiums:

- Many will lose Medicare altogether or face unlimited out-of-pocket expenses without their Medigap.
- Those who depend on COBRA will lose coverage for themselves and their families
- Those turning to Medi-Cal may face unaffordable spenddown requirements
- Many will lose insurance altogether and have to seek emergency dialysis at hospitals.

Finally, there is something very disturbing about the fact that folks in kidney failure are overwhelmingly black and brown. This is not true at the beginning of the disease when it affects all groups proportionately. Why is this the case? It is because we have a broken health care system that does not provide adequate access to care for low-income minority people. I urge you not to break the system even further by taking away the AKF safety net for people who are literally fighting for their lives.
And now, I want to introduce AKF grant recipient Russell Desmond.

About the American Kidney Fund

As the nation's leading independent nonprofit working on behalf of the 30 million Americans with kidney disease, the American Kidney Fund is dedicated to ensuring that every kidney patient has access to health care, and that every person at risk for kidney disease is empowered to prevent it. AKF provides a complete spectrum of programs and services: prevention outreach, top-rated health educational resources, and direct financial assistance

enabling low-income U.S. dialysis and transplant patients to access lifesaving medical care. AKF holds the highest ratings from the nation's charity watchdog groups, including Charity Navigator, which includes AKF on its "top 10" list of nonprofits with the longest track records of outstanding stewardship of the donated dollar, and GuideStar, which has awarded AKF its Platinum Seal of Transparency.

For more information, please visit **KidneyFund.org <http://www.kidneyfund.org/>** , or connect with us on **Facebook <http://www.facebook.com/americankidneyfund>** , **Twitter <http://www.twitter.com/kidneyfund>** and **Instagram. <https://instagram.com/americankidneyfund/>**

EXHIBIT 3

Donate Now

Health Insurance Premium Program (HIPP)

If you have kidney failure and have health insurance coverage but are unable to afford the cost of your premiums, the American Kidney Fund's Health Insurance Premium Program (HIPP) may be able to help. Patients may qualify for this program if they have demonstrated insufficient income and savings to pay their premium bills. HIPP covers premiums for Part B Medicare, Medigap, Medicare Advantage, Medicaid (in states that charge premiums), commercial plans (including Marketplace plans), employer group health plans and COBRA plans.

AKF is an independent nonprofit organization. Our HIPP program depends on the generosity of donors, and we accept new applications for HIPP assistance as funding becomes available.

- **What is HIPP?**
- **HIPP eligibility criteria**
- **Things you should know about HIPP**
- **Download the HIPP guidelines and patient handbook**
- **How do I get a copy of all HIPP programmatic forms?**
- **Dialysis providers who have signed AKF's Code of Conduct**
- **How AKF complies with Advisory Opinion 97-1**

What is HIPP?

If you have kidney failure and have health insurance coverage but are unable to afford the cost of your premiums, AKF's HIPP program may be able to help if you meet program eligibility qualifications.

HIPP covers premiums for:

- Medicare Part B
- Medicare Advantage Plans
- Medicaid (if your state requires a premium payment)
- Medigap
- Commercial plans (including Marketplace plans)
- Employer group health plans
- COBRA plans

Return to top

HIPP eligibility criteria

- You must live and receive dialysis treatment for end-stage renal disease (ESRD) in the U.S. or its territories.
- When an existing HIPP patient receives a transplant, we provide health insurance premium assistance to the patient through the end of the insurance coverage plan year. Persons eligible to receive post-transplant assistance must already have been receiving HIPP assistance for at least three consecutive months prior to the time of their transplant.
- You must meet the eligibility requirements of the insurance coverage for which premium assistance is being requested.
- You must show that you cannot afford your health coverage. AKF will review your household income, reasonable expenses and liquid assets before granting assistance.
- 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.
- For more detailed HIPP information and rules please review the HIPP guidelines available on AKF's Grants Management System (GMS).

Return to top

Things you should know about HIPP

1. HIPP is for people who can't afford their monthly insurance premiums. We determine your eligibility based on our financial need criteria.
2. 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.

3. When you receive grant assistance from AKF, it doesn't matter where you are treated. We will assist you whether or not your dialysis provider or transplant center makes charitable contributions to AKF, and you're free to change providers at any time. We do not help you choose a dialysis clinic or other health care providers.
4. Assistance with primary and secondary insurances is available (AKF will not assist with more than two types of insurance).
5. Once you have assistance from HIPP, you'll be able to access all of the health care services offered covered by your insurance, including transplant workups and transplants allowed under your plan.
6. When an existing HIPP patient receives a transplant, we provide health insurance premium assistance to the patient through the end of the insurance coverage plan year. For example, a patient whose health plan year is on a calendar basis and who receives a transplant in May would be eligible to receive HIPP assistance through the end of December. If the transplant occurs in the final quarter of a plan/policy year and AKF has already begun paying premiums for the next plan/policy year, then AKF will continue grant assistance for the full new plan/policy year.
7. We help you regardless of whether your health care provider makes charitable contributions to AKF.
8. Although you receive HIPP assistance from AKF, you are the policy holder for your health insurance. 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.
9. AKF reviews grant requests on a "first-come, first-served" basis. We are an independent nonprofit organization. Our HIPP program depends on the generosity of donors, and we accept new applications for HIPP assistance as funding becomes available.
10. AKF processes applications within 10–14 business days on average.
11. You should work with your dialysis social worker or HIPP coordinator to complete your HIPP application so that they have all the information to submit a complete and accurate application.
12. It is important that you bring your most current insurance bill (no older than 90 days) to your dialysis social worker before applying to AKF for assistance. You must also sign and date a HIPP patient consent form. Not providing all required documentation can slow down the grant approval process and delay getting the grant to you.
13. All applications must be submitted via AKF's online Grants Management System (GMS).

Return to top

Download the HIPP guidelines and patient handbook

Download PDF versions of our HIPP guidelines and patient handbook:

- **HIPP guidelines <http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-guidelines.pdf>**
- **HIPP patient handbook <http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-patient-handbook.pdf>**

Return to top

How do I get a copy of all HIPP programmatic forms?

All forms available within AKF's Grants Management System (GMS) please log into the **GMS site. <https://gms.kidneyfund.org/login>**

Return to top

Dialysis providers who have signed AKF's Code of Conduct

The American Kidney Fund's (AKF) voluntary Code of Conduct reflects our firm expectation that all renal providers and renal professionals who refer patients to AKF for HIPP program assistance will do so in an ethical manner and in compliance with Advisory Opinion 97-1, with the underlying goal of putting patients' interests first. By signing the Code of Conduct, companies have affirmatively agreed to educate patients about the HIPP program and to ensure that patients have access to accurate and impartial information about health insurance coverage options. This enables patients to make informed decisions about selecting the best coverage and their ability to receive assistance from AKF to pay for such coverage if they qualify for the HIPP program.

The following dialysis providers have signed the AKF Code of Conduct. AKF will update this information on a routine basis.

American Home Dialysis, LLC
American Renal Associates
Antelope Valley Kidney Institute
Boson Health
CentraCare Health
DaVita Kidney Care
Dialysis Center of Lincoln, Inc.
Dialysis Clinic, Inc.
Dreiling Medical Management
Fresenius Medical Care
Harrison Dialysis Center
Home Dialysis of North Alabama
Infiniti Dialysis Center of Cincinnati, LLC
Jefferson Health Dialysis
Kidney Care Center
Kidney Spa, LLC
NEA Baptist Clinic Dialysis Center
North Central PA Dialysis Clinic
Physicians Dialysis Trinity
Physicians Choice
Santa Barbara & Lompoc Artificial Kidney Centers

Satellite Healthcare
SNG Dialysis
Tift Regional Dialysis
U.S. Renal Care
Union County Dialysis Center
Waycross Dialysis Facility

Return to top

How AKF complies with Advisory Opinion 97-1

AKF's HIPP program operates under federal guidance in Advisory Opinion 97-1, with a strong compliance program that prevents conflicts of interest and ensures that the program operates in accordance with all applicable laws. **For further details, see our OIG Compliance Policy. <http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-oig-compliance-policy.pdf>**

Return to top

EXHIBIT 4

American Kidney Fund®

PATIENT HANDBOOK

HEALTH INSURANCE PREMIUM PROGRAM

Updated January 2, 2019

TABLE OF CONTENTS

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**.

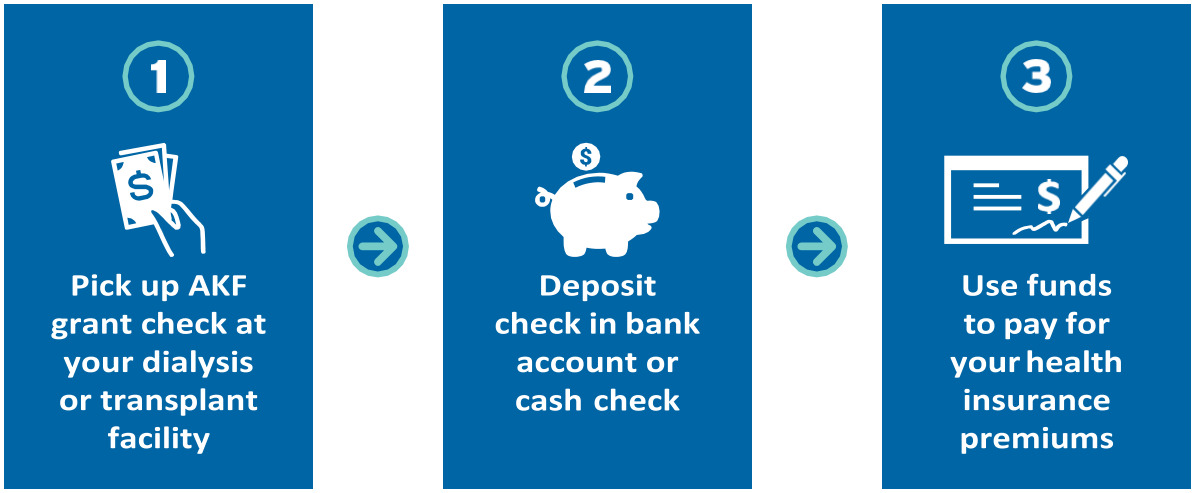
GRANT PAYMENTS

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

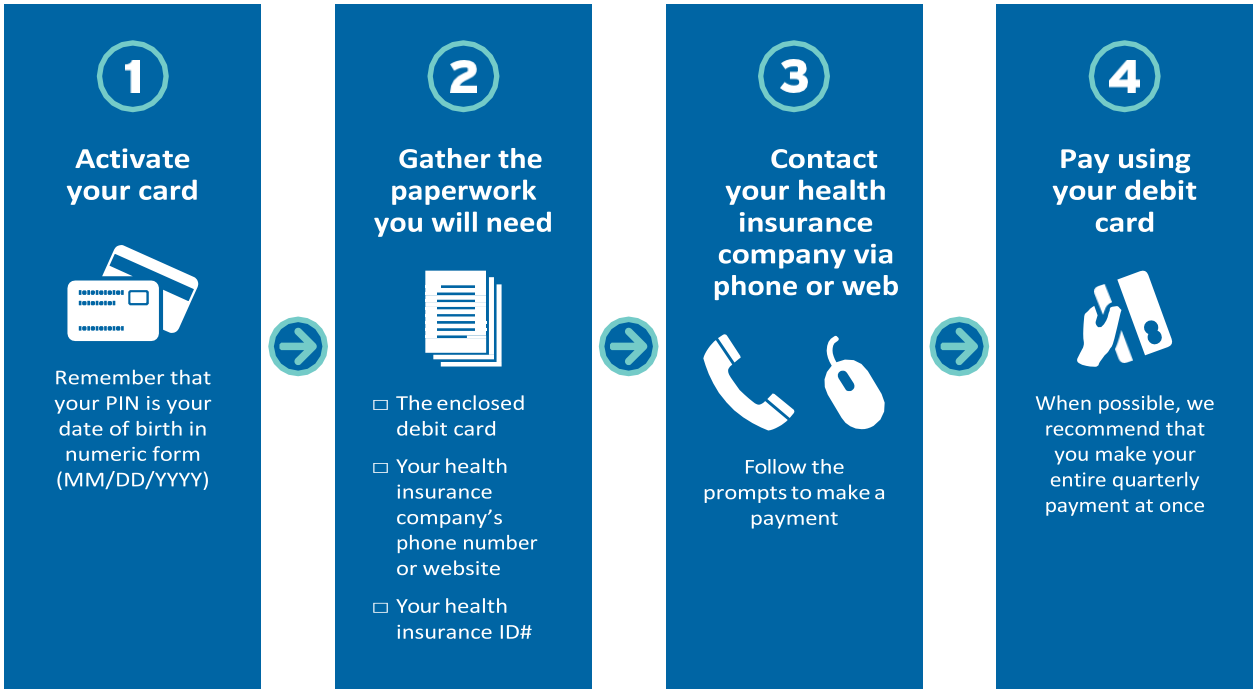
Debit cards are a payment method instituted by AKF for some, but not all, insurance plans. **AKF-issued debit cards will ONLY allow you to pay your insurance premiums. They may not be used for any other purpose.**

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?

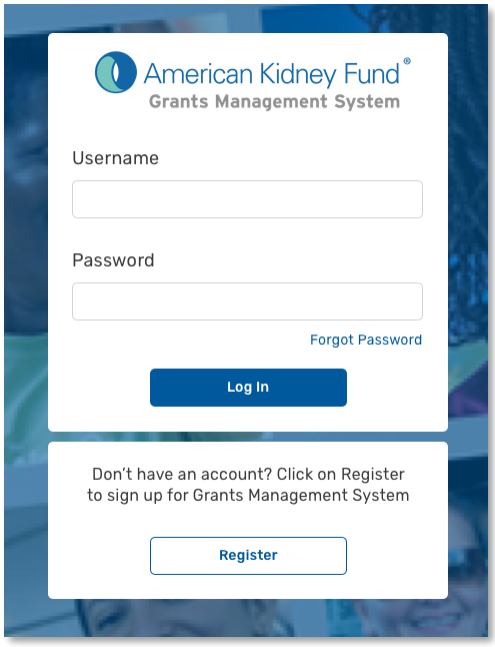
You can upload documents by emailing them as images on your cellphone:

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.

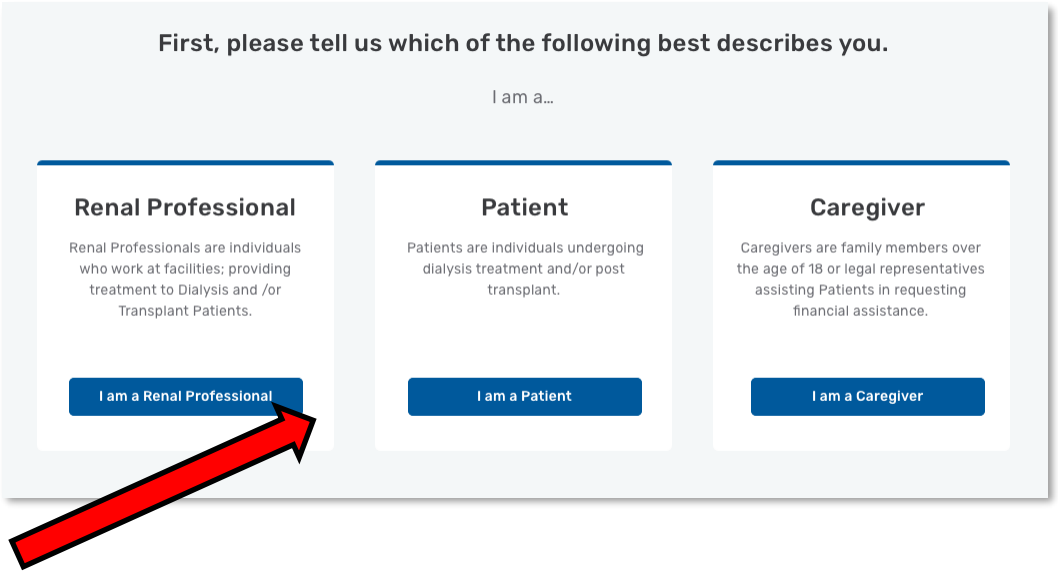
APPENDIX 1: GMS PATIENT PROFILE REGISTRATION GUIDE

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:

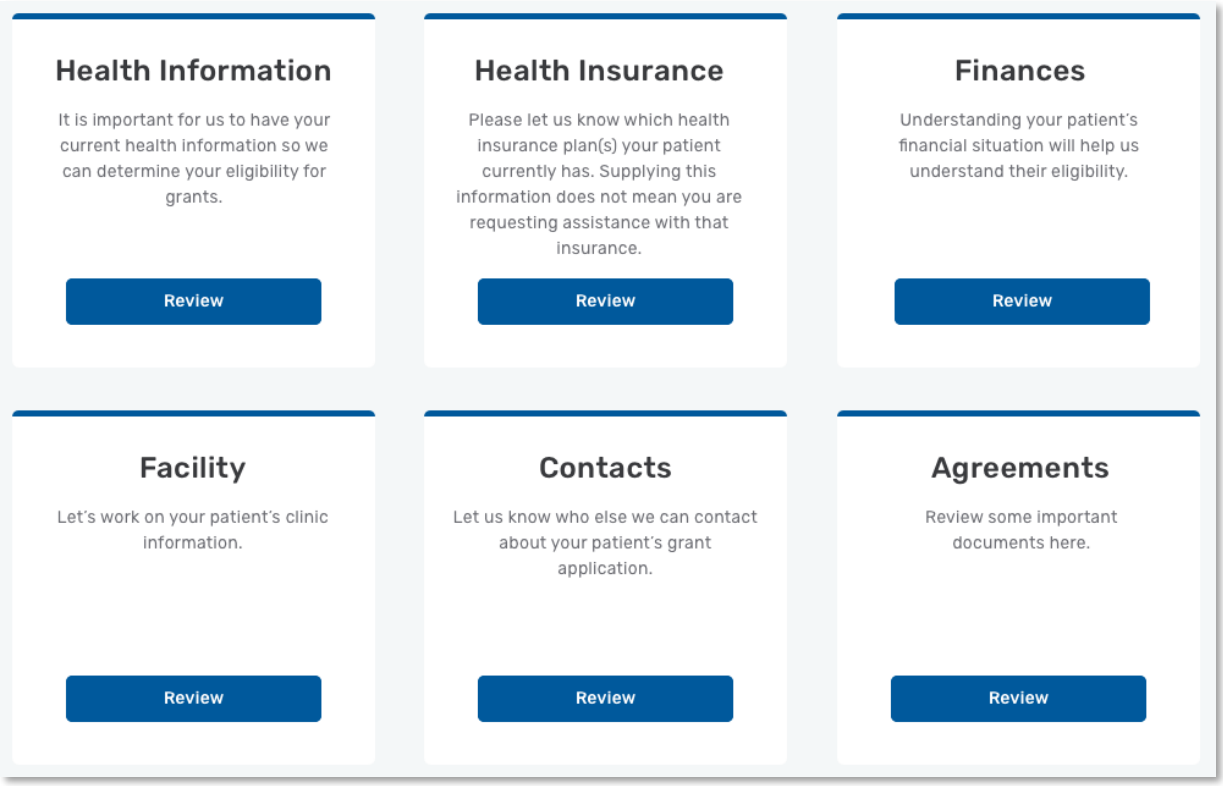


Step Three:

- 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 5

KATIE PORTER
45TH DISTRICT, CALIFORNIA

FINANCIAL SERVICES COMMITTEE
SUBCOMMITTEE ON
INVESTOR PROTECTION, ENTREPRENEURSHIP, AND CAPITAL MARKETS
SUBCOMMITTEE ON
CONSUMER PROTECTION AND FINANCIAL SERVICES

Congress of the United States
House of Representatives
Washington, DC 20515–0545

WASHINGTON OFFICE:
1117 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-5611

DISTRICT OFFICE:
2151 MICHELSON DRIVE
SUITE #195
IRVINE, CA 92612
(949) 668-6600

porter.house.gov

July 23, 2019

Joanne Chiedi
Acting Inspector General
Department of Health and Human Services
330 Independence Ave SW
Washington, DC 20201

Dear Inspector General Chiedi,

I am writing to request that the Office of the Inspector General (OIG) open an investigation into the American Kidney Fund's (AKF) relationship with leading dialysis providers, including DaVita, Fresenius Medical Care, and American Renal Associates (ARA), in the wake of recent revelations that suggest these organizations have collaborated to implement practices that benefit their bottom line at the expense of patients with kidney disease.

The last twenty years have seen a revolution in how the American Kidney Fund is funded, and this warrants OIG revisiting the conclusions of the 1997 Advisory Opinion that permitted the operation of the AKF's Health Insurance Premium Program (HIPP).

Background

People whose kidneys are failing, otherwise known as end stage renal disease (ESRD), require dialysis treatment, which performs the functions that kidneys typically do.[1] Dialysis usually involves treatments several times a week for several hours at a time.[2] There are few other options for patients other than kidney transplants.

The American Kidney Fund primarily operates a program, the Health Insurance Premium Program, which helps pay the insurance premiums for individuals who need dialysis. Specifically, HIPP covers premiums for Medicare, Medicaid, and private insurance plans.[3] Large dialysis clinics are major benefactors of the AKF. In short, dialysis clinics donate to AKF, provide treatment for patients whose insurance premiums were paid by AKF, and then receive payments from the patients' insurance companies for the treatment.

---

[1] "Dialysis | Hemodialysis | Peritoneal Dialysis." *MedlinePlus*, U.S. National Library of Medicine, 27 Dec. 2018, medlineplus.gov/dialysis.html.
[2] "What Is Dialysis?" National Kidney Foundation, 2 July 2018, www.kidney.org/atoz/content/dialysisinfo.
[3] "Health Insurance Premium Program (HIPP)." American Kidney Fund (AKF), www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/.

Complaints from patients and providers have yielded reports that the country's largest dialysis providers are using their financial influence over the American Kidney Fund to push patients toward more expensive insurance options. Doing so increases dialysis center profits while making it more difficult for patients to access kidney transplants due to policies that end premium assistance for patients who receive transplants despite patients needing proof of ongoing insurance in order to be eligible for a transplant. In some cases, the AKF has also reportedly denied patients financial assistance if they are not receiving care at a major AKF donor.

On July 10, 2019 the President issued an Executive Order announcing a new initiative for ESRD care. Secretary of Health and Human Services Alex Azar announced that the Administration hopes that, as a result of this initiative, 80 percent of end-stage renal disease patients will be receiving home dialysis or a kidney transplant by 2025 and double the number of kidneys available for transplant by 2030. Yet the practices described by patients and providers working with the AKF, DaVita, Fresenius, and American Renal Associates threaten to undercut the Department's ability to achieve these objectives.

Potential Conflicts of Interest and Kickbacks That Harm ESRD Patients

As you know, ESRD can be covered by Medicare, even for patients who are not 65 or older, and Medicaid. Yet recent reports from patients and health care providers suggest that the two largest providers of dialysis, DaVita and Fresenius Medical Care, are using their financial influence over AKF to steer patients toward more expensive private insurance options or to clinics who provide large donations.

HIPP has long raised concerns about potential violations of federal anti-kickback and anti-competition laws because of the potential tension between the financial interests of AKF and dialysis providers and the health and finances of patients. To address these concerns, AKF requested and received an OIG advisory opinion (No. 97-1) in 1997 that outlines conditions under which HHS would choose to exercise its enforcement discretion and not find this arrangement unlawful.[4] These conditions include treating all patient applications for assistance equally – regardless of the type of insurance they have or whether the clinics from which they receive treatment donate to AKF.

For example, HIPP provides financial assistance for "transportation, medication, and health insurance premiums," for low-income individuals with ESRD. In the advisory opinion, HHS OIG 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."[5] Essentially, AKF was not allowed to take into consideration whether or not a patient was receiving care at a provider that supported AKF financially.

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 ten percent" was provided by

[4] HHS OIG. Advisory Opinion No. 97-01. (1997). https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf
[5] Ibid.

the major dialysis providers.[6] In 2018, AKF received nearly 80 percent of all donations from DaVita and Fresenius.[7] 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.

This advisory opinion also predated the passage and implementation of the Affordable Care Act (ACA), which made major changes to the healthcare system affecting patients with kidney disease. Before the ACA, private insurance coverage was rarely an option for people with ESRD because ESRD was an expensive pre-existing condition. Since the ACA prohibits insurance companies from discriminating against patients with pre-existing conditions, those with kidney disease now have access to private insurance through the ACA exchanges.

It appears that the AKF and the large dialysis providers may have abused this reform by pushing patients to private plans that generate significantly higher reimbursements 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."[8] Since 2010, DaVita and Fresenius have experienced significant growth in annual profits, bringing in billions of dollars annually.[9] 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 astronomically higher than if they received insurance from Medicaid or Medicare.

Disturbing Revelations Regarding the American Kidney Fund's Practices

Based on recent investigative reporting and legal challenges, AKF and its donors' practices appear to be clear violations of OIG's 1997 Advisory Opinion and may be putting patients' lives at risk. In short, the dialysis providers providing the biggest donations seem to exert significant influence on how AKF distributes its financial assistance to patients and clinics.

In 2016, the New York Times published a detailed report about AKF's practices, including personal anecdotes from various social workers who had reached out to AKF to request financial assistance. One patient advocate informed the New York Times that "Each time … the charity's workers later demanded that the clinic make a donation that at a minimum covered the amount it

---

[6] Ibid.
[7] 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/.
[8] Reed Abelson and Katie Thomas. "Dialysis Chains Receive Subpoenas Related to Premium Assistance." *The New York Times*, 7 Jan. 2017, www.nytimes.com/2017/01/06/business/american-kidney-fund-fresenius-davita-subpoena.html.
[9] "Fresenius Medical Care Gross Profit 2006-2019: FMS." *Macrotrends*, 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.

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."[10]

One social worker, unaffiliated with a clinic donating to AKF, received an email responding to a request for support in which an AKF staff person attached a set of guidelines 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."[11]

According to a lawsuit in Massachusetts brought against American Renal Associates,

> "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.'"[12]

Sometime after the publication of the New York Times article, AKF removed language about this "fair share" requirement from its guidelines. While this "fair share" practice is no longer formally included in the HIPP program guidelines, reports from the New York Times, the Los Angeles Times, and social workers across the country assert that AKF is continuing to discriminate against patients at non-donor clinics.[13]

Insurers have also brought civil suits, which have since been settled, against DaVita in Pennsylvania and against American Renal Associates in Massachusetts and Florida.[14] 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."[15] The court denied DaVita's motion to dismiss the case on March 28, 2019 and the case is still ongoing.[16]

---

[10] Reed Abelson and Katie Thomas. "Dialysis Chains Receive Subpoenas Related to Premium Assistance." *The New York Times*, The New York Times, 7 Jan. 2017, www.nytimes.com/2017/01/06/business/american-kidney-fund-fresenius-davita-subpoena.html.
[11] 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.
[12] United States District Court of Massachusetts, Case 1:18-cv-10622-ADB.
[13] "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.
[14] Court of Common Pleas of Montgomery County, PA, Case 17-07795-0.
[15] "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.
[16] Shareholders Foundation, Inc. "Update: Lawsuit for Investors in Davita Inc (NYSE: DVA) Shares Announced by Shareholders Foundation." GlobeNewswire News Room, 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.

Discouraging Patient Access to Transplants

Not only do these alleged practices result in unnecessary spending, they may also interfere with the best interest of patients with ESRD. 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. This outcome hurts the financial interests of dialysis providers, especially if they are receiving high payments from commercial insurers. The lawsuits in Massachusetts and Florida examined this tension between the best interests of patients and the financial interests of the dialysis providers, noting that the dialysis providers "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."[17] This can make it difficult for patients who were steered into high premium private plans to pursue transplants, particularly since patients often must demonstrate proof of ongoing insurance to receive transplants.

On August 18, 2016, the Center for Medicare and Medicaid Services (CMS) 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) in which the regulator 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."[18]

The IFC was published in December 2016 and was scheduled to take effect on January 14, 2017, but Judge Amos Mazzant of the U.S. District Court for the Eastern District of Texas granted a request for a temporary restraining order from DaVita, Fresenius, and U.S. Renal Care on January 12, 2017 and permanently suspended the rule on January 25, 2017.[19] Mazzant found that CMS had not appropriately provided public notice for comment on the proposed rule prior to implementation and concluded that CMS did not have good cause to bypass notice and comment in moving from the RFI to the IFC.

---

[17] United States District Court of Florida, Case 9:16-cv-81180-KAM.
[18] 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.
[19] United States District Court for the Eastern District of Texas, Case 4:17-cv-00016-ALM.

Requesting HHS OIG Investigation

The Department of Justice is currently investigating pharmaceutical companies' financial support of charities that provide assistance to patients seeking support to cover out-of-pocket costs.[20] I request that the OIG (possibly in conjunction with the Department of Justice) undertake a similar investigation into the practices of the American Kidney Fund and its effects on the patients whose lives they may be putting at risk. In this investigation I request that you consider:

1. Whether or not AKF favors providers that donate funds to AKF;
2. Whether or not AKF terminates support for patients after they seek transplants; and
3. Whether or not AKF has violated anti-kickback laws in their practices.

During this time, I request that OIG suspend its agreement with the AKF and all relevant companies in order to reevaluate the legality of this agreement and the effects that it has on patients' ability to access affordable, quality ESRD care.

This would not be the first time that the OIG has rescinded an advisory opinion addressing concerns regarding a previously issued advisory opinion. In April 2006, the OIG published Advisory Opinion 06-04 for the Caring Voice Coalition (CVC).[21] CVC was similarly providing financial assistance for premium and cost-sharing obligations, though in this case 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 OIG rescinded Advisory Opinion 06-04, based on the charity's "failure to fully, completely, and accurately disclose all relevant and material facts to OIG."[22] 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."[23] I ask that you consider ways to ensure patients' continued access to care with your partners throughout HHS during this time. I hope that this can complement the Administration's efforts to drive down the cost of care for patients with ESRD, improve the quality of treatment, and increase the number of transplants.

Sincerely,

Representative Katie Porter

---

[20] Raymond, Nate. "Drug Charity Halts Patient Aid after U.S. Health Agency Pulls Approval." Reuters, 5 Jan. 2018, www.reuters.com/article/us-usa-healthcare-charity-idUSKBN1EU1V6.
[21] HHS OIG. Advisory Opinion No. 06-04. (2006). https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf
[22] "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/.
[23] HHS OIG. Advisory Opinion No. 06-04. (2006). https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf.

CERTIFICATE OF SERVICE

Case Name: **Jane Doe, et al v. Xavier Becerra, et al.** Case No.: **8:19-cv-2105-DOC-(ADSx)**

I hereby certify that on November 25, 2019, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

DECLARATION OF AMIE L. MEDLEY IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

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 the foregoing is true and correct and that this declaration was executed on November 25, 2019, at Los Angeles, California.

Colby Luong	/s/ Colby Luong
Declarant	Signature

SA2019106023
53924910.docx

XAVIER BECERRA
Attorney General of California
MARK R. BECKINGTON
Supervising Deputy Attorney General
P. PATTY LI
Deputy Attorney General
MARTINE D'AGOSTINO
Deputy Attorney General
KETAKEE KANE
Deputy Attorney General
KARLI EISENBERG
Deputy Attorney General
AMIE L. MEDLEY
Deputy Attorney General
State Bar No. 266586
300 South Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6226
E-mail: Amie.Medley@doj.ca.gov
Attorneys for Defendants Xavier Becerra, Ricardo Lara, Shelly Rouillard, and Sonia Angell, in their official capacities

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.

XAVIER BECERRA, 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 SUSAN FANELLI, in her Official Capacity as Acting Director of the California Department of Public Health,

Defendants.

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

DEFENDANTS REQUEST FOR JUDICIAL NOTICE IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

Date: December 16, 2019
Time: 8:30 a.m.
Courtroom: 9D
Judge: The Honorable David O. Carter
Trial Date: n/a
Action Filed: 11/5/2019

Defendants Xavier Becerra, 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 Susan Fanelli, in her Official Capacity as Acting Director of the California Department of Public Health[1] ("Defendants") request that the Court, under Federal Rule of Evidence 201(b), take judicial notice of the documents listed below in support of Defendants' opposition to the motion for preliminary injunction file by Plaintiffs Jane Doe; Stephen Albright; American Kidney Fund, Inc.; and Dialysis Patient Citizens, Inc. ("Plaintiffs").

Exhibit 1. A true and correct copy of a bill analysis of Assembly Bill 290, prepared for the July 3, 2019 hearing before the California Senate Health Committee, available at https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201920200AB290 (last accessed November 25, 2019).

Exhibit 2. A true and correct copy of an excerpt from the Federal Register, dated August 23, 2016, in which the United States Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), issued a request for information titled "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans." 81 Fed. Reg. 57554.

Exhibit 3. A true and correct copy of an excerpt from the Federal Register, dated December 14, 2016, in which CMS analyzed and drew conclusions based upon 800 public comments received in response to the request for information. 81 Fed. Reg. 90214.

[1] The current Director of the California Department of Public Health is Sonia Angell. Ms. Angell may be automatically substituted as a party in this action under Federal Rule of Civil Procedure 25(d).

Exhibit 4. 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=20190AB29099INT (last accessed November 25, 2019).

DISCUSSION

The documents listed above fall into two categories of which this Court may take judicial notice: legislative history materials and excerpts from the Federal Register.

First, Defendants request that the Court take judicial notice of a bill analysis of Assembly Bill 290, prepared for the July 2, 2019 hearing before the Senate Health Committee. "Courts frequently take judicial notice of legislative history." *Korematsu*, 584 F.Supp. at 1414 (citing *Territory of Alaska v. Am. Can Co.*, 358 U.S. 224, 227 (1959) (taking judicial notice of an act's legislative history). Defendants ask this Court to take judicial notice of the hearing transcript and bill analysis as part of the legislative history of the bill.

Second, Defendants ask this Court to take judicial notice of two excerpts from the Federal Register, published therein at the request of CMS. "The contents of the Federal Register are noticeable as a matter of law." *Sandoval v. PharmaCare, U.S., Inc.*, 145 F. Supp. 3d 986, 992 (S.D. Cal. 2015); 44 U.S.C. § 1507 ("The contents of the Federal Register shall be judicially noticed."); *Bayview Hunters Point Cmty. Advocates v. Metro. Transp. Comm'n*, 366 F.3d 692, 702 (9th Cir. 2004) (granting motion to take judicial notice of an EPA Proposed Rule published in the Federal Register). Even if Plaintiffs dispute the accuracy of the ultimate conclusions drawn by the CMS and reported in the Federal Register, "it is proper to take judicial notice of . . . the general nature and substance of [those] conclusions," which may be used to inform the Court's consideration of the effect of granting the motion for

preliminary injunction and what will serve public interest. *Korematsu v. U.S.*, 584 F.Supp. 1406 (N.D. Cal. 1984).

Dated: November 25, 2019

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
MARK R. BECKINGTON
Supervising Deputy Attorney General

/s/ Amie L. Medley
AMIE L. MEDLEY
Deputy Attorney General
Attorneys for Defendants Xavier Becerra, Ricardo Lara, Shelly Rouillard, and Sonia Angell, in their official capacities

EXHIBIT 1

SENATE COMMITTEE ON HEALTH

Senator Dr. Richard Pan, Chair

BILL NO: AB 290
AUTHOR: Wood
VERSION: June 25, 2019 Amended
HEARING DATE: July 3, 2019
CONSULTANT: Teri Boughton

SUBJECT: Health care service plans and health insurance: third-party payments

SUMMARY: Establishes requirements on financially interested providers and entities that make third-party premium payments on behalf of health plan enrollees and insureds, including that financially interested providers that make third-party premium payments or have a financial relationship with an entity making third-party payments on behalf of a patient, and large dialysis clinic organizations (LDOs) that have greater than 10% of California's market share be paid the lesser of an amount for covered services to that patient governed by the terms and conditions of the health plan contract/health insurance policy or the Medicare reimbursement rate.

Existing law:

1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans and the California Department of Insurance (CDI) to regulate health insurance. [HSC §1340 et seq. and INS §106, et seq.]

2) Prohibits the cancellation or non-renewal of health plan contracts and health insurance policies with exceptions, such as nonpayment of premiums by the individual, employer, or contract/policy holder after at least a 30-day grace period, or fraud, as specified. [HSC §1365 and INS §10273.5]

3) Establishes the Medi-Cal program, administered by the Department of Health Care Services (DHCS), under which qualified low-income individuals receive health care services with little to no cost-sharing or premium. [WIC §14000, et seq.]

4) Establishes Covered California as an independent entity in state government and requires the Covered California Executive Board to establish and use a competitive process to select participating plans and other contractors. [GOV §100500, et seq.]

5) Establishes, under federal law, the Medicare Program, administered by the Centers for Medicare and Medicaid Services (CMS), under which qualified individuals over 65 years old or individuals under aged 65 years old with qualifying disabilities receive health care, after applicable deductibles, coinsurance, or other required cost sharing. [42 USC §1395, et seq.]

6) Prohibits a health plan or insurer from denying or conditioning the offering or effectiveness of any Medicare supplement contract available for sale in California, nor discriminating in the pricing of a contract because of the health status, claims experience, receipt of health care, or medical condition of an applicant in the case of an application for a contract that is submitted prior to or during the six-month period beginning with the first day of the first month in which an individual is both 65 years of age or older and is enrolled for benefits under Medicare Part B. [HSC §1358 and INS §10192.11]

7) Requires each Medicare supplement contract currently available from a health plan or insurer to be made available to all applicants who qualify and who are 65 years of age or older. [HSC §1358 and INS §10192.11]

8) Requires a health plan or insurer to make available specified Medicare supplement standardized benefit plans, if currently available, to a qualifying applicant who is 64 years of age or younger and does not have end-stage-renal disease (ESRD). [HSC §1358 and IC §10192.11]

9) Requires, if a health plan or insurer rejects an applicant for a Medicare supplement policy due to the applicant having ESRD, the health plan or insurer to inform the applicant about the California Major Risk Medical Insurance Program (MRMIP) and about the new coverage options and the potential for subsidized coverage through Covered California. Requires the insurer to direct persons seeking more information to MRMIP, Covered California, plan or policy representatives, insurance agents, or an entity paid by Covered California to assist with health coverage enrollment, such as a navigator or an assister. [HSC §1389.25 and IC §10113.9]

This bill:

1) Requires a health plan or insurer to accept premium and cost-sharing payment from the following third-party entities:

   a) A Ryan White HIV/AIDS Program;
   b) An Indian Tribe, tribal organization, or urban Indian organization;
   c) A local, state, or federal government program, including a grantee directed by a government program to make payments on its behalf; and,
   d) A member of the individual's family, defined for purposes of this bill 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.

2) Requires a financially interested entity that is not described in 1) above and is making third-party premium payments to comply with all of the following:

   a) Provide assistance for the full plan/policy year and notify the enrollee/insured prior to an open enrollment period, if applicable, if financial assistance will be discontinued. Permits assistance to be discontinued at the request of the enrollee/insured or if the enrollee/insured dies during the plan year;
   b) Agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug or device, if the entity provides coverage for an enrollee/insured with ESRD;
   c) Inform an applicant of financial assistance, and annually inform a recipient, of all available health coverage options, including, but not limited to, Medicare, Medicaid, individual market plans, and employer plans, if applicable;
   d) Agree not to steer, direct, or advise the patient into or away from a specific coverage program option, health care service plan contract or health insurance policy; and,
   e) Agree that financial assistance is not conditioned on the use of a specific facility or health care provider.

3) Prohibits an entity described in 2) above from making a third-party premium payment unless the entity complies with both of the following:

   a) Annually provide a statement to the health plan/insurer that it meets the requirements set forth in 2) above; and,
   b) Disclose to the health plan/insurer, prior to making the initial payment, the name of the enrollee/insured for each health plan contract/insurance policy on whose behalf a third-party premium payment was made.

4) Requires reimbursement for covered services to a financially interested provider that makes a third-party premium payment or has a financial relationship with the entity making the third-party premium payment to a health plan or insurer on behalf of an enrollee/insured to be determined by the following:

   a) For a contracted or noncontracted provider payment for covered services reimbursement is governed by the terms and conditions of the health plan contract/health insurance policy or the Medicare reimbursement rate, whichever is lower;
   b) Requires the cost-sharing to be based on the amount paid by the plan or insurer under this bill, if the contract or policy imposes coinsurance. Prohibits enrollees/insureds from being billed or reimbursement from being sought, except for cost-sharing pursuant to the terms and conditions of the contract/policy; and,
   c) A claim submitted to a health plan or health insurer by a noncontracting financially interested provider may be considered an incomplete claim and contested by the health plan or insurer pursuant to existing law if the financially interested provider has not provided the information as required in 3) above.

5) States that third-party premium payments only include health plan/insurer premium payments made directly by a provider or other third party, made indirectly through payments to the individual, or provided to one or more intermediaries with the intention that the funds be used to make health plan/health insurer premium payments for the individuals.

6) Defines financially interested to include the following entities:

   a) A provider of health care services that receives 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 health care services, parent companies of providers of health care services, subsidiaries of health care service providers, or related entities; and,
   c) A chronic dialysis clinic that is operated, owned, or controlled by a parent entity or related entity that meets the definition of large dialysis clinic organization (LDO) under the Centers for Medicare and Medicaid Services (CMS) ESRD Care Model as of January 1, 2019.

7) Exempts from the definition of financially interested entity a chronic dialysis clinic that does not meet the definition of LDO or has no more than 10% of California's market share of licensed chronic dialysis clinics.

8) Requires a health plan/health insurer, if it subsequently discovers that a financially interested entity fails to provide disclosure pursuant to 2) above:

a) To be entitled to recover 120% of the difference between a payment made to a provider and the payment to which the provider would have been entitled pursuant to 4) above, including interest on that difference; and,
b) To notify DMHC/CDI of the amount by which the provider was overpaid and to remit to DMHC/CDI 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 4) above, including interest on that difference that was recovered pursuant to a).

9) Requires each health plan and health insurer to provide information regarding premium payments by financially interested entities and reimbursement for services to providers pursuant to this bill at least annually at the discretion of DMHC/CDI.

10) States that this bill:

a) Does not limit the authority of the Attorney General to take action to enforce this bill;
b) Does not affect a contracted payment rate for a provider who is not financially interested;
c) Does not alter any of a health plan/health insurer's obligations and requirements under existing law, including the obligation to fairly and affirmatively offer, market, sell, and issue a health benefit plan to any individual, or small employer, consistent with existing law; or, the obligations with respect to cancellation or nonrenewal as provided in existing law; and,
d) 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 (HIPAA).

11) Establishes legislative intent that this bill, to protect the sustainability of risk pools within the individual and group health insurance markets, shields 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 their oligopoly power to inflate commercial reimbursement rates and unjustly drive up the cost of care.

FISCAL EFFECT:

According to the Assembly Appropriations Committee:

1) Costs to DMHC to oversee and enforce the new disclosure requirements of approximately $140,000-$200,000 for the first three years and $65,000 annually thereafter (Managed Care Fund).

2) Costs to CDI to oversee and enforce the new disclosure requirements of approximately $200,000 for the first year-and-a-half, and $90,000 annually thereafter (Insurance Fund).

3) Potential, likely minor, General Fund (GF) penalty revenue.

To the extent this bill restricts or removes the incentive for third parties to pay for commercial insurance or Medicare wraparound insurance plans, this bill could result in unknown, potentially significant Medi-Cal costs associated with higher enrollment than under the status quo. The effect of this bill's restriction, as it pertains to how many patients would continue to be able to maintain their coverage via third-party payments, is unknown. If third-party premium assistance

is eliminated, GF Medi-Cal costs could be well in excess of $1 million for increased enrollment if patients seek Medi-Cal coverage instead of receiving coverage through a third-party payer. The state could also realize some level of offsetting cost savings if any individuals receiving third-party payments to maintain coverage for dialysis services through state-funded CalPERS plans disenroll from such plans.

PRIOR VOTES:

Assembly Floor:	46 - 15
Assembly Appropriations Committee:	12 - 3
Assembly Health Committee:	11 - 2

COMMENTS:

1) *Author's statement.* According to the author, this bill provides certain parameters on a practice where companies that provide certain types of care, donate money to a nonprofit that, in turn, pays for a patient's private coverage even though they qualify for coverage under Medicare or Medi-Cal, in order to receive a higher reimbursement rate. This bill will still allow providers, like dialysis companies, to donate to nonprofit organizations if they want to help provide premium assistance to patients, but it will not allow them to leverage those donations into higher reimbursement rates than they might otherwise receive through Medicare.

2) *Examples of problem*. There have been examples of financially interested health care providers or organizations funded by financially interested providers making health insurance premium payments available to encourage enrollment, or to maintain enrollment, in private health insurance, which typically reimburses health care providers more generously than a provider would otherwise receive on behalf of a patient with health coverage through Medicare or Medi-Cal. Media reports have identified this practice among substance abuse treatment providers or affiliates whom have offered to pay premiums for private insurance policies while enrolled in treatment programs. In 2016, the federal Department of Health and Human Services (HHS) had become concerned about the inappropriate steering of dialysis patients eligible for, or entitled to, Medicare or Medicaid into private plans by providers because of significantly higher reimbursement. One insurance company indicated that commercial coverage could pay more than ten times that of public coverage ($4,000 per treatment rather than $300 per treatment). HHS promulgated a rule to address these concerns that was blocked by a judge in the U.S. District in Eastern Texas who concluded the rule was unlawfully promulgated, arbitrary and capricious, and that preserving the status quo would ensure that ESRD patients have the choice to select private or public insurance options based on their health care needs and financial means.

3) *ESRD*. ESRD is the final stage of kidney disease. Patients suffering from ESRD must receive kidney dialysis or a kidney transplant to survive. Although many ESRD patients can receive treatments at hospitals or in their own homes, many receive treatments at chronic dialysis clinics. There are about 654 of these clinics serving approximately 70,639 ESRD patients in California. Some clinics are owned and operated by private nonprofit or public entities, two private for-profit entities (DaVita Healthcare Partners and Fresenius Medical Care) treat the vast majority of ESRD patients in California. DaVita indicates it treats 34,000 Californians with kidney disease. Fresenius Medical Care indicates that it treats over 16,200 Californians with kidney disease.

4) *Medicare and ESRD.* Generally speaking, Medicare provides health care coverage to qualifying individuals with ESRD regardless of age, including coverage for kidney transplantation, maintenance dialysis, and other health care needs. Typically a person with ESRD cannot enroll in Medicare Advantage plans (HMOs), and in some states (including California) cannot enroll in Medigap (also known as Medicare supplement insurance). However, if a person qualifies for Medicare based on age or other disability and becomes an ESRD patient, he or she can remain in their Medigap or Medicare Advantage plan. Medigap policies help Medicare enrollees meet deductible and copayment requirements. Medicaid also provides coverage for some people with ESRD, and some low income people can qualify for both Medicare and Medicaid, which will cover the Medicare cost sharing. Medicare coverage for individuals eligible because of ESRD typically starts three months after dialysis begins. During this three-month "waiting period," an individual's other health insurance coverage—such as an employer group health plan or Medicaid—pays for the individual's dialysis. All, or a portion of, the three-month waiting period may be waived if the individual participates in a self-dialysis training program, or if the individual has a kidney transplant within the three-month waiting period. People who are eligible for Medicare because of ESRD will lose Medicare coverage 12 months after the month he or she stops dialysis treatment or 36 months after the month of a kidney transplant.

   A person with ESRD who has employer sponsored or union coverage can also obtain Medicare coverage, but coordinating benefits can be complicated. Medicare acts as a secondary payer for the first 30-months of coverage (after the three-month waiting period) for someone with this type of dual coverage, meaning the private coverage pays first and Medicare pays for Medicare covered benefits not covered by the private coverage. After this coordination period, Medicare becomes the primary payer and the employer or union group health plan becomes the secondary payer. Medicare covers hospital care (Part A) and outpatient services (Part B). Part B requires the payment of a premium. Medicare can help someone with dual coverage who has cost-sharing, deductibles and coinsurance.

5) *Continuation coverage.* Continuation coverage, also referred to as COBRA (Consolidated Omnibus Budget Reconciliation Act) after the federal law that established it, allows an employee to maintain coverage through their group plan for a period of time (generally 18 to 36 months) after he or she separates from employment if he or she pays the full premium. Employers and group health insurance carriers are required to send a notice to former employees and dependents notifying them of their COBRA rights. COBRA and Medicare coordination can be complicated. In particular, Medicare Part B has an initial and annual open enrollment period and a penalty for late enrollment. Additionally, the end of the COBRA period does not entitle a Medicare eligible person to a special enrollment period which could mean a gap in coverage. Because of these complications, the Medicare.gov site advises an individual to consult a state health insurance program about Part B and Medicare before electing COBRA coverage. California's state health insurance program is the Health Insurance Counseling and Advocacy Program (HICAP). Some ESRD patients may find that they can no longer work because of their condition and may be in a position to extend their group coverage through COBRA, if they can afford the premium, or enroll in Medicare or, Medicaid if eligible.

6) *Major Risk Medical Insurance Program (MRMIP).* California's MRMIP program is the state's high risk pool, which prior to the Affordable Care Act (ACA), provided coverage for individuals who could not obtain coverage or were charged unaffordable premiums because of their health conditions. With the ACA, many MRMIP enrollees were able to obtain more

affordable and comprehensive coverage. However, the program remains available with a year to date enrollment of 832 individuals, including some with ESRD.

7) *Office of Inspector General (OIG).* Many third-party payers have sought advisory opinions from the federal OIG to determine if donations by providers to independent 501(c) (3) charitable organizations for the purpose of funding insurance premiums is in violation of federal law. The American Kidney Fund (AKF) is a 501(c) (3) that receives a majority of its revenue from donations by dialysis providers. AKF operates under OIG guidance issued in 1997, which indicates that, as described by AKF, the arrangement does not constitute a violation of HIPAA. HIPAA imposes civil penalties against any person who offers or transfers remuneration to any individual eligible for benefits under federal health care programs such as Medicare or Medicaid, that is likely to influence an individual to order or receive from a particular provider, practitioner, or supplier any item or service funded by the federal health care program. OIG indicates in the 1997 guidance that the AKF arrangement is not in violation of HIPAA because the contributions to AKF from dialysis providers are not made to or on behalf of beneficiaries. 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. The OIG states that 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.

8) *AKF.* According to AKF, AKF helped more than 3,700 low-income dialysis and transplant patients living in California pay for their health insurance premiums in 2018. AKF indicates that kidney patients usually have primary and secondary coverage, and some patients need help paying for both Medicare and employer coverage. In total, 3,756 patients were helped through a total of 4,367 policies. The policy breakdowns are as follows: 1,447 policies were for employer or COBRA coverage, 311 policies were other commercial, 1,154 policies were Medicare part B, 880 policies were Medigap, and 224 policies were Medicare Advantage. According to the AKF handbook, applicants must demonstrate that they cannot afford health coverage. Currently, the eligibility criteria are that monthly household income may not exceed reasonable monthly expenses by more than $600. If an applicant has no income at the time of application, the applicant 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 are not counted toward this amount). AKF also reserves the right to change HIPP financial eligibility thresholds at any time. Savings up to $1,500 formally set aside for burial expenses in a bank account, other financial instrument or prepaid burial arrangement are exempted as an asset.

9) *Related legislation.* SB 260 (Hurtado), among other provisions, requires as part of the existing notice from health plans and insurers when enrollees cease to be covered to also include information that individuals eligible for Medicare should examine their options carefully as delaying Medicare enrollment may result in substantial financial implications.

10) *Prior legislation.* SB 1156 (Leyva) would have established requirements for any financially interested entity making third-party premium payments for health plan enrollees or insureds. SB 1156 was vetoed by Governor Brown, who stated:

> *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.

11) *Support*. The California Labor Federation writes this bill will deter providers of specialty treatments, like dialysis and substance abuse treatment, from steering patients onto commercial insurance plans to reap profit from higher reimbursement rates. This practice shifts unnecessary costs onto commercial plans, driving up health care spending and increasing premiums for Californians already struggling with rising premiums, co-pays, and deductibles. It can also cause real harm to patients who can experience unnecessary coverage disruptions and higher out-of-pocket costs. Amendments taken address the AKFs claim that this bill would supposedly put them in conflict with a federal OIG letter. The amendments add a definition to "financially interested" that is specific to dialysis clinics that applies to clinics operated and controlled by a LDO as defined by CMS. This bill will not prevent providers or financially interested non-profits from paying insurance premiums for patients and it will not give insurance plans the right to refuse those payments or to cancel any patient's coverage. Instead, this bill will put reasonable requirements on financially interested entities who wish to pay patients' premiums. This bill requires the entity to agree to pay the patient's premiums for the full plan year, and prohibits balance billing. The California Council of the Service Employees International Union writes rising health care costs and health insurance costs impact California's workers and families, and profit maximizing schemes are contributing to rising costs. Certain providers are gaming the system by steering patients onto commercial insurance plans and then reaping the additional profit from commercial reimbursement rates. This bill will help better protect patients while also protecting California's consumers by helping to make health insurance more affordable. Blue Shield of California writes that this scheme creates real patient harm and has damaging consequences to the health care market place. These third-party premium payments can place some of our sickest and most vulnerable consumers at risk of harm by potentially exposing them to increased out of pocket costs for health care services, negatively impacting a patient's determination of readiness for a transplant, and placing consumers at significant risks of a mid-year disruption in health care coverage when they need it the most. Health Access California appreciates the amendment to assure that consumers continue to have the right to purchase and renew their health coverage regardless of pre-existing conditions. This bill is a measured response to a real problem of financially interested providers which have used the opportunities of coverage created under the ACA to put their financial interests in obtaining commercial-level reimbursement ahead of the financial interests of consumers in zero-cost/low-cost public coverage.

12) *Opposition*. AKF writes that this bill conflicts with state and federal laws governing patient privacy and as a result AKF will quickly be forced to stop providing assistance in California for all forms of primary and secondary coverage, including Medicare, Medigap and COBRA. AKF believes the bill creates liability under state and federal inducement and kickback laws because of the list of patients receiving premium assistance that must be disclosed to insurers. AKF believes this breaches the AKF firewall between patients and health insurance premium donations by requiring publication of confidential information. Fresenius Medical Care believes this bill is discriminatory policy against low-income ESRD patients receiving charitable assistance. Supporters have alleged dialysis providers steer patients toward commercial plans through improper utilization of premium assistance programs, 700/16,200

Fresenius patients receive assistance through AKF. On average, these patients did not receive assistance through the program until after they had been on dialysis for over 31 months, 408 patients use the assistance for Medicare or Medigap, and 270 patients use it for commercial plans or Covered California. The vast majority of patients have Medicare or Medi-Cal as their primary insurance but some choose to maintain private health coverage instead of applying for Medicare and it is their right to do so. Fresenius also indicates that private insurance rates are not many times the Medicare rate for dialysis patients, their average commercial rate in California is approximately two times the Medicare rate. Similar to most other areas of healthcare, contracted rates with commercial insurers must cover the gap for the public payor losses as well as provide for profit which allow them to engage in activity such as rolling money back into improving and upgrading facilities and equipment, etc. DaVita indicates that private insurance payments received for approximately 10% of dialysis patients cross-subsidize treatment for the 90% of dialysis patients who have government insurance. The number of dialysis patients utilizing commercial insurance has remained steady for decades. This bill effectively allows and enables insurers to more easily identify and potentially steer ESRD patients onto Medicare. This bill does not compel insurers to accept premium assistance. This bill threatens to undermine access to care because it would allow insurers to drastically lower the reimbursement rate previously negotiated. Dialysis Patient Citizens indicates that reduced payments will mean that dialysis patients are less likely to donate money so that patients can use charitable assistance, which can be life saving for a patient. The California Hospital Association writes that in addition to creating an arbitrary rate setting system for providers, it would undermine programs that pay for health insurance for certain patients. The California Medical Association writes that this bill links private sector payor's fee schedules to Medicare reimbursement rates, and in short sets rates.

SUPPORT AND OPPOSITION:

Support:
America's Health Insurance Plans
Association of California Life & Health Insurance Companies
Blue Shield of California
California Alliance for Retired Americans
California Association of Health Plans
California Association of Joint Powers Authorities
California Labor Federation, AFL-CIO
California State Council of Service Employees International Union
County Behavioral Health Directors Association of California
Health Access California
Health Net
Kaiser Permanente
Latino Coalition for a Healthy California
Pacific Business Group on Health
San Diego Electrical Health & Welfare Trust

Oppose:
Alameda-Contra Costa Medical Association
American GI Forum of California
American Kidney Fund
American Legion, Department of California
AMVETS, Department of California
California Association of County Veterans Service Officers
California Black Chamber of Commerce

California Dialysis Council
California Hepatitis C Task Force
California Hospital Association
California Medical Association
California State Commanders Veterans Council
California State Conference NAACP
California-Hawaii State Conference of the NAACP
Chambers of Commerce Alliance of Ventura and Santa Barbara Counties
Chronic Disease Coalition
Contra Costa Taxpayers Association
Davita
Desert AIDS Project
Dialysis Patient Citizens
Elk Grove Chamber of Commerce
FAIR Foundation
Filipino- American Chamber of Commerce Business Network
Fresenius Medical Care North America
Fresno Madera Medical Society
Fullerton Association of Concerned Taxpayers
Greater Bakersfield Chamber of Commerce
Greater Coachella Valley Chamber of Commerce
Imperial County Medical Society
Jewish War Veterans, Department of California
Kern County Medical Society
Latin Business Association
Long Beach Area Chamber of Commerce
Los Angeles County Business Federation
Los Angeles County Medical Association
Los Angeles Wellness Station
Merced- Mariposa Medical Society
Monterey County Medical Society
Napa County Medical Society
National Guard Association of California
National Hispanic Medical Association
National Medical Association
National Renal Administrators Association
National Veterans Foundation
Orange County Business Council
Orange County Medical Association
Oxnard Chamber of Commerce
Placer-Nevada County Medical Society
Renal Physicians Association
Riverside County Medical Association
ROA, Department of the Golden West
San Bernardino County Medical Society
San Francisco Marin Medical Society
San Joaquin Medical Society
San Mateo County Medical Association
Santa Clara County Medical Association
Scottish-American Military Society of California

Sierra Sacramento Valley Medical Society
Solano County Medical Society
Southwest California Legislative Council
Stanislaus County Society
Tuolumne County Medical Society
Valley Industry and Commerce Association
Ventura County Medical Association
Women Veterans Alliance
Yuba-Sutter-Colusa Medical Society
Numerous Individuals

-- END --

EXHIBIT 2

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

EXHIBIT 3

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.

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

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

[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

EXHIBIT 4

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.*

CERTIFICATE OF SERVICE

Case Name: **Jane Doe, et al v. Xavier Becerra, et al.** Case No.: **8:19-cv-2105-DOC-(ADSx)**

I hereby certify that on November 25, 2019, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

DEFENDANTS REQUEST FOR JUDICIAL NOTICE IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

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 the foregoing is true and correct and that this declaration was executed on November 25, 2019, at Los Angeles, California.

Colby Luong	/s/ Colby Luong
Declarant	Signature

SA2019106023
53924910.docx