IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 4:17-cv-16
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	

EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Plaintiffs hereby move on an emergency basis for a temporary restraining order and preliminary injunction against Defendants pursuant to Federal Rule of Civil Procedure 65, to prevent Defendants from implementing or enforcing the Interim Final Rule, published at 81 Fed. Reg. 90,211 (Dec. 14, 2016), titled *Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment*. The Rule—which was issued without notice-and-comment—is scheduled to go into effect **on January 13, 2017**. The standards for a temporary restraining order and preliminary injunction are satisfied here because Plaintiffs are likely to prevail on their procedural and substantive challenges to the Rule; Plaintiffs will suffer serious and irreparable harm absent preliminary relief; the balance of equities favors preliminary relief; and such relief would advance, not disserve, the public interest.

Plaintiffs have notified Defendants of this request, but Defendants have not consented to this relief. Defendants respectfully request the establishment of a due date for the filing of Defendants' opposition brief by 12:00 noon local time on Wednesday, January 11, 2017. Plaintiffs consent to Defendants' request.

Plaintiffs therefore respectfully request this expedited briefing schedule and, if desired by the Court, a hearing on their motion with sufficient time to permit relief to be entered **before January 13, 2017**. For the reasons explained below, Plaintiffs are entitled to a temporary restraining order and preliminary injunction.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES, RULES, AND REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

In a transparent effort to ensure its regulation takes effect before a new administration takes office, the Department of Health and Human Services ("HHS") on December 14, 2016, announced a sea-changing rule without any notice or comment—making it effective on an expedited basis on January 13, 2017—upending twenty years of HHS guidance governing the way in which End Stage Renal Disease ("ESRD") patients obtain health insurance coverage that is necessary to ensure life-sustaining care. *See Interim Final Rule with Comment Period, Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third-Party Payment*, 81 Fed. Reg. 90,211 (Dec. 14, 2016) ("Rule" or "Interim Final Rule") (Seibman Decl. Ex. 1).[1]

If permitted to take effect, the Rule will cause immediate and irreparable harm to patients who are among the most vulnerable in society: ESRD patients who require routine dialysis treatments or transplants to survive. For twenty years, HHS has consistently affirmed guidance permitting ESRD patients to obtain financial assistance from charitable organizations to secure the public or private health-insurance coverage enabling access to life-sustaining care. The Rule reverses that paradigm with no warning, requiring dialysis providers, within thirty days of the Rule's announcement, to make disclosures to and seek permission from insurance companies for these sick patients to continue to receive charitable premium assistance. The Department's about-face will dramatically disrupt thousands of patients' ability to obtain private insurance, interfering with and potentially compromising outright their access to life-sustaining medical treatment while remarkably imposing greater healthcare costs on many patients and their

[1] The Seibman Declaration is attached as Exhibit A. Plaintiffs have not highlighted exhibits because they are relying on the entire documents, and therefore highlighting is not required by Local Rule 7(b).

families. At the same time—with no offsetting benefits to patients—the Rule will impose significant and unrecoverable costs on dialysis providers, and threaten the economic viability of many dialysis facilities, potentially leading to facility closures that will damage providers and patients alike.

As the Rule's history and extraordinary timing make clear, HHS's true motive is to shift hundreds of millions of dollars in health-care costs from private insurers to taxpayers, making it more attractive for those insurers to offer qualified health plans (or "QHPs") under the Affordable Care Act ("ACA") (colloquially known as "Obamacare"). That objective, however, could not possibly have satisfied the demanding "good-cause" showing required by the Administrative Procedure Act ("APA") to implement a rule without notice-and-comment. For that reason, HHS purported to rationalize its Rule and emergency, pre-Inauguration Day implementation as necessary to prevent harm to ESRD patients. Those patient-harm claims collapse upon inspection. In fact, overwhelming evidence, logic, and common sense compel the conclusion that the Rule will create the very harms, including disruptions in coverage to care, that it is purportedly designed to prevent.

Because HHS's rush to enact its Rule without the benefit of notice-and-comment, and to put into effect a midnight rule before a new administration takes over, violates the APA in multiple respects, and because it would impose serious, discriminatory, and irreparable harm on thousands of ESRD patients—many of whom are members of Plaintiff DPC here—and on dialysis providers, the Court should grant this motion for an emergency temporary restraining order and preliminary injunction against the Rule's enforcement.[2]

[2] Counsel for Plaintiffs notified HHS of this motion, and HHS did not consent to the requested relief. Because Plaintiffs have provided notice of their request for a temporary restraining order, the Court may treat the motion as one for a preliminary injunction. *E.g.*, 11A Wright & Miller,

BACKGROUND

I. TREATMENT OF ESRD PATIENTS

ESRD is the last stage of chronic kidney disease. A person suffering from ESRD will die without regularly administered kidney dialysis or a kidney transplant. Ex. B ¶¶ 3-4 (Dialysis Patient Citizens Decl.); Ex. C (DaVita Inc. Decl.) ¶ 9; Ex. E ¶ 81 (Fresenius Medical Care Decl.); Ex. F (U.S. Renal Decl.) ¶ 7. Dialysis is a process of cleaning the blood and removing excess fluid from it, essentially simulating working kidneys, which is accomplished using specialized equipment in a specialized facility. Ex. B ¶ 3; Ex. C ¶ 10, Ex. E ¶ 15. Dialysis treatment is expensive. Each treatment typically lasts about four hours, and must be done three times per week. Ex. B ¶ 3; Ex. C ¶ 10. Paying those costs is out of reach for most Americans, requiring some form of insurance to pay the bills. But ESRD patients are particularly vulnerable, because they are sick and they disproportionally have extremely limited means. Ex. B ¶¶ 7, 38 (55% of DPC members were employed when they started on dialysis, but only 8% of those now on dialysis are still employed full time); Ex. D (American Kidney Fund Decl.) ¶ 15 (70% of clients are unemployed). ESRD also disproportionately affects minorities. Ex. B ¶ 7; Ex. C ¶¶ 9-12 (ESRD is 3.5 times more prevalent in African-Americans than Caucasians).

Congress has long recognized the importance of ensuring that ESRD patients have access to life-sustaining health insurance, while affording such patients meaningful options to elect the coverage that best serves each patient's health and financial needs. In 1972, Congress amended the Social Security Act to make ESRD patients under the age of 65 eligible for Medicare. *See* 42 U.S.C. § 426-1(a). But Congress did not *require* these ESRD patients to enroll in Medicare or

---

Federal Practice & Procedure § 2951 (3d ed.). Alternatively, the Court could grant the temporary restraining order and set a date for a preliminary injunction hearing. However the Court proceeds, Plaintiffs respectfully submit that it is imperative that the Rule be enjoined from taking effect on January 13, 2017.

any other public option. Indeed, ESRD is one of the very few disease states that Congress consistently has carefully regulated through extensions of the Medicare Secondary Payer period.

For many ESRD patients under age 65, electing commercial insurance coverage over government insurance affords them superior access to health care at a lower cost. For example, Medi-Gap assists Medicare enrollees with out-of-pocket expenses—which, due to Medicare's requirement that patients pay 20% coinsurance of treatment costs (among other out-of-pocket costs), can be substantial (thousands of dollars), Ex. C ¶ 51—but in 23 states Medi-Gap is not available to ESRD patients under 65. Ex. B ¶ 30; Ex. C ¶ 22; Ex. D ¶¶ 33-37; Ex. E ¶ 30.b; Ex. F ¶¶ 18-19. Nor are ESRD patients under 65 typically eligible for Medicare Advantage plans, which combine the coverage of the different parts of Medicare under a single plan. Ex. C ¶ 20.

ESRD patients on government insurance may likewise suffer reduced access to care for themselves and their families. For patients at any age, coverage under Medicaid—the public health insurance program governed by the States—is typically far more limited than Medicare and private insurance. Ex. B ¶¶ 24, 33, 36; Ex. C ¶ 23; Ex. D (American Kidney Fund Decl.) ¶ 50. In addition, many health-care providers are increasingly refusing to accept new Medicaid patients. Ex. B ¶ 33; Ex. C ¶ 58. QHPs allow patients to provide coverage for their families. Medicare, by contrast, does not cover family members, a particular concern to ESRD patients under 65 who are more likely to have minor children and Medicare-ineligible dependents than older patients. *E.g.*, Ex. B ¶ 55; Seibman Decl. Ex. 2 (American Kidney Fund RFI Resp.) 13.

Given the expense of ESRD treatment, charitable organizations—most notably American Kidney Fund ("AKF")—have long provided premium assistance to eligible ESRD patients. Ex. D ¶¶ 3-8. ESRD patients on either a government or a private plan may receive assistance, and grants are offered based on financial need. Ex. D ¶¶ 5, 20-26, 102(d). The majority (more than

60%) of those benefitting from charitable premium assistance use the funds to pay Medicare insurance premiums or the substantial costs of health-care Medicare does not cover. Ex. D ¶ 21.

Dialysis providers have long been committed to providing financial support to the AKF's premium assistance program. Ex. C ¶ 42; Ex. E ¶ 37. In 1997, the AKF and six unnamed providers obtained from the HHS Office of Inspector General ("OIG") an advisory opinion establishing that, if certain conditions are met, dialysis providers could make contributions to AKF without triggering certain statutory penalties. *See* Advisory Opinion No. 97-1, Office of Inspector General, Dep't of Health and Human Services at 5 (1997) (Seibman Decl. Ex. 3). The conditions include prohibitions on a dialysis provider disclosing to patients that it makes charitable contributions or suggesting to AKF that any contribution should be directed to a particular beneficiary or group of beneficiaries—a prohibition that the Interim Final Rule inexplicably requires providers to violate. *See infra* pp. 23-24. Further, the conditions of the 1997 opinion require AKF to provide assistance to patients whether or not they are being treated at facilities that contribute.[3] This guidance has provided the framework for the provision of charitable premium assistance to ESRD patients for two decades. *See* Ex. D ¶¶ 96-102.

II. HHS TAKES POST-ACA REGULATORY ACTIONS WITH RESPECT TO THIRD-PARTY PREMIUM ASSISTANCE

After the enactment of the ACA, insurers increasingly expressed concern with the fact that third-party assistance was enabling seriously ill—and thus expensive-to-insure—patients to acquire private coverage through QHPs. Ex. D ¶ 80. Concerned that insurers facing increased

[3] In subsequent years the OIG has issued additional opinions addressing the permissibility of various arrangements under which insurance premiums are paid by charitable organizations, including arrangements where donations to such charitable organizations have been made by providers. *E.g.*, Adv. Ops. 15-17, 07-18, 07-06, 06-13, 06-09, 06-04, 02-1, 01-15; *see also Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31,120 (May 30, 2014); *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623 (Nov. 22, 2005).

cost might abandon the ACA Exchanges, HHS expressed "significant concerns" in a November 4, 2013 Frequently Asked Question ("FAQ response") about "hospitals, other healthcare providers, and other commercial entities" supporting QHP premium and cost-sharing obligations, "because it could skew the risk pool and create an unlevel field in the Marketplaces." HHS mentioned no concerns about patient health. HHS, *Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces* (Nov. 4, 2013).[4]

As insurers in response began refusing payment from federal, state, and government-protected programs and grantees, however, HHS revised its position. On February 7, 2014, it issued additional FAQs responses stating that the earlier FAQ response did not apply to premium and cost-sharing payments on behalf of QHP enrollees made by Indian tribes and organizations, or state and federal government programs or grantees, such as the Ryan White HIV/AIDS Program. HHS, *Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces* (Feb. 7, 2014).[5] Nor did the earlier FAQ response apply to payments from private, not-for-profit foundations "if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status." *Id.*

When insurers continued to refuse payment, HHS published a rule *requiring* issuers offering individual market QHPs to accept premium and cost-sharing payments made on behalf of enrollees by the Ryan White HIV/AIDS Program; Indian tribes, tribal organizations, or urban Indian organizations; and state and federal government programs. This requirement does not

[4] *Available at* https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf.

[5] *Available at* https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf.

apply to not-for-profit charitable organizations. 79 Fed. Reg. 15,240 (March 19, 2014); 45 C.F.R. § 156.1250; *see also* Ex. D. ¶¶ 56-60 (providing additional context on this rule).

On August 16, 2016, HHS issued a request for information ("RFI") regarding concerns that health care providers or others were "offering premium and cost-sharing assistance in order to steer people eligible for or receiving Medicare and/or Medicaid benefits to [QHPs] for a provider's financial gain." *Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans*, 81 Fed. Reg. 57,554, 57,556 (Aug. 23, 2016) (Seibman Decl. Ex. 4). HHS expressed concern that this practice, if it exists, "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)." *Id.* at 57,554. Notably, two of these articulated concerns related to patients, while the other two related to systemic concerns—overall costs and risk pools—under the ACA. HHS stated that the RFI was for "information and planning purposes" only. *Id.* at 57,555. It did not propose new rules.

HHS received 829 responses to the RFI. Dozens of ESRD patients wrote personal letters explaining the value of charitable premium assistance and urging HHS to continue to permit the use of charitable premium assistance. Sixteen different patient advocacy organizations and charities, including AKF, explained the critical importance of their programs to patients and the rigorous controls in place to prevent steering and comply with the OIG guidance. Eighteen providers explained the benefits of such payments to patients, while also recognizing that any improper steering should be eliminated. On the other side, fifteen insurance companies

responded, urging HHS to end premium assistance. The social workers who responded came out on both sides, some supporting premium assistance and others urging greater transparency to patients.[6]

III. AFTER THE NOVEMBER ELECTION, HHS ISSUED AN "EMERGENCY" MIDNIGHT RULE

On November 8, 2016, Donald Trump was elected President, with his administration to take office on January 20, 2017. Weeks later, and despite being aware of the current paradigm for years, HHS suddenly and without notice and comment issued its Rule—contradicting its previously issued guidance—and set an effective date of January 13, only a week prior to the start of the new administration. At the same time, HHS sought comment on the Interim Final Rule as well as other potential changes. *E.g.*, 81 Fed. Reg. at 90,226. Although the RFI had sought information about all third-party premium and cost-sharing assistance, the Rule applies to kidney-dialysis providers alone.

The Rule amends "Conditions for Coverage" ("CfCs")—a set of rules governing dialysis providers' treatment of ESRD patients—to impose on providers' disclosure requirements aimed at helping insurance companies drive ESRD patients off QHPs. The Rule's requirements are poorly thought-through and ill-defined and will have immediate negative effects on ESRD patients. The Rule applies to any provider that "make[s] payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization …, or through another entity." 81 Fed. Reg. at 90,227. The Rule's breadth is staggering, because it applies not only to providers who directly support patients' premium payments; not only providers who contribute to organizations "that make[] a financial contribution to another organization[] that is able to use the funds to make payments of premiums for individual market

[6] All comments are available at https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=CMS-2016-0145&refD=CMS-2016-0145-0002.

plans"; but, indeed, to any provider "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." *Id*. at 90,219 n.16.

Among required disclosures to patients, the Rule requires providers to disclose to patients that they are contributing to charities like the American Kidney Fund, a required disclosure inconsistent with the 1997 OIG guidance. The Rule then imposes on such providers disclosure requirements expressly aimed at helping insurance companies drive ESRD patients off QHPs. It requires that a covered provider must disclose to insurers every policy that will be paid for, wholly or in part, through premium assistance paid by organizations to which the provider donates. The Rule does not say whether a provider may rely on its current knowledge of patients' use of premium assistance, whether it must actively solicit that information from patients, whether it must attempt to collect this information from organization to which it donates, or whether it must take other steps to obtain this information. A provider must then "[o]btain assurance" from each insurer that it will accept such payments for the plan year. And if insurers do not provide such assurances, the provider must "take reasonable steps" to ensure such payments are not made by the provider or by charitable organizations to which the provider contributes. Indeed, the Rule does not require that the insurer ever respond to a request. Moreover, the Rule does not describe what would constitute "reasonable steps," nor does it explain how a provider is to identify beneficiaries without violating the OIG prohibition on disclosing to patients that the provider "ha[s] contributed to AKF." Seibman Decl. Ex. 3 at 4. As a result, the insurers were provided with complete power to indefinitely delay or deny the patient or the provider's ability to comply. With limited exceptions, failure to comply with CfCs results in termination from Medicare. *See* 42 C.F.R. § 488.604; 42 U.S.C. § 1395rr(g)(1).

In purpose and effect, the Rule's insurer-disclosure obligations will drive ESRD patients to Medicare/Medicaid coverage—or deprive them of coverage altogether—by identifying patients receiving premium assistance and allowing insurers to decline coverage of such individuals. Ex. B ¶¶ 14-15, 37-48; Ex. C ¶¶ 90-91; Ex. D ¶¶ 105-115; Ex. E ¶ 75-78, 80. HHS concedes there is a "significant risk" that insurers will refuse to accept premiums from ESRD patients paid in part through charitable premium assistance when the insurer is informed of that fact. 81 Fed. Reg. at 90,217. Indeed, HHS itself assumes that 50% of patients currently receiving premium assistance will end up shifting to Medicare/Medicaid. *Id.* at 90,226. Further, HHS itself estimates that the cost to dialysis providers of complying with the burdensome requirements that the Rule imposes will be at least $32 million the first year and $28 million for subsequent years. *See id.* at 90,223.

Instead of providing an opportunity for public stakeholder comment on this significant regulatory change, as HHS was required to do under the APA and Medicare Act, the agency invoked the emergency good-cause exception, claiming that a health-related emergency made it necessary to upend an established paradigm that has existed for nearly twenty years. HHS also cut short the 60-day period from publication to effective date required under the Congressional Review Act, making the Rule effective on January 13, 2017, just 30 days after publication. Both procedural maneuvers were necessary—and quite obviously intended—to put a new rule into

effect before the incoming administration would as a matter of course suspend it as a pending midnight regulation.[7]

STANDARD OF REVIEW

Under the APA, the Court "shall hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (B). This Court's "review of the agency's legal conclusion of good cause," so as to avoid the APA's notice-and-comment requirements, "is *de novo*." *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014). If those legal requirements are not met, the court must vacate the Rule. *Id.* at 710.[8]

In addition, agency action "is arbitrary and capricious," when, among other things, an agency "entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to … the product of agency expertise." *Luminant Generation Co., LLC v.*

[7] Outgoing administrations often have substantial incentives to engage in "midnight rulemaking"—attempting to rush through significant regulatory changes consistent with their own political objectives or policy views before a new administration, with different objectives and perspectives, comes to power. CRS, *Midnight Rulemaking* 3 (July 18, 2012). Incoming administrations also regularly take steps to guard against such midnight rulemaking, but their ability to do so depends in important respects on whether a new rule has yet taken effect. For example, new Presidents often "postpone the effective dates of certain rules that were issued at the end of the previous President's term." *Id.* at 3. During that time, new administrations can carefully review and consider whether to repeal midnight rules before they take effect. Thus, "emergency" rulemaking like that at issue here, where an agency after an election peremptorily suspends notice-and-comment to make a rule effective before Inauguration Day, risks undermining the political checks new administrations use to control such rules.

[8] In rejecting an agency's invocation of good cause, the Fifth Circuit in *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011), referenced "the APA's standard: agency action may be set aside if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not accordance with law." Nothing in the opinion, however, suggests that the Fifth Circuit applied a deferential standard of review as to the legal question of whether the good-cause standard was satisfied. Indeed, the court rejected the government's explanation as not "persuasive." *Id.* at 928. HHS's explanations for good cause here are similarly "unpersuasive," regardless of the standard of review.

EPA, 675 F.3d 917, 925 (5th Cir. 2012). An agency violates those duties when it fails to "cogently explain why it has exercised its discretion in a given manner." *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48-49 (1983).

DISCUSSION

A temporary restraining order and preliminary injunction against enforcement of the Rule are necessary because: (1) there is a substantial likelihood of success on the merits of Plaintiffs' challenges to the Rule; (2) Plaintiffs would suffer irreparable injury absent preliminary relief; (3) the balance of equities favors such relief; and (4) the public interest would not by disserved by such relief. *See Planned Parenthood of Gulf Coast, Inc. v. Gee*, 837 F.3d 477, 488 (5th Cir. 2016); *Hart v. Wells Fargo Bank, N.A.*, 2014 WL 12531172, at *1 (N.D. Tex. Mar. 31, 2014) (standard for temporary restraining order and preliminary injunction are the same).

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THEIR CHALLENGES TO THE RULE

A. HHS Lacked "Good Cause" To Promulgate The Rule Without Notice And Comment And Thus Violated The APA

The APA requires an agency seeking to promulgate a substantive rule to do so through notice-and-comment procedures. 5 U.S.C. § 553. The Medicare Act—which was invoked here by HHS—imposes the same requirements. 42 U.S.C. § 1395hh(b)(1). Under those procedures, an agency must "publish[]" a "notice of proposed rulemaking"—also called a NPRM—"in the Federal Register," and the notice must include "the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). An agency must also "give

interested persons an opportunity to" submit "written data, views, or arguments." *Id.* § 553(c). After "consideration of the relevant matter presented," the agency publishes a final rule. *Id.*[9]

These requirements serve vital purposes, helping to ensure accountability and well-informed and reasoned decision-making. Congress intended "the notice and comment provisions" "'to assure fairness and mature consideration of rules.'" *Brown Exp., Inc. v. United States*, 607 F.2d 695, 701 (5th Cir. 1979). Indeed, these procedures are "one of Congress's most effective and enduring solutions to the central dilemma it encountered in writing the APA—reconciling the agencies' need to perform effectively with the necessity that the law must provide that … the regulator shall be regulated, if our present form of government is to endure." *New Jersey Dep't of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980). Notice-and-comment is "especially" important "in the context of health risks" because guaranteeing a role for stakeholder participation "assure[s]" the "dialogue" "necessary" for "reasonable rules." *Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir. 1980).

Congress has provided exceptions to notice-and-comment requirements, but given the requirements' importance to the rule of law, the exceptions are exceedingly "narrow[]" and "only reluctantly countenanced." *Tenn. Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1144 (D.C. Cir. 1992). An agency may dispense with the requirements for "good cause," which exists only when notice-and-comment would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B); 42 U.S.C. § 1395hh(b)(2)(C). This "exception" is "read narrowly," however, "to avoid providing agencies with an 'escape clause' from the requirements Congress prescribed." *United States v. Garner*, 767 F.2d 104, 120 (5th Cir. 1985); *Texas v. United States*,

[9] The APA typically requires that a final rule may not be effective until 30 days pass from publication. 5 U.S.C. § 553(d). For certain rules, however, a separate statute—the Congressional Review Act—imposes a 60-day delay before a rule may take effect. *See id.* § 801(a)(3).

809 F.3d 134, 171 (5th Cir. 2015). Otherwise, the good-cause exception would "carve the heart out of the statute." *Action on Smoking & Health v. CAB*, 713 F.2d 795, 800-801 (D.C. Cir. 1983).

HHS's invocation of good-cause does not remotely satisfy those standards. HHS asserted that notice-and-comment would be "contrary to the public interest," as delay would "harm" patients, 81 Fed. Reg. at 90,221. In particular, HHS asserted that delay would expose patients to kidney transplant risks; additional costs of QHP coverage; and mid-year coverage disruptions. *Id.* Those purported justifications cannot be squared with the facts or law.

1. HHS's Purported Good-Cause Rationales Are Meritless

HHS's core contention that dispending with notice and comment was necessary to protect patients has things precisely backwards. Far from addressing a bona fide health-care emergency, the Rule will *create* one by decreasing patient access to transplants and precipitously exposing impecunious patients to coverage gaps and interrupting the continuity of their care—ironically, the Rule will cause the very harms it is purported to prevent. If HHS had abided by its notice-and-comment obligations, Plaintiffs and others would have explained these flaws to HHS, and presumably have averted these irrational and harmful consequences.[10]

Alleged kidney transplant risk. HHS speculates that QHPs supported by premium assistance could interfere with a patient's ability to receive a transplant because, HHS asserts, when ESRD patients "are enrolled in [QHPs] supported by third parties, they may have difficulty

[10] HHS's claims of harm are also implausible on their face. At the time HHS issued the Interim Final Rule, HHS simultaneously began a thirty-day comment period in connection with promulgating a non-interim Final Rule. Following those procedures without immediately implementing the Rule as "Interim Final" would have at occasioned a delay of only several months (assuming, of course, that the new administration agreed that such a rule was necessary). HHS does not even attempt to explain why such a delay would cause harms severe enough to justify evading notice-and-comment requirements.

demonstrating continued access to care due to loss of premium support after transplantation." 81 Fed. Reg. at 90,215. This conjecture is unsupported and irrational.

First, HHS identifies no empirical support for this purported "harm." Although charitable premium assistance may sometimes be offered only during the period when a patient is receiving dialysis treatment, an ESRD patient—who is permitted without penalty to defer Medicare enrollment when beginning dialysis treatment—is unarguably permitted to enroll in Medicare at the time of transplant and to remain on Medicare for 36 months post-transplant. 42 C.F.R. § 406.13(e)(3) (eliminating waiting period for transplant patients); Ex. C ¶ 45. There is no genuine risk, therefore, that a patient seeking a transplant cannot demonstrate that he or she can obtain continued access to care.[11]

HHS conceded this, and even *admits* that "individuals could arrange for Medicare coverage to begin at the time of transplantation." 81 Fed. Reg. at 90,215. HHS speculates that patients may not "understand their coverage options," *id.*, but that stunningly ignores that existing HHS guidance *requires* providers to make those options known and dialysis providers work with patients to do just that, *e.g.*, Seibman Decl. Ex. 5 (Fresenius Medical Care RFI Resp.) at 4-5; Ex. C ¶¶ 30-39; Ex. E ¶¶ 24-28. It was entirely unreasonable for HHS to ignore those existing requirements in assessing the issue. *See Business Roundtable v. SEC*, 647 F.3d 1144, 1150 (D.C. Cir. 2011) (SEC acted unreasonably in ignoring legal requirements in predicting how parties would act).

Second, by enabling insurers to drop coverage of QHPs, the Rule makes disruption to transplants more, not less, likely, thus relegating patients to public options in which they are

[11] After 36 months, assuming the patient is not yet eligible for Medicare due to age, the patient will be positioned to re-enter the workforce and obtain coverage through an employer group plan or on the exchange. Ex. C ¶ 45; Ex. D ¶ 82.

statistically much less likely to receive a successful transplant. There is substantial evidence—already before HHS and that Plaintiffs could have identified during notice-and-comment rulemaking—demonstrating that public options, not private insurance, hamper ESRD patients' ability to receive transplants. Ex. B ¶ 35; Seibman Decl. Ex. 2 at 18-19 & n.35-36; Seibman Decl. Ex. 6 (Kidney Care Counsel RFI Resp.) at 3. For example, instead of increasing patients' access to transplants, ESRD patients forced to shift to Medicare or Medicaid could lose their place on a transplant list if the transplant facility or provider does not accept public insurance. *See* Seibman Decl. Ex. 7 (DaVita RFI Resp.) at 6.

Certain benefits of private insurance also contribute to making a patient significantly more likely to receive a kidney transplant and experience a successful one than patients on Medicare or Medicaid. Some Medicaid plans will not pay for live transplant surgery, the type of surgery with the highest success rate. Ex. C ¶ 65. In addition, patients on public coverage may lose access to specialists necessary for them to be eligible for a transplant in the first place. Ex. B ¶ 33; Seibman Decl. Ex. 2 at 17. For example, a common reason a patient is denied a transplant is if that patient suffers from dental infections that could threaten the viability of the transplant. But patients may not have access to dental coverage on Medicare or Medicaid, increasing the risk of dental infection and thus potentially keeping patients off transplant lists. Seibman Decl. Ex. 7 at 6 & n.13; Ex. F ¶ 28.

There is thus overwhelming evidence—that HHS ignored—that patients with private insurance have greater success in obtaining transplants than those on public options, and that patients are successful (with the assistance of providers) in demonstrating continued access to care. Ex. B ¶ 35; Ex. C ¶¶ 63-66 (patients with private insurance are three times more likely to

receive a kidney than those without); Ex. D ¶¶ 50-53. HHS's contrary assertion ignores all of this.

Alleged economic costs. HHS's claim that QHPs are "financially disadvantageous for some patients with ESRD," 81 Fed. Reg. at 90,216, 90,221, also provides no basis for bypassing notice-and-comment procedures. ***First***, even if HHS's factual premise were correct (it is not), marginal *economic* cost difference for some patients between public insurance and QHPs is not an "emergency" that supports the good-cause exception. *See Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93-94 (D.C. Cir. 2012) (treating economic injury as sufficient to support good-cause exception "would give agencies 'good cause' under the APA every time a [party] in a regulated field felt a new regulation imposed some degree of economic hardship").

Second, HHS's claim of additional costs for patients is unfounded. In fact, HHS admits that "for some" patients, there are "financial benefits from [QHPs] if total premiums and cost sharing are lower," 81 Fed. Reg. at 90,216, yet HHS made *no* effort to quantify or otherwise demonstrate whether ESRD patients in the aggregate would financially benefit from being forced into Medicare coverage by the Rule. Indeed, in advancing this cost rationale, HHS ignored that many patients with QHP would experience a significant *increase* in financial costs if they were forced into public coverage. *E.g.*, Seibman Decl. Ex. 2 at 12; Ex. B ¶¶ 30-32; Ex. C ¶ 52, 68-70; Ex. E ¶ 30. For example, patients who are ineligible for Medicaid and live in a State without supplemental coverage like Medi-Gap face uncapped out-of-pocket expenses under Medicare, which could increase a patient's out-of-pocket expenses by thousands of dollars per year. *E.g.*, Seibman Decl. Ex. 9 (Dialysis Patient Citizens RFI Resp.) at 6; Ex. B ¶¶ 30-31; Ex. C ¶ 51 & fig. 1; Ex. D ¶¶ 33-36; Ex. E ¶ 30.b. Still others would be ineligible for Medicare entirely, potentially subject to paying all their healthcare costs out of pocket until they have exhausted

their savings and become Medicaid-eligible. Ex. C ¶¶ 68-69; Ex. E ¶ 30.a. Indeed, in making this argument, HHS appears to ignore more than 80 individual comments from ESRD patients making these or similar points.

The cost-based reasons HHS does offer do not withstand scrutiny. For example, HHS theorizes that for some patients Medicaid may be better because it covers out-of-pocket costs. But HHS admits that a patient enrolled in a QHP can "be enrolled in both Medicaid and individual market coverage." 81 Fed. Reg. at 90,216. HHS speculates that such an arrangement would create "financial risk" for a patient who would need to "coordinate multiple types of coverage." *Id.* But providers regularly work with their patients to ensure that patients fully understand their coverage options and how to use both forms of insurance coverage. *E.g.*, Ex. C ¶¶ 29-40 (describing DaVita's extensive patient education program, which includes dedicated teams of social workers, insurance counselors, and medical professionals); Ex. E ¶ 24-28 (similar); Ex. F ¶ 11 (similar); Seibman Decl. Ex. 6 at 13; Seibman Decl. Ex. 8 (U.S. Renal Care RFI Resp.) at 2.

With respect to Medicare patients, HHS labors to identify ways that, in certain cases, some patients might pay slightly more for a QHP because of things like late enrollment penalties. 81 Fed. Reg. at 90,216. But those are considerations on which patients can be trusted to make decisions in their self-interest, *e.g.*, Ex. C ¶ 40, and in any event hardly represent an "emergency."

Alleged mid-year coverage disruptions. HHS's final justification for abandoning notice-and-comment is that immediate implementation of the Rule is necessary to prevent "mid-year disruptions in coverage for patients/individuals who have [QHP] for which third parties make premium payments." 81 Fed. Reg. at 90,217. That rationale contradicts HHS's own findings.

Indeed, the rationale for the Rule is to drive patients to transition to public options, as HHS acknowledges would happen. *See* 81 Fed. Reg. at 90,226 (conceding the Rule will drive 50% of QHP patients receiving charitable premium assistance to public options). It is thus the Rule, not the status quo, that precipitate the very disruptive transitions between insurance coverage that the Rule claims harms consumers. *See* Ex. B ¶¶ 14-15, 37-48; Ex. C ¶¶ 90-91; Ex. D ¶¶ 105-115; Ex. E ¶ 31, 80; Seibman Decl. Ex. 6 at 13-14.

It was entirely irrational for HHS to enact a Rule to prevent coverage disruptions when the agency knew the Rule would cause those very disruptions. Ex. B ¶ 29. HHS compounded that harm by rushing to make the Rule effective during an enrollment, knowing that many patients had already made coverage selections for the year based on an expectation that they could receive charitable premium assistance. And, if HHS were truly concerned about this risk, it could have exercised its authority over Exchanges by barring insurers from dropping coverage, at least while HHS invited notice-and-comment on these issues.[12]

2. HHS's Justifications Are Also Legally Insufficient

HHS's proffered justifications for bypassing notice-and-comment fail as a matter of law for additional reasons. ***First***, each of HHS's theories of harm reflect nothing more than anecdotes and speculation. *See* 81 Fed. Reg. at 90,224 (asserting that RFI responses "indicated that dialysis facilities *may* be encouraging patients to move from one type of coverage into another"; QHP "*may* result in harm to the individual"; and although enrollment trends are not "evidence of inappropriate behavior" they "*raise[] concerns*" of steering) (emphases added).

[12] That "[t]his is the time of year when patients often make enrollment decisions, with Open Enrollment in the individual market ongoing and General Enrollment Period in Medicare about to begin on January 1," 81 Fed. Reg. at 90,221, adds nothing to HHS's good-cause analysis. HHS controls the timing of the enrollment periods and HHS's announcement of the Rule and implementation on an expedited basis near the enrollment period has in fact caused immeasurable confusion and concern among ESRD patients. Ex. B ¶ 49; Ex. D ¶¶ 110-114.

Such "speculation is" ordinarily "an inadequate replacement for the agency's duty to undertake … reasoned analysis." *Horsehead Resource Development Co., Inc. v. Browner*, 16 F.3d 1246, 1269 (D.C. Cir. 1994) (per curiam). And that is particularly so under the good-cause exception: fear a problem "*could*" occur might prompt a "[c]ause for concern," but "hardly" demonstrates a "crisis" sufficient to bypass notice-and-comment. *Sorenson Commc'ns*, 755 F.3d at 706-707.

Second, the problems identified by the Rule do not amount to an emergency sufficient to constitute "good cause" as a matter of law. The "public interest" prong of the exception—the only one invoked by HHS—is "rare[ly]" satisfied, *Mack Trucks*, 682 F.3d at 94, and the justifications offered by HHS do not remotely satisfy that standard. Even were HHS correct that the Rule would in fact provide some health or financial benefits to ESRD patients, that would not excuse bypassing notice-and-comment. "[T]he bare need to have regulation" is not good cause. *Marshall*, 628 F.2d at 621. Most, "if not all," agency rules "are designed to eliminate some real or perceived harm. If the mere assertion that such harm … were enough to establish good cause, then notice and comment would always have to give way." *United States v. Reynolds*, 710 F.3d 498, 512 (3d Cir. 2013). Indeed, the "argument could as easily be used to justify immediate implementation of any sort of health or safety regulation, no matter how small the risk for the population at large or how long-standing the problem." *American Acad. of Pediatrics v. Heckler*, 561 F. Supp. 395, 401 (D.D.C. 1983).[13] Thus, Plaintiffs are likely to success on their claim (set forth in Count I of the Complaint), that all of HH's purported justifications for emergency rulemaking fail, and the Interim Final Rule must be vacated for that reason.

[13] Of course, these limited health-related gains are not HHS's true purpose in promulgating the Rule. Instead, HHS reveals its true motivations in a footnote: it acknowledges that it could address the purported problem of insurers dropping coverage by "requiring issuers to accept [third-party] payments," but it asserts that result "would destabilize the individual market risk pool." 81 Fed. Reg. at 90,218; *see also id.* at 90,226 (rejecting such a requirement as an alternative to the rule, under the same reasoning).

Furthermore, as evidenced by OIG's decades-old opinion as well as more recent guidance issued by HHS, questions of charitable donations and third-party premium assistance have long been on HHS's radar. This is thus decidedly not a case in which an agency faces an a new or escalating threat, and invokes the good-cause exception to head off or respond to that emergency. *See Hawaii Helicopter Operators Ass'n v. FAA*, 51 F.3d 212, 214 (9th Cir. 1995) (finding good cause based on "recent escalation of fatal air tour accidents"); *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (finding good cause to change rules following 9/11).

Thus, in the end, the only true "emergency" HHS faced here was a political one: it wanted to put its regulation into effect before Inauguration Day. But an election and orderly transition of power obviously do not provide good cause for dispensing with basic legal requirements of reasoned rulemaking.[14]

B. The Rule Is Arbitrary And Capricious

For the reasons explained above, HHS's failure to follow notice-and-comment procedures without good cause requires vacatur of the Rule. Independently, Plaintiffs are likely to prevail on their challenges to the Rule as arbitrary and capricious. 5 U.S.C. § 706(2)(A); *see, e.g.*, *American Acad. of Pediatrics*, 561 F. Supp. at 399 (applying arbitrary-and-capricious

[14] That HHS invited "post-promulgation comments" on the Interim Final Rule and a final rule does not "excuse compliance with APA procedures." *Johnson*, 632 F.3d at 929; *accord Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012); *Marshall*, 628 F.3d at 621-622. Nor is the APA violation harmless. Plaintiffs' submissions make clear "they can mount a credible challenge to the [Rule] and were thus prejudiced by the absence of an opportunity to do so before" HHS issued the Rule. *Utility Solid Waste Activities Group v. EPA*, 236 F.3d 749, 754 (2001). And the RFI is no substitute for an NPRM. An NPRM must "describe the range of alternatives being considered with reasonable specificity," *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983), so that stakeholders can respond with an "adversarial critique of the agency," *HBO, Inc. v. FCC*, 567 F.2d 9, 55 (D.C. Cir. 1977). Nothing about the RFI fulfilled those objectives. The RFI was "issued solely for information and planning purposes," 81 Fed. Reg. 57,555, and did not set forth a proposed rule on which to comment.

review to interim HHS rule issued without notice-and-comment); Compl. ¶¶ 127-149. Given the emergency nature of Plaintiffs' request for preliminary relief, and the clear illegality of HHS's evasion of notice-and-comment, Plaintiffs address these substantive challenges only briefly, and reserve the right, of course, to develop them more fully in further proceedings in this litigation.

First, HHS irrationally ignored the disadvantages of the Rule. "[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2016). Here, HHS based the Rule on the supposed benefits of driving ESRD patients from QHPs to Medicare/Medicaid coverage. *See* 81 Fed. Reg. at 90,217; Ex. B ¶ 16. Before putting into motion such a consequential chain of events, however, reasoned decision-making required HHS to acknowledge the *benefits* of QHPs for some patients and weigh the advantages and disadvantages of its Rule.

Numerous responses to the RFI detailed the benefits of QHPs. For example, individual patients and others explained that many patients have *lower* costs under QHPs than public options. *E.g.*, Seibman Decl. Exs. 10-16 (Patient RFI Resps.); *see* Seibman Decl. Ex. 2 at 12-18; Seibman Decl. Ex. 17 (Kidney Care Partners RFI Resp.) at 4-5. In addition, patients explained that, unlike QHPs, Medicare's out-of-pocket costs are not capped, and many have no way to cover those costs, either because they live in a State without supplemental coverage like Medi-Gap or because they are not eligible for Medicaid. *E.g.*, Seibman Decl. Ex. 14. Inexplicably, HHS ignored the substance of those comments, focusing entirely on the "potential harm to patients" in justifying the Rule and making no effort to judge whether QHP benefits outweighed

those harms. *See* 81 Fed. Reg. at 90,215-90,217. It was irrational to adopt a Rule purportedly aimed at helping patients without weighing the *disadvantages* as well as benefits of the Rule.[15]

Second, the risk that the Rule would lead to unlawful discrimination by insurers was quite obviously an "an important aspect of the problem," *State Farm*, 463 U.S. at 43, that HHS was required to, but did not, address. The ACA prohibits covered insurers from discriminating on several prohibited bases, incorporating by reference provisions from federal anti-discrimination law. *See* 42 U.S.C. § 18116; 45 C.F.R. § 92.101. Insurers' refusal to accept charitable assistance from ESRD patients violates that mandate on at least two prohibited bases—disability and race, because ESRD is a disability protected under the statute and ESRD patients are disproportionally racial minorities, as RFI responses made clear. *E.g.*, Seibman Decl. Ex. 5 at 11-13. Insurers who drop coverage of ESRD patients as a result of the Rule will thus do so in violation of these non-discrimination requirements.[16]

In addition, HHS was obligated—but failed—to consider the significant problem that the Rule enables coverage denials based on pre-existing conditions. The ACA prohibits insurers from imposing eligibility rules based on that basis, *see* 42 U.S.C. § 300gg-4(a), but those who receive charitable assistance are usually those who need it because of an existing health

[15] HHS did reference that it received over 600 comments in a "letter-writing campaign" from patients receiving premium assistance from Patient Services, Inc. (PSI), an organization that provides support to patients with a range of chronic diseases. But none of those patients were dialysis patients because dialysis patients do not qualify for PSI assistance. Approximately 80 individual patients, in their own words (not through a form letter), expressed satisfaction with QHPs. HHS's cursory dismissal of those patient letters was indefensible.

[16] HHS asserts that the Rule "does not alter" requirements relating to "guaranteed availability" or "non-discrimination-related regulations," 81 Fed. Reg. at 90,220, but it does not even attempt to explain how insurers could comply with those requirements while also dropping coverage after learning of premium payments through the Rule's insurer disclosure requirements.

condition (whether ESRD, HIV/AIDS, or something else). Ex. B ¶ 7-8; Ex. D ¶¶ 56-66, Ex. E ¶ 37. HHS wholly ignored this important issue in promulgating the Rule.

Third, HHS unreasonably departed from decades-old guidance without acknowledging or justifying the break with precedent. Although an agency may change its position, the APA "ordinarily demands[] that [the agency] display awareness that it *is* changing position." *FCC v. Fox Television Stations*, 556 U.S. 502, 515 (2009). Thus, "[a]n agency may not … depart from a prior policy *sub silentio* or simply disregard rules that are still on the books." *Id.* HHS disregarded those requirements here. As noted above, in 1997, HHS OIG issued an opinion allowing AKF to operate HIPP while permitting providers to join the thousands of donors supporting AKF and other charities. The opinion recognized the value of premium assistance in enhancing patient choice and it set forth guidelines expressly aimed at ensuring that donors would be walled from HIPP's operations and to prevent undue influence or patient steering in selecting a provider. *See* Seibman Decl. Ex. 3. The guidance has successfully governed charitable giving in this context for almost two decades. *See* Ex. D ¶¶ 96-102; Seibman Decl. Ex. 5 at 8.

The Rule abruptly breaks from that longstanding precedent. Under OIG precedent, charitable premium assistance by AKF was legitimate and lawful. The Rule, however, permits and encourages insurers to *reject* charitable assistance that complies with OIG guidance. Indeed, in the wake of the Rule's announcement, insurers are doing just that. *E.g.*, Ex. C ¶¶ 90-91; Ex. D ¶¶ 105-107; Ex. E ¶ 61 (describing letter received from Blue Cross Blue Shield of Minnesota stating that third-party premium assistance is not permitted for "fully-insured commercial lines of business, including individual/family plans and group plans"). Moreover, as discussed above, the Rule breaks with OIG guidance in other ways, for example, by forcing providers to make

disclosures that violate longstanding OIG-imposed requirements in this area. Ex. C ¶¶ 94-101; Ex. E ¶¶ 70-74. HHS's failure to display "awareness" it was "changing [its] position" from its longstanding guidance requires vacatur of the Rule. *Fox Television Stations*, 556 U.S. at 515.

II. THE RULE WILL IRREPARABLY HARM PLAINTIFFS

Preliminary relief is also appropriate and necessary because Plaintiffs are "likely to suffer irreparable harm, that is, harm for which there is no adequate remedy at law." *Daniels Health Scis., LLC v. Vascular Health Scis., LLC*, 710 F.3d 579, 585 (5th Cir. 2013).

A. Individual Patients Will Suffer Irreparable Harm

Patients—whose interests are represented by DPC, *see Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 286 (5th Cir. 1999) (entity can represent patient interests); *Oak Park Health Care Ctr., LLC v. Johnson*, 2009 WL 331563, at *3 (W.D. La. Feb. 10, 2009) (same)—face irreparable injury in at least two ways.

First, although the Rule ostensibly seeks to protect ESRD patients, it in fact exposes patients to serious and immediate health risks by forcing a transition exclusively to public coverage, as demonstrated above. *See supra* pp. 18-19 (explaining how the Rule will drive patients off QHPs); *see also* Ex. B ¶¶ 14-15, 37-48; Ex. C ¶¶ 90-91; Ex. D ¶¶ 105-115; Ex. E ¶¶ 31, 78. For example, for patients who are compelled to switch to Medicaid only, there is a severe shortage of Medicaid providers—especially in rural areas and among specialists—which can jeopardize care for ESRD patients. Ex. B ¶ 33; Ex. C ¶ 58; Ex. D ¶¶ 37-38; Ex. E ¶ 30.f. "Only 67% of primary care providers treat Medicaid patients, and only 44% of those providers accept new Medicaid patients." Ex. C ¶ 58. Thus, under the Rule, patients may not be able to find specialists in the Medicaid network close by, or if they can, there can be unreasonable waits

to get an appointment. For dialysis patients, this lost time can have a significant impact on health. Ex. D ¶¶ 43-45, Ex. E ¶ 83.

There are equally serious access-to-care risks for patients forced to switch to Medicare. Not all ESRD patients qualify for Medicare, due to duration-of-work requirements or citizenship requirements, and under the Rule those individuals would lose access to any insurance option in perpetuity. Ex. C ¶¶ 17, 49-50 (over 1,000 DaVita patients ineligible for either Medicare or Medicaid); Ex. E ¶ 32; Ex. F ¶ 17 (approximately 310 U.S. Renal Care patients are ineligible for either Medicare or Medicaid). Without dialysis ESRD patients risk a serious medical setback, even death. Ex. B ¶¶ 3-4; Ex. C ¶ 9; Ex. E ¶ 81. "No harm could be more irreparable." *Knowles v. Horn*, 2010 WL 517591, at *7 (N.D. Tex. Feb. 10, 2010); *see also Int'l Res., Inc. v. N.Y. Life Ins. Co.*, 950 F.2d 294, 302 (6th Cir. 1991) (loss of health insurance, which would "adversely effect the proper maintenance of [plaintiff's] health," as well "interruption of the care might cause irreversible physical harm," was sufficient to establish irreparable harm).

In addition, Medicare does not extend to family members, and most households with an individual suffering ESRD lack financial resources to afford private insurance for other household members. QHPs may provide such coverage. Ex. B ¶ 34; Ex. C ¶ 55; Ex. D ¶¶ 31-32, 39-40; Ex. E ¶ 30. Thus, under the Rule, those family members would be left without *any* health insurance—which is also irreparable harm. *See United Steelworkers of America v. Ft. Pitt Steel Casting, Div. of Conval–Penn, Inc.*, 598 F.2d 1273, 1280 (3d Cir. 1979) (possible denial of "adequate medical care as a result of having no insurance would constitute 'substantial and irreparable injury"); *Whelan v. Colgan*, 602 F.2d 1060, 1062 (2d Cir. 1979) ("threatened termination of … medical coverage for workers and their families obviously raised the spectre of

irreparable injury"); *United Steelworkers of America v. Textron, Inc.*, 836 F.2d 6, 8 & 9 (1st Cir. 1987) (similar).

Second, patients will be irreparably harmed by the loss of *choice* of coverage. *See* Ex. D ¶¶ 20-29, 71, 84, 105-115. Patient choice is a cornerstone of the ACA, 42 U.S.C. § 18032, and Congress has long recognized the right of ESRD patients to remain on private insurance for certain periods of time, 42 U.S.C. § 426-1(a); *see also* Ex. B ¶¶ 18-28; Ex. C ¶ 14. The Rule countermands those judgments by steering patients exclusively to public coverage, even when a patient would prefer private coverage. That deprivation of choice is irreparable harm. *See Planned Parenthood of Gulf Coast, Inc. v. Gee*, 837 F.3d 477, 501 (5th Cir. 2016) (denial of "access to a much needed medical provider and the legal right to the qualified provider of their choice" is "irreparable harm").

B. Provider Plaintiffs Will Suffer Irreparable Harm

Absent preliminary relief, Provider Plaintiffs will also suffer multiple types of irreparable injury. ***First***, the Rule likely will lead to dialysis-facility closure. The cost of treating patients covered by public insurance is often more than the reimbursement received from the government for that treatment. Dialysis providers are able to remain in business largely because the reimbursements they receive from private insurers are sufficient to make provision of care to all patients, including those covered by public insurance, financially viable. Because of the Rule, however, many ESRD patients receiving private insurance will switch to public insurance. This will cause at least some of Plaintiff Providers' facilities to become financially unsustainable, potentially leading to facility closures, employee lay-offs, and harm to the vulnerable patients who will need to travel significant distances to receive treatment multiple times per week. Ex. C ¶¶ 73-77 (six majority-owned DaVita facilities in Texas may close); Ex. E ¶¶ 69, 82-84 (at least

two FMCNA facilities in the Eastern District of Texas, which treat approximately 170 patients, may close); Ex. F ¶¶ 52-53, 60-62. These harms are irreparable. *See Texas v. EPA*, 829 F.3d 405, 434 (5th Cir. 2016) ("unemployment and the permanent closure of plants" are "irreparable" harms); *Planned Parenthood of Cent. N. Carolina v. Cansler*, 804 F. Supp. 2d 482, 499 (M.D.N.C. 2011) (similar).

Second, the Rule risks catastrophic economic injury resulting from termination from Medicare. Given the complexity, uncertainty, and inconsistency of the Rule as well as the unrealistic timeline for implementation, although Provider Plaintiffs will work hard to comply, there is a significant risk they will be unable to do so. Ex. C ¶¶ 82-106 (explaining four reasons why compliance will be challenging); Ex. E ¶¶ 51-62, 64; Ex. F ¶ 51. Under the Medicare Act and HHS rules, the default sanction for non-compliance with a CfC is termination from Medicare. 42 U.S.C. § 13955rr(g), 42 C.F.R. § 488.604. Termination would be financially ruinous for providers, *e.g.*, Ex. C ¶¶ 78-81 (termination would "risk[] insolvency"); Ex. E ¶¶ 69, 82-84; Ex. F ¶¶ 52-53, and the risk of such catastrophic economic harm is irreparable injury, *see Humana, Inc. v. Avram A. Jacobson, M.D., P.A.*, 804 F.2d 1390, 1394 (5th Cir. 1986) (affirming irreparable-harm finding because "[l]oss of Medicare funding would directly deprive [plaintiff] of more than 50% of its business"); *New Orleans Home for Incurables, Inc. v. Greenstein*, 911 F. Supp. 2d 386, 408 (E.D. La. 2012).

Third, significant and substantial compliance costs—which cannot be recovered later from the government—are also irreparable. *See American Health Care Ass'n v. Burwell*, 2016 WL 6585295, at *15 (N.D. Miss. Nov. 7, 2016) (considering compliance costs as part of irreparable injury analysis); *Nevada v. United States Dep't of Labor*, 2016 WL 6879615, at *7 (E.D. Tex. Nov. 22, 2016) (same). The Rule will compel significant changes to Provider

Plaintiffs' operations, and impose substantial costs, particularly given the compressed thirty-day compliance schedule. Ex. C ¶¶ 107-110 ($11 million in compliance costs for DaVita); Ex. E ¶¶ 50-59; Ex. F ¶¶ 54-57; *see* 81 Fed. Reg. at 90,225 (estimating compliance costs of more than $29 million annually).[17] These injuries are, by definition, irreparable because "[n]o mechanism … exists for the [plaintiffs] to recover the compliance costs they will incur if the [challenged] [r]ule is invalidated on the merits." *Texas v. EPA*, 829 F.3d at 434; *Planned Parenthood Gulf Coast, Inc. v. Kliebert*, 141 F. Supp. 3d 604, 650 (M.D. La. 2015) (similar).

Finally, the Rule risks serious reputational injury to Provider Plaintiffs and interference with their business relationships. Because the Rule applies only to providers who donate to organizations that provide third-party assistance, the Rule may drive patients to other providers not covered by the Rule, so they can keep their QHP coverage. Ex. C ¶¶ 112-113; Ex. F ¶ 70. The Rule also compels providers to disclose private details about how patients are paying for their insurance; thus, patients will lose QHP coverage, and they may blame their provider for this result, damaging Providers' reputations and undermining goodwill. Ex. C ¶¶ 114-115; Ex. F ¶¶ 68-71. Provider Plaintiffs will also suffer reputational harm if facilities are terminated for non-compliance with the CfCs imposed by the Rule. Ex. E ¶¶ 64-68. Those harms are all irreparable. *E.g.*, *Humana*, 804 F.2d at 1394 (interference with patient relationships is irreparable harm); *Kliebert*, 141 F. Supp. 3d at 650 ("reputation[al] harm" was irreparable).

III. THE BALANCE OF EQUITIES SUPPORTS PRELIMINARY RELIEF

Preliminary relief is also necessary because the "threatened injury outweighs the harm to [HHS]." *Gee*, 837 F.3d at 488. Here, the balance of equities weighs decisively in favor of

[17] Compounding the compliance problems, the Rule poses a dilemma, requiring providers to attempt to comply with the seemingly contradictory requirements of the Interim Final Rule and longstanding OIG guidance. Ex. C ¶¶ 94-101; Ex E. ¶¶ 70-74; Ex. F ¶¶ 45-46.

preliminary relief. As explained above, Plaintiffs will suffer concrete and irreparable injury if the Rule takes effect. On the other side of the ledger, HHS would suffer no comparable harm were the Rule—which will substantially disrupt the status quo—delayed while the Court resolves Plaintiffs' claims. *See American Health Care Ass'n*, 2016 WL 6585295, at *18 ("balance of the harms … [is] determined partly in terms of whether it would be better to give the courts an opportunity to consider the merits of a Rule which sharply alters the pre-existing status quo, before it goes into effect"). Harm to HHS is further minimized by the fact that HHS is currently conducting a rulemaking on these issues that may result in implementation of these or similar regulations in a few months, provided HHS considers them appropriate in the light of comments and further consideration. Thus, "the threatened injury [to Plaintiffs] if the injunction is denied outweighs any harm that will result if the injunction is granted." *Texas*, 809 F.3d at 186.

IV. PRELIMINARY RELIEF IS IN THE PUBLIC INTEREST

Finally, preliminary relief "will not disserve the public interest." *Gee*, 837 F.3d at 489. To the contrary: the public interest strongly favors such relief to preserve the status quo.

First, the public interest lies in ensuring that ESRD patients have access to insurance coverage options of their choice, regardless whether they receive support for their premiums. *See Gee*, 837 F.3d at 502 ("public interest weighs in favor of … allowing some of the state's neediest individuals to continue receiving medical care from a much needed provider"). The serious risks and substantial confusion created by the Rule with respect to access to care are reason enough to enjoin the Rule pending judicial review. Ex. D ¶¶ 110-114.

Second, there is a strong "public interest" in ensuring that "government agencies be enjoined from acting in a manner contrary to law." Order Granting Preliminary Injunction 30, *Assoc. Builders & Contractors of SE Tex. v. Rung*, No. 1:16-cv-00425-MAC, Dkt. #22 (E.D.

Tex. Oct. 24, 2016). For that reason, courts in this Circuit regularly grant relief to preserve the status quo pending judicial review of agency rules. *See, e.g.*, *Nevada*, 2016 WL 6879615, at *8; *American Health Care Ass'n*, 2016 WL 6585295, at *18; *Texas v. United States*, 2016 WL 4426495, at *17 (N.D. Tex. Aug. 21, 2016). Here, HHS made a deliberate choice to bypass the APA, for the political goal of tying the hands of a future Presidential administration. Sanctioning such gamesmanship would disserve the public interest and provide a road map for future conduct by government agencies. Moreover, requiring HHS to engage in the notice-and-comment period contemplated by the APA before regulating in this area will ensure more reasoned decision-making permitting fair consideration of all competing concerns that would presented to HHS during a rulemaking.

V. THIS COURT HAS JURISDICTION

This Court has jurisdiction over this dispute. Because HHS has argued that review of rulemaking is available only through the agency appeal process, 42 U.S.C. §§ 405(g), (h). Any such jurisdictional objection would fail here for at least two reasons.

First, the Supreme Court has recognized that federal-question jurisdiction under 28 U.S.C. § 1331 remains available "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *See Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 19 (2000). That exception applies where, as here, "plaintiffs can show there is no way of having their claims reviewed" or "there exists a 'serious practical roadblock' to having the[] claims reviewed in any capacity, administratively or judicially." *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 655 (5th Cir. 2012).

Patients and DPC have *no* administrative means to challenge CfCs or the Rule, and thus have "no way of having their claims reviewed." *Physician Hosps. of Am.*, 691 F.3d at 655. By

definition, patients affected by the Rule are those who receive insurance premium assistance *outside* of Medicare, and they have no Medicare remedy. And patients have unique and, in many ways distinct, interests from others affected by the Rule given the life-threatening implications that will result from the Rule's disruptions to access to care. Section 1331 jurisdiction exists in such cases. *E.g.*, *Furlong v. Shalala*, 238 F.3d 227, 234 (2d Cir. 2001); *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 711-714 (D.C. Cir. 2011).

Provider Plaintiffs also have no genuine recourse to agency review, and therefore may invoke jurisdiction under § 1331 to challenge the Rule. Although providers could theoretically violate the Rule and the challenge the Rule's legality in lengthy and multi-layered administrative proceedings—they would face "serious practical roadblock[s]" to pursuing that option. The default sanction for violating a CfC is Medicare termination. 42 U.S.C. § 13955rr(g), 42 C.F.R. § 488.604. Thus, any provider seeking administrative review would risk "termination from the Medicare program," which is such a "draconian sanction"—equivalent to "economic suicide"—that such an administration option, courts have held, amounts to "no review at all." *Nat'l Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 38-39 & n.4 (D.D.C. 2000); *American Lithotripsy Soc. v. Thompson*, 215 F. Supp. 2d 23, 29 (D.D.C. 2002) (similar); *see* Ex. C ¶¶ 78-81; Ex. E ¶¶ 12, 64-69, 83; Ex. F ¶ 43. Indeed, the Supreme Court held that an analogous scheme did not provide "a meaningful avenue of relief" because it "require[d] plaintiffs to bet the farm … [to] test[] the validity of the law." *Free Ent. Fund v. Public Co. Acctg. Oversight Bd.*, 561 U.S. 477, 490-91 (2010) (citations omitted).

Second, this Court has mandamus jurisdiction under 28 U.S.C. § 1361. "[Section] 405(h) does not preclude mandamus jurisdiction." *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 765 (5th Cir. 2011). Mandamus is available "when (1) the plaintiff has a clear right to

relief, (2) the defendant a clear duty to act, and (3) no other adequate remedy exists." *Id.* at 768. Those standards are satisfied here, at least with respect to Plaintiffs' notice-and-comment claim. Plaintiffs have a clear right to enforce HHS's non-discretionary duty to follow notice-and-comment procedures, and no other remedy exists because it would be legally or practically impossible and futile to pursue that objection through an administrative process, where no subordinate HHS official could compel compliance with APA requirements.

CONCLUSION

The Court should enter a temporary restraining order and preliminary injunction against enforcement of the Rule.

Dated: January 6, 2017

Respectfully submitted,

/s/ Clyde M. Siebman

Clyde M. Siebman (TX Bar No. 18341600)
Siebman, Burg, Phillips & Smith, LLP
Federal Courthouse Square
300 N. Travis St.
Sherman, TX 75090
clydesiebman@siebman.com
Tel: 903-870-0070
Fax: 903-870-0066

Elizabeth S. Forrest (TX Bar No. 24086207)
Siebman, Burg, Phillips & Smith, LLP
4949 Hedgcoxe Rd., Suite 230
Plano, TX 75024
elizabethforrest@siebman.com
Tel: 214-387-9100

David W. Ogden (*pro hac vice* forthcoming)
Kelly P. Dunbar (*pro hac vice* forthcoming)
Stephen V. Carey (*pro hac vice* forthcoming)
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
David.Ogden@wilmerhale.com

Lynn E. Calkins (*pro hac vice* forthcoming)
Steven D. Gordon (*pro hac vice* forthcoming)
Holland & Knight LLP
800 17th Street, N.W., Suite 1100
Washington, D.C. 20006
lynn.calkins@hklaw.com
steven.gordon@hklaw.com
Tel: 202-955-3000
Fax: 202-955-5564

Thomas M. Melsheimer (TX Bar No. 13922550)
Fish & Richardson, P.C.
1717 Main Street, Suite 5000
Dallas, TX 75201
melsheimer@fr.com
Tel: 214-747-5070
Fax: 214-747-2091

Counsel for Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America

Stuart S. Kurlander (*pro hac vice* forthcoming)

Abid R. Qureshi (*pro hac vice* forthcoming)
Michael E. Bern (*pro hac vice* forthcoming)
Latham & Watkins LLP
555 Eleventh Street, NW, Suite 1000
Washington, D.C. 20004
stuart.kurlander@lw.com
abid.qureshi@lw.com
michael.bern@lw.com
Tel: 202-637-2200
Fax: 202-637-2201

Counsel for U.S. Renal Care Inc.

Kelly.Dunbar@wilmerhale.com
Stephen.Carey@wilmerhale.com
Tel: 202-663-6000
Fax: 202-663-6363

Counsel for DaVita Inc.

Jay Angoff (*pro hac vice* forthcoming)
Joanna Wasik (*pro hac vice* forthcoming)
Mehri & Skalet PLLC
1250 Connecticut Ave NW, Suite 300
Washington, D.C. 20036
jay.angoff@findjustice.com
jwasik@findjustice.com
Tel: 202-822-5100
Fax: 202-822-4997

Counsel for Dialysis Patient Citizens

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Emergency Motion for Temporary Restraining Order and Preliminary Injunction has been served by certified mail on the following, this 6th day of January, 2017:

Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

United States Department of Health and Human Services
Office of the General Counsel
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Sylvia Mathews Burwell, In Her Official Capacity
United States Secretary of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

United States Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Andy Slavitt, In His Official Capacity
Acting Administrator, United States Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Civil-Process Clerk
The United States Attorney's Office
Eastern District of Texas
110 North College, Suite 700
Tyler, Texas 75702

/s/ Clyde M. Siebman
Clyde M. Siebman (TX Bar No. 18341600)
Siebman, Burg, Phillips & Smith, LLP
Federal Courthouse Square
300 N. Travis St.

Sherman, TX 75090
clydesiebman@siebman.com
Tel: 903-870-0070
Fax: 903-870-0066

Elizabeth S. Forrest (TX Bar No. 24086207)
Siebman, Burg, Phillips & Smith, LLP
4949 Hedgcoxe Rd., Suite 230
Plano, TX 75024
elizabethforrest@siebman.com
Tel: 214-387-9100

David W. Ogden (*pro hac vice* forthcoming)
Kelly P. Dunbar (*pro hac vice* forthcoming)
Stephen V. Carey (*pro hac vice* forthcoming)
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
David.Ogden@wilmerhale.com
Kelly.Dunbar@wilmerhale.com
Stephen.Carey@wilmerhale.com
Tel: 202-663-6000
Fax: 202-663-6363

Counsel for DaVita Inc.

CERTIFICATE OF CONFERENCE

I hereby certify that Plaintiffs have complied with the meet and confer requirement in Local Rule CV-7(h). David Ogden, Kelly Dunbar, and Stephen Carey, counsel for Plaintiff DaVita Inc., conferred with Peggy Dotzl, Acting General Counsel for Defendant Department of Health and Human Services, via telephone on January 5 and 6, 2017, and spoke with Joel McElvain, Assistant Branch Director for the Federal Programs Branch of the U.S. Department of Justice, via telephone on January 6, 2017, regarding the Plaintiffs' Emergency Motion for Temporary Restraining Order and Preliminary Injunction and Request for Oral Argument and Expedited Consideration. Counsel for Defendants stated that the Defendants opposed the requested injunction. The discussions conclusively ended in an impasse, leaving an open issue for the court to resolve. LR CV-7(i).

/s/ Clyde M. Siebman
Clyde M. Siebman (TX Bar No. 18341600)
Siebman, Burg, Phillips & Smith, LLP
Federal Courthouse Square
300 N. Travis St.
Sherman, TX 75090
clydesiebman@siebman.com
Tel: 903-870-0070
Fax: 903-870-0066

Elizabeth S. Forrest (TX Bar No. 24086207)
Siebman, Burg, Phillips & Smith, LLP
4949 Hedgcoxe Rd., Suite 230
Plano, TX 75024
elizabethforrest@siebman.com
Tel: 214-387-9100

David W. Ogden (*pro hac vice* forthcoming)
Kelly P. Dunbar (*pro hac vice* forthcoming)
Stephen V. Carey (*pro hac vice* forthcoming)
Wilmer Cutler Pickering Hale and Dorr LLP

1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
David.Ogden@wilmerhale.com
Kelly.Dunbar@wilmerhale.com
Stephen.Carey@wilmerhale.com
Tel: 202-663-6000
Fax: 202-663-6363

Counsel for DaVita Inc.

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No._____
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	

DECLARATION OF CLYDE M. SIEBMAN IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

I, Clyde M. Siebman, declare and state as follows:

1. I am an attorney licensed to practice law in Texas. I am a member at Siebman, Burg, Phillips & Smith, LLP, and counsel for DaVita Inc. ("DaVita"), in the above-captioned case. I make this Declaration to the best of my knowledge, information, or belief and in support of Plaintiffs' Emergency Motion for Temporary Restraining Order and Preliminary Injunction.

2. Attached as Exhibit 1 is, upon information and belief, a true and correct copy of the interim final rule titled *Medicare Program; Conditions for Coverage for End-State Renal Disease Facilities—Third Party Payment*, published in the Federal Register on December 14, 2016 by the Department of Health and Human Services ("HHS") and Centers for Medicare & Medicaid Services ("CMS").

3. Attached as Exhibit 2 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0779, submitted by the America Kidney Fund, Inc. on September 22, 2016 in response to the HHS and CMS RFI.

4. Attached as Exhibit 3 is, upon information and belief, a true and correct copy of the Office of the Attorney General ("OIG") 1997 Advisory Opinion, No. 97-1 issued on June 11, 1997.

5. Attached as Exhibit 4 is, upon information and belief, a true and correct copy of a notice titled "Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans" ("RFI") published in the Federal Register on August 23, 2016 by HHS and CMS.

6. Attached as Exhibit 5 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0802, submitted by Fresenius Medical Care North America ("FMCNA") on September 22, 2016 in response to the HHS and CMS RFI.

7. Attached as Exhibit 6 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0815, submitted by the Kidney Care Counsel on September 22, 2016 in response to the HHS and CMS RFI.

8. Attached as Exhibit 7 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0792, submitted by DaVita on September 22, 2016 in response to the HHS and CMS RFI.

9. Attached as Exhibit 8 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0791, submitted by U.S. Renal Care, Inc. ("USRC") on September 22, 2016 in response to the HHS and CMS RFI.

10. Attached as Exhibit 9 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0814, submitted by the American Kidney Fund ("AKF"), Dialysis Patient Citizens ("DPC"), and the National Kidney Foundation ("NKF") on September 22, 2016 in response to the HHS and CMS RFI.

11. Attached as Exhibit 10 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0690 submitted in response to the HHS and CMS RFI.

12. Attached as Exhibit 11 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0691 submitted in response to the HHS and CMS RFI.

13. Attached as Exhibit 12 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0697 submitted in response to the HHS and CMS RFI.

14. Attached as Exhibit 13 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0708 submitted in response to the HHS and CMS RFI.

15. Attached as Exhibit 14 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0729 submitted in response to the HHS and CMS RFI.

16. Attached as Exhibit 15 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0755 submitted in response to the HHS and CMS RFI.

17. Attached as Exhibit 16 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0803 submitted in response to the HHS and CMS RFI.

18. Attached as Exhibit 17 is, upon information and belief, a true and correct copy of Comment No. CMS-2016-0145-0809, submitted by Kidney Care Partners ("KCP") on September 22, 2016 in response to the HHS and CMS RFI.

I, Clyde M. Siebman, declare under penalty of perjury that the foregoing is true and correct. Executed this day, January 6, 2017 in Sherman, Texas.

Respectfully submitted,

/s/ Clyde M. Siebman
Clyde M. Siebman (TX Bar No. 18341600)
Siebman, Burg, Phillips & Smith, LLP
Federal Courthouse Square
300 N. Travis St.
Sherman, TX 75090
clydesiebman@siebman.com
Tel: 903-870-0070
Fax: 903-870-0066

Counsel for DaVita Inc.

EXHIBIT 1

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] Brazoria County Chambers County Fort Bend County Galveston County Harris County Liberty County Montgomery County Waller County	.....	Nonattainment	1/13/17	Moderate.
* * *	*	*	*	*

[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 2

American Kidney Fund®

September 22, 2016

BY ELECTRONIC SUBMISSION
Attn: Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201
http://www.regulations.gov

Re: U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans, RIN 0938-ZB31 (File Code: CMS-6074-NC)

Dear Mr. Slavitt:

The American Kidney Fund, Inc. ("AKF") submits the following response to the request from the U.S. Department of Health and Human Services ("HHS") Centers for Medicare & Medicaid Services ("CMS") for information regarding "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans" (the "RFI").

AKF is the nation's leading nonprofit organization working on behalf of the 31 million Americans with kidney disease. Our mission is to help people fight kidney disease and live healthier lives, and we fulfill that mission by providing a complete spectrum of programs and services: top-rated health education materials, including brochures, fact sheets, and webinars; free kidney disease screenings in more than 20 cities nationwide; and need-based financial assistance enabling one in five U.S. dialysis patients to access lifesaving medical care, including dialysis and transplantation. Our award-winning website educates more than three million people each year about the prevention and treatment of kidney disease, and our toll-free HelpLine provides live support to people who need health information. We invest in clinical research to improve outcomes for kidney patients, and we work on Capitol Hill for legislation and policies supporting the issues that are important to the people we serve. We provide these critically needed services while maintaining the top rating (4-stars) from Charity Navigator, the nation's leading charity watchdog agency. We spend 97 cents of every donated dollar on programs that directly serve and educate patients and the public.

11921 Rockville Pike | Suite 300 | Rockville, MD 20852
301.881.3052 voice | 301.881.0898 fax | 800.638.8299 toll-free | 866.300.2900 Español
Member: CFC 11404 | www.**KidneyFund**.org

We are a member of Kidney Care Partners ("KCP") and work closely with various patient advocacy organizations. In addition to our response below, we support and are signing on to the letters that KCP and the joint advocacy groups are submitting in response to the RFI.

INTRODUCTION

We thank CMS for its concern regarding improper steering of patients away from the health care coverage best suited to their and their family's individual circumstances. AKF is similarly concerned about any actions that would infringe upon a patient's right to choose their health care coverage. Indeed, the core mission of AKF's Health Insurance Premium Program ("HIPP") is to allow low-income kidney patients with end-stage renal disease ("ESRD") to maintain the health care coverage best suited to their needs when they otherwise could not afford to do so.

People confronted with an ESRD diagnosis face life-altering challenges relating to their serious medical condition, including reduced ability to work and care for themselves and their families, the burden of needing regular dialysis treatment, a decline in health and capacity, and the corresponding financial impact of living with and treating ESRD. These challenges have prompted federal law to recognize ESRD as a disability. Fortunately, there exists a range of health care coverage options for people living with ESRD, options which have only expanded with the Patient Protection and Affordable Care Act ("ACA").[1] The benefits and drawbacks of each coverage option are as varied as the choices themselves. And because each ESRD patient's personal circumstances are likewise unique, each will have a coverage option best suited to his or her needs. This may be coverage under Medicaid, Medicare—including with Medigap or other supplemental coverage—an employer group health plan ("EGHP"), a COBRA plan, a qualified health plan ("QHP") offered under the ACA's health insurance marketplaces (each a "Marketplace"), or other individual market coverage.

None of these options comes without a cost to the patient. HIPP exists to preserve each eligible low-income ESRD patient's ability to choose and maintain the coverage that is best for them, no matter what that coverage option is. That is why AKF is gratified to see the RFI's repeated emphasis on maintaining individuals' rights to make coverage decisions "based on their specific circumstances, and health and financial needs."[2]

AKF shares CMS's concerns surrounding improper steering of patients, since improperly influenced enrollment driven by the financial incentives of health care providers rather than by the specific circumstances and needs of individual patients would be antithetical to AKF's mission of ensuring patient choice. Because HIPP provides premium assistance for patients enrolling in individual market plans, along with every other form of coverage (Medicare, Medigap, COBRA, EGHP, and other commercial plans), AKF is eager to address any HIPP-

[1] Pub. L. 111-148 (2010).
[2] *See, e.g.*, RFI at p. 6.

related concerns that CMS may have, and AKF looks forward to working with CMS and all interested parties to the extent that there are HIPP issues requiring further attention.

In response to the RFI, AKF provides information detailing its longstanding institutional and operational safeguards and procedures—designed in consultation with, and approved by, the HHS Office of the Inspector General ("OIG")—allowing AKF to operate HIPP while permitting dialysis providers to join the thousands of donors supporting AKF's mission. AKF has operated HIPP continuously since 1997 under these federally approved guidelines designed to wall off provider-donors from HIPP's operations and to prevent any undue influence or patient steering in selecting a dialysis provider through HIPP. AKF also responds to the RFI with specifics about its more recent improvements to its policies and procedures, including enhancements currently under way, further designed to eliminate any risk of improper patient steering by providers whose patients are applying for or receiving HIPP funding. AKF also addresses its position on specific instances of alleged misconduct by market actors. In short, AKF takes allegations of misuse or abuse of its programs extremely seriously, and AKF is working, and will continue to work, to ensure that providers, insurers, their employees, and other market participants are not taking advantage of HIPP or its patient beneficiaries for their own financial gain.

AKF also describes how the safeguards and procedures that it follows, those it is additionally implementing, and a robust approach to incidents of alleged misconduct, provide the best path forward for addressing concerns about the possibility of improper steering of ESRD patients, without undermining consumer choice. AKF has serious concerns that health insurance companies do not want expensive-to-insure ESRD patients on their insurance rolls and are concertedly exaggerating discrete, anecdotal allegations of misconduct in an attempt to lobby for broader regulation that would cut off coverage options for low-income people with chronic health conditions, including those with ESRD. In the event that specific instances of inappropriate conduct have occurred, they should be addressed directly, rather than penalizing an entire class of disabled persons from choosing and paying for one or more forms of insurance coverage that may be best for their particular situation, including individual market plans. Indeed, while the RFI is limited to concerns about improper steering of patients into individual market plans—and any resulting regulatory action or guidance presumably would not apply to Medigap, EGHP, COBRA, or other types of commercial plans—the ACA's guaranteed-issue and anti-discrimination provisions and enabling regulations make clear that ESRD patients, like all other Americans, have every right to enroll in an individual market plan, including a QHP, if they determine that is best for them.

More broadly, AKF submits that certain health insurance companies are unfairly steering patients away from their plans in an effort to keep people living with ESRD off their rolls. This practice constitutes undue influence and undermines patient choice in the same way as improperly steering patients from Medicare or Medicaid coverage to individual market plans. One very overt way health insurance companies are dropping ESRD patients from their rolls is by attempting to refuse premium assistance from AKF and other charities. The same dynamic

was at play shortly after the ACA's implementation, when Louisiana's three Marketplace health insurance companies announced that they were refusing premium assistance payments from the Ryan White HIV/AIDS Program (the "Ryan White Program") on behalf of low-income people living with HIV. The insurance companies then, like now, raised unspecific allegations of fraud and abuse and rote arguments about the risk pool as their rationale for refusing premiums from people living with HIV—which, like ESRD, is a federally recognized disability.[3] In response to a class action lawsuit filed on behalf of Ryan White Program recipients, brought under (among other laws) the ACA's anti-discrimination provisions—the very provisions guaranteeing ESRD patients equal access to choice of coverage—a federal court restrained the insurers from implementing their plan.[4] Shortly thereafter, HHS published an interim final rule *requiring* insurers to accept such third-party payments, adopted at 45 C.F.R. § 156.1250. Because turning away premium payments from disabled people living with ESRD constitutes unlawful discrimination in the same way, AKF urges CMS to step in to protect these disabled Americans as it did for Ryan White Program recipients.

Beyond refusing to accept charitable premium payments on behalf of their members, some insurers have taken other actions that appear designed to direct ESRD patients to Medicare or Medicaid for primary coverage. Some plans offer to pay the Medicare coinsurance amounts if members will change their primary coverage to Medicare. Some plans have suggested to ESRD patients that federal law requires them to enroll in Medicare four months after an ESRD diagnosis. Such practices constitute steering and interfere with patients' ability to freely choose the plan that is in their best interests.

* * *

Because AKF serves in a unique role for ESRD patients in comparison to, for example, dialysis companies, renal social workers, health insurance companies, and other relevant participants, AKF is not positioned to answer all of the RFI's specific queries. Rather, the following response is directed to the RFI's principal inquiries focused on (1) maintaining the integrity of patient choice and (2) preventing improper patient steering. To that end, we ***first*** provide the historical and regulatory background of AKF's decades-long charitable mission to assist low-income people living with kidney disease, including the condition of AKF beneficiaries that underscores their need for assistance. This context—particularly the OIG's 1997 Advisory Opinion approving and setting the guidelines for HIPP in the form in which it substantially operates to this day[5]—is critical to understanding AKF's longstanding commitment to the independent administration of HIPP, free from improper influence. ***Second***, we explain the

---

[3] *See Fiscus v. Wal-Mart Stores, Inc.*, 385 F.3d 378, 382 (3d Cir. 2004) (finding that ESRD is a physical impairment that substantially limits one or more major life activities and therefore meets the definition of "disability" under the Americans with Disabilities Act).

[4] *East v. Blue Cross and Blue Shield of Louisiana, et al.*, No. 3:14-cv-115, 2014 WL 8332136 (M.D. La. Feb. 24, 2014), Exhibit 1; *see also* Complaint, *East v. Blue Cross and Blue Shield of Louisiana, et al.*, No. 3:14-cv-115, (M.D. La. Feb. 20, 2014), ECF No. 1, Exhibit 2.

[5] '97 Advisory Opinion, Exhibit 3.

current patchwork of insurance coverage options for people living with ESRD and provide background on critical considerations they face in choosing the coverage option best for them, including, in some cases, an individual market plan. *Third*, we detail AKF's policies and procedures—old, new, and forthcoming—designed to prevent fraud, abuse, and undue influence, and specifically those focused on providing patients with complete and balanced information about their coverage options and preventing improper patient steering. *Fourth*, we call to CMS's attention the improper patient steering occurring in the other direction—that is, health insurance companies dissuading or discriminating against disabled ESRD patients in efforts to keep them off their plans even when such plans are in the patients' best interests.

We again thank CMS for its efforts to ensure the integrity of patient choice. AKF is committed to working with CMS to establish a lasting regulatory framework protective of charitable third-party assistance, which establishes clear guardrails to eliminate the potential for improper steering, and that, at the same time, cannot be used by health insurers as a pretext for discrimination against, or improperly limiting choice of coverage for, Americans living with a particular disability.

I. BACKGROUND ON AKF'S MISSION TO ASSIST KIDNEY PATIENTS IN MAINTAINING THE COVERAGE AND CARE BEST FOR THEM

AKF has been the safety net for U.S. dialysis patients since we were founded in 1971 to help one dialysis patient afford care. We have consistently taken a comprehensive approach to ensuring the integrity of our work on behalf of the ESRD patients we serve. Over the past 45 years, in addition to providing an array of programs and services to educate the public about kidney disease prevention and treatment, we have helped more than one million low-income ESRD patients to access health care—including dialysis, transplantation, and other health care services—through our various grant programs. Our grant programs include not only the HIPP program, but also Safety Net Grants for expenses that insurance does not cover, such as transportation to and from dialysis treatment, free medications for low-income dialysis patients to treat common side effects of kidney failure, summer camp scholarship grants for pediatric kidney patients, and disaster relief grants for dialysis patients living in communities affected by natural disaster. For example, over the past month, we have assisted Louisiana ESRD patients affected by historic flooding with over $50,000 in disaster relief grants. Our donors include more than 63,000 individuals from all 50 states, as well as corporations and foundations. We receive no government funding and consistently receive the highest possible ratings from the nation's top charity watchdog groups for our stewardship of each donated dollar.

A. AKF's Longstanding Operation of HIPP Under Federal Guidance

HIPP is a critical part of the nation's health care safety net for ESRD patients. The program was established according to our own high standards and those approved by the federal government. Through HIPP, AKF provides grants to low-income people living with ESRD to

allow them to pay premiums for the health insurance that best suits their individual circumstances.

In 1997, AKF, together with six dialysis providers, requested an advisory opinion from the OIG, seeking approval of, and guidance regarding, continued operation of HIPP while allowing providers to donate to the program. Prior to seeking the OIG's opinion on HIPP, AKF had for some time been operating a program to help patients with their medical expenses, including payment of health insurance premiums. When AKF sought the OIG's advisory opinion in 1997, AKF described for the OIG in detail how AKF had been operating its patient assistance program.

In providing its advisory opinion (the "'97 Advisory Opinion"), the OIG reviewed the information provided and concluded that continuation of our operating procedures in an expanded HIPP program—that allowed for dialysis providers to voluntarily contribute funding for the program—would enhance patient choice with regard to dialysis providers and ensure that provider contributions would not be used to influence patients' choice of providers. In approving the '97 Advisory Opinion, the Inspector General stated:

> In sum, the interposition of AKF, a bona fide, independent, charitable organization, and its administration of HIPP provides sufficient insulation so that the premium payments should not be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of HIPP assistance their patients receive bears any relationship to the amount of their donations. Indeed, the Companies are not guaranteed that beneficiaries they refer to HIPP will receive any assistance at all. . . . Simply put, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice.[6]

The '97 Advisory Opinion was the first of its kind, and featured hallmarks that set the standard for all of the OIG's similar opinions to follow: (1) AKF is an independent 501(c)(3) organization; (2) Providers are not required to contribute to HIPP in order for their patients to receive assistance; (3) AKF has total discretion to determine applicant eligibility, based on AKF-established criteria of financial need; (4) Assistance from AKF does not restrict patients' choice of provider; and (5) Grants follow patients, regardless of providers chosen, and as a result, these grants increase patient choice instead of restricting it.

Ever since then, our program has consistently aligned with evolving federal standards for provider-funded assistance programs.

---

[6] *See* '97 Advisory Opinion, Exhibit 3, at pages 6-7.

In 2002, the OIG issued a special advisory bulletin on patient inducements.[7] That bulletin expressly highlights AKF's HIPP as the example of how a provider-funded assistance program can operate within federal law, because of two hallmarks: (1) the independent determination of patient financial need; and (2) the fact that a patient's receipt of assistance does not depend on the patient's use of any particular provider.

By 2005, the OIG was receiving numerous requests from charities wishing to establish patient assistance programs, particularly medication assistance programs under Medicare Part D. In the OIG's responsive bulletin, specifically focused on pharmaceutical programs, the OIG affirmed its longstanding policy first espoused in the '97 Advisory Opinion and noted specific concerns notably *not* applicable to programs with HIPP's design. This 2005 bulletin was notable for the clear guidance it provided to nonprofit organizations wishing to establish patient assistance programs. AKF's program, then and now, operates entirely free from the major concerns CMS elucidated. The 2005 bulletin:

- Expressed concerns with programs that were funded under the auspices of a single provider; **whereas** AKF's program receives funding from over 200 dialysis providers, ranging from small independent clinics to large dialysis organizations, and whereas many of our HIPP grant recipients are treated at providers who do not contribute to AKF at all;
- Declared that any patient assistance program must "sever the nexus" between patient grants and the providers; **whereas**, as explained below, AKF's protective firewalls ensure that there is no connection between donations and grants; and
- Identified a standard requiring that charities' aid be provided broadly and that all applicants for charitable assistance be treated alike; **whereas** AKF provides assistance to any financially qualified dialysis patient who applies, on a first-come first-served basis, and does not take into consideration the severity of a person's illness, where they are treated, or what kind of health insurance they have.

In 2014, the OIG further updated its 2005 guidance with a new special bulletin that similarly demarcated distinctions between programs that prompt concerns and the model represented by HIPP.[8] The bulletin:

- Voiced concern that the narrower the categories of patients who qualified for assistance, the greater the chance the assistance would steer patients to use a particular donor's product or service; **whereas** AKF's program is open broadly to all ESRD patients who depend on dialysis for survival, regardless of specific dialysis modality or provider;

[7] 70 Fed. Reg. 70623 (Nov. 22, 2005).
[8] 79 Fed. Reg. 31120 (May 30, 2014).

- Cautioned that assistance could not be narrowly defined in terms of a patient's stage within a disease, or need for a particular treatment; **whereas,** unlike pharmaceutical co-pay programs that help individuals who need a specific drug therapy, our program helps people who may need a full range of medical services through insurance, including everything from dialysis treatment, to cardiovascular care, to diabetes medications.

In short, HIPP has always operated within the guidance that the OIG has established (and continually refined) for charities wishing to operate provider-funded patient assistance programs. In practice, as detailed below, there are several core protective tenets and firewalls built into HIPP's operation, guided by the '97 Advisory Opinion, that we follow to this day to ensure the integrity and objectivity of the program:

Donations:[9]

- All contributions to HIPP are voluntary.
- Donor funding is provided to AKF without any restrictions or conditions whatsoever—funds go into one funding pool, and from that pool we administer the program, providing grants to eligible low-income dialysis patients on a first-come first-served basis to pay for their insurance premiums.
- Our Board of Trustees is independent and includes a subcommittee with responsibility for oversight of HIPP. Our Trustees are volunteers who are not compensated and have a wide range of backgrounds and expertise.[10] Membership on the HIPP committee excludes anyone associated with a dialysis center, including employees, officers, shareholders, or owners of such centers.
- The '97 Advisory Opinion states that HIPP is not to be publicly advertised by dialysis providers.

Grant Selection:[11]

- Using voluntary donor funding, we provide help to patients *solely on the basis of their financial need*. We do not consider a patient's health status in awarding financial assistance.
- We carefully review each applicant's financial status and require that they meet specific income-to-expense criteria in order to qualify for assistance.
- As part of the application process, the patient must complete and sign a detailed statement of income, assets, and expenses.

---

[9] *See* HIPP Guidelines, Rules and Procedures, http://www.kidneyfund.org/assets/pdf/financial-assistance/hipp-guidelines.pdf.

[10] *See* Instructions for Form 990, Internal Revenue Service, at 18-19, https://www.irs.gov/pub/irs-pdf/i990.pdf (setting forth requirements for independence of governing members of charitable organizations).

[11] *See* HIPP Guidelines, *supra* note 9.

- We provide financial assistance without regard to the type of insurance a patient has, where they live, who their dialysis provider is, or whether their dialysis provider is a contributor to our program.[12] In fact, most of our beneficiaries are enrolled in government health insurance programs.
- Patients choose their health insurance coverage with no input from AKF. While we support providing patients with the information they need to make an informed choice about their health insurance, AKF is not involved in helping patients find new insurance and does not advocate that patients keep or switch insurance.
- Patients may change their health insurance coverage—and their provider—at any time, and AKF will continue to help them until their grant period expires. (Patients who so change are of course eligible, like all other AKF grant recipients, to apply for a new grant at the end of the grant period.) Their grant period is at least equal to their full health insurance premium year so long as the patient continues to meet qualifying criteria.
- Many dialysis providers with patients being assisted by our program do not contribute to AKF. In fact, almost 40 percent of the referring providers do not make voluntary contributions to the pool at all. Critically, our staff responsible for processing and approving grants is barred from accessing information about which providers have contributed to HIPP.
- Donors' contributions to AKF are not contributions made on behalf of individual patients. By participating in HIPP, providers agree that there is no "earmarking" of contributions to specific patients within the HIPP pool.
- There is no guarantee that the patients referred by donors to the HIPP program will receive assistance. The decision to provide assistance is at all times subject to the sole and absolute discretion of AKF—there is no "right" to a grant of financial assistance, regardless of the amount or frequency of donations by the referring provider.

The nation's leading charity watchdog organizations—including Charity Navigator, Consumer Reports, CharityWatch, and the Better Business Bureau Wise Giving Alliance—have recognized AKF as one of the nation's most trusted and respected charities.[13] In fact, in 2015, Charity Navigator, the nation's premier charity evaluator, scored AKF a perfect 100 out of 100 on its "Accountability & Transparency" rating, and awarded AKF its "highest, 4-star" rating overall.[14] This is the 14th consecutive time AKF has received the 4-star rating from Charity

---

[12] While AKF does not condition eligibility for HIPP assistance on the type of insurance coverage (*e.g.*, Medicare/Medicaid, Medigap, EGHP, COBRA, or individual market coverage), HIPP is designed to provide premium assistance only in connection with primary and secondary health insurance coverage; thus, HIPP does not assist with tertiary coverage of any kind. *See* HIPP Guidelines, *supra* note 9.

[13] For links to and descriptions of the ratings and recognition AKF has received from these charity watchdog organizations, see the "Putting Your Donations to Work" section of AKF's website (http://www.kidneyfund.org/about-us/vision-and-mission/putting-donations-to-work.html).

[14] *See id*.

Navigator, placing AKF on Charity Navigator's list of the "ten charities [that] have earned the most consecutive 4-star ratings demonstrating an ongoing fiscal excellence."[15]

In recognition of the important role that AKF plays within the ESRD community, and reflecting its longstanding reputation as one of the nation's most trusted and respected charities, the National Institute of Diabetes & Digestive & Kidney Diseases—part of the National Institutes of Health within HHS—directs patients with ESRD to AKF for assistance.[16]

B. The Vital Importance of AKF's Premium Assistance to ESRD Patients in the U.S.

Under HIPP, in 2015 alone, AKF provided health insurance premium assistance to more than 79,000 low-income dialysis patients in all 50 states—that is, *we help nearly one out of every five dialysis patients in the U.S. to afford their health care*. More than 60 percent of our grants fund Medicare Part B and Medigap premiums. We also provide premium assistance to financially needy dialysis patients who are enrolled in QHPs, other individual market plans, COBRA, and EGHPs. Our grants to assist patients with QHPs constitute a small fraction of our overall grant assistance, as detailed below.

Importantly, patients begin the HIPP application process *after* selecting the health plan that best meets their financial and medical needs following consultation with the patient's renal professional. By providing assistance for the full range of insurance options and otherwise being independent of the decision-making process, we ensure that our grant decisions cannot steer patients toward any particular type of coverage. Our commitment to funding all types of insurance also reflects our mission. We firmly believe that it is our obligation not only to provide premium assistance to ESRD patients, but also to provide them the ability to choose and maintain the health care coverage that they believe is best for them.

Most often, we make premium payments directly to insurance carriers on behalf of patients. This ensures that no patient will lose coverage due to a late or incomplete payment, and also that the funds are used for their intended purpose. For nearly 20 years this process has worked effectively to remove significant barriers to maintaining coverage for the low-income, chronically ill population we serve, who often do not have the financial means to transact premium payments on their own behalf.

Fully 70 percent of the patients we serve are unemployed, while another 20 percent work only part-time—reflective of the fact that the dialysis treatment regimen makes it difficult to stay employed. To qualify for HIPP assistance, a patient's monthly household income may not exceed reasonable monthly expenses by more than $600. Indeed, 60 percent of the patients

---

[15] Charity Navigator, "10 Charities with the Most Consecutive 4-Star Ratings," https://www.charitynavigator.org/index.cfm?bay=topten.detail&listid=100 (last visited Aug. 18, 2016).

[16] *See* National Institute of Diabetes and Digestive and Kidney Diseases, "Financial Help for Treatment of Kidney Failure," https://www.niddk.nih.gov/health-information/health-topics/kidney-disease/financial-help-for-treatment-of-kidney-failure/Pages/facts.aspx (last visited Sept. 9, 2016).

we assist have annual household incomes under $20,000. At the same time, our nation's ESRD patients have average annual out-of-pocket medical expenses of close to $7,000. The patient population we serve is more advanced in age, with 48 percent above 60 years old, and 77 percent above 50 years old. Kidney failure also disproportionately impacts racial and ethnic minority populations that historically have been underserved. African Americans and Hispanics develop kidney failure at higher rates than Caucasians and so are disproportionally affected by any barriers to maintaining health coverage. Over half of our HIPP grant recipients are people of color (38 percent African American, 15 percent Hispanic).

In October 2015, we conducted a survey of renal social workers in North Carolina to further understand the unique challenges faced by our recipient population. As reported by social workers working directly with ESRD patients, our survey helps to clarify why payment of third-party premiums directly to insurers is so important. The survey found that the following conditions make it particularly difficult for our patient population, even if they are given or already have the funds, to conduct the transactions necessary to pay their own health insurance premiums:

- Many patients were living in assisted living or nursing homes, which meant they had more limited capabilities.
- Patients lacked bank accounts.
- Patients had low literacy.
- Patients struggled with limited or unreliable transportation, making it challenging to get to a bank or check-cashing business so they could obtain and send in an insurance premium payment.
- Patients tended to be reliant on others to help them with their finances and business transactions.

In addition to the high costs of obtaining health coverage, what may be to others the simple act of maintaining that coverage by paying bills in a timely fashion can be extraordinarily difficult for people with a debilitating disease. For many reasons, the patients with ESRD whom we serve are some of the most vulnerable in the country. The assistance that AKF provides is vital for their continued health and stability and potentially prevents them from needing additional federal and state financial assistance.

II. ANY FUTURE REGULATION SHOULD NOT IMPEDE PATIENT CHOICE

The ACA and the existing regulatory landscape—particularly as it relates to these vulnerable kidney patients—unmistakably reflect the strong public policy favoring and protecting patient choice. AKF fully supports CMS's efforts to ensure that patients' coverage choices are in no way being manipulated, and AKF is pursuing its own efforts to that end (*see* Part III below). At the same time, it is critical that CMS does not—in an attempt to rectify or prevent specific instances of alleged misconduct by individual actors—respond in a way that will

indiscriminately limit for an entire class of kidney patients the coverage and health care choices that best meet their needs but which have only been possible with the help of assistance from AKF. The longstanding statutory and regulatory policy of promoting choice for kidney patients, and the many and varied life-impacting reasons patients might chose an individual market plan for themselves and their families, underscore the imperative of ensuring that kidney patients' right to make their own health care choices is not infringed.

A. The Current Health Insurance Landscape For Kidney Patients

While Medicare and Medicaid provide health care coverage for many individuals living with ESRD, such government safety net programs are not the ideal choice for everyone. The premiums, deductibles, and co-insurance obligations under Medicare, for example, can be burdensome and often financially crushing for its beneficiaries, particularly because Medicare has no out-of-pocket limit. The severe shortage of providers accepting Medicaid, especially in rural areas and among specialists, can jeopardize access to care for ESRD patients. Fortunately, the insurance landscape that has developed in the past few decades, including, most importantly, through the introduction of the ACA, has resulted in a range of possible insurance coverage options and scenarios for individuals facing ESRD. HIPP is intended to help ESRD patients afford whatever option best meets their health and financial needs and preferences.

Recognizing the significant health and financial burdens faced by individuals living with ESRD, Congress in 1972 created a special Medicare benefit for individuals with ESRD, particularly in response to the growing incidence of the disease.[17] With this benefit, all individuals with ESRD who have earned a certain level of eligibility for Social Security benefits (or are dependents of those who have attained that level) are entitled to benefits under Medicare Part A and are eligible to enroll in Medicare Part B.[18]

While Medicare coverage is a critical component of the health care safety net for individuals with ESRD, it is not always the best option for every patient.

At the onset, it is important to note that ESRD patients are different from other Medicare beneficiaries—both demographically and with respect to coverage rights and options—and as a result they must consider even more factors when seeking to identify the insurance coverage that is best for them and their families. For example, the rules around eligibility for public programs and coordination of insurance with commercial plans, including those in Marketplace exchanges, are very complex and also different for patients with ESRD, as

---

[17] *See* 42 U.S.C.A. § 426-1.

[18] *See id*. In general, the waiting period for ESRD-based eligibility (*i.e.*, for individuals under age 65 who are not otherwise eligible for Medicare) is 3 months after initiation of dialysis. *See* 42 U.S.C.A. § 426-1(b)(1). During the 3-month waiting period, treatment is covered, if at all, by the individual's existing group or individual market plan (if any). Coverage can begin the first month of dialysis, for those able to undergo home-based treatment. *See* Medicare.gov, How to sign up for Medicare if you have End-Stage Renal Disease (ESRD), https://www.medicare.gov/people-like-me/esrd/getting-medicare-with-esrd.html#collapse-3170.

compared to other Medicare beneficiaries. Accordingly, patients must carefully evaluate the rules and options that apply to their individual situations before making a decision on insurance coverage.

One key consideration is that ESRD patients are younger than the typical Medicare beneficiary, and are often supporting families; Medicare covers only the ESRD patient, not dependents.

Medicare also leaves recipients with substantial cost-sharing obligations—including a 20 percent coinsurance requirement that can be financially crushing for individuals with chronic conditions like ESRD.[19] For instance, Medicare Part B payments on behalf of ESRD patients generally cover only 80 percent of the rate for Medicare-covered maintenance dialysis services, as well as 80 percent of physician services and certain ancillary services. In addition, most people must pay a monthly premium for Part B coverage (the standard premium for 2016 is $104.90 per month, although it may be higher based on income). Coverage is also subject to an annual deductible: the Part A deductible for 2016 is $1,288 per benefit period, while the Part B deductible is $166. The average patient living with ESRD covered by Medicare incurred $6,918 in annual out-of-pocket expenses in 2010.[20]

For those individuals who do not meet the stringent eligibility requirements for the various "Medicare Savings Programs" designed to defray such cost-sharing obligations for the lowest-income beneficiaries,[21] Medigap policies sold by private insurance companies may be available to help cover the annual deductible and coinsurance obligations under Medicare. However, the federal government does not require carriers to offer Medigap to ESRD patients under 65, and regulations vary from state to state. Only 27 states mandate that insurance carriers offer Medigap to ESRD patients under age 65, leaving patients in the other 23 states without access to this important supplemental insurance.[22] If a company does sell Medigap to individuals under 65, including ESRD patients, such policies will generally cost more than policies sold to people over 65.[23] Additionally, in many states, the only Medigap plan available to ESRD patients under 65 is Plan A, which is the most basic plan, does not cover Part A and B deductibles, and does not cover expenses such as skilled nursing facilities.

---

[19] Individuals with ESRD not only must undergo regular dialysis treatments (in addition to regular monitoring of laboratory values, diet, and medication regimens), but also commonly suffer from certain co-morbidities including diabetes, anemia, hypertension, and congestive heart failure.

[20] Juliette Cubanski, Christina Swoope, Anthony Damico, & Tricia Neuman, *How Much Is Enough? Out-of-Pocket Spending Among Medicare Beneficiaries: A Chartbook* (July 21, 2014), http://kff.org/report-section/how-much-is-enough-out-of-pocket-spending-among-medicare-beneficiaries-section-1/.

[21] To qualify, an individual generally must have a monthly income of less than $1,357 ($1,823 for a couple) in 2016, with total liquid assets of $7,280 or less ($10,930 or less for a couple). CMS, MEDICARE COVERAGE OF KIDNEY DIALYSIS & KIDNEY TRANSPLANT SERVICES 43 (May 2016), https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf.

[22] CMS, MEDICARE COVERAGE OF KIDNEY DIALYSIS & KIDNEY TRANSPLANT SERVICES 42 (May 2016), https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf.

[23] *Id*. at 42.

In short, Medicare, or Medicare with a Medigap supplemental plan, is not a one-size-fits-all coverage solution for our nation's ESRD patients and their families.

Before the enactment of the ACA—when health insurers could routinely deny or limit coverage for people with expensive-to-treat diseases like HIV/AIDS, cancer, or ESRD—people with pre-existing conditions could generally only access private insurance if they had coverage under employer- or union-sponsored plans. Individuals with ESRD who were fortunate enough to have such group health coverage could choose to enroll in Medicare, either in addition to or instead of their EGHP. In cases where an individual with ESRD is covered by both Medicare and an EGHP plan, federal law provides for a 30-month coordination-of-benefits period, during which time a patient may maintain the EGHP as the primary payor and Medicare as the secondary payor.[24] This Medicare Secondary Payer enactment, originally passed in 1981, secures for ESRD patients the choice to maintain their EGHP as primary—if, for example, continuity of care or family benefits are determinative priorities—for a substantial period after starting dialysis, even though they are eligible for Medicare. Over the years, Congress extended the maximum period of time that patients can retain their EGHP as primary coverage, setting it at its current 30 month-limit in 1996.

Now, thanks to the guaranteed-issue and other insurance market reforms implemented under the ACA,[25] ESRD patients who do not have access to an EGHP finally can obtain coverage for themselves and their families on the individual market, including subsidized coverage through a QHP offered in an ACA Marketplace. It is important to note that the ACA and its implementing regulations have clearly preserved the ability of ESRD patients to choose individual market coverage over Medicare. CMS, for example, has clarified that "[i]ndividuals with ESRD who do not have either Medicare Part A or Part B are eligible to enroll in individual market coverage"—including in QHPs offered through an ACA Marketplace—"because the Medicare anti-duplication statute does not apply; therefore, individual market guaranteed issue rights apply under the ACA."[26] Further, IRS guidance clarifies that ESRD patients under the age of 65 can qualify for tax credits and cost-sharing subsidies in connection with such QHP coverage.[27] There are many reasons why individual market coverage may be the

---

[24] 42 U.S.C. § 1395y(b)(1)(C).

[25] *See* 45 C.F.R. § 147.104(a) (requiring insurers offering coverage in the individual or group markets to "accept any individual or employer that applies" for coverage).

[26] *See* CMS Frequently Asked Questions Regarding Medicare and the Marketplace (Aug. 1, 2014), https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf. Similarly, people who are Medicaid-eligible are permitted to enroll in the exchange. They may or may not be eligible for subsidies depending on their individual circumstances, but they can buy full-priced plans. AKF's assistance allows Medicaid-eligible ESRD patients to afford a Marketplace plan if such a plan is better for them than Medicaid.

[27] *See* IRS Notice 2013-41, https://www.irs.gov/pub/irs-drop/n-13-41.pdf (stating that, for purposes of the premium tax credit, an individual whose Medicare eligibility is "based solely on a finding of disability or illness"—such as ESRD patients under the age of 65—is "eligible for minimum essential coverage under Medicaid or Medicare . . . only upon a favorable determination of eligibility"); *see also* Medicare.gov, Signing up for Medicare: special conditions, https://www.medicare.gov/sign-up-change-plans/get-parts-a-and-b/special-

preferred option for some individuals with ESRD—not unlike patients choosing to keep their EGHP coverage as primary—as detailed in Part II.B below. These policies advanced by the ACA and CMS clearly promote and protect equal access to individual market coverage for ESRD patients, if that is the best option for them.

Across this entire patchwork of insurance coverage options that a patient with ESRD may have over the course of his or her treatment, HIPP is the means by which ESRD patients can maintain the dignity of choosing the best health insurance option for their circumstances. With HIPP, choice in coverage under the law is not available only in the abstract—it is a reality for ESRD patients irrespective of their income. Without HIPP, only the nation's relatively wealthy ESRD patients would have access to the array of insurance options beyond Medicare and Medicaid.

B. Kidney Patients' Coverage and Care Options in Practice

In practice, one important option available to individuals with ESRD is coverage under an individual market plan if it best suits the patient's circumstances. Indeed, the ACA's express provisions barring discrimination based on preexisting conditions or disability (and ESRD is a disability under federal law) guarantee, in the very law providing for coverage through the Marketplaces, equal rights to such coverage for people living with ESRD.[28]

AKF shares the RFI's concerns about providers allegedly inappropriately "steer[ing] people eligible for or receiving Medicare and/or Medicaid benefits to individual market plans *for a provider's financial gain*."[29] AKF takes very seriously allegations of inappropriate steering or any other misconduct by health care providers, and it has longstanding institutional and operational safeguards and practices to prevent and combat improper use of HIPP—safeguards and practices that AKF is working to strengthen further today. *See* Parts I & III. But efforts to address alleged instances of abuse should not trump patients' rights to choose the best coverage for them, including if that plan is an individual market plan. Individual market coverage (including Marketplace coverage) may be preferable to Medicare or Medicaid for certain kidney patients, for any number of reasons—including some of the same reasons people choose to retain their COBRA or EGHP coverage as the primary payer throughout the 30-month coordination-of-benefits period, as discussed above. For example,

---

conditions/special-conditions.html#collapse-5277 (last visited Sep. 20, 2016) ("People with ESRD aren't required to sign up for Medicare. If you have ESRD and don't have either Medicare Part A or Part B, you can get a Marketplace plan. ***You may also be eligible for tax credits and reduced cost-sharing through the Marketplace***.") (emphasis added).

[28] 45 C.F.R. § 147.104 (requiring insurers offering coverage in the individual or group markets to "accept any individual or employer that applies" for coverage, and prohibiting such insurers from employing marketing practices or benefit designs that "will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage" or that otherwise discriminate based on an individual's "present or predicted disability" or other protected grounds including "expected length of life, degree of medical dependency, quality of life, or other health conditions"); *see* Part IV, *infra*.

[29] RFI at 9 (emphasis added).

individuals with ESRD may wish to have the same coverage—with the same network of physicians and other providers, and the same cost-sharing requirements—for all members of their family, including a spouse or child who does not qualify for Medicare or Medicaid. Taking one example, an individual with ESRD may find that her child's pediatrician's practice group is not enrolled in Medicare or is not taking new Medicare patients but is in-network for a QHP in the area. Choosing Medicare for such patient would foreclose her ability to choose one group provider for her and her child. While it would be wrong for a self-interested provider to "steer" such a person away from Medicare for the provider's own financial gain, it would be equally wrong for an insurer or regulator to "steer" the person away from a QHP for which they are otherwise eligible by denying their right to receive HIPP assistance to help pay their QHP premium.

Individuals may also be motivated by differences with respect to plan benefits, provider access, and/or quality of care. For example, individual market plans typically offer better integration of medical, prescription, and dental coverage compared to what is offered through Medicare alone, or through Medicare with Medigap wrap-around coverage. Additionally, compared with Medicaid plans in most states, individual market plans often offer greater access to providers,[30] especially specialists.[31] Lack of access is a problem that impacts all Medicaid recipients, but is particularly challenging for patients with ESRD. An ESRD patient has to find not just a dialysis center that accepts Medicaid, but also a cadre of other providers such as cardiologists, endocrinologists, and pulmonologists. ESRD patients may not be able to find geographically proximate specialists in the Medicaid network, or if they can, they must

[30] Studies show that less than half of Medicaid-enrolled physicians accept new patients. See KAISER FAMILY FOUNDATION & COMMONWEALTH FUND, Experiences and Attitudes of Primary Care Providers Under the First Year of ACA Coverage Expansion: Findings from the Kaiser Family Foundation/Commonwealth Fund 2015 National Survey of Primary Care Providers (2015), http://www.commonwealthfund.org/publications/issue-briefs/2015/jun/primary-care-providers-first-year-aca (noting that "[c]omparisons of the current survey with a similar study conducted in 2012 find that the reported rate of new patient acceptance among primary care physicians has declined slightly (89% to 83%), but [that] the share accepting new Medicaid patients remains about the same at 50 percent"). Even if a greater proportion of Medicaid-enrolled providers began accepting new Medicaid patients, the overall number of Medicaid-enrolled providers is limited in many states. In Florida, for example, there is a severe shortage of primary care physicians taking Medicaid patients. AKF knows of a patient in that state who went without a primary care physician for six years while on Medicaid, and after securing QHP coverage, was able to see a primary care physician within one week.

[31] Kevin D. Dayaratna, Ph.D., *Studies Show: Medicaid Patients Have Worse Access and Outcomes than the Privately Insured*, http://www.heritage.org/research/reports/2012/11/studies-show-medicaid-patients-have-worse-access-and-outcomes-than-the-privately-insured (noting that "academic literature has consistently illustrated that Medicaid patients—adults and children—have inferior access to health care," and observing that "it is becoming increasingly difficult for Medicaid patients to find access to primary and specialty care physicians"). Many states also prohibit out of state coverage for Medicaid recipients, which can cause isolation and temporary lack of coverage when a patient must travel to family or needs to move closer to caregiving family members.

wait extended periods of time to get an appointment; for dialysis patients, this lost time can have a significant impact on their health.[32]

Individual market plans may also offer better prescription drug benefits than either Medicare or Medicaid. Most Medicare drug plans, for example, have a coverage gap (also called the "donut hole"). In 2016, beneficiaries are responsible for paying 45 percent of the plan's cost for covered brand name prescription drugs and 58 percent of the cost for generic drugs while the beneficiary is in the coverage gap.[33] For ESRD patients who take multiple medications, an ACA plan may offer better drug coverage at lower cost. Similarly, many state Medicaid programs have limited formularies or caps on the number of prescriptions that can be filled per month,[34] which can lead to patient non-adherence and additional costs on the health care system. Limited prescription benefits under Medicare and Medicaid can even force some patients to make the impossible decision of choosing between their medications and groceries. Dialysis patients often need numerous prescriptions to manage their various conditions. AKF has seen patients with more than 20 prescriptions who are able to get only 10 filled at any one time, due to prescription drug caps under their state Medicaid program. These patients must then ration prescriptions and determine which ones they will fill. After moving to a Marketplace plan, these patients are able to fill all prescriptions and maintain better outcomes.

In addition, individual market plans may provide coverage that Medicare or Medicaid plans do not offer, may have lower coinsurance obligations, and may have features to better assist ESRD patients with the full range of their health care needs, including preparing for and obtaining a kidney transplant. QHPs often offer wellness programs, preventive care, health coaching, and other services not provided by traditional Medicare or Medicaid programs.

And notably, evidence indicates that ESRD patients with commercial coverage have better health outcomes, including higher transplant rates, fewer infections, and lower hospitalization rates.[35] For instance, research has shown that access to transplants is almost three times

---

[32] The access problem is particularly acute in rural areas; AKF has heard of ESRD patients in such areas who do not have access to a vascular surgeon to place a fistula, for example.

[33] *See* Medicare.gov, Costs in the coverage gap, https://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html.

[34] *See, e.g.*, National Health Law Program, Factsheet: Prescription Drug Coverage Under Medicaid, http://www.healthlaw.org/publications/factsheet-prescription-drug-coverage-under-medicaid (last visited Sept. 8, 2016).

[35] Research has shown that patients with commercial insurance have fewer hospitalizations and lower mortality rates than patients with Medicare fee for service insurance. *See* Jesse D. Schold et al., *Barriers to Evaluation and Wait Listing for Kidney Transplantation*, 6 CLINICAL J. AMER. SOCIETY OF NEPHROLOGY 1760 (2011), http://cjasn.asnjournals.org/content/6/7/1760.full (finding that "[o]lder age, lower median income, and ***noncommercial insurance*** were associated with decreased likelihood to ascend steps to receive a transplant") (emphasis added) (emphasis added); Tracy Sanders, OPTUM, MANAGING END-STAGE RENAL DISEASE: IMPROVING CLINICAL OUTCOMES AND REDUCING THE COST OF CARE FOR MEDICARE ADVANTAGE, MEDICAID AND COMMERCIAL POPULATIONS 5, https://www.optum.com/content/dam/optum/resources/whitePapers/managing-end-stage-renal-disease-wp.pdf (noting that "Medicare populations typically present higher risks than commercial plan memberships due

higher under commercial coverage than with Medicare, and 14 times higher for African Americans.[36]

The RFI raises the issue of delayed enrollment penalties for ESRD patients. AKF completely agrees that, before a Medicare-eligible individual with ESRD chooses individual market coverage, it is imperative that they fully understand the regulations surrounding Medicare enrollment and that they follow the correct procedures so that they avoid possible late enrollment penalties and coverage gaps.[37] If an individual determines that enrolling in or maintaining QHP coverage is best for them, even if doing so will result in a late enrollment penalty, that choice should be the individual's.

The issues surrounding choice of insurance coverage are complex for ESRD patients. Because dialysis providers are required by Medicare to employ social workers,[38] they institutionally and logistically are well positioned to help patients understand the complexities of Medicare enrollment, inform patients of the tradeoffs between Medicare/Medicaid and individual market coverage, and to help patients navigate the web of other coverage options referenced above, including Medigap, COBRA, and EGHPs. AKF is eager to work with the providers' social services units and the interested governmental actors and other stakeholders to formulate the clearest and most robust and balanced means of presenting ESRD patients with their coverage options. *See* Part III. At the same time, the potential benefits of an individual market plan over Medicare and Medicaid, as described above, are real and will be significant for certain kidney patients. AKF wants to ensure that any regulatory action does not impede patient choice or unduly influence patients against individual market coverage if that is the best option for them. It is also critical that regulatory action does not set off unintended consequences that more broadly harm ESRD patients' ability to pay for, with AKF's help, other forms of coverage that are best for them. The result would be *no choice* for low-income people living with ESRD.

III. ADDRESSING THE POTENTIAL FOR IMPROPER PATIENT STEERING

As the foregoing backdrop makes clear, empowering patients to maintain the coverage and care that is best for them and their families is central to AKF's mission. Accordingly, the phenomenon of patients being steered away from the coverage that is in their best interests is

---

to their relatively advanced age, increased co-morbidities, changes in cognition and memory, reduced resources (personal and financial), and limitations in transportation access and self-care capabilities").

[36] A.M. Reeves-Daniel, A.C. Farney, et al., *Ethnicity, medical insurance, and living kidney donation*, http://www.ncbi.nlm.nih.gov/pubmed/23781870; U.S. News & World Report, *Black Medicaid Recipients Less Likely to Get Living-Donor Kidney: Study* (June 26, 2013), http://health.usnews.com/health-news/news/articles/2013/06/26/black-medicaid-recipients-less-likely-to-get-living-donor-kidney-study.

[37] RFI at 7-8.

[38] *See, e.g.*, 42 CFR § 494.80 (requiring dialysis facilities to have an "interdisciplinary team consist[ing] of, at a minimum, the patient, . . . a registered nurse, a physician treating the patient for ESRD, *a social worker*, and a dietitian") (emphasis added); 42 CFR § 494.140(d) (requiring dialysis facilities to have a social worker meeting certain educational or training qualifications).

antithetical to AKF's mission, and so the concerns raised in the RFI are AKF's concerns. AKF has always operated its programs to protect patient choice, and we continuously evaluate and refine those programs to ensure that AKF meets evolving changes and challenges to achieving that goal. We detail below AKF's (A) longstanding program safeguards designed to prevent improper influence and misuse and abuse of HIPP, (B) the initiatives AKF has implemented (or will soon implement) to even further ensure the integrity of HIPP and to specifically protect patients' independent and informed decision-making, and (C) AKF's perspective on any specific instances of alleged individual misconduct.

A. AKF's Independent Operation Is a Key Component of Patient Choice

When the '97 Advisory Opinion was issued, it required firewalls that would prevent fraud and abuse, specifically in the form of beneficiary inducements or inappropriate patient "steering."[39] As the historical and regulatory background from Section I emphasizes, HIPP's model of insulating its operations from its donors, to which AKF has strictly adhered for nearly 20 years, remains recognized as the model for all such independent charitable third-party premium assistance programs. From this posture, AKF is well positioned, and has done so over the years, to respond quickly and effectively to any new concerns relating to alleged conduct that could undermine patient choice and exploit HIPP and its beneficiaries. Indeed, if independence is the cornerstone of our compliance model under the '97 Advisory Opinion, patient freedom of choice is the very heart of our mission.

We firmly believe that the answer to new challenges is not to limit third-party premium assistance for low-income people living with ESRD from *bona fide* charitable organizations like AKF, but to work within the structure that has been effective for two decades to make appropriate enhancements tailored to the new health insurance landscape. To that end, we have in the past proposed to CMS and to regulators in various states certain guardrails that we believe make it possible for legitimate charities to continue helping low-income patients pay for insurance, while also protecting against fraud and abuse:

- Bona fide 501(c)(3) charitable organization;
- Independent Board of Directors;
- Notification to or registration with a state agency such as the Department of Insurance;
- Procedures that include an application process, independent determination of financial need by the charity's employees, and geographic diversity;
- Procedures that completely wall off provider donation information from the charity's determinations of patient eligibility for grant assistance;

[39] *See generally* '97 Advisory Opinion, Exhibit 3; *supra* Section I.A.

- Procedures that protect patient choice and prohibit any direction that the patient use only certain insurers or providers, and provide assistance for a full range of insurance products;
- Assistance to cover the entire policy year (not short-term assistance);
- Annual certification of a uniform set of income and asset criteria used to determine eligibility; and
- Compliance with all other applicable federal, state, and local laws and regulations.

Like the safeguards discussed in Section I, these guardrails address charitable organizations' independence from their donor sources—what we believe to be the central tenet of the '97 Advisory Opinion and essential for the mission-focused and transparent operation of HIPP and any charitable organization that funds third-party premium assistance for a particular disease. However, these guardrails are not static, and we remain nimble in our own policies and procedures to ensure they are responsive to the evolving health care landscape, including the concerns now raised by CMS.

We have worked hard to establish measures to ensure that AKF could not influence the type of insurance a patient chooses. However, we also recognize that individuals must have access to complete and balanced information to make their own informed coverage choices, free from undue influence from other market participants. AKF recognizes and shares CMS's goal that patients must be enabled to make informed choices about their health insurance coverage, which, in the case of ESRD patients, includes information sufficient to weigh the pros and cons of each type of insurance against other options, which will involve varying considerations for different patients.

As the administrator of the HIPP program, which supports all forms of coverage, we are uniquely positioned to furnish patients with basic information about health coverage tailored to ESRD patients that is consistent, accurate, and balanced. While a charitable organization's own unique context will dictate the contours of the information provided, we believe that promoting patient choice and deterring inappropriate steering is best achieved by providing patients with accessible information at the appropriate time. We can also provide patients with information on objective, credible organizations and websites that may help in evaluating specific plans.

We have always endeavored to take an active but balanced role between being ESRD patient advocates and also ensuring that patients remain independent and autonomous in their decision-making, especially with respect to choosing health insurance and providers. In an ongoing effort to be responsive to the needs of our patient community as well as respond to CMS's concerns, we outline below the AKF initiatives either underway or soon anticipated that are designed to further strengthen patient choice while mitigating any opportunity for market participants to engage in inappropriate patient steering.

B. AKF's Ongoing Efforts to Promote Informed Patient Choice and to Mitigate Inappropriate Steering

AKF's longstanding mission has been to provide ESRD patients who otherwise would have limited or no choice in their health coverage with access to a full spectrum of coverage options. However, what makes AKF's assistance so valuable is when it is coupled with the knowledge necessary to make the choice that is *best for that individual*. As discussed above, AKF's institutional and operational policies and procedures ensure that AKF does not, through its administration of HIPP, unduly influence patients' decisions in choosing either their coverage or their provider. Today, however, AKF sees an opportunity to further its role as a patient educator and advocate, and it is pursuing several steps to that end. The following are enhanced procedures that we have developed and/or are currently developing in an effort to promote informed patient choice and to mitigate any inappropriate patient steering:

- AKF currently publishes a patient guidebook, which is available to the public on our website as well as at the dialysis centers.[40] It is written in plain language and contains important information about HIPP, including by outlining eligibility, confirming AKF's independence, clarifying that patients are free to choose their own provider and can change providers at any time, and highlighting that HIPP assistance will not continue past the end of the current policy payment period after a patient receives a kidney transplant.[41]
- We are currently adding to the patient guidebook a section entitled "Patients' Rights and Responsibilities," which will inform patients of their rights in selecting insurance that best suits their needs and in applying to HIPP for assistance. It will also list the patient's role and responsibilities in the process of selecting his or her own insurance and in the HIPP application process.
- To ensure that this information reaches any patient who is considering applying for HIPP assistance, we will require providers to furnish the patient with this information prior to the HIPP grant being approved. In the Patient Consent Form, signed by the patient, the patient will also initial that he/she has received these materials and understands the HIPP guideline that it is the patient's choice to select insurance from the available options. We also will be asking each patient's provider to certify to the best of their knowledge that the patient's request for HIPP assistance is accurate and that the selection of the insurance was the patient's.

---

[40] *See* Introduction to the American Kidney Fund, http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp.pdf.

[41] HIPP provides comprehensive coverage that pays for transplant workups for patients on the transplant waiting list, enabling them to stay on and possibly move up the list, and the HIPP-covered insurance pays for the transplant procedure itself. The conclusion of HIPP assistance *after* a transplant is a function of the fact that, after a transplant, kidney patients are usually able to go back to work and retain coverage from an employer. So, like Medicare, AKF winds down after an individual has had a transplant. 42 U.S.C.A. § 426-1(b)(2) (providing that coverage under the Medicare ESRD program "shall end, in the case of an individual who receives a kidney transplant, with the thirty-sixth month after the month in which such individual receives such transplant").

- We are developing a "Provider Code of Conduct," which will set forth standards of conduct, including pro-patient-choice and anti-steering provisions, for all dialysis professionals who refer patients to the HIPP program. We believe that such standards—which will be a required condition for providers' participation in HIPP—should also be provided to patients as a way to increase transparency and accountability by advising patients of the standards they should expect from providers.

AKF believes that these initiatives, on top of its current model designed to ensure independent operation of HIPP, will further promote complete and balanced patient choice of coverage and enhance existing measures to prevent any discrete instances of improper patient steering. At the same time, these expanded efforts on the part of AKF will help to ensure that patients will be provided information and education that they need to make informed choices. Furthermore, AKF remains willing to work with CMS and other market participants to implement other appropriate procedures to the end of supporting informed patient choice. AKF has formally requested a meeting with CMS to further explain its specific initiatives and to discuss any input that CMS may have.

C. AKF is Committed to Addressing Specific Instances of Potential Misconduct

AKF's charitable mission is to help low-income people living with ESRD. We operate programs in pursuit of this mission with the utmost efficiency and focus on stewardship over our resources. In fact, 97 cents of every dollar received go to fund those programs and services. We take any allegation of abuse of our limited resources extremely seriously.

We welcome the opportunity to address specific allegations of past or present abuse, although we think it is important to note several considerations in this context. First, while some insurers have suggested misuse of HIPP by certain dialysis providers, we have not received from any insurer a single specific complaint, information regarding, or example of such misuse that would support action on our part. The litigation surrounding supposed misuse pending in Florida provides a good example. AKF was provided no specific details or evidence of the purported misconduct alleged in the Florida complaint, and the most specific allegations central to the complaint's alleged scheme of patient steering are made "upon information and belief"—meaning that they are made with no evidence or first-hand information.[42] Obviously, if there are specific instances of misconduct involving a provider's interaction with the HIPP program—*e.g.*, if the Florida plaintiffs made the effort to provide AKF with actionable information of such misconduct—we would act on any proof that our funds or mission had been subverted. We want to be clear: AKF strongly rejects any claim or

[42] *E.g.*, *UnitedHealthcare of Florida, Inc., et al. v. American Renal Assocs. Holdings, Inc., et al.*, No. 16-cv-81180, First Amended Compl. (S.D. Fla.) ¶ 88 ("Upon information and belief, many patients were insured by the Medicaid program before ARA counseled them to enroll into United's plans, as described herein.").

implication that it has been somehow complicit, never mind an active participant, in illegal or unethical activity.[43]

The Florida case also raises some noteworthy considerations. The litigation demonstrates that, in the first instance, the most appropriate avenue for insurers to investigate and address purported instances of fraud and abuse by providers or policy-holders is by employing existing laws addressing specific alleged improper behavior within their relationships with the provider at issue. The '97 Advisory Opinion did not place any law enforcement duties on AKF to ensure that insurers and/or providers are not attempting to "game the system." Whether before the ACA or after, the insurers, providers, HHS, and law enforcement are best positioned and equipped to uncover, investigate, and ameliorate fraud and other misconduct. This is in contrast to an approach that would cut off one or more coverage options for an entire class of low-income and disabled HIPP beneficiaries in order to preemptively curtail an unknown number of alleged specific instances of alleged misconduct. Nonetheless, as noted, AKF is, at counsel's direction, conducting an independent, privileged investigation and review of the Florida allegations to ensure that AKF's mission has not been distorted by insurer or provider misconduct and to take appropriate steps if any improper conduct emerges.

More broadly, as outlined above, AKF is implementing procedures to increase accountability and transparency on the part of providers, and it fully intends to work with any market actor or governmental body to address known instances of fraud or abuse in relation to HIPP. To the extent any patient or other person communicates and provides documentation of a specific instance of steering or any other potentially inappropriate conduct by an insurer, a provider, or one of their employees or agents, we will document the communication and will directly refer the matter to the relevant entity's compliance department in writing and provide all of the relevant information we have. We will maintain a record of all such communications. To the extent we become aware of any improper conduct, such as lack of

---

[43] Health insurers, including the plaintiff in the Florida case, recently have attempted to imply by innuendo some impropriety simply in AKF's appeals for grant funding, pointing to, for example, AKF's HIPP Honor System, through which providers are asked to make "equitable" financial contributions to AKF and to contribute their "fair share." Of course AKF asks providers to make equitable contributions to HIPP—that is the *sine qua non* of the '97 Advisory Opinion. The '97 Advisory Opinion's allowance for provider donations necessarily entails AKF's requesting those donations, in order to continue its mission. The HIPP Guidelines, Rules and Procedures, recently misconstrued by insurance companies, underscore how, in accord with the '97 Advisory Opinion, (1) there is never any guarantee that patients of donor-providers will receive grant funding at all, (2) whether and how much providers donate is entirely voluntary, and (3) that AKF's only method to encourage equitable contributions is a moral one, *i.e.,* no patient will be considered differently based on whether the referring provider does or does not contribute. Further, about forty percent of the providers whose patients AKF assists *make no contribution at all to the HIPP funding pool*, and AKF has never turned away a needy patient on the basis of their being treated by a non-contributing provider, demonstrating the fact that charitable contributions are in no way tied to AKF's patient grants. AKF's motivation in requesting voluntary contributions is purely mission-focused: putting patients first and ensuring there are resources in the HIPP pool to support the 79,000 patients in the HIPP program. Nonetheless, we are redoubling our ongoing scrutiny of our charitable fundraising communications to ensure that they could not be misconstrued to suggest that our grants in any way tie to particular providers' contributions.

informed consent, undue influence, fraudulent documentation, or other behavior that undercuts patient choice, we will take action to redress the situation for the patient in each particular instance, and work with the responsible entities to halt the misconduct immediately.

We already correspond with our patients on a quarterly basis through a patient newsletter to ensure that we are available and in close contact for any patient questions or concerns. Going forward, we will place further emphasis on encouraging our patients to communicate to us any behavior in relation to HIPP that they perceive as inappropriate, whether by providers, insurers, or otherwise.

IV. INSURERS ARE UNDERMINING CHOICE OF COVERAGE FOR ESRD PATIENTS IN VIOLATION OF STATE AND FEDERAL ANTI-DISCRIMINATION LAWS

Whereas alleged incidents of patient steering away from public coverage appear to be isolated at the most, health insurance companies across the country have commenced an overt and forceful campaign to steer low-income ESRD patients off or away from their commercial plans—notwithstanding that such plans may be best for patients—by refusing or attempting to refuse patients' premium payments provided by AKF. In addition to impeding patient choice and freezing out countless low-income individuals from their coverage, this conduct implicates violations of federal and state law prohibiting discrimination on the basis of disability.

AKF's HIPP program plays a critical role in ensuring that ESRD patients can benefit from the full range of insurance options to which they are entitled under the law. Without HIPP, the choice of coverage options described above is an illusory one for far too many low-income ESRD patients who could not otherwise afford their premium payments or cost-sharing obligations, whether under Medicare, Medigap, COBRA, group coverage, or individual market plans. As noted in the '97 Advisory Opinion, the assistance provided by AKF "enhanc[es] patient freedom of choice in health care providers."[44]

Individual ACA market coverage comprises a very small fraction of the assistance provided through HIPP—indeed, only 6,400 HIPP grant recipients, representing approximately 8 percent of our total HIPP grant recipients, and a tiny fraction (.05 percent) of the total 12.7 million individual market coverage enrollees, receive HIPP assistance to pay for individual market coverage.[45] Nonetheless, supporting *all* applicable forms of coverage is an important part of AKF's mission to enhance patient freedom of choice. Notably, one of the goals of the ACA was to open doors to such coverage for millions of Americans with life-threatening and expensive-to-treat conditions like ESRD. Indeed, the ACA acts expressly to guarantee dialysis

[44] '97 Advisory Opinion, Exhibit 3, at 5.

[45] *See* HHS.Gov, "Fact Sheet: About 12.7 million people nationwide are signed up for coverage during Open Enrollment" (Feb. 4, 2016), http://www.hhs.gov/about/news/2016/02/04/fact-sheet-about-127-million-people-nationwide-are-signed-coverage-during-open-enrollment.html.

patients the right to choose their health plan and—according to the plain text of the ACA—not to be subject to discriminatory practices.

Unfortunately, some insurers have taken steps to deny premium assistance payments made by AKF for individual market coverage, undermining the choice of coverage for thousands of ESRD patients receiving HIPP assistance in certain states.

Insurance companies in some states are advising policyholders that they will be refusing premium assistance from any source other than the policyholder or other insurer-approved source, such as a family member or entity whose premium assistance federal regulation requires that insurers accept (*e.g.*, the Ryan White Program, Indian tribes and related organizations, and other government programs).[46] Insurers are setting policies that give themselves complete discretion to refuse premium assistance from charitable organizations that the insurer deems to be "[f]inancially interested"—if, for example, the organization receives a majority of its funding from entities with an interest in health insurance reimbursements.[47]

Such policies are transparently directed at charities focused on helping patients with specific disabilities and other conditions to pay for their coverage, and they blatantly violate basic principles of fairness in insurance contracting. Prior to the ACA, insurance companies for years were happy to accept third-party premium assistance payments, since the insurers could simply charge patients with ESRD and other disabilities higher premiums based on their conditions. After reaping those benefits for years, now that insurers can no longer discriminate in this way, they seek complete discretion to turn those same patients away *en masse*. Apart from the basic unfairness of this practice, its real world impact would be devastating not only for the 6,400 AKF beneficiaries with individual market coverage, but innumerable others as well. Depending on how insurance companies determine whether a charity is "financially interested"—a question on which the insurers make themselves the sole arbiter—untold numbers of low-income people with numerous disabilities and conditions could be summarily frozen out of their coverage. These include beneficiaries of the myriad charitable foundations that raise funds from industry donors whose missions also include premium and other cost-sharing assistance for low-income patients with particular conditions, such as the CancerCare Co-Payment Assistance Foundation, Leukemia and Lymphoma Society Co-Pay Assistance Program, National Multiple Sclerosis Society, A.L.S. Association, and American Transplant Foundation, among many others.[48] And specifically as

---

[46] *See, e.g.*, Letter from Blue Shield of California re: Notification of November 7, 2016 Updates to the Blue Shield Hospital and Facility Guidelines, Aug. 29, 2016, at 2, Exhibit 4.

[47] *Id.*

[48] Other potentially affected patients include beneficiaries of HealthWell Foundation; Patient Advocate Foundation Co-Pay Relief Program; The Assistance Fund; Patient Access Network Foundation; Patient Services, Inc.; National Organization for Rare Disorders; and Chronic Disease Fund. These nonprofit foundations also raise funds from the health care industry to provide financial assistance to patients suffering from countless serious health issues, including cancer; cardiovascular disease; endocrine conditions; immunodeficiency conditions;

to AKF, such a policy completely ignores the fact that HIPP operates with the help of provider funding with written approval from the OIG, which expressly concluded that HIPP's design insulates AKF from precisely the supposed conflicts on which these insurers purport to base their policies.

Relatedly, as health insurance companies have begun refusing third-party payments from reputable charities like AKF, we have had to change the method by which we provide charitable grant assistance. In instances where an insurance carrier will not accept a grant assistance check from AKF, we send the patient a charitable grant that will allow the patient to pay their insurance bill. As described above, the patients we serve often have challenges cashing their grant assistance check, as many do not have bank accounts. The patients often lose a portion of their grant in check cashing and money order fees, and thus jeopardize their ability to pay their premium. Some do not have reliable transportation to get to a bank or even to get to the post office to ensure that their payment is timely made. We believe that insurance carriers have adopted these third-party payment prohibitions in the hope that some patients will not be able to pay their premiums on time, giving the carrier justification to terminate coverage for non-payment. This is a form of adverse selection.

We also are very concerned about the question in the RFI that states: "Are issuers capable of determining when third party payments are made directly to a beneficiary and then transferred to the issuer?" Insurance carriers have implied that direct charitable assistance to nonprofits' constituents is somehow improper. At least one major carrier, United Healthcare, adopted an extremely restrictive policy for 2016, promising to terminate the QHP coverage of any member who receives direct charitable assistance from entities not mandated as third-party payors by the federal government. This carrier and its subsidiaries have sent letters to policyholders requiring them to sign attestations, under penalty of perjury, that they are not receiving charitable assistance to help them pay their premiums, and advising that their policy will be cancelled if they accept such assistance. Filings for 2017 Marketplace plans signal the expansion of this practice. Cigna, Healthnet, and subsidiaries of UnitedHealthcare are seeking to prohibit people from using direct charitable assistance to pay their insurance premiums. We believe it is a fundamental right of every American to receive charitable assistance and to use that assistance for important needs, including health coverage. In asking about sources of funding in the RFI, it is our hope that the federal government is not adopting a position antithetical to our nation's fundamental principles of free speech and freedom of association. The government must not permit health insurance carriers to dictate to Americans what they may and may not do with charitable assistance that they have received from recognized 501(c)(3) charities.

Wholly apart from the policy concerns articulated above with respect to fairness, freedom of choice, and the impact on ESRD patients and other recipients of charitable aid, such actions by

---

digestive and urinary conditions; bleeding disorders; infectious conditions; nervous system conditions; respiratory conditions; and others.

insurers raise serious legal concerns under anti-discrimination law. At the federal level, the ACA requires all insurers offering coverage in the individual or group markets to "accept any individual or employer that applies" for coverage, and it prohibits such insurers from employing marketing practices or benefit designs that "will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage" or that otherwise discriminate based on an individual's "present or predicted disability" or other protected grounds, including "expected length of life, degree of medical dependency, quality of life, or other health conditions."[49] Insurers offering plans through ACA Marketplaces are, by virtue of receiving federal funds (including via the tax credits and subsidies provided for under the ACA), subject to even broader non-discrimination requirements.[50] Individuals applying for or receiving coverage from such insurers must not, "on the basis of race, color, national origin, sex, age, *or* ***disability***, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination" in the "provision or administration of . . . health-related insurance coverage."[51]

An insurance company may not use a seemingly neutral classification—such as receipt of premium assistance payments by third parties—as a proxy to evade prohibitions on intentional discrimination.[52] Even if intentional discrimination could not be established in a particular case, the ACA forbids conduct that has an unjustifiable disparate impact on individuals in protected classes, regardless of the violating party's intent.[53] A *prima facie* case of disparate impact is established when a party can show that a facially neutral practice "operated more harshly on one group than another."[54]

It is significant in this context that ESRD has been recognized as a disability under federal law[55] and therefore constitutes one of the protected grounds under the ACA nondiscrimination provision.[56] Given the demographics of HIPP recipients, the refusal by an

---

[49] 45 C.F.R. § 147.104.

[50] *See* 42 U.S.C. § 18116(a); 45 C.F.R. § 92.101.

[51] 45 C.F.R. § 92.101*;* 45 C.F.R. § 92.4 (emphasis added). Notably, the anti-discrimination provisions apply to "all operations" of insurers offering coverage through an insurance exchange, and not just to an insurer's exchange line of business. *See* 45 C.F.R. § 92.4.

[52] *Cf., e.g., McWright v. Alexander*, 982 F.2d 222, 228 (7th Cir.1992) ("[A]n employer cannot be permitted to use a technically neutral classification as a proxy to evade the prohibition of intentional discrimination. An example is using gray hair as a proxy for age: there are young people with gray hair (a few), but the 'fit' between age and gray hair is sufficiently close that they would form the same basis for invidious classification.").

[53] *See, e.g.*, *Alexander v. Choate*, 469 U.S. 287, 299 (1985); *see also Kelly v. Boeing Petroleum Servs. Inc.*, 61 F.3d 350, 365 (5th Cir. 1995) (recognizing disparate impact as a valid basis for a claim under § 504 of the Rehabilitation Act of 1973, and thus under Section 1557 of the ACA, which provides that "the enforcement mechanisms provided for and available under . . . section 504. . . shall apply for purposes of violations of this subsection").

[54] *See Chance v. Rice Univ.*, 989 F.2d 179, 180 (5th Cir. 1993) (internal quotation marks omitted).

[55] *See Fiscus*, *supra* note 3, 385 F.3d at 382.

[56] *See* 45 C.F.R. § 92.4 (defining "disability" to mean "a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having

insurer to accept premium assistance payments from HIPP may also have an illegal disparate impact (*i.e.,* "operate more harshly") with regard to race and national origin.

For example, African Americans are more at risk for kidney failure than any other race.[57] More than one in three kidney failure patients living in the United States is African American.[58] Diabetes is the leading cause of kidney failure, causing nearly 40 percent of all cases of kidney failure in the United States.[59] African Americans get diabetes more often: they are almost twice as likely as whites to have diabetes.[60] About one in eight (13.2 percent) African American adults has diabetes.[61] High blood pressure is the second leading cause of kidney failure.[62] It causes about one out of four cases in the United States.[63] Like diabetes, high blood pressure is a serious problem for African Americans: almost half (over 42 percent) of African American adults have high blood pressure,[64] and African Americans are, on average, nearly six times more likely to get kidney failure from their high blood pressure than whites.[65] The statistics for Hispanics are similar, with Hispanics almost twice as likely as whites to have been diagnosed with diabetes.[66] Diabetes also leads to kidney failure more often in Hispanics than in non-Hispanic whites.[67]

Unfortunately, insurer discrimination against low-income, disabled people is nothing new. From the time the ACA first prohibited health insurers from denying coverage or charging more by discriminating against people with preexisting conditions,[68] certain health insurers have attempted to exclude from coverage groups with a specific condition or disability by virtue of the fact that such groups receive third-party premium or cost-sharing assistance from a charitable program focused on that disability. In 2014 for example, as noted above, the three health insurers in Louisiana's ACA Marketplace, including Blue Cross and Blue Shield of

---

such an impairment, as defined and construed in the Rehabilitation Act [] which incorporates the definition of disability in the ADA") (citations omitted).

[57] United States Renal Data System ("USRDS"), 2015 Annual Data Report: Epidemiology of Kidney Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, https://www.usrds.org/adr.aspx.

[58] Race, Ethnicity, and Kidney Disease (Mar. 5, 2014), https://www.niddk.nih.gov/health-information/health-communication-programs/nkdep/learn/causes-kidney-disease/at-risk/race-ethinicity/Pages/race-ethnicity.aspx (last visited Sep. 20, 2016).

[59] USRDS 2015 Annual Data Report, *supra* note 57.

[60] Treatment and Care for African Americans (Oct. 1, 2014), http://www.diabetes.org/living-with-diabetes/treatment-and-care/high-risk-populations/treatment-african-americans.html (last visited Sep. 20, 2016).

[61] *Id*.

[62] USRDS 2015 Annual Data Report, *supra* note 57.

[63] *Id*.

[64] High Blood Pressure Facts, (Feb. 19, 2015), http://www.cdc.gov/bloodpressure/facts.htm (last visited Sep. 20, 2015).

[65] USRDS 2015 Annual Data Report, *supra* note 57.

[66] *Id*.

[67] *Id*.

[68] *See* 42 U.S.C. §§ 300gg, 300gg–1, 300gg–3.

Louisiana ("BCBSL"), announced that they would refuse to accept most premium assistance, including from the federal Ryan White Program enacted to help low-income people living with HIV. BCBSL and the other insurers cited purported concerns about fraud and abuse, tied to third-party payments, affecting the insurance markets as grounds for refusing Ryan White premium assistance.[69] In response to a class action lawsuit filed on behalf of Ryan White Program recipients, brought under the anti-discrimination provisions of the ACA and state contract and insurance law, a federal court restrained the insurers from implementing their plan.[70] Shortly thereafter, HHS published an interim final rule *requiring* insurers to accept such third-party payments, adopted at 45 C.F.R. § 156.1250.[71] The vague complaints raised by insurers regarding HIPP reflect the same attempt to leverage generic policy concerns over fraud and abuse as a pretext to exclude an expensive-to-cover class of people with a disability—in this case, ESRD—from its insurance rolls.

Such systematic and discriminatory patient steering cannot stand, and CMS should act to protect people living with ESRD from such discrimination, just as it did to protect people living with HIV.

V. CONCLUSION

In sum, AKF takes the potential for improper use of HIPP, including improper patient steering, very seriously. We are committed to investigating and addressing allegations of improper conduct by providers and insurers, because such conduct tarnishes our well-earned reputation for excellence and transparency, undermines our charitable mission, and, most importantly, affects the patients we are committed to serving with the highest level of support. To further its continuing efforts toward these goals, AKF is:

- Maintaining its commitment to strict adherence to the '97 Advisory Opinion and the OIG's subsequent policy guidance affirming HIPP's operational design;
- Enhancing policies and procedures designed to ensure that patients receive clear and balanced information regarding their coverage options and that the choice of selecting coverage is theirs;
- Adopting a code of conduct for providers and professionals designed to preclude steering and other abuses, which will be furnished to patients for added accountability, and making providers' participation in HIPP strictly conditioned on adherence to the code of conduct's anti-steering and other provisions;
- As it relates to our HIPP program, we will consistently document patient and other complaints or concerns about steering or other abuses by both providers and insurers,

---

[69] *See, e.g.*, Ted Griggs, *Insurers Block Obamacare Coverage . . . Move Affects Poor HIV/AIDS Patients*, THE ADVOCATE, Feb. 13, 2014, at B8, Exhibit 5.
[70] *East,* 2014 WL 8332136, *supra* note 4, Exhibit 1; *see also* Complaint, *East, supra* note 4, Exhibit 2.
[71] *See* 79 Fed. Reg. 15240 (Mar. 19, 2014).

and we will formally communicate, in writing, any such complaints or concerns to the relevant entity's compliance department;

- Committing to address demonstrated, actionable allegations of misconduct and cooperating with the responsible party to investigate and eliminate any improper use of HIPP;
- Committing to work with CMS, beginning with our request for a near-term, formal meeting, to discuss these initiatives and any other areas in which AKF can assist CMS in promoting patient choice and in combatting improper steering and discrimination; and
- Continuing to notify CMS when AKF becomes aware of insurance carrier actions that are improperly steering patients away from a particular carrier and/or onto Medicare or Medicaid.

AKF fully supports the desire to have a robust commercial health insurance market. In keeping with the imperative of patient choice central to AKF's mission and the ACA's policy, this market must be one in which all eligible Americans, including Americans with disabilities, are welcome.

Thank you very much for your attention to this matter, and we very much look forward to a continuing dialogue in the days and weeks ahead.

Very truly yours,

LaVarne A. Burton
President & Chief Executive Officer
American Kidney Fund

Attachments

Exhibits to the American Kidney Fund's Response to
CMS Request for Information No. CMS-6074-NC

Table of Contents	
Tab	Document Description
1	*East v. Blue Cross and Blue Shield of Louisiana, et al.,* Temporary Restraining Order
2	*East v. Blue Cross and Blue Shield of Louisiana, et al.,* Complaint
3	97-1 OIG Advisory Opinion
4	Letter from Blue Shield of California re: Notification of November 7, 2016 Updates to the Blue Shield Hospital and Facility Guidelines, Aug. 29, 2016
5	Ted Griggs, *Insurers Block Obamacare Coverage . . . Move Affects Poor HIV/AIDS Patients* , The Advocate, Feb. 13, 2014

EXHIBIT 1

2014 WL 8332136
Only the Westlaw citation is currently available.
United States District Court,
M.D. Louisiana.

John EAST, et. al.
v.
BLUE CROSS AND BLUE SHIELD OF LOUISIANA, et. al.

Civil Action No. 3:14–cv–00115–BAJ–RLB.
|
Signed Feb. 24, 2014.

Attorneys and Law Firms

Harry A. Rosenberg, Bryan Edward Bowdler, Phelps Dunbar, New Orleans, LA, Amanda R. Phillips, Ropes & Gray LLP, Boston, MA, Anthony C. Biagioli, Ropes & Gray LLP, Washington, DC, Jeffrey J. Bushofsky, Nicholas M. Berg, Timothy R. Farrell, Ropes & Gray LLP, Chicago, IL, Kenneth D. Upton, Lambda Legal Defense & Education Fund, Inc., Dallas, TX, Scott A. Schoettes, Lambda Legal Defense & Education Fund, Inc., Chicago, IL, Susan L. Sommer, Lambda Legal Defense & Education Fund, Inc., New York, NY, for John East, et. al.

Charles A. O'Brien, III, Allison Nunley Pham, Baton Rouge, LA, Adam P. Feinberg, Anthony F. Shelley, Miller And Chevalier Chartered, Washington, DC, Brandon Kelly Black, Jones, Walker, Baton Rouge, LA, Richard John Tyler, Jones Walker LLP, New Orleans, LA, for Blue Cross and Blue Shield of Louisiana, et. al.

TEMPORARY RESTRAINING ORDER

BRIAN A. JACKSON, Chief Judge.

***1** Before the Court is putative class representative John East's ("East") **APPLICATION FOR A TEMPORARY RESTRAINING ORDER (Doc. 7) ("Application"),** requesting that the Court enjoin Defendants Blue Cross and Blue Shield of Louisiana ("Blue Cross"), Vantage Health Plan, Inc. ("Vantage"), and Louisiana Health Cooperative, Inc. ("Louisiana Health)" from changing their existing policies as they relate to Ryan White HIV/AIDS Program funds ("Ryan White Funds"), and/or implementing new policies related to Ryan White Funds, *(id.* at p. 4). East's Application is filed in accordance with Fed.R.Civ.P. ("Rule") 65 and this Court's Local Rules, *see* M.D. La. LR65. Defendants Blue Cross and Vantage each oppose East's Application. (Doc. 8; Doc. 17). Defendant Louisiana Health has not filed a notice of appearance, nor given any indication as to its position regarding East's Application.

For reasons explained below, the Court **GRANTS** East's Application as to all Defendants. In accordance with Rule 65, this Temporary Restraining Order shall be effective as of **6:00 p.m., Monday, February 24, 2014** and shall expire 14 days after the time of entry, unless otherwise ordered by this Court. *See* Fed.R.Civ.P. 65(b)(2)-(3). A hearing to determine whether a preliminary injunction shall supplant and/or follow this Order shall proceed at **12:00 p.m., Tuesday, February 25, 2014.**

Rule 65 provides, in relevant part:

> The court may issue a temporary restraining order without written or oral notice to the adverse party or its attorney only if:
>
> (A) specific facts in an affidavit or a verified complaint clearly show that immediate and irreparable injury, loss, or damage **will** result to the movant before the adverse party can be heard in opposition; and
>
> (B) the movant's attorney certifies in writing any efforts made to give notice and the reasons why it should not be required.

Fed.R.Civ.P. 65(b)(1). Additionally,

> Every temporary restraining order issued without notice must state the date and hour it was issued; describe the injury and state why it is irreparable; state why the order was issued without notice; and be promptly filed in the clerk's office and entered in the record.

Id. at 65(b)(2). Further, "[i]f the order is issued without notice, the motion for a preliminary injunction must be set for hearing at the earliest possible time, taking precedence over all other matters except hearings on older matters of the same character ." *Id.* at 65(b)(3). Finally, "[t]he court may issue ... a temporary restraining order only if

the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." *Id.* at 65(c).

Here, the Court is satisfied that East has met the requirements for the temporary relief he seeks. First, East has scrupulously adhered to Rule 65's procedural requirements. His Application is accompanied by an affidavit describing the nature of the "irreparable injury" that will result absent a temporary restraining order ("TRO"), (Doc. 7–2), as well as his attorney's certified description of the efforts that have been made to contact all Defendants in this case, including Defendant Louisiana Health, (Doc. 7–3). *See* Fed.R.Civ.P. 65(b)(1). Further, East's Application adheres to this District's requirements that: (1) the Application "be made in a document separate from the complaint"; and (2) "actual notice of the time of making the application" be included in the Application, (*see* Doc. 7–3 at p. 1). M.D. La. LR65.1.

***2** East has also satisfied Rule 65's substantive requirements. His affidavit (Doc. 7–2) and his Complaint (Doc. 1) each contain "specific facts" indicating that "immediate injury, loss, or damage will result" if a TRO is not issued. In particular, East states: (1) he is "an individual living with HIV," (Doc. 7–2 ¶ 2); he "take[s] two medications [each day] to treat [his] HIV," (*id.* at ¶ 4); his insurance provider, Blue Cross, has heretofore accepted full payment for his insurance premiums from "the Louisiana Health Insurance Program which receives funding from the Ryan White Program," (*id.* at ¶¶ 11–12, 19); East is otherwise unable to pay his monthly insurance premium of $1,306, (*id.* at ¶¶ 19, 24); Blue Cross and the other named Defendants—Vantage and Louisiana Health—recently decided "that they will no longer be accepting Ryan White assistance payments for health insurance premiums," (*id.* at ¶¶ 23, 26); this decision has caused East to miss his most recent payment, which means that he is "now without insurance coverage," (*id.* at ¶ 24); East does not otherwise qualify for health care assistance, (*id.* at ¶¶ 8, 10); and, finally, lacking insurance. East will "run out of ... essential medication," which will, eventually, result in his death, (see *id.* at ¶¶ 6, 30).

It goes without saying that Mr. East's eventual death is an irreparable injury. *See* Fed.R.Civ.P. 65(b)(2) ("Every temporary restraining order issued without notice must ... describe the injury and state why it is irreparable...."). Further, this result is hardly speculative given HIVs pathology, and the known consequences of discontinuity in its treatment. (*See* Doc. 1 at ¶ 56). Given the severe ramifications to Mr. East and other members of his putative class if their insurance coverage is allowed to lapse, the Court is convinced that this Order should be issued, thereby ensuring that the status quo is temporarily maintained, even in the absence of Louisiana Health's notice of appearance, and/or the opportunity for an evidentiary hearing on the issue. *See* Fed.R.Civ.P. 65(b)(2) ("Every temporary restraining order issued without notice must state ... why the order was issued without notice...."). [1]

Accordingly,

IT IS ORDERED that East's **APPLICATION FOR A TEMPORARY RESTRAINING ORDER (Doc. 7)** is **GRANTED.** Specifically,

1. Defendants are enjoined from changing their policies of accepting Ryan White HIV/AIDS Program funds ("Ryan White Funds") from current or prospective applicants to, or policy holders of, Defendants' health insurance plans;

2. Defendants are enjoined from implementing or executing their new policies of refusing Ryan White Funds from current or prospective applicants to, or policy holders of, Defendants' health insurance plans;

3. Given the nature of the issues and the parties involved, it is unnecessary for Plaintiffs to post a bond in this matter; and

***3** 4. This Order expires in 14 days or as modified by the Court.

IT IS FURTHER ORDERED that a hearing to determine whether a preliminary injunction shall supplant and/or follow this Order shall proceed at **12:00 p.m., Tuesday, February 25, 2014.**

All Citations

Not Reported in F.Supp.3d, 2014 WL 8332136

Footnotes

1 To the extent that East must satisfy the traditional 4–prong preliminary injunction test before a TRO may issue, see *Garcia v. United States,* 680 F.2d 29, 31 (5th Cir.1982) (indicating that "the requirements justifying a temporary restraining order" are equivalent to those justifying a "preliminary injunction"), the Court also finds that each of these requirements are met. First, East has made a preliminary showing that he is likely to succeed on the merits of his claim because the Affordable Health Care Act contains an express Nondiscrimination provision, requiring that "an individual shall not ... be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance," 42 U.S.C. § 18116; second, as explained, East has demonstrated a substantial threat of irreparable injury—specifically, declining health and eventual death—if his insurance is discontinued; third, this threat to East's well-being far outweighs any injury to Defendants because Defendants are simply required to maintain their existing policies of accepting Ryan White Funds paid on behalf of insureds in East's position; finally, the TRO serves the public interest because it ensures that insureds in East's position maintain their current health care coverage, thereby avoiding, among other things, additional costs resulting from lost health care coverage, such as emergency room treatment in lieu of regularly scheduled doctor appointments and medications. *See Texans for Free Enter. v. Tex. Ethics Comm'n,* 732 F.3d 535, 536–37 (5th Cir.2013) ("A preliminary injunction is an "extraordinary remedy" that should be granted only if the movant establishes (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.")(quotation marks omitted).

End of Document

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA

JOHN EAST, individually and on behalf of all other persons similarly situated, Plaintiffs, v. BLUE CROSS and BLUE SHIELD of LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC., Defendants.	Civil Action No.: 14-115 Section Magistrate **COMPLAINT- CLASS ACTION** **JURY DEMANDED**

Plaintiff JOHN EAST, individually and on behalf of all other persons similarly situated (collectively, "Plaintiffs" or the "Plaintiff Class"), through his undersigned counsel, for his Complaint against Defendants BLUE CROSS AND BLUE SHIELD OF LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC., (collectively, "Defendants"), alleges the following upon knowledge as to his individual conduct and interactions and upon information and belief as to the conduct of others:

PRELIMINARY STATEMENT

1. This action seeks injunctive and declaratory relief to halt Defendants' abrupt and systematic policy of targeted discrimination on the basis of Plaintiffs' disability, *i.e.*, their

infection with the human immunodeficiency virus ("HIV"),[1] in violation of sections 1557(a) and 1311(c) of the Patient Protection and Affordable Care Act (codified at 42 U.S.C. §§ 18116(a) and 18031), and in contravention of Louisiana state law.

2. To ensure equal access to health care under the Affordable Care Act, Congress placed robust antidiscrimination requirements on health insurers that profit from the billions of federal dollars flowing into the health care insurance market and from the vast new market of health insurance consumers made available to insurers through the Affordable Care Act's health insurance exchanges.

3. One such safeguard is section 1557 of the Affordable Care Act, which expressly prohibits health insurers that receive federal funds, as do Defendants, as well as entities established under Title I of the Affordable Care Act, from discriminating against any individual on the basis of a disability for purposes of the individual's participation in or enjoyment of the benefits of health insurance coverage.

4. The "Plaintiff Class" consists of all Louisiana residents living with HIV who are qualified for health insurance premium assistance from the Ryan White HIV/AIDS Program.[2]

5. The Plaintiff Class includes a subclass of persons who have existing or past insured relationships with one or more Defendants ("Insured Plaintiffs").

6. The Plaintiff Class is fully eligible for coverage under Defendants' available plans. Insured Plaintiffs have been paying their premiums in full—some of them for decades—and all Plaintiffs are and remain ready, willing, and able to pay premiums with federal funds designed precisely for that purpose.

[1] HIV, when left untreated, causes AIDS.

[2] The Ryan White HIV/AIDS Program is a federal program that makes grants to states, cities, and non-profit organizations to provide people living with HIV with access to health care, including by assisting in the payment of health insurance premiums.

7. The Plaintiff Class benefits from health insurance premium assistance funded by federal grant money from the Ryan White HIV/AIDS Program, which is available exclusively for people living with HIV in need of financial assistance, and without which none of the Plaintiffs can afford individual health insurance premiums.

8. Defendants have routinely accepted funds from the Ryan White HIV/AIDS Program ("Ryan White Funds") for dozens of their policy-holders' health insurance premiums. Blue Cross and Blue Shield of Louisiana ("BCBS") has accepted Ryan White Funds since at least 2009, and upon information and belief, the other defendants have accepted such funds since each began offering health insurance in Louisiana and Ryan White HIV/AIDS Program premium assistance became available through the Louisiana Health Insurance Program.

9. In or around January 2014, however, BCBS took the position that it would no longer accept Ryan White Funds for premium payments and advised the Louisiana Health Insurance Program of this change to its longstanding policy of accepting these payments.

10. BCBS's new policy excludes Plaintiff class members from access to BCBS coverage, which Plaintiffs can afford only with Ryan White Funds, as surely as if BCBS had posted a sign saying "low-income people with HIV need not apply."

11. BCBS's abrupt policy change coincides with the open enrollment period of the Affordable Care Act's insurance exchange marketplace. BCBS's initial explanation for its dubiously timed policy change was guidance issued by the Centers for Medicare & Medicaid Services ("CMS," a lead federal agency administering the Affordable Care Act) on November 4, 2013 (the "November 2013 Regulatory Guidance"). This guidance discouraged insurers from accepting third-party premium payments from *hospitals, health care providers, and other commercial entities* that might fraudulently seek to attract health care consumers with promises

to make their premium payments, or to defray the costs of otherwise uncompensated care by paying the premiums of those whose coverage would soon lapse.

12. That guidance, however, did ***not*** discourage insurers from accepting payments from other sources, such as federal programs designed specifically to provide premium support. In fact, in a more recent statement, CMS expressly stated that its earlier guidance regarding third-party premium payments "does not apply to payments for premiums and cost sharing made on behalf of QHP [Qualfied Health Plan] enrollees by . . . state and federal government programs or grantees (such as the Ryan White HIV/AIDS Program)."

13. Even after CMS repudiated BCBS's sole justification for refusing these payments, BCBS did not acknowledge its misinterpretation—or mischaracterization—of the earlier guidance and did not resume its longstanding policy to accept Ryan White HIV/AIDS Program payments.

14. Instead, BCBS disregarded CMS' clarification and doubled-down on its discriminatory actions, thereby attempting to skew the Louisiana health insurance market in its favor. BCBS issued a statement on February 13, 2014 making clear that it was going ahead with its discriminatory policy, which would have the effect of keeping low-income individuals living with HIV from enrolling in a BCBS individual insurance plan.

15. In turn, the other state-wide insurers in Louisiana have followed BCBS's lead. Around the time that CMS issued its clarifying guidance, Defendant Louisiana Health Cooperative, Inc. ("Louisiana Health Cooperative") began informing enrollees that it too would no longer accept Ryan White HIV/AIDS Program third-party premium payments. Shortly thereafter, Vantage Health Plan, Inc. ("Vantage") announced that while it would continue to

accept such payments for the time-being, it would reconsider its policy if BCBS and the Louisiana Health Cooperative continued to refuse Ryan White Funds.

16. To avoid the costs associated with more people living with HIV on their insurance rolls, Defendants are intentionally discriminating against Ryan White Funds recipients.

17. Indeed, in an email that was recently made public, a Congressional staffer in Senator Mary Landrieu's office wrote that

> ***BCBS LA told me their decision was not due to the CMS [Centers for Medicare & Medicaid Services] guidance or any confusion (as we thought before) but was in fact due to adverse selection concerns.***

18. The National Association of Insurance Commissions defines adverse selection to include "insurance purchasing decisions based on [consumers'] own knowledge of their insurability . . . [including when] the applicant might have information about the risk that is not known to the insurer, or the insurer might have access to the information but be unable to incorporate it fully into the price of coverage, due to factors such as antidiscrimination laws." *Adverse Selection Issues and Health Insurance Exchanges Under the Affordable Care Act*, Nat'l Ass'n of Ins. Comm'rs (2011), *available at* http://www.naic.org/store/free/ASE-OP.pdf.

19. Against the backdrop of the Affordable Care Act prohibiting health insurers from incorporating applicants' pre-existing conditions into the price of coverage, BCBS candidly admitted that it was excluding a large group of expensive-to-insure individuals—Plaintiffs—for no other reason than to avoid adverse selection.

20. Due to the eligibility requirements of the Ryan White HIV/AIDS Program, which is designated to be a payor of last resort, Plaintiffs by definition do not have employer-provided insurance, are ineligible for Medicare, Medicaid, or other federal health care programs, and cannot afford private insurance on their own. Without Ryan White HIV/AIDS Program

assistance, Plaintiffs cannot obtain health insurance, without which Plaintiffs cannot maintain the continuous access to care and prescription medications that literally keep them alive.

21. Defendants' plans are Plaintiffs' only viable health insurance options.[3] Defendants' discriminatory policy of refusing to accept Ryan White Funds puts Plaintiffs in a situation that class representative John East describes as "a matter of life and death."

22. As a result of Defendants' unlawful discrimination in violation of sections 1557 and 1311 of the Affordable Care Act, hundreds—if not thousands—of low-income Louisianans with HIV face being dropped immediately from their health care coverage, and those who are currently uninsured will have no health care coverage option to which they can turn.[4]

23. As a result of Defendants' unlawful discrimination and refusal to accept Insured Plaintiffs' premium payments via the Ryan White HIV/AIDS Program, Defendants have violated their contractual obligations to Insured Plaintiffs, their duty of good faith and fair dealing, as well as other duties under state law.

---

[3] The residents of Jefferson Parish who are currently eligible for assistance through the Louisiana Health Insurance Program may be able to pay for a health insurance plan offered by Humana Medical Plan, Inc., using Ryan White Funds, though it is unclear whether that plan will adequately meet the health care needs of all of these individuals, cover the specific medications currently being prescribed to these individuals, or allow these individuals to remain with the physician currently providing them with care and treatment. Furthermore, unless the other insurers doing business in Jefferson Parish are prevented from discriminating against low-income people living with HIV and kicking them off their insurance rolls, Humana may have difficulty maintaining its position as the only insurer in Louisiana complying with the nondiscrimination mandates of the Affordable Care Act and providing these individuals with coverage.

[4] Through nondiscrimination provisions, and regulations promulgated thereunder, the ACA prohibits precisely the tactic Defendants are employing to rid their insurance rolls of people living with HIV. In addition to section 1557, section 1311 requires that participating health insurance plans not employ benefits designs or marketing practices that discourage people with significant health needs from enrolling, and regulations promulgated under section 1311 further elucidate these standards. *See, e.g.*, Section 1311(c)(1)(A) of the ACA provides that "to be certified, a plan shall, at a minimum (A) . . . not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs. . . ." *See* 42 U.S.C. § 18031. *See also, e.g.*, 45 C.F.R. § 147.104(e) (prohibiting insurers from "employ[ing] marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's . . . present or predicted disability . . . or other health conditions"); 45 C.F.R. § 156.125(a) ("[a]n issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's . . . present or predicted disability . . . or other health conditions"); 45 C.F.R. § 156.225(b) (prohibiting insurers from "employ[ing] marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs").

24. As a result of Defendants' longstanding practice of accepting and benefiting from Ryan White Funds, which induced Plaintiffs' reliance that Defendants would continue to do so, Defendants must also be estopped from taking their new position leaving Plaintiffs with no viable health insurance option.

JURISDICTION AND VENUE

25. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1343(a)(4) where this action arises under, *inter alia*, sections 1557 and 1331 of the Affordable Care Act and 29 U.S.C. § 794. The Court has jurisdiction over Plaintiffs' state law claims, which arise from a common nucleus of operative facts as Plaintiffs' federal claims, pursuant to 28 U.S.C. § 1367(a).

26. Venue is proper in this district pursuant to 28 U.S.C. § 1391 because, upon information and belief, Defendant BCBS resides in the Middle District of Louisiana and all Defendants are residents of Louisiana, and because all or a substantial part of the events giving rise to the claims in this action occurred and are occurring in the Middle District of Louisiana.

27. Declaratory relief is authorized pursuant to 28 U.S.C. § 2201 and 28 U.S.C. § 2202. A declaration of the law is necessary and appropriate to determine the respective rights and duties of the parties to this action.

NAMED PARTIES

PLAINTIFF

28. Plaintiff John East, a resident of Louisiana, has purchased insurance coverage from BCBS continuously since 1985. Mr. East is living with HIV. Despite working two jobs, in 2009 Mr. East's escalating health insurance premium costs became unaffordable, and he realized he soon would be unable to make his payment on his own. Because he is a low-income person

living with HIV, Mr. East qualified for and obtained Ryan White HIV/AIDS Program health insurance premium assistance.

29. Mr. East, whose coverage with BCBS began in 1985, never missed a premium payment and his coverage never lapsed. Since he became qualified for premium assistance in approximately 2009, BCBS has been accepting Ryan White Funds premium payments for Mr. East.

30. At the beginning of this year, however, BCBS advised that it would no longer accept Ryan White Funds, leaving Mr. East with no means to make his premium payments. After BCBS's announcement, Mr. East's next payment was due on February 15, 2014, and he now faces the loss of health insurance for the first time in 29 years. Mr. East has since learned that Defendant Louisiana Health Cooperative will no longer accept Ryan White HIV/AIDS Program premium payments. He has also learned that Vantage, his only other potential option for health insurance coverage paid for with Ryan White funds, will likely follow BCBS and Louisiana Health Cooperative and stop accepting Ryan White Funds in March 2014.

DEFENDANTS

31. Defendant BCBS is a Louisiana corporation, with headquarters in Baton Rouge, Louisiana. BCBS offers insurance policies to residents of every Parish in Louisiana through the federal healthcare exchange. Defendant BCBS is the administrator for the Federal Employees Health Benefit Plan in Louisiana. It also offers Health Maintenance Organization and Preferred Provider Organization insurance plans through the federal healthcare exchange, in connection with which it receives federal premium tax credits and cost-sharing subsidy payments directly from the federal government. Finally, Defendant BCBS has received federal money via the very program at issue here—the Ryan White HIV/AIDS Program.

32. Defendant Louisiana Health Cooperative is a non-profit health care company, with headquarters in Metairie, Louisiana. Defendant Louisiana Health Cooperative received a loan for $65,040,660 in 2012 from the Department of Health and Human Services Consumer Oriented and Operated Plan Loan Program to assist with establishing its health insurance business. Defendant Louisiana Health Cooperative is a "Consumer Operated and Oriented Plan" established under title I of the Affordable Care Act. It offers Health Maintenance Organization and Point of Sale insurance plans through the federal healthcare exchange, in connection with which it receives federal premium tax credits and cost-sharing subsidy payments directly from the federal government. Finally, Defendant Louisiana Health Cooperative has received federal money via the very program at issue here—the Ryan White HIV/AIDS Program.

33. Defendant Vantage is a Louisiana corporation, with headquarters in Monroe, Louisiana. It offers Point of Sale insurance plans through the federal healthcare exchange, in connection with which it receives federal premium tax credits and cost-sharing subsidy payments directly from the federal government. Vantage also receives federal funds to administer its Medicare Advantage health insurance plans. Finally, Defendant has received federal money via the very program at issue here—the Ryan White HIV/AIDS Program.

CLASS ACTION ALLEGATIONS

34. The named individual Plaintiff brings this action individually and on behalf of the Plaintiff Class pursuant to Federal Rule of Civil Procedure 23(a) and (b)(2). The class consists of all Louisiana residents living with HIV who are qualified for health insurance premium assistance from the Ryan White HIV/AIDS Program. The class includes a subclass of Plaintiffs who have existing or past insured relationships with one or more Defendants (defined above as "Insured Plaintiffs") who, by virtue of those relationships, are entitled to additional relief under state law.

35. Numerosity. The size of the class is indefinite, and includes at least 1400 individuals who are eligible to apply for and enroll in a health insurance policy offered by one of the Defendants—including a subset of individuals who have existing or past insured relationships with one or more Defendants—but whose premium payments will now be refused under Defendants' discriminatory policies, leaving the Plaintiff Class with no viable health insurance coverage option.

36. Adequacy of Representation. The named Plaintiff will represent fairly and adequately the interests of the class and subclasses defined above. Plaintiffs' attorneys include counsel experienced in insurance, health care, and civil rights matters who have litigated cases involving similar issues and claims, and have experience in class action litigation.

37. Common Questions of Law and Fact. Common questions of law and fact affecting the entire class are involved, including but not limited to questions of law and fact regarding Defendants' actions, such as adopting policies that discriminate against Plaintiffs on the basis of their disability.

38. Typicality of the Claims of Class Representatives. The named Plaintiff's claims are typical of the claims of the class as a whole, and of those of the Insured Plaintiffs subclass. The named Plaintiff is a member of the class and subclass defined herein and has suffered, and will continue to suffer, discriminatory denial of equal access to otherwise available health care coverage. The named Plaintiff alleges that he and the members of the class and subclass he seeks to represent are and will be subject to discrimination based on disability due to the conduct complained of in this action.

APPLICABLE LAW

39. Section 1557(a) of the Affordable Care Act, 42 U.S.C. § 18116(a), provides that "an individual shall not . . . be excluded from participation in, be denied the benefits of, or be

subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance" on the ground prohibited under, *inter alia*, section 504 of the Rehabilitation Act.

40. Section 504 of the Rehabilitation Act, 29 U.S.C. § 794, prohibits discrimination based upon disability. A "disability" under section 504 is "a physical or mental impairment that substantially limits one or more major life activities." 29 U.S.C. § 794(a); 29 U.S.C. § 705(20)(B); 42 U.S.C. § 12102(1)(A). "[A] major life activity . . . includes the operation of a major bodily function, including . . . functions of the immune system." 42 U.S.C. § 12102(1)(A) & (2)(B).

41. Section 1557 states that "[t]he enforcement mechanisms provided for and available under . . . section 504 . . . shall apply for purposes of [section 1557(a)]." 42 U.S.C. § 18116(a).

42. Section 504 may be enforced by "any person aggrieved by any act or failure to act . . ." according to the same "remedies, procedures and rights set forth in[, *inter alia*,] Title VI of the Civil Rights Act." 29 U.S.C. § 794(a)(2).

43. Section 1557 also prohibits discrimination on the basis of disability status by "any entity established under [title I of the Affordable Care Act] (or amendments)." 42 U.S.C. § 18116(a).

44. Section 1322 of the Affordable Care Act, 42 U.S.C. § 18042, establishes the Consumer Operated and Oriented Plan ("CO-OP") program.

45. Under section 1311(c)(1)(A) of the Affordable Care Act, a "qualified health plan" certified and offered on a federal exchange must "not employ marketing practices or benefit

designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs." 42 U.S.C. § 18031(c)(1)(A).

46. Section 2702(a) of the Public Health Services Act provides that "each health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every . . . individual in the State that applies for such coverage." 42 U.S.C. § 300gg-1.

47. Louisiana Revised Statute section 22:1964 ("section 1964") declares what are, in the insurance business, "[m]ethods, acts, and practices which are defined as unfair or deceptive." LA. REV. STAT. § 22:1964.

48. Section 1964(7) enumerates "unfair discrimination" as an "unfair or deceptive" practice. Section 1964(7) (incorporating Louisiana Revised Statute section 22:34) defines "unfair discrimination," *inter alia*, as

> unfair discrimination in favor of particular individuals or persons, or between insureds or subjects of insurance having substantially like insuring risk, and exposure factors, or expense elements, in the terms or conditions of any insurance contract, or in the rate or amount of premium charged therefor, or in the benefits payable or in any other rights or privileges accruing thereunder.
>
> LA. REV. STAT. § 22:1964(7).

49. Section 1964(14)(a) enumerates as an "unfair or deceptive" practice the act of "[c]ommitting or performing with such frequency as to indicate a general business practice any of the following: (a) Misrepresenting pertinent facts or insurance policy provisions relating to coverages at issue . . . " LA. REV. STAT. § 22:1964(14)(a).

50. Louisiana Revised Statute section 22:861 states that

> Any insurer may insert in its policies any provisions or conditions required by its plan of insurance or method of operation which are not prohibited by the provisions of this Code.
>
> LA. REV. STAT. § 22:861.

51. Louisiana Revised Statute section 22:880 states that

> Any insurance policy, rider, or endorsement hereafter issued and otherwise valid, which contains any condition or provision not in compliance with the requirements of this Code, shall not be rendered invalid, but shall be construed and applied in accordance with such conditions and provisions as would have applied had such policy, rider, or endorsement been in full compliance with this Code.

LA. REV. STAT. § 22:880.

FACTS

The Current State of Low-Income People Living with HIV in Louisiana

52. According to a study by the Centers for Disease Control and Prevention ("CDC"), Louisiana is the State with the second highest rate of HIV infection in the United States and the fourth highest rate of AIDS among adults and adolescents.

53. As of 2012 there were nearly 19,000 people living with HIV in Louisiana. As of 2009, there were 9,228 total HIV-related deaths among people living with HIV in the state.

54. HIV and AIDS disproportionately affect low-income populations, including in Louisiana. According to remarks by the Director of the CDC's National Center for HIV/AIDS, Dr. Jonathan Mermin, individuals with household incomes below $10,000 per year are 10 times more likely to have HIV than individuals with household incomes above $50,000 per year.

55. Twenty-two percent of people in Louisiana are living below the Federal Poverty Level, which is set at an annual income of $11,670 for an individual in 2014.

Critical Importance of Continuous Health Care Coverage for People Living with HIV

56. According to the CDC and many peer-reviewed articles, retention and continuity of health care for people living with HIV is directly linked to better health outcomes and a significantly decreased chance of transmitting HIV to others.

57. Continuity of care is critical for people living with HIV because it allows them to obtain and maintain a regimen of antiretroviral medication, reduce their viral load, and ultimately reduce mortality rates.

58. Viral load is a measurement of the amount of HIV in an individual's blood. It indicates the degree of infection and is used to determine treatment strategies. A health care provider will typically test an HIV patient's viral load every three to six months, and more often when changing or starting treatment.

59. Antiretroviral medications are the primary method of combatting HIV infection and reducing viral load. Antiretroviral medications work by interfering with the replication process of HIV. Standard antiretroviral treatment typically involves a combination of at least three drugs taken daily.

60. Consistent care and treatment, including access to antiretroviral medication, has been shown to greatly reduce illness and death attributable to HIV, particularly when introduced at an early stage of infection, and can lead to a reduction in viral load to undetectable levels.

61. Studies have shown that an undetectable viral load dramatically reduces the chance of HIV transmission and results in a life expectancy commensurate with individuals in the general population.

62. Unfortunately in Louisiana, late diagnosis and lack of medical care contributes to a rate of death from AIDS nearly double the national average.

63. In Louisiana, 25% of people who received an AIDS diagnosis between 2002 and 2006 died within 36 months of receiving their diagnosis. Nationally, over the same period, 17% of people receiving an AIDS diagnosis died within 36 months.

Health Insurance Options for Low-Income People Living with HIV in Louisiana

64. There are significant gaps in availability of affordable health care coverage for low-income people living with HIV in Louisiana.

65. Louisiana has not expanded Medicaid coverage to include all individuals with a household income at or below 133% of the federal poverty level, as contemplated by the Medicaid expansion provisions of the Affordable Care Act. Accordingly, low-income people living with HIV in Louisiana who are not yet eligible for Medicare may obtain health insurance coverage through Medicaid only under limited circumstances.

66. While the Affordable Care Act's new provision for private health insurance exchanges provides an opportunity for some low-income people living with HIV to obtain insurance, affordability remains a problem.

67. Indeed, according to a state health reform modeling project undertaken by the Harvard Law School, only 8% of Louisiana's Ryan White Funds-eligible clients will be eligible for health insurance subsidies under the Affordable Care Act. Individuals with a household income below 100% of the Federal Poverty Level do not qualify for premium assistance through the health care exchanges. For people living with HIV in this income group, purchasing private insurance on the exchange is impossible without the assistance of Ryan White Funds.

68. Even people living with HIV who qualify for a subsidy to purchase private health insurance on the exchange still need Ryan White Funds to assist them in meeting their remaining individual premium obligation.

69. Plaintiff John East is one such. Mr. East, who is currently under-employed, cannot afford the premiums for his legacy insurance policy without assistance from the Ryan White HIV/AIDS Program. While Mr. East also would be eligible to apply for a plan on the federal exchange, and he may qualify for a subsidy, any subsidy he would qualify for still would

not suffice to cover his premium payment, and he continues to need the Ryan White HIV/AIDS Program's assistance.

70. The good news is that, with the assistance of Ryan White Funds, Plaintiffs can obtain insurance under the Affordable Care Act's protections, because no health insurance plan offered on the exchange can discriminate in coverage or price of premium based on their condition living with HIV.

The Ryan White HIV/AIDS Program

71. The Ryan White HIV/AIDS Program is a critical bridge over the health insurance coverage gap for Plaintiffs, making it possible for these low-income individuals living with HIV to pay premiums for private health care coverage that they would not otherwise be able to afford.

72. In 1990, Congress passed the Ryan White Comprehensive AIDS Resources Emergency Act (Ryan White CARE Act), funding what is now the Ryan White HIV/AIDS Program. The Ryan White HIV/AIDS Program makes grants to states, cities, and non-profit organizations to provide people living with HIV with access to health care, including by assisting in the payment of health insurance premiums.

73. At the federal level, Ryan White Funds are administered by the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

74. In 2010, the U.S. government released the "National HIV/AIDS Strategy for the United States," reemphasizing the Ryan White HIV/AIDS Program's important role as part of the national HIV/AIDS prevention and treatment strategy. A critical goal of the "National HIV/AIDS Strategy for the United States" is to increase by 2015 the "proportion of Ryan White HIV/AIDS Program clients who are in continuous care (at least 2 visits for routine HIV medical care in 12 months at least 3 months apart) from 73% to 80% (or 237,924 people in continuous care to 260,739 people in continuous care)."

75. In Louisiana, the Louisiana Health Insurance Program administers the Ryan White HIV/AIDS Program. In fiscal year 2012, Louisiana received $50,704,888 in total funding for Ryan White Program activities.

76. Louisiana state and municipal grantees have been accepting and utilizing Ryan White Program Funds since 1991. These funds and the programs they support are central to Louisiana's strategy for combating HIV/AIDS.

77. Since 1994, the Louisiana Health Insurance Program has been assisting eligible individuals—Louisiana residents living with HIV who have a household income below 300% of the Federal Poverty Level—to make their individual health insurance premium payments.

78. The HIV/AIDS Alliance for Region II (the "HIV/AIDS Alliance") is the not-for-profit entity that administers the Louisiana Health Insurance Program's health insurance premium payment function.

79. Potential Ryan White HIV/AIDS Program premium assistance recipients apply through the HIV/AIDS Alliance. Once a recipient becomes enrolled, the HIV/AIDS Alliance sends premium checks to insurers on behalf of the participant.

80. The Health Resources and Services Administration HIV/AIDS Bureau, which is the Federal Administrator of the Ryan White HIV/AIDS Program, requires Ryan White HIV/AIDS Program Grantees to make payments directly to service providers and insurance companies. Grantees are not permitted to make direct payment to Ryan White HIV/AIDS Program beneficiaries.

81. Well before the Affordable Care Act's implementation, Insured Plaintiffs including John East, received Ryan White HIV/AIDS Program support to pay their premiums for health insurance plans purchased in the private marketplace from BCBS and Vantage, making

this a critically important means for low-income people living with HIV to obtain care and treatment.

82. With the implementation of the federally sponsored health insurance exchange in Louisiana beginning in October 2013, the federal government made clear that Ryan White HIV/AIDS Program premium support will play an equally important role in assisting low-income people living with HIV pay their private health insurance premiums for plans purchased through the exchange.

83. Indeed, the Health Resources and Services Administration has issued many policy statements providing guidance on the continued use of Ryan White Funds as premium assistance for eligible people living with HIV to purchase and maintain health insurance plans offered on the federal exchange.

Defendants' Past Acceptance of Ryan White Funds

84. Long before the implementation of the Affordable Care Act's health exchanges, Defendant BCBS, and upon information and belief Defendant Vantage, established an unequivocal pattern and practice of accepting Plaintiffs' Ryan White Funds premium payments.

85. BCBS has continuously and habitually accepted Ryan White Funds for its policy holders' premium payments at least since as early as 2009.

86. Vantage and Louisiana Health Cooperative also have received and accepted Ryan White Funds for its policy holders' premium payments.

87. Plaintiff John East's most recent BCBS insurance policy includes a section entitled "Due Date for Premium Payments," which states:

> 1. Premiums are owed by Subscriber. Premiums may not be paid by third parties unless related to the Subscriber by blood or marriage. Premiums may not be paid by Hospitals, Pharmacies, Physicians, automobile insurance carriers or other insurance carriers. Company will not accept premium payments by third parties unless required by law to do so. The fact that We may have

> previously accepted a premium from an unrelated third party does not mean that we will accept premiums from these parties in the future.

88. Despite this term in BCBS's recent written policy, when announcing its policy of refusing Ryan White HIV/AIDS Program and other third-party premium payments on February 10, 2014 and again on February 13, 2014, BCBS made no mention that such a term already existed in its insurance policies. Rather, BCBS made its announcements on February 10 and 13, 2014 as if no such term previously existed.

89. Despite this term in its recent written policy, BCBS announced on February 10 and 13, 2014 that the policy would not take effect until March 1, 2014, and that BCBS would continue honoring third-party premium payments up through February 28, 2014.

90. Despite this term in its recent written policy, BCBS went on to accept Mr. East's (and others') Ryan White HIV/AIDS Program premium payments after Mr. East undertook his most recent policy renewal.

91. Wanting to ensure that his coverage never lapses, Mr. East routinely called BCBS to ensure that BCBS had received his premium payment of Ryan White Funds and applied it toward his account. BCBS representatives always assured Mr. East that his Ryan White HIV/AIDS Program premium had been received and accepted like any other premium payment.

92. Defendants' policy, pattern, and custom of accepting Ryan White Funds caused Insured Plaintiffs to repeatedly renew their coverage in reliance on Defendants' prior practices, and based on their understanding that their only means of paying their premium in full—via Ryan White Funds—was acceptable to Defendants.

93. For instance, Plaintiff John East annually had the opportunity to renew his BCBS policy or shop for health insurance elsewhere. While Mr. East did make inquiries with other

health insurers, he always renewed his BCBS policy, largely based on his belief that there would be no issue with his Ryan White Funds payments being accepted by BCBS.

94. Defendant BCBS's longstanding policy, pattern, and custom of accepting Ryan White Funds persisted even after BCBS inserted boilerplate language in its insurance policies that it would not receive third party premium payments.

95. Defendants outwardly maintained their policy, pattern, and custom of accepting Ryan White Funds even on the eve of Defendants' changing that position, including at times when Defendants knew they would soon be changing that position, in furtherance of receiving and benefiting from Plaintiffs' Ryan White Funds premium payments.

Defendants' Abrupt Change of Policy and Purported Justification

96. In January 2014, BCBS abruptly advised state agencies and entities administering Ryan White funds, including the Louisiana Health Insurance Program and the HIV/AIDS Alliance for Region II, that it would no longer accept Ryan White Funds for Plaintiffs' premium payments.

97. At that time, healthcare advocates and case workers of HIV and AIDS support programs such as the NO/AIDS Task Force ("NO/AIDS") also learned that BCBS would be refusing Ryan White premium payments and that BCBS's explanation for its policy was that the November 2013 Regulatory Guidance prevented BCBS from accepting premium payments from third parties.

98. In mid-January, Plaintiff John East learned of BCBS's policy of refusing Ryan White funds from his case worker at NO/AIDS.

99. BCBS provided Mr. East himself with no such notice. However, BCBS did send Mr. East his premium bill as usual. If not for his conversation with NO/AIDS, Mr. East would

have continued to believe that BCBS would accept his Ryan White HIV/AIDS Program premium payments as it always had.

100. The November 2013 Regulatory Guidance that BCBS purportedly relied on addressed CMS' concern that private or commercial parties might distort the marketplace in attracting patients to consume their healthcare services, or in shifting the costs of uncompensated care, by paying those patients' premiums or cost-sharing payments.

101. To that end, the November 2013 Regulatory Guidance stated that "HHS [Department of Health and Human Services] discourages this practice and encourages issuers to reject such third party payments."

102. Consistent with its purpose of targeting the practice of third parties who seek to attract patients with offers to pay premiums and cost-sharing obligations, the November 2013 Regulatory Guidance was limited to discouraging the acceptance of third-party premiums paid only by "hospitals, other healthcare providers, and other commercial entities."

103. Nonetheless, BCBS announced publically in a February 10, 2014 media release that its policy of not accepting any third-party payments (including Ryan White Funds) was in response to the November 2013 Regulatory Guidance, which BCBS characterized as "strongly advising [insurers] not to take ***any*** third-party payments." (Emphasis added.)

104. In another media release on February 13, 2014, BCBS again offered only one justification for its policy—its purported concerns based on the November 2013 Regulatory Guidance that people or organizations might fraudulently seek to attract health care consumers with promises to make their premium payments or to defray the costs of otherwise uncompensated care by paying the premiums of those whose coverage would soon lapse.

105. BCBS has offered no justification for its refusal to accept Ryan White Funds from Plaintiffs, other than its claimed inapposite concerns over "fraud, waste and abuse" as discussed in November 2013 Regulatory Guidance.

The November 2013 Regulatory Guidance Never Supported BCBS's Only Purported Justification, and the Centers for Medicare & Medicaid Services Expressly Refuted BCBS's Incoherent Justification

106. BCBS's only justification for its refusal to accept Plaintiffs' Ryan White Funds premiums is a false pretext under which BCBS is attempting to keep what it perceives to be a more expensive class of insureds—people living with HIV—off its insurance rolls.

107. On February 7, 2014, very shortly after BCBS began advising that it would reject Ryan White Funds from Plaintiffs, CMS responded with clarifying guidance (the "February 2014 Regulatory Guidance"), in Question-and-Answer format, entitled, "Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces."

108. In response to the question whether the November 2013 Regulatory Guidance applied to "premium and cost sharing payments on behalf of [Qualified Health Plan] enrollees from . . . state and federal government programs or grantees (such as the Ryan White HIV/AIDS Program)," the February 2014 Regulatory Guidance stated that it did not apply:

> ***No. The November 4, 2013 FAQ does not apply to payments for premiums and cost sharing made on behalf of . . . state and federal government programs or grantees (such as the Ryan White HIV/AIDS Program). QHP issuers and Marketplaces are encouraged to accept such payments***.

(Emphasis added.)

109. The February 2014 Regulatory Guidance went on to confirm that earlier Health Resources and Services Administration guidance on the Ryan White HIV/AIDS Program "specifically describes how grantees can use grant funds to pay premiums and cost sharing for eligible individuals enrolled in QHPs."

110. BCBS's media releases of February 10, 2014 and February 13, 2014 each acknowledged the February 2014 Regulatory Guidance, but asserted that, in this more recent guidance, "CMS [Centers for Medicare & Medicaid Services] changed its position" and "issued a different communication."

111. BCBS supported its assertion that "CMS changed its position" by asserting that the earlier November 2013 Regulatory Guidance "strongly advis[ed insurers] not to take ***any*** third-party payments." (Emphasis added.)

112. The foregoing statements by BCBS on February 10 and 13, 2014, are deliberately false and misleading.

113. The November 2013 Regulatory Guidance did not discourage insurers from taking "any" third-party payments, but rather explicitly tailored its caution to those third-party payors that might actually seek to exploit patients with premium assistance for their own personal gain—"hospitals, other healthcare providers, and other commercial entities."

114. The November 2013 Regulatory Guidance certainly did not include federal Ryan White Funds or any other government program specifically designed to assist people living with HIV to pay their health insurance premiums.

115. Contrary to BCBS's assertion that "CMS changed its position" through its February 2014 Regulatory Guidance, the February 2014 Regulatory Guidance was ***consistent with*** the November 2013 Regulatory Guidance. Neither supports a policy of refusing federal funds to assist Plaintiffs to pay their health insurance premiums.

116. BCBS has not explained in any of its public statements how refusing Ryan White Funds premium payments from Plaintiffs, rather than refusing payments only from hospitals,

other healthcare providers, and other commercial entities, furthers BCBS's purported goal of safeguarding against patient-steering by private actors and other fraudulent activity.

117. BCBS's justification based solely on BCBS's characterization of the policy is unsupported by any regulatory guidance and is explicitly negated by the February 2014 Regulatory Guidance.

118. The vast majority of Blue Cross and Blue Shield affiliates across the country have not adopted this policy.

Defendants' True Motivation in Refusing Ryan White Funds Is to Exclude Individuals Based on Their HIV/AIDS Status from Defendants' Insurance Rolls

119. In reality, Defendants' policy is intended to exclude Louisianans living with HIV who cannot by themselves afford to pay the premiums for the health insurance offered by Defendants.

120. Defendants are motivated to keep people living with HIV off their insurance rolls and reduce the increased costs associated with paying for the care and treatment provided to people living with HIV.

121. This is demonstrated in an email made public via various news outlets, in which a Congressional staffer in Senator Mary Landrieu's office reported that,

> ***BCBS LA told me their decision was not due to the CMS [Centers for Medicare & Medicaid Services] guidance or any confusion (as we thought before) but was in fact due to adverse selection concerns.***

(Emphasis added.)

122. As defined by the National Association of Insurance Commissions:

> Adverse selection . . . occurs whenever people make insurance purchasing decisions based on their own knowledge of their insurability or likelihood of making a claim on the insurance coverage in question. This can happen in a variety of ways. For example, the applicant might have information about the risk that is not known to the insurer, or the insurer might have access to the

> information but be unable to incorporate it fully into the price of coverage, due to factors such as antidiscrimination laws . . .

Adverse Selection Issues and Health Insurance Exchanges Under the Affordable Care Act, Nat'l Ass'n of Ins. Comm'rs (2011), *available at* http://www.naic.org/store/free/ASE-OP.pdf.

123. People living with HIV have medical needs requiring regular doctor visits (preferably with an infectious disease specialist), periodic blood tests and other lab work, and uninterrupted access to the medications they take on a daily basis.

124. Without regular medical care and monitoring and continuous access to (often expensive) medications, people living with HIV face the strong likelihood of a deteriorating immune function, debilitating illness, and premature death.

125. In light of their pressing need for consistent medical care and their lack of sufficient resources to pay for such care out of pocket, Plaintiffs' need for health insurance is particularly high.

126. Pursuant to Affordable Care Act reforms effective January 1, 2014, Plaintiffs cannot be prevented from purchasing most private health insurance plans, including Defendants', from which they historically have been excluded based on pre-existing condition exclusions.

127. The Affordable Care Act's reforms also prevent insurers from denying claims or basing premiums on a person' pre-existing condition, such as HIV or AIDS.

128. Plaintiffs' elevated need for health care and correspondingly high demand for health insurance, combined with the Affordable Care Act's provisions preventing Defendants from discriminating against people living with HIV in coverage or in premium cost, is consistent with BCBS's admission to Senator Landrieu's aide that its policy not to accept Ryan White Funds is intended to exclude Plaintiffs and thereby avoid "adverse selection."

129. Defendants' sudden refusal to accept Ryan White Funds also has the ***effect of*** discriminating against people living with HIV.

130. By definition, all individuals eligible for Ryan White HIV/AIDS Program are living with HIV (or AIDS) and find themselves currently unable to afford private health insurance premiums without Ryan White Funds.

131. Accordingly, 100% of those affected by Defendants' refusal to accept Ryan White Funds are individuals with a disability as defined by the Rehabilitation Act, and 100% of those affected will be unable to purchase health insurance on the federal exchange or otherwise.

132. Tellingly, in its February 13, 2014 media release, BCBS specifically assured the public that Ryan White HIV/AIDS Program recipients were not the only individuals affected by its new policy of refusing third party payments.

133. BCBS, however, cited only one example, concluding that "some Louisiana universities pay for student athletes' premiums. This policy affects them as well."

134. Like its justification for its discriminatory policy, BCBS's conclusory attempt to paint its policy as one of general application appears wholly unsupported.

135. In fact, Louisiana State University, the largest public university in Louisiana, has stated that BCBS's policy does not affect it or its student athletes.

Defendants' Abrupt Change in Policy to Refuse Ryan White Funds Leaves Plaintiffs with No Access to Health Insurance

136. In early February 2014, after BCBS publicized its plan to refuse Ryan White funds, Defendant Louisiana Health Cooperative, announced it too would refuse Ryan White Funds. The remaining Defendant, Vantage, announced that it would reexamine its policy of accepting Ryan White Funds in the near future, signaling an intent to adopt positions similar to

BCBS's and Louisiana Health Cooperative's if those insurers are allowed to continue their practice.

137. The concerted effort by these three insurers to exclude Plaintiff Ryan White HIV/AIDS Program beneficiaries effectively freezes Plaintiffs out of the federal health insurance exchange—the only market offering affordable health insurance plans that cannot exclude Plaintiffs or charge more on the basis of their HIV or AIDS diagnosis.

138. BCBS, the Louisiana Health Cooperative, and Vantage, represent three out of the four Louisiana health insurers that offer plans on the federal health insurance exchange.

139. The fourth insurer offering health insurance through the federal insurance exchange offers policies in only Jefferson Parish.

140. According to BCBS's own media release, BCBS is the only "meaningful" state-wide insurance option offered in the federal exchanges in Louisiana:

> [BCBS] is the only insurer that is fully participating in the Marketplace, offering plans at every metal level in every parish and every ZIP code in the state. . . . Our competition has chosen, for the most part, not to participate in any meaningful way.

141. With Defendants' new discriminatory policy in place, there are no health insurance policies offered through the federal insurance exchange that cover the other 63 Parishes of Louisiana (besides Jefferson Parish) in which Plaintiffs could participate, because now no provider of such policies accepts Ryan White Funds premium payments.

142. As noted above, Plaintiffs fall into Louisiana's insurance gap of individuals who do not qualify for Medicaid, Medicare, or other federal health care programs, but who cannot afford private health care insurance on their own.

143. Beyond their need for Ryan White Funds to afford their insurance premiums, Plaintiffs are qualified to participate in and receive the benefits of their existing or prospective

health insurance plans. The lone obstacle to Plaintiffs retaining or obtaining insurance is Defendants' sudden refusal to accept Ryan White Funds.

144. The introduction of the Affordable Care Act's health insurance exchanges offered new and more favorable options to Insured Plaintiffs with existing policies, and finally offered to Plaintiffs currently without insurance an opportunity to secure insurance and not be turned away or gouged based on an HIV or AIDS diagnosis.

145. Plans purchased outside of an exchange are far less likely to be affordable because Plaintiffs will not be eligible for premium credits or cost sharing subsidies, as they will be in connection with plans purchased through an exchange.

146. Even the plans in the federal exchange, however, despite the availability of premium credits and cost-sharing subsidies, are still too costly for Plaintiffs to carry the premiums themselves, making Ryan White Funds essential for Plaintiffs to be able to participate in, and enjoy the benefits of, the new market of health insurance free of discrimination based on disability or pre-existing conditions. Defendants know this fact.

147. With the major market player, BCBS, refusing Ryan White Funds, and with ***all*** insurance options outside of Jefferson Parish doing likewise (or, as to Vantage, threatening to do so in the near future), Defendants' discriminatory policy freezes Plaintiffs out of any access to health care coverage.

148. Even Plaintiffs living in Jefferson Parish, from whom one insurer may accept Ryan White Funds, are frozen out of coverage from BCBS, who, by its own assertion, is the only health insurer "to participate [in the exchange] in any meaningful way."

The Effect of Defendants' Intentional Discrimination Could Mean Illness and Death for Plaintiffs Forced Off Their Insurance Coverage

149. The circumstances facing Plaintiffs due to Defendants' intentionally discriminatory policy could not be more dire.

150. Plaintiff John East described the effect of this policy as being a "matter of life and death."

151. As set forth above, most Plaintiffs must take a number of costly prescription drugs every day, in various combinations tailored to boost their individual immune systems.

152. These drugs literally keep Plaintiffs alive. As Plaintiff John East has stated, "I could die if I don't get my meds."

153. To ensure that the medications remain effective and that the virus has not mutated and developed a resistance to the particular medications being taken, Plaintiffs also must engage in routine doctor visits and regularly undergo blood work and other medical monitoring tests.

154. Without health insurance coverage, the Plaintiff class members, including Plaintiff John East, cannot afford any of the care that they need to remain healthy and, ultimately, to stay alive.

155. With Defendants' policy of refusing Ryan White Funds in place, premiums due this month will go unpaid, Plaintiffs' prescriptions will begin to run out, and Plaintiffs may be turned away from their health care providers if there is uncertainty as to whether their coverage remains in place.

156. In addition, the health effects of losing—or even the threat of losing—health coverage for Plaintiffs, who so desperately depend on it, substantially impair Plaintiffs' ability to work and support themselves and their families.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF- AS TO THE PLAINTIFF CLASS (Intentional discrimination in violation of section 1557(a) of the Patient Protection and Affordable Care Act)

157. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

158. Defendants meet the qualifications for being a "health program or activity, any part of which is receiving Federal financial assistance" under section 1557 of the Affordable Care Act.

159. Plaintiffs are "individual[s] with a disability" under section 504 of the Rehabilitation Act.

160. Plaintiffs are qualified to participate in and receive the benefits of their respective health insurance plans.

161. Defendants have violated and continue to violate section 1557(a) of the Affordable Care Act by intentionally causing Plaintiffs to "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance" based on their disability, which is a prohibited ground of discrimination under section 504 of the Rehabilitation Act.

162. Plaintiffs have been aggrieved by this violation of section 1557 of the Affordable Care Act and have no adequate remedy at law for Defendants' violation of their rights. Defendants' unlawful discrimination will irreparably harm Plaintiffs because they will be unable to obtain necessary medical care.

163. Declaratory and injunctive relief are required to define Plaintiffs' rights under section 1557 and related statutes, to remedy the Defendants' violation of section 1557 of the

Affordable Care Act, and to secure ongoing compliance with the antidiscrimination provisions of the Affordable Care Act and incorporated federal law

SECOND CLAIM FOR RELIEF- AS TO THE PLAINTIFF CLASS
(Disparate impact discrimination in violation of section 1557(a) of the Patient Protection and Affordable Care Act)

164. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

165. Even if Defendants did not act with discriminatory intent, Defendants' refusal to accept premium payments from third parties other than those CMS considers to be potentially problematic has a disparate impact on individuals with a disability, namely their HIV or AIDS diagnosis, who as a result of Defendants' policy necessarily will be denied meaningful access to, excluded from participation in, and denied the benefits of any health program or activity, any part of which is receiving Federal financial assistance, in violation of Affordable Care Act section 1557(a).

166. Plaintiffs' request that Defendants maintain the status quo and continue to accept Ryan White Funds—as they have for years—requests only a "reasonable accommodation" under, not a substantial modification to or fundamental alteration of, Defendants' insurance programs, to ensure Plaintiffs meaningful access to Defendants' health insurance.

167. Plaintiffs have been aggrieved by this violation of section 1557 of the Affordable Care Act and have no adequate remedy at law for the Defendants' violation of their rights. Plaintiffs will be irreparably harmed by Defendants' unlawful discrimination by being unable to obtain necessary medical care.

168. Declaratory and injunctive relief are required to define Plaintiffs' rights under section 1557 and related statutes, to remedy the Defendants' violation of section 1557 of the

Affordable Care Act, and to secure ongoing compliance with the antidiscrimination provisions of the Affordable Care Act.

THIRD CLAIM FOR RELIEF- AS TO THE PLAINTIFF CLASS
(Employment of unlawful marketing practice to discourage enrollment in health insurance plans by individuals with significant health needs in violation of section 1311(c)(1)(A) of the Patient Protection and Affordable Care Act)

169. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

170. Defendants offer "qualified health plans" on federal insurance exchanges established under the Affordable Care Act.

171. Defendants' refusal to accept Ryan White Funds is a "marketing practice[] . . . that [has] the effect of discouraging the enrollment in [Defendants' insurance plans] by individuals with significant health needs," namely individuals with HIV or AIDS.

172. Plaintiffs have been aggrieved by this violation of section 1311 of the Affordable Care Act and have no adequate remedy at law for the Defendants' violation of their rights. Plaintiffs will be irreparably harmed by Defendants' unlawful discrimination by being unable to obtain necessary medical care.

173. Declaratory and injunctive relief are required to define Plaintiffs' rights under section 1311, to remedy the Defendants' violation of section 1311 of the Affordable Care Act, and to secure ongoing compliance with the antidiscrimination provisions of the Affordable Care Act.

FOURTH CLAIM FOR RELIEF - AS TO THE PLAINTIFF CLASS
(Violation of the Guaranteed Availability requirements of section 2702 of the Public Health Service Act)

174. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

175. Defendants offer health insurance coverage in the individual and group markets of Louisiana.

176. By engaging in discriminatory marketing practices prohibited by section 1311 of the Affordable Care Act, Defendants refused to accept each individual in Louisiana who applied for coverage and thus violated the guaranteed availability requirements of section 2702 of the Public Health Service Act (42 U.S.C. § 300gg-1), as amended by section 1201 of the Affordable Care Act.

177. Defendants' refusal to accept Ryan White Funds is a "marketing practice[] . . . that [has] the effect of discouraging the enrollment in [Defendants' insurance plans] by individuals with significant health needs," namely individuals with HIV or AIDS.

178. Plaintiffs have been aggrieved by this violation of section 2702 of the Public Health Service Act and have no adequate remedy at law for the Defendants' violation of their rights. Plaintiffs will be irreparably harmed by Defendants' unlawful discrimination by being unable to obtain necessary medical care.

179. Declaratory and injunctive relief are required to define Plaintiffs' rights under section 1311, to remedy the Defendants' violation of section 2702 of the Public Health Service Act, and to secure ongoing compliance with the antidiscrimination provisions of the Affordable Care Act.

FIFTH CLAIM FOR RELIEF- AS TO THE PLAINTIFF CLASS
(Equitable Estoppel)

180. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

181. Defendants have, by their words and conduct, long represented that they will receive and accept Ryan White Funds as payment for health insurance premiums and that those payments will be treated no differently than any other health insurance premium payments.

182. Insured Plaintiffs have justifiably relied on Defendants' policy and custom of accepting Ryan White Funds.

183. Insured Plaintiffs have maintained, renewed, or applied for health insurance policies offered by Defendants, and have forborn from making alternative arrangements based on their justifiable reliance induced by Defendants.

184. As a result of Defendants' abrupt change in position that Defendants now will not accept Ryan White Funds, Insured Plaintiffs have been aggrieved, and have been and will continue to be irreparably harmed by being unable to obtain necessary medical care and medications.

185. Injunctive relief is required to equitably estop Defendants from changing their longstanding policy of accepting Ryan White Funds.

SIXTH CLAIM FOR RELIEF- AS TO INSURED PLAINTIFFS
(Breach of Contract)

186. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

187. A valid insurance contract exists between BCBS and Plaintiff John East, and exists or has existed as well as between one of more Defendants and all other Insured Plaintiffs.

188. Defendants are under an obligation to provide health insurance coverage to Insured Plaintiffs in exchange for receiving health insurance policy premium payments.

189. Plaintiff John East and Insured Plaintiffs have performed all the obligations required of them under their policies, and remain ready, willing, and able to continue performing, including allowing the continued payment of their health insurance premiums.

190. Any term in Insured Plaintiffs' insurance policy with Defendants relating to the refusal of third party payments is waived and modified by Defendants' past conduct.

191. Unfairly discriminating against individuals with like insuring risk in the terms or conditions of any insurance contract violates the Louisiana Insurance Code, including without limitation, section 22:1964(7)(c) and section 22:34.

192. Any term in Insured Plaintiffs' insurance policy with Defendants relating to the refusal of third party payments is void as against Louisiana public policy and must be read out of any insurance policy, rider, or endorsement issued by Defendants, pursuant to the Louisiana Insurance Code section 22:861(4) and section 22:880.

193. Defendants breached their contractual obligations by refusing to accept premium payments on Insured Plaintiffs' accounts, whether received from the Ryan White HIV/AIDS Program (via the Louisiana Health Insurance Program or the HIV/AIDS Alliance) or otherwise.

194. Defendants' refusal to accept Insured Plaintiffs' premium payments constitutes a unilateral repudiation of Defendants' contractual obligations to cover Insured Plaintiffs during the policy term so long as premium payments are made.

195. As a result of Defendants' breach of their agreement to provide health insurance coverage, Insured Plaintiffs have been aggrieved, and have been and will continue to be irreparably harmed by being unable to obtain necessary medical care and medicine.

196. Monetary damages are not adequate to remedy Defendants' breach of their contractual obligations.

197. Declaratory and injunctive relief are required to define Plaintiffs' rights under their insurance policies and to require specific performance by Defendants of their vital contractual obligations.

SEVENTH CLAIM FOR RELIEF- AS TO INSURED PLAINTIFFS
(Breach of the Duty of Good Faith and Fair Dealing)

198. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

199. Defendants owe a duty of good faith and fair dealing to Insured Plaintiffs, their insureds.

200. Defendants have breached their duties of good faith and fair dealing not to discriminate against individuals with like insuring risk in the terms or conditions of any insurance contract, pursuant to the Louisiana Insurance Code section 22:1964(7)(c) and section 22:34.

201. Defendants have breached their duties of good faith and fair dealing not to misrepresent to Insured Plaintiffs over a period of time that they would accept premium payments to induce Insured Plaintiffs to continue choosing Defendants' health insurance coverage when Defendants knew they later would not accept such payments, pursuant to the Louisiana Insurance Code section 22:1964(14)(a).

202. As a result of Defendants' breaches of their duties of good faith and fair dealing, Insured Plaintiffs have been aggrieved, and have been and will continue to be irreparably harmed by being unable to obtain necessary medical care and medicine.

203. Declaratory and injunctive relief are required to enjoin Defendants from their continued and ongoing breaches of their duties not to discriminate and not to mislead Insured Plaintiffs.

EIGHTH CLAIM FOR RELIEF - AS TO INSURED PLAINTIFFS
(Negligent Misrepresentation)

204. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

205. Defendants owe a duty of care to Insured Plaintiffs, their insured.

206. Defendants have a pecuniary interest in their relationship with Insured Plaintiffs insured by Defendants.

207. Defendants have long represented, for the guidance of Insured Plaintiffs, that Defendants will receive and accept Ryan White Funds as payment for health insurance premiums and that those payments will be treated no differently than any other health insurance premium payments.

208. Defendants carelessly maintained that guidance even after including in some of their insurance policies terms relating to the refusal of third party payments, continuing to induce Insured Plaintiffs' reliance in maintaining and applying for Defendants' health insurance plans.

209. Defendants carelessly maintained that guidance even immediately before Defendants announced their refusal to accept Ryan White Funds, continuing to induce Insured Plaintiffs' reliance in maintaining and applying for Defendants' health insurance plans.

210. Insured Plaintiffs justifiably relied on Defendants' policy and custom of accepting Ryan White Funds.

211. Insured Plaintiffs have maintained, renewed, or applied for health insurance policies offered by Defendants, and have forborn from making alternative arrangements based on their justifiable reliance induced by Defendants.

212. As a result of Defendants' longstanding practice of accepting Ryan White Funds followed by Defendants' abrupt change in position, Defendants breached their duty of care to

Insured Plaintiffs and Insured Plaintiffs have been aggrieved, and have been and will continue to be irreparably harmed by being unable to obtain necessary medical care and medicine.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the Court to enter an Order

(a) Certifying the proposed class and subclasses of Plaintiffs;

(b) With respect to the class:

(i) Enjoining Defendants from changing their policy of accepting Ryan White HIV/AIDS Program funds from current or prospective applicants to, or policy holders of, Defendants' health insurance plans;

(ii) Enjoining Defendants from implementing or executing their new policy of refusing Ryan White HIV/AIDS Program funds from current or prospective applicants to, or policy holders of, Defendants' health insurance plans; and

(iii) Declaring that Defendants' actions described above constitute discrimination in violation of section 1557 of the Affordable Care Act;

(iv) Estopping Defendants from taking the position of refusing to accept Ryan White HIV/AIDS Program funds for Plaintiffs' health insurance premium payments; and

(c) With respect to the subclass of Insured Plaintiffs:

(i) Requiring specific performance by Defendants of their contractual obligations to accept Ryan White HIV/AIDS Program premium payments from Plaintiffs currently insured by Defendants, and to maintain coverage so long as such premium payments are received;

(ii) Declaring that Defendants' actions described above constitute unfair discrimination in violation of Louisiana Revised Statute section 22:1964(7) and is therefore void pursuant to Louisiana Revised Statute 22:861(4) and section 22:880;

(iii) Declaring that Defendants' actions described above constitute a breach of Defendants' contractual obligations to Plaintiffs currently insured by Defendants;

(iv) Declaring that Defendants' actions described above constitute a breach of Defendants' duty of good faith and fair dealing to Plaintiffs currently insured by Defendants;

(d) Awarding reasonable attorneys' fees and costs; and

(e) Awarding other equitable and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs request a trial by jury on all issues so triable.

Respectfully submitted,

Dated: February 20, 2014

/s/ Harry Rosenberg

ROPES & GRAY LLP
Jeffrey J. Bushofsky (*pro hac vice pending*)
Timothy R. Farrell (*pro hac vice pending*)
191 North Wacker Drive, 32nd Floor
Chicago, IL 60606
Telephone: (312) 845-1200
Facsimile: (312) 845-5500
E-mail: jeffrey.bushofsky@ropesgray.com

-AND-

ROPES & GRAY LLP
Amanda R. Phillips (*pro hac vice pending*)
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
Telephone: (617) 951-7000
Facsimile: (617) 951-7050
E-mail: amanda.phillips@ropesgray.com

-AND-

ROPES & GRAY LLP
Anthony C. Biagioli (*pro hac vice pending*)
One Metro Center
700 12th Street, NW, Suite 900
Washington, DC 20005-3948
Telephone: (202) 508-4776
Facsimile: (202) 508-4650
Email: anthony.biagioli@ropesgray.com

-AND-

LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
Scott A. Schoettes (*pro hac vice pending*)
Kenneth D. Upton (*pro hac vice pending*)
Susan L. Sommer (*pro hac vice pending*)
120 Wall Street, 19th Floor
New York, NY 10005-3904
Telephone: (212) 809-8585
Facsimile: (212) 809-0055
E-mail:
sschoettes@lambdalegal.org

kupton@lambdalegal.org
ssommer@lambdalegal.org

-AND-

PHELPS DUNBAR LLP
Harry Rosenberg (Bar No. 11465)
Bryan Edward Bowdler (Bar No. 32097)
365 Canal Street, Suite 2000
New Orleans, LA 70130
Telephone: (504) 584-9219
Facsimile: (504) 568-9130
E-mail: harry.rosenberg@phelps.com
bryan.bowdler@phelps.com

Attorneys for Plaintiff John East and all others similarly situated

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

John East, individually and on behalf of all other persons similarly situated

(b) County of Residence of First Listed Plaintiff Orleans Parish
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
See attached.

DEFENDANTS

Blue Cross and Blue Shield of Louisiana, Louisiana Health Cooperative, Inc., and Vantage Health Plan, Inc.

County of Residence of First Listed Defendant East Baton Rouge Parish
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ❒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
42 U.S.C. 18116(a) and 18031

Brief description of cause:
Injunctive and declaratory relief to halt Defendants' abrupt and systematic policy of discrimination based on Plaintiffs' disability

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
02/20/2014

SIGNATURE OF ATTORNEY OF RECORD
/s/Harry Rosenberg

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

Print Save As... Reset

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

ATTACHMENT TO CIVIL COVER SHEET

Section I.
Attorneys representing Plaintiffs

Harry Rosenberg (#11465)
Bryan Edward Bowdler (#32097)
Phelps Dunbar, LLP
365 Canal Street, Suite 2000
New Orleans, LA 70130-6534
Telephone: (504) 566-1311
Telecopier: (504) 568-9130
harry.rosenberg@phelps.com
bryan.bowdler@phelps.com

-AND-

ROPES & GRAY LLP
Jeffrey J. Bushofsky (*pro hac vice pending*)
Timothy R. Farrell (*pro hac vice pending*)
191 North Wacker Drive, 32nd Floor
Chicago, IL 60606
Telephone: (312) 845-1200
Facsimile: (312) 845-5500
E-mail: jeffrey.bushofsky@ropesgray.com

-AND-

ROPES & Gray LLP
Amanda R. Phillips (*pro hac vice pending*)
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
Telephone: (617) 951-7000
Facsimile: (617) 951-7050
E-mail: amanda.phillips@ropesgray.com

-AND-

Ropes & GRAY LLP
Anthony C. Biagioli (*pro hac vice pending*)
One Metro Center
700 12th Street, NW, Suite 900
Washington, DC 20005-3948
Telephone: (202) 508-4776
Facsimile: (202) 508-4650
Email: anthony.biagioli@ropesgray.com

-AND-

LAMBDA Legal DEFENSE AND EDUCATION FUND, INC.
Scott A. Schoettes (*pro hac vice pending*)
Kenneth D. Upton (*pro hac vice pending*)
Susan L. Sommer (*pro hac vice pending*)
120 Wall Street, 19th Floor
New York, NY 10005-3904
Telephone: (212) 809-8585
Facsimile: (212) 809-0055
E-mail: sschoettes@lambdalegal.org
kupton@lambdalegal.org
ssommer@lambdalegal.org

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Louisiana

JOHN EAST, individually and on behalf of all persons similarly situated,

Plaintiff(s)

v.

BLUE CROSS and BLUE SHIELD of LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BLUE CROSS AND BLUE SHIELD OF LOUISIANA
c/o Its Registered Agent For Service of Process
Michele S. Calandro
5525 Reitz Avenue
Baton Rouge, LA 70809

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Harry Rosenberg
Bryan Edward Bowdler
Phelps Dunbar LLP
365 Canal Street, Suite 2000
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Louisiana

JOHN EAST, individually and on behalf of all persons similarly situated,

Plaintiff(s)

v.

BLUE CROSS and BLUE SHIELD of LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* LOUISIANA HEALTH COOPERATIVE, INC.
c/o Its Registered Agent For Service of Process
Rudolph R. Ramelli, Esq.
Jones Walker Waechter Poitevent Carrere & Denegre
201 St. Charles Avenue, Suite 5100
New Orleans, LA 70170

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Harry Rosenberg
Bryan Edward Bowdler
Phelps Dunbar LLP
365 Canal Street, Suite 2000
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Louisiana

JOHN EAST, individually and on behalf of all persons similarly situated,

Plaintiff(s)

v.

BLUE CROSS and BLUE SHIELD of LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* VANTAGE HEALTH PLAN, INC.
c/o Its Registered Agent For Service of Process
Robert Bozeman
130 Desiard Street, Suite 300
Monroe, LA 71201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Harry Rosenberg
Bryan Edward Bowdler
Phelps Dunbar LLP
365 Canal Street, Suite 2000
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

EXHIBIT 3

[Names and addresses of Requestors have been redacted]

Re: Advisory Opinion No. 97-1

Dear [Names have been redacted]:

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

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

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

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

I. FACTUAL BACKGROUND

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

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

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

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

B. Parties to the Proposed Arrangement

1. The Companies

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

2. American Kidney Fund

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

---

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

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

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

C. Health Insurance Premium Program

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

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

---

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

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

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

D. The Proposed Arrangement

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

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

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

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

II. LEGAL ANALYSIS

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

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

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

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

A. Donations By The Companies Do Not Constitute

---

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

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

Remuneration To An Eligible Beneficiary

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

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

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

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

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

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

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

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

III. LIMITATIONS

The limitations applicable to this opinion include the following:

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

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

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

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

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

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

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

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

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

Sincerely,

/S/

D. McCarty Thornton
Chief Counsel to the Inspector General

EXHIBIT 4

blue of california

August 29, 2016

Subject: **Notification of November 7, 2016 Updates to the Blue Shield *Hospital and Facility Guidelines***

Dear Provider:

We have revised our *Hospital and Facility Guidelines*. The changes listed on the following pages are effective November 7, 2016.

On that date, you can search and download the revised manual on Provider Connection at www.blueshieldca.com/provider in the *Provider Manuals* section under the *Guidelines & Resources* tab.

The *Hospital and Facility Guidelines* is referenced in the agreement between Blue Shield of California (Blue Shield) and the hospitals and other facilities contracted with Blue Shield. If a conflict arises between the *Hospital and Facility Guidelines* and the agreement held by the hospital or other facility and Blue Shield, the agreement prevails.

If you have any questions regarding this notice about the revisions that will be published in the November 7, 2016 version of this manual, please contact your Blue Shield Provider Relations Coordinator.

Sincerely,

Network Management
Blue Shield of California

UPDATES TO THE *HOSPITAL AND FACILITY GUIDELINES*

Section 1: Introduction

ENROLLMENT AND ELIGIBILITY

Added *the following new section regarding member premium payments:*

Premium Payment Policy

The member is responsible for payment of premiums to Blue Shield. Blue Shield does not accept direct or indirect payments of premiums from any person or entity other than the member, his or her family members or a legal guardian, or an acceptable third party payor, which are:

- Ryan White HIV/AIDS programs under Title XXVI of the Public Health Services Act;
- Indian tribes, tribal organizations or urban Indian organizations;
- A lawful local, State, or Federal government program, including a grantee directed by a government program to make payments on its behalf; and
- Bona fide charitable organizations and organizations related to the member (*e.g.*, church or employer) when all of the following criteria are met: payment of premiums is guaranteed for the entire plan year; assistance is provided based on defined financial status criteria and health status is not considered; the organization is unaffiliated with a healthcare provider; and the organization has no financial interest in the payment of a health plan claim. (Financially interested institutions/organizations include institutions/organizations that receive the majority of their funding from entities with a financial interest in the payment of health insurance claims, or institutions/organizations that are subject to direct or indirect control of entities with a financial interest in the payment of health insurance claims.)

Upon discovery that premiums were paid directly or indirectly by a person or entity other than the member or an acceptable third party payor, Blue Shield has the right to reject the payment and inform the member that the payment was not accepted and that the premiums remain due. Payment of member premiums by a Blue Shield contracted provider represents a material breach of the provider's agreement. Please note that processing any payment does not waive Blue Shield's right to reject that payment and future payments under this policy.

EXHIBIT 5

*Insurers block Obamacare coverage *** Move affects poor HIV/AIDS patients*

The Advocate (Baton Rouge, Louisiana)

February 13, 2014 Thursday, Main Edition

Section: B; Pg. 08

Length: 1035 words

Byline: TED GRIGGS

tgriggs@theadvocate.com

Body

Close to 2,000 poor Louisiana residents with HIV/AIDS won't be able to buy coverage under Obamacare because three of the four companies in the state offering coverage through the federal insurance exchange won't accept payments from a federal program that helps those patients pay their premiums.

The fourth company, Humana, accepts third-party payments from state and federal programs or grantees such as the Ryan White HIV/AIDS Program, spokesman Mitchell Lubitz said. However, Humana's offerings through the Obamacare marketplace are only available in Orleans Parish.

Scott Schoettes, HIV project director at Lambda Legal, said the insurance companies' actions completely defeat the purpose of the Affordable Care Act.

Schoettes said it's not surprising that other insurers respond when Blue Cross and Blue Shield of Louisiana, the state's largest insurer, skews the market by denying coverage to people the company knows have significant health needs. The other insurers will take whatever actions they can to avoid having those patients pushed onto their rolls, he said.

In the business, enrolling a disproportionately high percentage of high-cost individuals is known as "adverse selection."

Billy Justice, a spokesman for Vantage Health Plan in Monroe, said smaller health insurance companies have no choice but to follow Blue Cross's lead.

Eric Evans, advocacy coordinator at Shreveport's Philadelphia Center, said the Louisiana Health Cooperative has already informed some center clients the co-op will not accept third-party payments.

Officials with the cooperative could not be reached for comment.

Blue Cross spokesman John Maginnis said beginning March 1, the company will not accept third-party payments for individual members' premiums.

Blue Cross covers 1.4 million people in Louisiana, the vast majority through group policies. Only 139,000 are covered by individual policies.

Third-party payment recipients are a very small percentage of the company's individual policies, which are a very small percentage of the company's total business, Maginnis said.

"We realize that some organizations have directly paid premiums for members in the past .... Those organizations can still provide the members with financial support toward their premiums, but they must let the members make the premium payments directly for their health insurance policies," Maginnis said.

For example, the groups that now make the third-party payments could make grants to their clients, who could then use that money to pay health care premiums, he said.

The federal Health Resources and Services Administration, which oversees the Ryan White program, does not allow states, cities and nonprofits who receive funding to make payments to individuals.

"In no case may Ryan White HIV/AIDS Program funds be used to make direct payments of cash to recipients of services," the agency website says.

Maginnis said Blue Cross, which is the only insurer fully participating in the federal marketplace with plans at every level in every parish, developed the policy to prevent patient steering and other fraudulent activity.

Some providers and medical equipment suppliers will steer people to specific health plans and offer to pay the premiums so they can make more money by billing the insurance company for those patients' covered services, Maginnis said. This kind of activity can increase health care costs for everyone.

The insurer's policy affects more people than those receiving Ryan White funding, he said. Some Louisiana universities pay for student athletes' premiums.

LSU spokesman Michael Bonnete said Blue Cross's policy change does not affect LSU athletics.

According to the state Department of Health and Hospitals, as of Jan. 7, Louisiana used Ryan White funds to pay the insurance premiums for 1,355 people. An additional 493 were enrolled in the federally run Pre-Existing Condition Insurance Plan, which will stop offering coverage on March 31.

In addition, 329 individuals attempted to enroll in Blue Cross's Blue Plan with the intention of covering the premiums with Ryan White funds, according to DHH.

Schoettes said it's increasingly clear that Blue Cross is trying to avoid covering these high-cost patients.

The company made noises about preventing fraud or abuse, but CMS's most recent instructions make it clear third-party payments coming from the federal government are acceptable, he said.

Evans said the issue is much larger than rejecting third-party payments.

"This is them saying, 'We really don't want to insure people with HIV because there's no profit in it,'" Evans said.

The prescriptions for an HIV patient can cost $5,000 or $10,000 a month, Evans said. Those costs far outweigh the premiums patients pay, but insurance companies have known about this for decades.

America's Health Insurance Plans recently issued a brief noting: "The ACA's risk adjustment program is designed to spread risk among health plans to prevent problems associated with adverse selection. Under this program, health plans that enroll disproportionately higher risk populations (such as individuals with chronic conditions) will receive payments from plans that enroll lower risk populations."

People forget that the first two words in the Affordable Care Act's full title are "Patient Protection," Evans said. The law was designed to stop insurance companies from discriminating against people with pre-existing conditions.

Schoettes said Lambda is considering amending its complaint to include the other insurers who reject third-party payments.

The nonprofit group may also file a lawsuit, among other steps, if the complaint doesn't achieve the desired result, he said. Lambda hasn't set a deadline to file the lawsuit.

"Sooner rather than later because every day that goes by is another day where low-income people living with HIV don't know where to turn and don't know where they're going to get their insurance," Schoettes said.

Evans said the scary thing is that the full impact of Blue Cross's decision won't be seen until after March 1, just weeks before the Affordable Care Act open enrollment deadline of March 31.

"Then what are these people going to do for the next year?" Evans said. "It's very frustrating and very angering."

Classification

Language: ENGLISH

Publication-Type: Newspaper

Subject: AIDS & HIV (90%); AIDS & HIV POLICY (89%); ASSOCIATIONS & ORGANIZATIONS (89%); OBAMA HEALTH CARE REFORM (78%); NONPROFIT ORGANIZATIONS (78%)

Company: ANTHEM BLUE CROSS & BLUE SHIELD OF OHIO (83%)

Industry: INSURANCE (92%); HEALTH INSURANCE (90%); HEALTH INSURANCE MARKETPLACE (90%); INSURANCE POLICIES (89%); AIDS & HIV POLICY (89%); INSURANCE PREMIUMS (89%); OBAMA HEALTH CARE REFORM (78%); GOVERNMENT HEALTH INSURANCE (77%); HEALTH CARE (77%); DENIAL OF INSURANCE COVERAGE (72%)

Geographic: SHREVEPORT, LA, USA (79%); LOUISIANA, USA (94%)

Load-Date: February 26, 2014

End of Document

EXHIBIT 3

[Names and addresses of Requestors have been redacted]

Re: Advisory Opinion No. 97-1

Dear [Names have been redacted]:

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

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

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

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

I. FACTUAL BACKGROUND

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

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

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

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

B. Parties to the Proposed Arrangement

1. The Companies

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

2. American Kidney Fund

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

---

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

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

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

C. Health Insurance Premium Program

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

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

---

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

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

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

D. The Proposed Arrangement

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

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

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

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

II. LEGAL ANALYSIS

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

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

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

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

A. Donations By The Companies Do Not Constitute

---

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

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

Remuneration To An Eligible Beneficiary

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

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

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

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

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

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

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

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

III. LIMITATIONS

The limitations applicable to this opinion include the following:

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

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

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

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

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

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

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

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

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

Sincerely,

/S/

D. McCarty Thornton
Chief Counsel to the Inspector General

EXHIBIT 4

V. Proposed Action

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

VI. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

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

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

Dated: August 9, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

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

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 402, 420, and, 455

[CMS–6074–NC]

RIN 0938–ZB31

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

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

ACTION: Request for information.

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

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

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

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–*6074*–NC, P.O. Box 8010, Baltimore, MD 21244–*8010.*

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

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

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

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

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

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

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

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

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

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

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

I. Background

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

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

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

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

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

[3] 45 CFR 155.210.

[4] 45 CFR 155.220.

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

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

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

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

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

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

II. Solicitation of Comments

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

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

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

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

[8] 2017 HHS Payment Notice Final Rule.

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

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

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

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

III. Collection of Information Requirements

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

Dated: August 16, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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

BILLING CODE 4120–01–P

EXHIBIT 5

September 22, 2016

BY ELECTRONIC SUBMISSION

Attn: Andrew M. Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201
http://www.regulations.gov

Re: U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans, RIN 0938-ZB31 (File Code: CMS-6074-NC) (referred to herein as the RFI)

Dear Mr. Slavitt:

Fresenius Medical Care North America (FMCNA) appreciates the opportunity to respond to CMS' Request for Information (RFI). Our patient populations include 187,000 end-stage renal disease (ESRD) patients, who comprise ~.06% of the general population and ~.33% of the Medicare population. Patients with ESRD are a vulnerable patient population that needs the protections of the Affordable Care Act (ACA) and access to the individual market exchanges (Marketplaces). With the enactment of the ACA, formerly underinsured and uninsured patients like ours are now provided a choice of health insurance coverage options for the first time in history. In 2013, CMS and Internal Revenue Service (IRS) determined that dialysis patients would have the option to enroll in Marketplace plans even if eligible for Medicare or Medicaid coverage. Approximately 1,600 (fewer than 1%) of our patients have opted for Marketplace coverage. We explain below our understanding of the reasons why patients make this choice. For instance, for chronically ill patients who have co-morbidities and a high utilization of healthcare services, they may be able to reduce their personal, annual out-of-pocket costs of care by $8,000 or more by selecting Marketplace coverage rather than Medicare. The reason for this differential is that Marketplace plans offer out-of-pocket caps on deductibles and co-pays, while Medicare coverage does not. Choice of coverage requires complex and individualized analysis, and it simply is not the case that Medicare coverage is always the best choice for the patient.

FMCNA does not engage in steering. Our role is to educate the patient so that the patient can choose coverage options. Our education aims to identify choices that are in the patient's best interest. Under the Conditions for Coverage under which we operate, we are required to provide counseling to patients by (a) "providing information and helping patients apply for Medicare, Medicaid and other insurance

benefits to assure payment for care,"[1] and (b) evaluating "financial capabilities and resources; access to available community resources; and eligibility for federal, state, or local resources".[2] FMCNA discharges these obligations by providing such counseling and education in a manner that is consistent with the best interests of the patients.[3] FMCNA does not steer patients to any particular type of coverage choice. Instead, we help optimize patients' ability to make informed choices through education and counseling.

FMCNA has worked with the American Kidney Fund (AKF) for twenty years to provide our patients with access to the AKF's Health Insurance Premium Program ("HIPP").[4] The AKF is an independent charitable organization that enables dialysis patients to afford the coverage of their choice, based solely on financial need. The AKF provides premium support on a first-come, first-served basis without regard to the patient's selection of provider or type of health insurance coverage, and it funds premium payments according to the patient's choice of coverage, including Medicare Part B, Medigap, Medicare Advantage, employer group health plans, and Marketplace plans. Over 75% of our patients who receive AKF premium grants use those grants to pay for government-program related health insurance coverage (including Medicare, Medigap, and Medicare Advantage). As noted, less than 1% of our patients are on Marketplace plans. Fewer still, approximately 700, or four-tenths of one percent (0.4%) of our patient population, receive AKF premium assistance for their Marketplace plan premiums.

While we do not steer patients to particular health insurance plans, we are aware of insurers who do. We are concerned that insurers are increasingly deploying inappropriate tactics to steer patients away from Marketplaces with the effect of restricting consumer choice and access to care, discriminating against patients in violation of the ADA and other statutes, and creating a backdoor means to impose pre-existing condition exclusions contrary to the goals of the ACA and the Marketplaces. CMS is correct to focus on inappropriate steering, but the steering issue needs to be evaluated from *both* the provider and insurer perspectives.

We would like to work cooperatively with CMS and all industry participants to restore balance and stability throughout the healthcare system by assuring that

---

[1] ESRD Surveyor Training, Interpretive Guidance Final Version I.1 (Oct. 2008), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-certification/guidanceforlawsandregulations/dailysis.html (hereinafter "Interpretive Guidance") (interpreting 42 C.F.R. §494.140(d)).

[2] Interpretive Guidance (interpreting 42 C.F.R. § 494.80(a)(7)).

[3] Under the Conditions for Coverage, dialysis providers are required to recognize the individualized and personal needs, wishes and goals of the patient and to honor the patient's right to be informed about and participate in all aspects of care. *See* 42 C.F.R. § 494.70 and § 494.80 and the interpretive guidance issued thereunder.

[4] The Office of Inspector General reviewed and approved the HIPP program and its safeguards against fraud and abuse in 1997, in OIG Advisory Opinion 97-1.

there are adequate means to address any unscrupulous steering practices and by adopting clear guardrails to allow charities like the AKF to continue to pursue the charitable mission of assuring patient choice and access through premium grants.

I. Dialysis patients face challenging clinical and socioeconomic conditions, and they need and deserve the ability to choose the health insurance options that suits their individual circumstances.

A. Dialysis patients are predominantly disabled, low-income and poorly educated.

An ESRD patient must navigate multiple issues including health coverage, co-payments and co-insurance, interaction with multiple physician specialists, management of multiple co-morbidities and multiple medications,[5] and balancing medical appointments and dialysis treatments with the normal affairs of life. Due to their disability and chronic illness, dialysis patients face serious challenges in balancing these competing needs. Adding to these challenges, this predominately disabled patient population is disproportionately concentrated in disadvantaged communities associated with low-incomes[6] and reduced educational opportunities.[7]

---

[5] The typical patient with ESRD typically takes 7 – 10 medications per month. Jai Radhakrishnan, "The burden of prescription coverage of kidney failure patients in the United States," Kidney International (2006) 69, 1099 – 1100.

[6] The relationship between an individual's socioeconomic characteristics and ESRD diagnosis is well documented. Multiple studies show that low-income status is strongly correlated with a patient's heightened risk of developing ESRD. In one study, low-income individuals, defined as persons earning less than $15,000, were associated with a 50% increased risk of ESRD. *See* Lipworth L., Mumma M.T., Cavanaugh K.L., et al: Incidence and predictors of end-stage renal disease among low-income blacks and whites. PLoS One 2012; 7: pp. e48407. In another, researchers found that "neighborhood poverty was strongly associated with ESRD incidence in both blacks and whites." Volkova, Nataliya et al. "Neighborhood Poverty and Racial Differences in ESRD Incidence." *Journal of the American Society of Nephrology : JASN* 19.2 (2008): 356–364. *PMC.* Web. 6 Sept. 2016.

[7] Research has shown that dialysis patients are widely lacking in "health literacy," which is defined as the "ability to obtain, process, and understand basic health information to make appropriate health decisions about one's health and medical care." *See* Nielsen-Bohlman LT, Panzer AM, Hamlin B, Kindig DA, editors. (Eds.): Health Literacy: A Prescription to End Confusion, Washington DC, Committee on Health Literacy, Board on Neuroscience and Behavioral Health, National Academies Press, 2004. One study concluded that limited health literacy among dialysis patients is associated with a higher risk of death. *See* Cavanaugh, Kerri L. et al. "Low Health Literacy Associates with Increased Mortality in ESRD." *Journal of the American Society of Nephrology : JASN*21.11 (2010): 1979–1985. *PMC.* Web. 13 Sept. 2016. The researchers noted that although print materials are commonly used to educate dialysis patients on their condition, these materials are often written at high reading levels and therefore are potentially ineffective at achieving their purpose. *See id.*

B. The Conditions for Coverage require dialysis providers to assist patients with understanding the financial and insurance aspects of their care.

The Conditions for Coverage[8] applicable to dialysis providers set forth an array of requirements for dialysis facilities, including substantial obligations to provide holistic counseling services designed to treat the whole patient, and not merely the patient's ESRD. For example, dialysis providers must convene an "interdisciplinary team" to undertake "comprehensive assessment" of patient needs, including "psychosocial needs," "evaluation of the patient's abilities, interests, preferences, and goals," and "evaluation of family and other support systems."[9] This assessment informs an "individualized comprehensive plan of care that specifies the services necessary to address the patient's needs," including monitoring "psychosocial status" and providing "necessary monitoring and social work interventions to assist the patient in achieving and sustaining an appropriate psychosocial status."[10] In Appendix H of the State Operations Manual, CMS notes that one obligation of this assessment is for the dialysis facility to "identify community social agencies and other resources and assisting patients and families to utilize them."[11] As discussed more fully below, the American Kidney Fund is one such option.

The interpretive guidance for the Conditions for Coverage further elaborates that dialysis providers must "provide services such as . . . providing information and helping patients apply for Medicare, Medicaid and other insurance benefits to assure payment for care".[12] They must also evaluate "financial capabilities and resources; access to available community resources; and eligibility for federal, state, or local resources[13]," and "make good faith efforts to help the patient resolve nonpayment issues" prior to discharge or transfer for nonpayment of fees[14]. The guiding principle in providing these services is that the provider should act in the best interest of the patient.[15]

Because many dialysis patients do not have strong networks of social, financial and other supports when undertaking treatment, providers like FMCNA

---

[8] 42 C.F.R. § 494 et seq. *See also* 73 Fed. Reg. 20370, Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities, Centers for Medicare and Medicaid Services, April 15, 2008.

[9] 42 C.F.R. § 494.80(a).

[10] 42 C.F.R. § 494.90(a)(6).

[11] State Operations Manual Appendix H, Tags V-447 and 493.

[12] Interpretive Guidance (interpreting 42 C.F.R. §494.140(d)).

[13] Interpretive Guidance (interpreting 42 C.F.R. § 494.80(a)(7)).

[14] Interpretive Guidance (interpreting 42 C.F.R. 494.180(f)(1)).

[15] *See e.g.,* 42 C.F.R. § 494.80.

play a comprehensive role under the Conditions for Coverage requirements in patients' care, including informing patients as to the financial and insurance aspects of that care. FMCNA takes these obligations seriously, and is guided by its core value of putting patients' interests first.

C. Because of the ACA and prior legislative enactments, individuals with ESRD have multiple health coverage options, including both government-sponsored and commercial coverage.

1. Individuals with ESRD who qualify for Medicare have the option to enroll in Medicare or in Marketplace plans, and they may also qualify for premium tax credits under the Marketplace plans.

Although most dialysis patients are eligible for Medicare, dialysis patients are not required to choose Medicare as their only health insurance option.[16] FMCNA strongly supports this position because it enhances patient choice.

Very early in the implementation of the ACA, policymakers considered whether individuals with ESRD could qualify for a Marketplace premium tax credit to purchase a plan on a Marketplace. While individuals generally cannot qualify for premium tax credits for a qualified health plan purchased on a Marketplace if they are "eligible for minimum essential coverage"[17] (such under Medicare),[18] both the Internal Revenue Service and CMS concluded in guidance issued before the ACA took effect that dialysis patients could enroll in Marketplace plans and be eligible for premium tax credits despite their Medicare eligibility. Noting the statutory requirement that individuals with ESRD must "file an application" to be entitled to Medicare and the need to determine the patient's ESRD diagnosis, the IRS concluded in IRS Notice 2013-41 that an individual was only eligible for minimum essential coverage (and therefore ineligible for premium tax credits) when the "responsible agency" had made a determination that the individual has a disability or a particular illness.[19] Because no such determination is made until the individual files an application for Medicare, individuals who might be entitled to Medicare had they applied may opt instead to enroll in a Marketplace plan and claim premium tax credits.

---

[16] *See* 42 U.S.C. §§ 18031(d)(2)(a), 18032(a)(1); 42 U.S.C. § 18032(f); 45 C.F.R. § 147.104; CMS, "Frequently Asked Questions Regarding Medicare and the Marketplace," Questions A.3, B.1 and B.2 (Aug. 1, 2014, last updated April 28, 2016).

[17] Internal Revenue Code § 36B(c)(2)(B)(i).

[18] *Id.* at § 5000A(f)(1)(A)(i).

[19] Internal Revenue Bulletin 2013-29, Notice 2013-41, C-2 (July 15, 2013), *available at* https://www.irs.gov/pub/irs-irbs/irb13-29.pdf.

CMS concurred with the IRS's interpretation. In a series of Frequently Asked Questions, CMS clarified that individuals with ESRD are not required to enroll in Medicare, that individuals with ESRD who do not have Medicare may enroll in a Marketplace plan, and that individuals with ESRD who do not have Medicare may qualify for a Marketplace premium tax credit.[20] Any final CMS policy on this issue that results from this RFI should, therefore, reaffirm that a dialysis patient who is eligible for, but not yet enrolled in, Medicare and who has made an informed choice to enroll in a Marketplace plan should be able to retain the coverage of his/her choice and not be forced into Medicare.

2. Individuals with ESRD who qualify for Medicaid have the option to enroll in Medicaid and/or Marketplace plans, and they may also qualify for premium tax credits under the Marketplace plans.

Similarly, those dialysis patients who are eligible for Medicaid are not required to enroll in Medicaid, and instead, may purchase Marketplace plan coverage.[21] Those who do purchase Marketplace plan coverage may or may not qualify for premium tax credits. In our patient population, very few dialysis patients choose Marketplace plan coverage over Medicaid – primarily, we think, because the total personal cost of care for most patients would be higher with Marketplace plan coverage.

The ACA created a new Medicaid eligibility category based solely on income.[22] Thirty-one states and the District of Columbia have adopted this category. In the remaining nineteen states, our dialysis patients must satisfy a low income test and also must demonstrate a categorical basis for Medicaid eligibility (e.g.,

---

[20] CMS, "Frequently Asked Questions Regarding Medicare and the Marketplace," Questions B-1, B-2 and B-3 (Aug. 1, 2014, last updated August 28, 2014), *available at* https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf.

[21] *See* 42 U.S.C. §§ 18031(d)(2)(a), 18032(a)(1) (requiring Marketplaces to make qualified health plans available to "qualified individuals," and providing that "[a] qualified individual may enroll in any qualified health plan available to such individual and for which such individual is eligible"; 42 U.S.C. § 18032(f) (defining "qualified individuals" without regard to eligibility for other health insurance coverage); 45 C.F.R. § 147.104 (guaranteeing the availability of Marketplace coverage); 45 C.F.R. § 155.310 (giving individuals applying for Marketplace coverage the right to decline an eligibility determination for Medicaid); CMS, State Health Official/State Medicaid Director Letter Re: Minimum Essential Coverage, SHO No. 14-002 (Nov. 7, 2014) (indicating that individuals eligible for certain forms of Medicaid coverage that qualify as minimum essential coverage are ineligible for premium tax credits but not suggesting that those individuals are barred from enrolling in Marketplace plans altogether), *available at* https://www.medicaid.gov/federal-policy-guidance/downloads/sho-14-002.pdf.

[22] *See* § U.S.C. 1902(a)(10)(A)(i)(VIII) (creating new category). *See also* NFIB v. Sebelius, 567 U.S. ___, 132 S. Ct. 2566 (2012) (holding that Medicaid expansion was optional for the states).

disability).[23] This difference plays out under the Marketplace rules in this manner: a dialysis patient who qualifies for Medicaid eligibility solely on the basis of income is considered eligible for minimum essential coverage, and as such, is ineligible for premium tax credits. To this patient, Marketplace coverage would likely be unattractive because the personal out-of-pocket costs to the patient would be much higher under the Marketplace plan.

By contrast, a dialysis patient who qualifies for Medicaid eligibility on the basis of meeting the low income test and the categorical test for disability ***is*** eligible for premium tax credits under the Marketplaces unless and until the patient applies for Medicaid coverage and is determined by the Medicaid program as meeting the categorical requirement.[24] Thus, many Medicaid eligible individuals (those that qualify through a disability category) remain eligible to enroll in Marketplace plans and receive federal Marketplace premium tax credits so long as they have not applied for Medicaid coverage.

Adding further complication for potential Medicaid enrollees, the IRS and CMS do not treat some forms of Medicaid coverage as minimum essential coverage even if an individual is actually enrolled in Medicaid. Relevant for ESRD patients, CMS has determined that coverage under the optional "medically needy" eligibility group is not sufficiently comprehensive in some states to qualify as minimum essential coverage, and that coverage in all states with this optional category is not minimum essential coverage for individuals who must "spend down" to be eligible.[25] Thus, premium tax credits are available for many patients in this optional eligibility group even if they actually enroll in Medicaid. Indeed, CMS has made clear that these individuals may enroll in both a qualified health plan and Medicaid, and has acknowledged that it may be in the best interest of the individual *not* to enroll solely in Medicaid, as doing so may violate the ACA's individual mandate and lead to penalties unless the individual is eligible for a hardship exemption.[26]

While a Medicaid-eligible patient may choose Medicaid as the best option, education about available coverage options is particularly critical for Medicaid eligible patients to be able to make an informed choice based on their individual circumstances. We strongly urge that any final CMS policy on this issue that results recognize the complexity in Medicaid coverage options and that there is not a "one

---

[23] *See* 42 U.S.C. § 1902(a)(10)(A)(i)(II)(bb).

[24] Internal Revenue Bulletin 2013-29, Notice 2013-41, C-2 (July 15, 2013). *See also* CMS, State Health Official/State Medicaid Director Letter RE: Minimum Essential Coverage, SHO NO. 14-002 (Nov. 7, 2014).

[25] CMS, Medicaid Secretary-Approved Minimum Essential Coverage (Feb. 16, 2016), *available at* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/downloads/state-mec-designations.pdf. *See also* CMS, State Health Official/State Medicaid Director Letter Re: Minimum Essential Coverage, SHO No. 14-002 (Nov. 7, 2014).

[26] *Id.*

size fits all" approach to health coverage. As a result, such guidance or regulations should not only unequivocally reinforce our obligation to educate patients about their coverage options, but also provide the flexibility so that each ESRD patient have same rights as other Americans to select the health coverage that makes the most sense for him or her.

II. The American Kidney Fund has a 19-year history of assisting dialysis patients with premium payments under guidance issued in 1997 by the Office of Inspector General.

A. The AKF's Health Insurance Premium Program advances patient choice and patient access.

Through HIPP, the AKF assists dialysis patients in paying health insurance premiums for Medicare, Medigap, Medicare Advantage, Marketplace and other commercial plan coverage. Less than one-half of one percent of our patients receive grant assistance from the AKF to fund Marketplace plan coverage.

The AKF's HIPP was designed based on guidance provided to the AKF by the Office of Inspector General (OIG) in "Advisory Opinion 97-1" (AO 97-1). Under this guidance, eligibility for HIPP assistance is available to *any* financially needy ESRD patient regardless of the patient's choice of dialysis provider and regardless of whether that provider supports the AKF through donations. While we and other dialysis providers make charitable contributions to AKF, we do not participate in their decisions to award patient grants in accordance with AO 97-1.

The OIG noted with approval HIPP's built-in safeguards to protect against inappropriate influence exerted by donors to HIPP. Donors contribute to HIPP on a voluntary basis and are not permitted to disclose to each other or other dialysis providers the amounts they contribute to AKF. Providers are prohibited from advertising the availability of possible financial assistance to the public. The OIG also noted that donors make their contributions unconditionally and without any guarantee or promise that "patients referred to AKF for possible financial assistance with their insurance premiums will receive such assistance."[27] Premium grants are awarded on a first-come, first-served basis regardless of the identity of the patient's dialysis provider to ensure that no provider may influence the selection of grantees.

The safeguards detailed in OIG's AO 97-1 for AKF's operation of HIPP have provided a structure that has enhanced patient choice for nearly two decades. The OIG's determination that HIPP was "not likely to influence patients to order or receive services from particular providers" was based on the program's robust internal firewalls to prevent fraud and abuse.[28] More importantly, HIPP supports

---

[27] Office of Inspector General, "Advisory Opinion No. 97-1," *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf.

[28] Furthermore, in a FAQ dated February 7, 2014, CMS expressly encouraged insurers to accept third-party payments from private, not-for-profit foundations made on behalf of QHP

patients' freedom to choose the health coverage that best suits their needs and does not in any way influence patients in making that choice.[29] As the OIG accurately observed in 1997, "AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice."[30] In ensuring that patients have health insurance options, the AKF's HIPP is aligned with the fundamental principles underlying the ACA.

B. FMCNA provides counseling to patients about potential premium assistance in accordance with OIG guidance and does not steer patients.

In discharging our obligations under the Conditions for Coverage, we offer our patients the assistance of a "financial coordinator" who is charged with assisting patients with the financial components of their care, including identifying all available sources of assistance for which they qualify. This may include assistance from HIPP. For patients who wish to apply for an AKF grant, the financial coordinator will assist the patient in completing the application after acquiring the necessary documentation, including a signed and dated consent form from the patient. The financial coordinator then submits the application for the patient utilizing the AKF Grant Management System. Providing this assistance is consistent with the conditions of participation imposed on dialysis providers by the CMS Conditions for Coverage.

In assisting patients who wish to apply for premium support, FMCNA has carefully adhered to the parameters delineated in AO 97-1 and complied with its obligations under the Conditions for Coverage. We prohibit advertising to the public about the availability of potential assistance through HIPP, prohibit disclosing directly or indirectly to patients our contributions to HIPP, and do not state or suggest that patients applying for HIPP will be guaranteed premium assistance or other financial support. In the interest of transparency, FMCNA publicly acknowledges that we make periodic donations to the AKF in support of HIPP. We also clearly state that our Corporate Finance Committee, which approves donations, does not track the amount of premium support that HIPP provides on behalf of patients dialyzing in our units for the purpose of determining the amount of FMCNA donations.

---

enrollees who satisfied defined criteria based on financial status without consideration to the enrollee's health; HIPP meets this criteria. *See* "Third Party Payments of Premiums for Qualified Health Plans in the Marketplace," Feb. 7, 2014, *available at* https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf.

[29] *See* "HIPP Guidelines August 2016," American Kidney Fund, *available at* http://www.kidneyfund.org/assets/pdf/financial-assistance/hipp-guidelines.pdf.

[30] Advisory Opinion No. 97-1.

III. FMCNA supports further analysis and safeguards against steering by both providers and insurers.

A. FMCNA has seen evidence of steering by insurers who are targeting dialysis patients in an effort to cancel their Marketplace plan or other commercial coverage.

FMCNA has growing concerns about steering by insurers as they deploy measures aimed at removing dialysis patients from their commercial plans without legal basis. These practices have created an effective "end run" around the prohibition on pre-existing condition exclusions enacted as part of the ACA[31] and threaten to undermine the consumer choice principles of the law.

Insurers in several states have informed patients with ESRD that they cannot use AKF grant funds to pay the premiums on their Marketplace plans. Many plans are requiring patients to sign attestations "under penalties of perjury" regarding the source of patient funds to pay premiums. They are holding premium payment checks written by the AKF until only a few days before policies may be cancelled for nonpayment of premium, and then notifying patients only days before cancellation that they will not accept AKF checks. By singling out a patient class with a particular diagnosis and telling those patients that they must use their own funds to purchase a health insurance plan they have chosen but cannot afford without help, insurers are effectively denying coverage to a patient based on a pre-existing medical condition – in direct contravention of the ACA. [32]

Insurers have also engaged in the practice of designing plan benefits to limit coverage for dialysis treatment in an effort to deprive dialysis patients of the value of their health insurance and to prompt them to drop commercial coverage. By way of example, numerous group health plans attempt to escape their responsibilities under the Medicare Secondary Payer statute, by designing plans that effectively exclude coverage for dialysis long before the end of the mandated coordination of benefits period.[33] Despite the fact that group health plans are required to provide

---

[31] 42 U.S.C. § 300gg-3(a). See also, *See* Remarks on the Patient Protection and Affordable Care Act, DAILY COMPILATION OF PRESIDENTIAL DOCUMENTS, (quoting President Obama: "uninsured Americans with a pre-existing condition ... will finally be able to purchase the coverage they need") (March 23, 2010), *available at* http://www.presidency.ucsb.edu/ws/index.php?pid=87658&st=&st1=.

[32] The ACA prohibits a health plan in the group or individual market from imposing "any pre-existing condition exclusion with respect to" the plan or coverage. A pre-existing condition exclusion, under the statute, is "a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage." *Id.* at § 2704(b)(1)(A). By refusing to accept the only means that a patient with ESRD has to afford their health insurance coverage, the plan has effectively denied coverage to the patient based on a condition that existed before the patient enrolled in coverage.

[33] Social Security Act § 1862(b)(1)(B)(ii); (b)(1)(C).

coverage under those plans to individuals who have ESRD for 30 months, health plans provide incentives to individuals with ESRD to switch their employer-based coverage to Medicare, and there are instances where group health plans change the benefit design of their plans as soon as an enrollee is diagnosed with ESRD, both in direct contravention of CMS regulations on these very issues.[34] Similarly, we are aware of Marketplace plans that reduce benefits to a percentage of Medicare after a specified number of treatments (usually 42 treatments) that get the patient through the three-month waiting period for Medicare coverage. The effect of these benefit designs is to move patients to Medicare and eliminate the Marketplace option. These practices are unfair and have a serious adverse impact on dialysis patients.

Although CMS has partially addressed third-party premium payments,[35] it has not clearly addressed the situation where a charitable organization makes a grant to a dialysis patient to assist that patient in paying for health insurance expenses. We urge the agency, in its final guidance on this issue, to state clearly that a grant payment made to an individual with ESRD that is consistent with the stringent guidelines set forth in OIG Advisory Opinion 97-1 may be used for payment of premiums and cost sharing on a Marketplace plan, and *must* be accepted by the insurer of that plan.

B. Insurer actions have the effect of deterring racial minorities and disabled individuals from enrolling into individual Marketplace plans in violation of the ACA's nondiscrimination provision.

The practices in which insurers are engaging violate the nondiscrimination provision outlined in Section 1557 of the ACA and the implementing regulations promulgated by the Office of Civil Rights (OCR).[36] Through their policy of rejecting

---

[34] *See* 42 C.F.R. § 411.108(a) (listing prohibited actions); *see also id.* at § 411.102.

[35] *See* 45 C.F.R. § 156.1250 (requiring that insurers accept payments from federal government programs such as Ryan White). CMS has indicated that grants from charitable organizations to Marketplace enrollees do not present the same concerns as grants directly from providers. *See* CMS, Frequently Asked Question Regarding Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces (Feb. 7, 2014), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf.

[36] 42 U.S.C. § 18116 (2016); 81 Fed. Reg. 31376 (May 18, 2016). Section 1557 applies to "any health program or activity" which receives federal financial assistance. The provision incorporates four different anti-discrimination statutes: title VI of the Civil Rights Act of 1964, which prohibits discrimination based on race, color, and national origin; title IX which prohibits discrimination based on sex; the Age and Discrimination Act which prohibits discrimination based on age; and section 504 of the Rehabilitation Act of 1973, which prohibits discrimination based on disability. Section 1557 also explicitly states that "the enforcement mechanisms provided for and available under [the four different statutes] shall apply for purposes of violations of this subsection." In the OCR final rule, the agency confirmed the broad reach of section 1557. Although OCR declined to extend section 1557's applicability to discrimination based on "health status, claims experience, medical history," OCR expressly recognized that depending on the facts, discrimination based on these characteristics can effectively constitute discrimination on a basis prohibited by section 1557. OCR also clarified that it is well established that *deterrence* from participation in a health program or

premium payments from third-party payers, insurer actions have the effect of steering dialysis patients away from individual Marketplace plans, and are compelling them to enroll in Medicare/Medicaid rather than exercise their legal right to choose their preferred insurance coverage without fear that they would be rejected for pre-existing conditions. Some insurers have also pressured dialysis patients to enroll in Medicare by altering their benefit plan designs to cover only three months of dialysis.

As described further below, these policies constitute intentional discrimination under Section 1557 because they discriminate against an individual based upon an ESRD diagnosis, a diagnosis which has been legally recognized as a "disability" and therefore constitutes a protected class under Section 1557. In addition, because dialysis patients are disproportionately from racial and ethnic minority groups, this policy likely violates Section 1557 because it disproportionately targets individuals based on their race, a protected class, by utilizing their ESRD diagnosis as a proxy through which to effectuate discrimination.

Insurers who engage in these practices effectively deny enrollment to an individual based on a pre-existing condition which, if the insurer had done so directly, would have been a clear violation of the insurance reform provisions of Title I of the ACA.[37] As a consequence, the insurers are able to exclude these patients from their risk pools, even though dialysis patients have as much of a statutory right to enroll in the plan of their choosing as everyone else does – as CMS and the IRS have expressly clarified.

---

activity on the basis of a prohibited criterion is itself a form of discrimination. For example, arbitrary coverage limitations that disproportionately affect a protected class without any basis for the normal operation of a health program can constitute discrimination. Importantly, OCR also explicitly adopted the position that a violation of section 1557 can be asserted both under disparate treatment or disparate impact theory irrespective of the underlying protected class. See 42 U.S.C. § 18116 (2016); 81 Fed. Reg. 31376 at 31440 (May 18, 2016). ("OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation."). In other words, a facially neutral policy could violate section 1557 so long as its application disproportionately and adversely affects members of any protected class, even without evidence of intentional discrimination. The OCR's interpretation regarding the causes of action available to plaintiffs under section 1557 is significant. Because the various anti-discrimination statutes incorporated by section 1557 had different causes of action, such as requiring the showing of intentional discrimination (disparate treatment) while others inferred discrimination based on a policy's disproportional effects (disparate impact), it was unclear whether a uniform right of action was available to plaintiffs under section 1557, or whether the right of action changed depending on the basis of plaintiff's protected class. In concurring with prior legal precedent that interpreted section 1557 to create a uniform cause of action, OCR effectively asserted that enforcement of section 1557 will not be avoided through subtle discriminatory tactics and facially neutral policies. *See id.* (citing *Rumble v. Fairview Health Servs*, No. 14-cv-2037, 2015 U.S. Dist. LEXIS 31591, at *29-31). Therefore OCR's implementing regulations confirmed that section 1557 was intended to be a comprehensive nondiscrimination provision.

[37] 42 U.S.C. § 300gg-3(a).

Most remarkable is the fact that these reverse steering practices are conspicuously targeting individuals because of their disability, a protected class under section 1557.[38] In the final rule implementing section 1557, OCR clarified that the definition of "disability" for the purposes of section 1557 would incorporate the definition of disability set forth in the Americans with Disabilities Act (ADA).[39] More critically, ESRD has been recognized as a disability under the ADA because it substantially limits an individual's major life activity of eliminating waste and cleansing blood from their body.[40] Therefore when insurers engage in activities that steer patients with ESRD away from the individual markets by compelling them to enroll in a federal program against their statutorily protected freedom of choice, there is a strong basis for the OCR to find that insurers are intentionally deterring individuals from participating in a "health program" because of their disability. Indeed, were it not for their ESRD disability, insurers would not be singling patients out for enrollment in Medicare.

Alternatively, because dialysis patients are predominately African-American or Hispanic,[41] these insurers are discriminating against racial minorities by using a patient's ESRD diagnosis as a surrogate through which to effectuate discrimination. The OCR has explicitly stated that it will not turn a blind eye to discrimination being performed under the guise of a seemingly legitimate attribute, such as health status, if the facts demonstrate that it is actually producing a discriminatory impact on a protected class.[42] Considering together the evidence that dialysis patients are being deterred from participating in individual Marketplace plans, and the overwhelming evidence that dialysis patients are significantly more likely to be racial and ethnic minorities, the OCR could find that insurers' steering activities are in violation of section 1557 because they produce a disparate impact based on race.[43] Put differently, the policies adopted by insurers can be interpreted as discriminating based on health status, i.e. ESRD, which serves as a proxy for disproportionately deterring racial minorities from enrolling in Marketplace plans.

---

[38] 42 U.S.C. § 18116(a) (incorporating 29 U.S.C. § 794(a)).

[39] 81 Fed. Reg. 31376, at 31407.

[40] *See Fiscus v. Wal-Mart Stores, Inc.*, 385 F.3d 378, 384 (3d Cir. 2004).

[41] *See supra* Part II.A.

[42] *See* 81 Fed. Reg., 31736, at 31405.

[43] *See Raytheon Co. v. Hernandez*, 540 U.S. 44, 52 (2003) (asserting that a *prima facie* disparate-impact theory of discrimination involves a facially neutral policy which, in practice, "falls more harshly on one group than another....").

IV. Responses to CMS Questions

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

Dialysis providers have regulatory obligations under the Conditions for Coverage to provide education to patients about their coverage options.[44] We provide patients with information so that patients may make informed choices from the health coverage options available to them. While an unscrupulous provider could seek to unduly influence a patient to select coverage options that are to the provider's advantage and not in the patient's best interest, we do not engage in such practices. Our numbers are inconsistent with any such scheme. As noted, only a small number of our patients opt for coverage under a Marketplace plan. Among our 187,000 patients nationwide, only about 1,600, constituting less than 1 percent of our patients, have elected to obtain Marketplace coverage. Of those, only approximately 700, representing *fewer than four-tenths of one percent* of our patients, receive AKF assistance to help fund their Marketplace plan premiums. These numbers are consistent with individual patient choice, and are not indicative of a program to steer patients to Marketplace plans.

Further, we do not believe that the AKF is involved in steering patients to any particular type of coverage, or that it is in a position to do so. As a preliminary matter, the AKF is not a provider affiliated organization. The AKF is an independent charitable organization. It is not affiliated with or subject to the control of providers. FMCNA, and other dialysis organizations, make charitable contributions to the AKF, but there is no link between our donations and the AKF's grant-making activities, and there are numerous safeguards in place to prevent any influence over grant awards. As AO 97-1 makes clear, when an organization – like the AKF - makes an independent determination of financial need, and receipt of assistance does not depend upon the patient's use of a particular provider or coverage option, such assistance is lawful and, in our experience, an important tool in promoting patients' ability to choose the health insurance coverage options that suit their circumstances.

Due to the nature of its grant-making process, we do not believe the AKF has any opportunity to steer. The AKF awards premium grants based solely on two factors: the patient's confirmation of ESRD status and financial need. AKF grants are made on a first-come, first-served basis, without regard to the patient's choice of insurance coverage (whether government or commercial) and without regard to the patient's choice of provider. Our patients use AKF premium grants to defray the costs of all types of coverage. In fact, among our patients who receive some level of AKF premium support, the vast majority (over 75%) use AKF grants to fund premiums for Medicare Part B, Medicare Supplemental Insurance (Medigap), and

[44] See discussion, infra pp. 1-2.

other government-program related products (such as Medicare Advantage) and not for premiums for stand-alone commercial insurance (such as employer-sponsored group health plans and individual plans on or off the Marketplace).

To the extent that other providers are inappropriately steering patients by unduly influencing their choice of insurance coverage or provider, FMCNA supports CMS' efforts to address those situations. In doing so, however, CMS should also take care not to dismantle or impede the important and lawful charitable work of independent charitable programs like the AKF HIPP, which has benefited chronically ill and financially needy patients since long before the enactment of the ACA.

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

The impact to the Marketplace risk pool when Medicare eligible consumers elect Marketplace coverage in lieu of governmental programs depends on the demographics of those who make that election. Obviously, if those consumers are healthy, the impact would be positive for the risk pool, and if those consumers are very sick (or seeking coverage for a select period of time during which utilization of medical services is unusually high), the impact would be negative. In the case of our patients, the impact to the risk pool would likely be negative since these patients are chronically ill and suffer from co-morbidities. As noted, however, the ESRD patient population is small. These patients represent a mere .006% of the total 11.1 million effectuated enrollment in ACA Marketplace plans (or about one in every 16,000 Marketplace plan enrollees).[45]

Patients should be able to make an informed choice from among all available health insurance options, free from undue influence. Accordingly, if there are providers who are inappropriately steering patients to Marketplace plans, or, conversely, if there are insurers who are inappropriately steering patients away from Marketplace plans, those activities should be addressed. The solution, however, should not penalize consumers by reducing their coverage options. The fundamental purpose of the ACA and the Marketplace program was to give vulnerable patient populations – like the ESRD patient population – a choice of coverage options. For many of our patients, Medicare/Medicaid coverage is among those options, and for many it is the right one, but it is not the only one. CMS and the IRS have rightly concluded that ESRD patients have the option to choose commercial coverage. They are not forced to choose the government-sponsored

[45] March 31, 2016 Effectuated Enrollment Snapshot (June 30, 2016), *available at* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fect-sheets-items/2016-06-30.html (stating that "[o]n March 31, 2016, about 11.1 million consumers had effectuated Health Insurance Marketplace coverage").

option, but have the right to choose the coverage that best suits their individual circumstances.

While we do not have a means to determine whether insurers have accurately anticipated composition of the risk pool for the Marketplaces, we do note that there are many reasons why insurers should have anticipated that formerly underinsured and uninsured ESRD patients would elect Marketplace coverage. For example:

- Federal law makes Marketplace coverage an option for dialysis patients who are eligible for Medicare or Medicaid coverage. The federal subsidies that are available to a large portion of the dialysis population created a financial incentive for these patients to consider and potentially select Marketplace coverage. Insurers should have anticipated that some consumers would elect Marketplace coverage.
- ESRD patients are often unemployed since their disease is debilitating and they have to spend considerable hours receiving treatment during normal work hours. It follows that many patients do not have access to employer-sponsored health plans. The Marketplaces give these patients a commercial coverage option, and insurers should have anticipated that some patients would elect that option.
- With the elimination of the pre-existing condition limit for Marketplace plans, the ACA provided commercial insurance options to ESRD patients for the first time in history, and insurers should have anticipated that some patients would elect that option.
- ESRD patients do not generally qualify for Medicare coverage during the first three months after the onset of ESRD (except for those for whom home therapy is an option). As such, insurers should have anticipated that ESRD patients would seek Marketplace coverage at least during this three-month waiting period, and that some would opt to continue coverage beyond the initial three-month period, for reasons including continuity of care.
- With regard to Medicaid eligibility, we understand that eligibility status can change throughout the year as patients experience changes in job status and income. For these patients, rather than risk moving in and out of Medicaid coverage, Marketplace coverage may provide more stable coverage and may avoid the obligation to satisfy multiple deductibles in a plan year as coverage switches multiple times from Medicaid to a Marketplace plan.

3. *Are there examples of steering practices that specifically target people eligible for or receiving Medicare and/or Medicaid benefits to enroll in individual market plans? In what ways are people eligible for or receiving Medicare and/or Medicaid 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?*

We are aware of steering practices by insurers that specifically target people eligible for or receiving Medicare and/or Medicaid benefits and that are aimed at pushing them off the Marketplace plans or other coverage options of their choice. Insurers have sent intimidating, incomplete and misleading information to our patients and have invoked fear of losing coverage for critical, life-saving care. For instance:

- An insurer held a patient's premium check written by the AKF for thirty (30) days (and did not deposit it). It then sent notices to the patient stating that they would not accept AKF checks, and as such, the patient's insurance would lapse in a matter of days. The patient had little time to challenge the insurer's practices or to develop a plan for paying the premium to avoid a lapse in coverage.
- Another insurer issued a Bulletin to its patients stating that it "may" decline to accept premium payments made directly or indirectly by any third party "in accordance with law." The insurer did not explain the parameters of any such "law," and importantly, did not explain that state regulators were then considering whether and how insurers may be allowed to reject premium payments. Instead, the insurer stated to patients "You are required to immediately notify [us] of any change in information provided with respect to any third party payment" and "Any person or entity that violates these restrictions and/or makes any ineligible third party payment described above will be held responsible . . . ".[46]
- Some insurers have demanded, without legal basis or justification, that patients sign affidavits or attestations swearing under the penalties of perjury as to the source of the funds used to pay their premiums.[47]
- Patients have had to delay or reschedule treatment due to an insurer's rejection (sometimes without notice to the patient) of a third-party payment.

---

[46] *See* Provider Bulletin issued by BlueCross BlueShield of Minnesota on August 22, 2016, attached as Exhibit 1.

[47] *See* letter dated June 9, 2016, from United Healthcare to a patient, attached as Exhibit 2.

Demanding that members of a patient population that is typically low income and poorly educated sign legal documents under "penalties of perjury" and threatening vague legal consequences for using premium support, all without stating any legal basis for doing so, is unfair, deceptive, and discriminatory. The use of such aggressive tactics and the rejection of premium payments aimed at terminating commercial coverage for a chronically ill, largely economically disadvantaged, and disproportionately minority patient population constitute a particularly insidious type of "steering."

These steering tactics are directly at odds with the principle of patient choice embodied in the ACA and threaten the ability of ESRD patients to make coverage decisions that best suit their needs by maximizing continuity of coverage and minimizing out-of-pocket costs. Insurer steering also violates the ACA's prohibition on discrimination in the offering of health care coverage on the basis of disability, race or national origin. It is well-established that African Americans are more at risk for kidney failure than any other race, comprising more than a third of kidney failure patients in the United States.[48] Hispanic, Asian, and Native Americans, similarly, are far more likely to experience the conditions that lead to ESRD - such as high blood pressure and diabetes - than are Caucasians.[49] Insurers should not be permitted to use the receipt of third party premium support as a proxy for prohibited discrimination on a pre-existing condition, particularly where such discrimination has a disparate impact on racial and ethnic minorities, and on a patient population that is disabled.

In some states, Departments of Insurance have intervened to address these heavy-handed and discriminatory practices, but insurers continue to innovate to adopt new strategies aimed at keeping ESRD patients off the Marketplaces and other commercial plans. We therefore urge CMS to give all states clear guidance that these insurer "steering" practices are impermissible under the law.

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

---

[48] Choi, Andy I. et al. "White/Black Racial Differences in Risk of End-Stage Renal Disease and Death." *The American Journal of Medicine* 122.7 (2009): 672–678.*PMC*. Web. 6 Sept. 2016.

[49] Nicholas S.B., Kalantar-Zadeh K., and Norris K.C.: Racial disparities in kidney disease outcomes. Semin Nephrol 2013; 33: pp. 409-415.

Since FMCNA does not pay premiums and does not steer individuals to Marketplace plans, we are unfamiliar with methods that may lead to inappropriate steering. As noted above, with less than 1% of our patients enrolling in Marketplace plans and only 0.4% receiving AKF premium support for Marketplace plan premiums, the facts fully support our position that we do not steer. With regard to the AKF, while it does pay premiums, its grants are awarded on a first-come, first-served basis, once the patient establishes an ESRD diagnosis and financial need. Grants are awarded without regard to the patient's choice of insurance coverage, whether governmental or commercial. Thus, the AKF process does not provide the AKF any opportunity to steer patients into Marketplace plans.

With regard to transparency, FMCNA supports a HIPP program that is transparent. The payment procedure that is most effective for our patients is one in which the AKF sends premium checks directly to insurers and thereby, gives insurers transparency on the source of funds. Due to insurer efforts to steer patients away from commercial coverage by refusing to accept AKF checks, the AKF has implemented different procedures in some states, but again, we favor a program that is entirely transparent.

5. *How are enrollees impacted by the practice of a health care provider or provider-affiliated organizations enrolling an individual into a Marketplace 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.*

For those patients who elect to enroll in commercial coverage, we advise them of any programs available to them to help pay those premiums consistent with our obligations under the Conditions for Coverage. We strive to offer the highest level of service possible, while taking all aspects of our patients' health and well-being into account. When we discharge our responsibilities properly, the impact is that our patients have the choices that the ACA and the Marketplaces were designed to provide as well as the information needed to choose the coverage that best suits their individual circumstances.

While many patients choose to enroll in Medicare or Medicaid when eligible, other patients report to our financial counselors a wide variety of reasons why they want to delay enrollment in Medicare or Medicaid or choose a Marketplace plan or other commercial coverage. For example:

- A patient has family members covered under existing coverage such that, if coverage is dropped in favor of Medicare coverage for ESRD, their family

members would not have coverage unless they, too, access the Marketplaces, in which case total out-of-pocket costs may be higher.

- A Marketplace plan offers a travel/housing benefit for the transplant donor as well as the patient, and the patient wants to keep individual market coverage until he/she rules out that a potential family member would need to travel a long distance to take part in a transplant.
- A Marketplace plan offers a more advantageous prescription drug benefit.
- A patient cannot afford Medicare Part D.
- A Marketplace plan offers an out-of-pocket maximum that is financially advantageous. By comparison, there is no limit to a patient's responsibility for the deductibles and co-pays payable under Medicare.
- A patient lives in a state without Medigap coverage, and as such, cannot adequately insure exposure for deductibles and co-pays. Note that Medigap coverage is available in only 27 states for ESRD patients under age 65.
- A patient may have better continuity of care and may be able to avoid resetting deductibles and out-of-pocket cost limits by remaining on a Marketplace plan instead of moving on and off of Medicaid due to income fluctuations.
- A patient may want to continue coverage that provides access to particular physicians who may not participate in Medicare or Medicaid.
- A patient simply exercises the choice that the law allows.

Many patients are focused on minimizing their out-of-pocket costs for care, and as such, these financial considerations play a big role in their decision making. To appropriately determine the total financial implications to an individual, we simulated the movement of individuals who are representative of the population for a target market, Manhattan, to a Marketplace Bronze and Silver plan. For ESRD patients, who have patterns of high utilization compared to the general population, there are substantial savings in out-of-pocket spend realized by switching to a Marketplace plan (or Medicare Advantage) from a Medicare fee-for service (FFS) plan without Medigap coverage. (See **Figure 1** and **Figure 2** below). The main driver behind this savings is the benefit of an out-of-pocket maximum that is not provided by Medicare FFS. Given that the financial implications for individuals are dependent upon their personal situations, any steps taken to address inappropriate steering should take these considerations into account. Our simulation leads us to believe that retaining the option to enroll in Marketplace coverage when it best suits an individual's personal situation (regardless of whether or not eligible for Medicare and/or Medicaid) is integral to the overall wellbeing of our patients.

Figure 1 - Individual Financial Obligation (Out-of-pocket Spend Only, Excludes Premiums) Comparison across Payer Types – Manhattan Market

Financial Impact on Individuals in 25th Percentile: Manhattan Market
Annual Individual Financial Expenditures (Excluding Premiums) ($)

Condition	Medicare FFS[2]	Medicare Advantage	Silver Exchange Plan	Bronze Exchange Plan
(1) Diabetic	$2,956	$1,671	$4,739	$6,728
(2) ESRD	$17,114	$3,923	$6,850	$6,850
(3) CHF	$4,689	$2,004	$6,238	$6,850
(4) Cancer	$4,058	$1,875	$5,474	$6,850
(5) Healthy / Limited HCCs	$928	$1,804	$2,968	$2,968

Financial Impact on Individuals in 75th Percentile: Manhattan Market[1]
Annual Individual Financial Expenditures (Excluding Premiums) ($)

Health Conditions	Medicare FFS[2]	Medicare Advantage	Silver Exchange Plan	Bronze Exchange Plan
(1) Diabetic	$3,960	$5,729	$6,850	$6,850
(2) ESRD	$24,022	$7,392	$6,850	$6,850
(3) CHF	$7,040	$7,737	$6,850	$6,850
(4) Cancer	$6,465	$6,170	$6,850	$6,850
(5) Healthy / Limited HCCs	$2,305	$5,078	$4,831	$6,850

1. Financial analysis excludes premium payments; Assumes $4,900 and $6,850 OOP maximum for MA and ACA plans, respectively; Assumes Commercial/ACA average allowed unit costs 30% higher than Medicare FFS 2. Assumes Medicare Supplementary coverage is not purchased

Source: Analysis of 2014 MarketScan, 2014 Medicare 5% claims and Public Use files

Figure 2 - Individual Financial Obligation (Out-of-pocket Spend and Premiums) Comparison across Payer Types – Manhattan Market

Financial Impact on Individuals in 25th Percentile: Manhattan Market[1]
Annual Individual Financial Expenditures ($)

Condition	Medicare FFS[2]	Medicare w/ Plan F	Medicare Advantage	Silver Exchange Plan	Bronze Exchange Plan
(1) Diabetic	$4,612	$7,035	$1,671	$17,915	$18,356
(2) ESRD	$18,770	$9,614	$3,923	$17,292[3]	$16,066[3]
(3) CHF	$6,346	$8,148	$2,004	$19,414	$18,478
(4) Cancer	$5,714	$7,864	$1,875	$18,650	$18,478
(5) Healthy / Limited HCCs	$2,584	$5,406	$1,804	$16,144	$14,596

Financial Impact on Individuals in 75th Percentile: Manhattan Market[1]
Annual Individual Financial Expenditures ($)

Health Conditions	Medicare FFS[2]	Medicare w/ Plan F	Medicare Advantage	Silver Exchange Plan	Bronze Exchange Plan
(1) Diabetic	$5,617	$7,035	$5,729	$20,026	$18,478
(2) ESRD	$25,679	$9,614	$7,392	$17,292[3]	$16,066[3]
(3) CHF	$8,697	$8,148	$7,737	$20,026	$18,478
(4) Cancer	$8,122	$7,864	$6,170	$20,026	$18,478
(5) Healthy / Limited HCCs	$3,961	$5,406	$5,078	$18,007	$16,170

1. Financial analysis includes premium payments for individuals and drug costs; Assumes $4,900 and $6,850 OOP maximum for MA and ACA plans, respectively; Assumes Commercial/ACA average allowed unit costs 30% higher than Medicare FFS 2. Assumes Medicare Supplementary coverage is not purchased 3. ESRD premiums may be lower on exchange compared to other Medicare populations due to prevalence of ESRD individuals under 65 and ACA premium rate setting based on age
Source: Analysis of 2014 MarketScan, 2014 Medicare 5% claims and Public Use files

The total financial obligation differential for our ESRD patients is of particular interest. As seen in **Figure 1** and **Figure 2**, out-of-pocket expenditures for individuals in Medicare FFS can be high, especially for those individuals under 65 who cannot purchase supplemental plans. In particular, the simulation in **Figure 2** shows that if a high-utilizing Medicare FFS member with ESRD does not have supplemental coverage, this individual can save ~$8,000 dollars a year in healthcare expenditures by enrolling in a Marketplace plan. As indicated, there are savings realized whether or not the individual is paying the premiums or has premium support, though the savings to the individual are obviously greater in cases where the individual also has access to premium assistance. Given that currently only 27 states offer Medigap plans to ESRD patients under the age of 65, we believe this analysis highlights the importance of avoiding a "one size fits all" approach to health coverage and ensuring that each individual, regardless of health status, retain the right and ability to select the type of coverage that makes the most sense for him or her.

For a Medicaid-only eligible individual, in almost all cases, our expectation is that Medicaid coverage would be superior to a Marketplace plan from a pure cost perspective. This is true, in part, because federal law limits states' ability to charge

premiums, co-payments and other forms of cost sharing.[50] Thus, Medicaid beneficiaries may get their coverage at little or no out-of-pocket expense to them. In addition, access to outpatient prescription drugs in Medicaid is usually generous. A Marketplace plan, by contrast, may not be as generous. We counsel our patients in accordance with this understanding, and while patients are always free to make their own choices, the result is that we have very few Medicaid-only eligible patients who elect Marketplace coverage.

Setting aside the positive financial impact of choosing a Marketplace plan over Medicare for select, high utilizing, portions of the population (such as our ESRD patients), and the cost factors that may lead patients to choose Medicaid if eligible for it, we believe that respecting individual choice of health insurance options is a vitally important aim in itself. Individuals need to have the ability to independently evaluate all of the attributes that make up the value proposition of a healthcare product (both financial and non-financial) to ensure they select an option that meets their personal situation. FMCNA is clearly not alone in this view. Indeed, the ACA, and healthcare.gov, were designed to promote consumer choice and informed decision making.

6. *How are enrollees impacted by the practice of a health care provider enrolling an individual into a Marketplace 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 co-payments 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 co-payments and deductibles where the enrollee's chosen provider is out-of-network to the individual market plan.*

Because we do not enroll patients in health insurance plans or pay premiums, we have limited insight into the issues raised by this question. As illustrated in greater detail in our response to question 5 above, it is inaccurate to assume that Medicare and/or Medicaid coverage is always the best option for patients, financially or otherwise. Patient choices regarding coverage can be quite complex and should take into account a number of factors that are unique to the patient and that are then weighed against the availability of other coverage options,

---

[50] *See generally* Social Security Act § 1916(a)(3) (providing that cost sharing under a plan must be "nominal in amount"). *But see id.* at § 1916A (providing states with limited flexibility to charge greater cost sharing for Medicaid beneficiaries with incomes above 100% of the federal poverty level).

both government and commercial. In the end, it should be up to the patient to make that choice.

Currently, ~56 million people are enrolled in Medicare and ~73 million people are enrolled in Medicaid. Current take-up rates (i.e. the proportion of eligible individuals who choose to enroll in government programs) of ~99% for Medicare and ~68% for Medicaid indicate that while most individuals enroll for Medicare if eligible, a large portion of individuals eligible for Medicaid are not enrolled in the program.[51] Approximately 32 million people are eligible for but not enrolled in Medicaid. While secondary research did not yield employer sponsored coverage rates for Medicaid eligible populations, if we assume that 55% of these individuals have access to health insurance coverage through their employer (based on the average employer-sponsored coverage rates for the non-elderly), that leaves ~18 million individuals who are Medicaid eligible but not enrolled.[52] These uninsured individuals would experience both financial and non-financial changes from enrolling in any health plan, including a health plan offered on a Marketplace.

Exactly which health plan would most benefit a non-insured individual, however, is highly dependent upon personal factors, which is why patient choice and education are critical. As noted in our response to Question 5, while many ESRD patients decide that Medicare or Medicaid coverage makes the most financial sense for them, some can realize savings by enrolling in Marketplace plans with out-of-pocket maximums.[53] Still other individuals have other reasons to want to obtain Marketplace coverage, such as continuity of care or family coverage. The Conditions for Coverage obligate us to educate patients on these factors and provide the information needed for them to make a decision that best suits their individual circumstances.

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

AO 97-1 was issued by the OIG in response to the requestor's (including the AKF's) questions about compliance with the Civil Monetary Penalties Law in relation to HIPP. We believe that CMS should consider the attributes of a well-run HIPP as

---

[51] Kaiser Family Foundation. "Total Number of Medicare Beneficiaries". 2015; Kaiser Family Foundation. "Total Monthly Medicaid and CHIP enrollment" (June 2016); The Milbank Quarterly. "Health Insurance Coverage and Take-Up: Lessons from Behavioral Economics". March 2012; Assistant Secretary for Planning and Evaluation. "Understanding Participation Rates in Medicaid: Implications for the Affordable Care Act" (March 2012).

[52] Kaiser Family Foundation. "Employer-Sponsored Coverage Rates for the Nonelderly by Age" (2014).

[53] *See, e.g.*, Figure 1 and Figure 2 above.

expressed in AO 97-1 and should consider memorializing the guidance therein in regulations applicable to charities that fund premiums for government-sponsored programs, including the Marketplaces (which receive government support in the form of premium tax credits and reinsurance and risk corridor protections). In addition, we would suggest some additional safeguards to protect the transparency and integrity of programs run by charitable originations, like HIPP. Such guardrails should include:

- The organization must operate in accordance with the legal requirements of AO 97-1;
- The organization must award grants on a first-come, first-served basis to applicants who establish financial need based on the organization's objective financial need criteria to ensure that no preferential treatment is given to applicants who receive treatment for particular providers;
- The organization must establish an appropriate separation between fund-raising activities and grant-making activities, thereby assuring the independence of grant-making decisions;
- Premium grants must be portable so that a patient can switch providers during the grant year;
- The organization awards grants in a manner that allows patients freely to choose their provider and their coverage option, such as grant awards that cover an entire policy year.
- The charitable organization must require periodic certifications from providers who assist patients in applying for grants to the effect that such providers are not providing any assurances or guarantees to patients that they will receive grant assistance, since the grant-making decision rests entirely with the charitable organization.

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

Our financial coordinators do screen for Medicare and Medicaid eligibility as part of their counseling process since the patient needs to evaluate all options to make a coverage decision. That said, at times, we lack complete information about a patient's Medicaid eligibility and/or enrollment, and would appreciate any efforts by CMS to work with states to provide more accurate information for us to inform patient choice.

The task of educating patients on the advantages and disadvantages of various coverage options -- including the impact of signing up for a Marketplace plan – is most effectively assigned to providers. Dialysis providers, in particular, are already charged with this responsibility under the Conditions for Coverage. These patients are in our clinics at least three times weekly and have a relationship of trust and confidence with our social workers and financial coordinators. Our financial coordinators receive in-depth training on the requirements for eligibility for commercial insurance programs, plans available through the Marketplace, as well Medicare and Medicaid. Additionally, they are trained to discuss health insurance options with patients, based on what is best for the patient's care and financial situation. Charitable organizations like the AKF do not have these patient relationships and do not have the physical proximity with the patient or the technical know-how to undertake this role. Requiring them to perform this function would increase their overhead, unnecessarily divert funds from their charitable mission, and duplicate services that dialysis providers, in particular, are required to provide under the Conditions for Coverage.

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

While we do not offer or provide any assurance of premium assistance to our patients, we do provide education on coverage options to our patients as required by the Conditions for Coverage. Our approach is individualized for each patient since each patient may consider different factors and weight the multiple factors differently. Since most patients need to consider how to pay for their care, we do assist patients in assessing eligibility for various coverage options, evaluating the costs to the patient of each coverage option and gathering information about a patient's financial resources, such as assets, income and expenses. When a patient has determined that commercial insurance may be a better fit for his or her personal needs, we will offer information to the patient about available financial assistance and how to apply for such assistance. We do not guarantee to any patient that he or she will receive such financial assistance, since decisions are made by the charities that provide the assistance, not by FMCNA. Donations to such charities by FMCNA are not linked to or conditioned upon the receipt of assistance by any particular patient, and the receipt of grant assistance by a patient does not hinge upon the use of a particular provider or coverage option.

If a patient receives a premium grant, the most efficient process is for the charitable organization to send a check directly to the insurer. We understand that AKF uses that process, when possible. As insurers have increasingly deployed methods to deter patients from enrolling in commercial coverage by refusing to accept payments made directly to the insurers by such charities, the AKF has modified its procedures in some instances. For instance, under a modified

procedure, AKF would send checks payable to the patient to the patient's dialysis center, and the checks would be held for patient until the next treatment. At the next treatment, one of our counselors would open the check with the patient as part of a dialogue about the patient's coverage choices. For those patients choosing commercial insurance coverage, the patient would then endorse the check to the insurer. We understand that checks are not sent directly to patients' homes because of concerns about theft or about patients' ability to manage their financial affairs in a manner to assure timely premium payment.

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

FMCNA does not offer or provide assurances regarding premium assistance to Marketplace patients (or any patients), and as such, we do not object to any such prohibitions on providers' making such offers or assurances.

With regard to cost-sharing waivers, we do have an indigent waiver program that is consistent with the waiver exception and safe harbor under the anti-kickback statute. Our indigent waiver program applies equally to patients with federal health program and commercial coverage. Our expectation is that all providers provide cost-sharing waivers on this basis.

We do not believe that Medicare Part A eligibility should prohibit a provider from making a patient aware of the potential for third party assistance for Marketplace or other commercial coverage. Both CMS and the IRS have expressly determined that Medicare and Medicaid-eligible individuals have the option to seek coverage from Marketplace plans under the ACA, and a small segment of our patients currently make this choice because the Marketplace plan better suits their personal needs.

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

Under the Conditions for Coverage, dialysis providers are already required to recognize the individualized and personal needs, wishes and goals of the patient and to honor the patient's right to be informed about and participate in all aspects of care. As such, and as FMCNA recognizes, the decision on coverage options lies with

the patient, it is incumbent upon the provider to provide neutral, practical advice regarding the potential costs and benefits of various options to help inform a patient's decision. That being said, we support and would like to contribute to an effort to develop further guidance about how to ensure that patients are fully informed of their insurance options and provided all available choices.

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

We support CMS' efforts to implement measures that address any tactics used by providers or insurers to unduly influence patients in a manner that steers them into or away from any type of coverage, including Marketplace plans. FMCNA commits to collaborate with CMS and others to devise means to identify and eliminate any such abusive practices and to support reporting and other data sharing activities that produce demonstrable results in enhancing patient access and choice without undue influence by providers or insurers.

In this regard, it is possible that additional reporting and data sharing regarding the correlation between patient assistance programs and cost-sharing waivers in certain scenarios may assist in this effort. For example, if a provider is out-of-network and does not have a contract with the insurer for a negotiated reimbursement rate for dialysis treatment and that provider's data shows a high correlation between patients who receive premium assistance and patients who receive cost-sharing waivers, this data may raise concerns regarding steering.

Our numbers regarding Marketplace coverage enrollment by our patients and AKF support of those patients show that we are not engaged in steering.[54] We support initiatives to create transparency to CMS regarding these numbers.

In addition, the counseling that we provide patients would be better informed if CMS would share more data with us about patient eligibility for premium tax subsidies and coverage eligibility. In particular, when providing coverage options to our patients, we often lack clear and accurate information about the patient's eligibility and /or enrollment in Medicaid. Any gaps in our information diminish our ability to advise patients of their coverage choices. If CMS could work with state Medicaid programs to provide us better information about patient Medicaid status, our patients would be better informed about their coverage options.

---

[54] We have over 187,000 patients nationwide, and only about 1,600, constituting less than 1% of our patient population, have elected to obtain Marketplace coverage. Of these, only approximately 700, representing only 0.4% of our patients, receive AKF assistance to help fund their Marketplace plan premiums. Our Marketplace plan patients represent only about 1 in every 7,000 Marketplace plan subscribers. Those with AKF support represent only about 1 in every 16,000 Marketplace plan enrollees.

We also urge CMS to consider requiring insurers to report information that would enable CMS to better understand and respond to any instances of insurer steering.

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

FMCNA generally negotiates provider contracts with payors throughout the country to establish mutually agreeable rates for the services provided. Our experience is that insurers consider a number of factors when negotiating these rates, as do we. These negotiations are private matters, and the parties on each side are sufficiently sophisticated to protect their own interests.

Based on some of the press articles that we have seen on this topic, it appears that some providers may be adopting a comprehensive out-of-network strategy in which they refuse generally to contract with payors with the aim of receiving per-treatment dialysis reimbursement in excess of the negotiated rates payable to contracted providers. Insurers already have ample means to protect themselves in these situations by limiting benefits for out-of-network providers. But patients may not have a means to protect themselves if the out-of-network provider does not adequately disclose to the patient that the provider is out-of-network; in this instance, unless the provider is routinely waiving the patient cost-sharing obligation (a practice which may raise other concerns), the patient will be subject to higher co-pays and deductibles.

We recommend that CMS consider requiring out-of-network providers to disclose to patients the extent of their cost-sharing obligations under a Marketplace plan and that CMS seek data to determine whether these same patients receive both premium assistance and cost-sharing waivers from these out-of-network providers. In addition, we suggest that CMS consider applying some of the network adequacy and out-of-network reimbursement rules that are applicable to Medicare Advantage plans for application to Marketplace plans. Medicare Advantage plans have network adequacy requirements that ensure an appropriate level of provider contracting, and in addition, Medicare Advantage plans impose Medicare-based rates on out-of-network providers. Applying similar rules in the Marketplace context would address steering concerns.

14. *We seek comment on policies that would allow individual market plans to make retroactive payment adjustments to providers, when health care providers are*

found to have steered Medicare or Medicaid beneficiaries to enroll in a Marketplace plan for the provider's financial gain.

Insurers have sufficient legal recourse under existing law to challenge providers who purportedly steer Medicare or Medicaid beneficiaries to enroll in a Marketplace plan for the provider's financial gain. Insurers have access to the courts to address these private commercial issues, including any claimed retroactive payment adjustment. Indeed, United Healthcare's recent complaint against American Renal Associates is a good example of the type of recourse available. As such, additional remedies, need not, and should not, come from CMS.

We support CMS' providing clear standards for determining standards for appropriate education of patients and for third party premium support.

Conclusion

FMCNA welcomes the opportunity to collaborate with CMS and industry participants to address concerns about patient steering while preserving the premium assistance support that many of our patients have relied on for almost two decades. Without that premium assistance, many of our patients lack the resources to access the coverage options offered by the Marketplaces, as well as coverage options offered by Medicare, Medigap, Medicare Advantage and other commercial coverage. Their insurance options become illusory without the support of organizations like AKF.

We support measures to assure that premium assistance programs are properly run and that neither providers nor insurers are steering or improperly influencing patient choice. We think that greater expanded data reporting and data access might be an effective tool to highlight and then eliminate inappropriate steering practices. Greater transparency would be an effective regulatory means to address inappropriate provider or insurer behavior.

Thank you for your attention to this matter. We look forward to a continuing dialog and to working with CMS to advance the interests of our patients.

Very truly yours,

Ronald J. Kuerbitz
Chief Executive Officer

Exhibit 1

PROVIDER BULLETIN
PROVIDER INFORMATION

BlueCross BlueShield Minnesota

August 22, 2016

Updated: Third Party Payments of Premium and/or Cost-Sharing

The information in this Bulletin replaces Provider Bulletin P50-15, which was published on December 7, 2015.

As required by law and applicable regulatory guidance, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) will accept premium and cost-sharing payments made on behalf of enrollees by the following persons/entities:

(1) the Ryan White HIV/AIDS Program;
(2) other Federal and State government programs (or grantees) that provide premium and cost-sharing support for specific individuals;
(3) Indian tribes, tribal organizations, and urban Indian organizations;
(4) family (related legally or by blood) and individual friends of the enrollee; and
(5) religious institutions and other not-for-profit organizations, but only **when each of the following criteria has been demonstrated** (as such criteria may be modified in accordance with applicable law or regulatory guidance): (a) the assistance is provided on the basis of the enrollee's financial need; (b) the institution or organization is not a healthcare provider; and (c) the institution or organization is financially disinterested, e.g., the institution/organization does not receive funding from entities with a pecuniary interest in the payment of health insurance claims.

Blue Cross may, in its sole discretion and in accordance with applicable law and regulatory guidance, **decline to accept** premium and cost-sharing payments made directly or indirectly* by any third-party that is not listed above, and any other person or entity from which Blue Cross is not required by law to accept third-party premium and/or cost-sharing payments. "Payments" include those made by any means, for example: cash, check, money order, credit card payment, electronic fund transfer, etc. Third parties not listed above are referred to as "ineligible third parties." For purposes of clarity, but not limitation, commercial (or for-profit) entities, hospitals, and other healthcare providers (including, without limitation, suppliers) are ineligible third parties. Religious institutions and other not-for-profit organizations that do not meet the criteria set forth above are also ineligible third parties.

Any cost-sharing paid by ineligible third parties will not be counted toward an enrollee's deductible or out-of-pocket maximum. "Cost-sharing" includes payments such as deductibles, copayments and coinsurance. Blue Cross may make retroactive adjustments to account for any payments made by ineligible third parties.

You are required to immediately notify Blue Cross of any change in information provided with respect to any third-party payment.

Any person or entity that violates these restrictions and/or makes any ineligible third party payment described above will be held responsible for and will be required to reimburse Blue Cross for all costs associated with the relevant plan or policy related to the violation or ineligible payment.

Payments of premiums and/or cost-sharing by ineligible third parties have the potential to create conflicts of interest, skew the health coverage risk pool and increase the risk of adverse selection. This is detrimental to the long-term viability of the health coverage market overall and can result in increased rates for the entire market.

Continued on back

Blue Cross maintains sole discretion with respect to its acceptance of third-party payments. Blue Cross may make changes to its administration of same at any time and as otherwise needed to support compliance with law and/or applicable regulatory guidance.

If you have questions about this third-party payment policy or whether Blue Cross will accept premium and/or cost-sharing payments made by a specific person or entity, please contact provider services at **(651) 662-5200** or **1-800-262-0820**.

*Indirect payments include, for example, an ineligible third-party making a check out to or otherwise paying the enrollee to permit the enrollee to pay amounts due to Blue Cross.

2

Exhibit 2

UnitedHealthcare

June 9, 2016

via overnight delivery

Member:
Carrier Name: UnitedHealthcare of North Carolina, Inc.
Policy #:

Dear

Thank you for your payment in the amount of $ on June 3, 2016, for the above medical policy.

Our records show that the American Kidney Fund may have improperly paid your premiums in the past. Your medical policy does not allow a party like the American Kidney Fund to pay your medical premium.

We need to make sure that you paid your premium with your own money. We also need to make sure you do not expect to be reimbursed for this payment from a party like the American Kidney Fund.

What do I need to do?

We want to ensure that you get the help you need. Please sign the attached document and send it back in the envelope we have provided by **June 20, 2016.**

What happens if I don't send back the document?

If you don't sign and return the document, we will not be able to accept your payment. We will return any payment received and you will not have coverage.

What happens if I did receive money from American Kidney Fund to pay my premium?

Please call us right away. You will need to make your payment from your own money.

Do I have any other options?

- You may be eligible to enroll in Medicare if you have End-Stage Renal Disease. We have nurses available to talk to you about this option and other aspects of managing your care. Please call us toll-free at 866-561-7518, TTY 711. We will help you understand all of your options.

- You may be eligible to enroll in North Carolina Medicaid coverage. Please contact the North Carolina Division of Medical Assistance to discuss whether you can access the care you need through their program. Call toll-free **1-800-662-7030**, TTY 1-877-452-2514.

DECLARATION

Under penalty of perjury, I, hereby state that the following information is true and correct to the best of my knowledge and belief, as of the date that I signed this document.

1. I am over the age of majority, suffer from no legal disabilities, and have personal knowledge of the information contained in this Declaration.

2. I am the policyholder listed on Policy Number issued by UnitedHealthcare of North Carolina, Inc. (the "Policy").

3. I applied for the Policy of my own free will after considering available options.

4. I am aware that the Policy states that I must pay my own premium unless payment is made by one of the following parties:

    a. Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act;
    b. Indian tribes, tribal organizations or urban Indian organizations; or
    c. State and Federal Government programs.

5. I hereby certify that the funds used to make the payment on June 3, 2016, in the amount of were not supplied to me (and will not be reimbursed to me) by any third party entity other than one listed in 4 above. Further, I will not pay any future premium for the Policy with funds received from (or reimbursed by) a prohibited third party entity.

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

Executed _____, 2016, at _____, _____.
DATE CITY STATE

_____
SIGNATURE

EXHIBIT 6

THE KIDNEY CARE COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

September 22, 2016

VIA ELECTRONIC FILING
www.regulations.gov

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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

Dear Acting Administrator Slavitt:

Thank you for providing the Kidney Care Council (KCC) with the opportunity to provide comments on the "Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans"[1] (RFI). KCC strongly supports the commitment of the Centers for Medicare and Medicaid Services (CMS) to ensuring the long-term existence and stability of the Health Insurance Marketplace created by the Affordable Care Act (ACA). The Health Insurance Marketplace has enabled individuals with kidney disease to purchase insurance without discrimination based on their health status for the first time in history. These individuals are disproportionately low-income, minority populations with greater health needs and high rates of chronic disease. As such, KCC appreciates CMS's desire to strengthen the Marketplace, which benefits millions of Americans, including these vulnerable individuals. While we thus recognize that CMS pursues laudable, important goals with the policies discussed in the RFI to strengthen the Marketplace, these suggested policies miss the mark and would, if finalized, result in significant discrimination against the very individuals the ACA was designed to protect.

KCC is the nation's association of dialysis providers serving the complex clinical needs of more than 425,000 individuals with End Stage Renal Disease (ESRD) in more than 5,355 dialysis facilities across the United States. Our member companies include large, medium, and small providers, both for profit and not-for-profit, serving individuals with ESRD in all geographies across the country. The patients served by our member companies face significant health challenges, and the nondiscrimination

[1] 81 Fed. Reg. 57554 (Aug. 23, 2016).

principles central to the ACA play a critical role in enabling individuals with ESRD to access health insurance coverage on an equitable basis with individuals who do not have ESRD.

In response to the RFI, the discussion below seeks to: provide critical information about ways to ensure all Americans, regardless of their medical condition would not be subject to the unintended, discriminatory effects; identify activities to strengthen the safety net for low-income chronically ill individuals and challenge the unwarranted assumptions underlying the RFI; and present a more accurate and holistic description of the current state of the law and guidance governing the dialysis industry and how current practices are in compliance with these authorities. We hope CMS will carefully evaluate policy choices that could significantly affect individuals' opportunities to choose the health insurance coverage options that best meet their needs. Most importantly, we strongly encourage CMS to ensure that insurers are prevented from discriminating against individuals based on health status. We support the Agency's work historically to protect individuals with ESRD and we urge CMS to avoid adopting policies that threaten to undermine this foundation.

I. Overarching Principles of the ACA: Nondiscrimination, Coverage Expansion, Improvement of Health Insurance Options

The ACA is built upon the fundamental principles that individuals should have freedom of choice in their health insurance decisions and that issuers may not discriminate against individuals based on health status. Section 1557 of the ACA, in particular, codified these principles by stating explicitly that "an individual shall not … be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance …"[2] This nondiscrimination protection has been in effect since 2014, and both CMS and the Department of Health and Human Services (HHS) more broadly have taken a wide variety of actions consistent with this priority.

As Secretary Sylvia Burwell has emphasized, HHS remains committed to promoting "a better, smarter and healthier health care system with engaged, educated and empowered people at the center of it."[3] Part of being an engaged and empowered consumer is having the opportunity to "pick[] the right coverage."[4] Being engaged and empowered is particularly important for dialysis patients, and the nondiscrimination protections of the ACA—as interpreted and applied by both CMS and the Treasury Department over the past few years—have helped individuals with ESRD maintain their autonomy and exercise their freedom of choice. Because these individuals are disproportionately minority, low-income,

[2] ACA § 1557(a), codified at 42 U.S.C. § 18116(a).
[3] Sylvia Mathews Burwell and Valerie Jarrett, "Invest In Your 'Healthy Self' (and Post a #HealthySelfie While You're At It!)," *HHS Blog* (June 11, 2015) (*available at https://www.whitehouse.gov/blog/2015/06/11/invest-your-healthy-self-and-post-healthyselfie-while-you-re-it* and last accessed Dec. 7, 2015).
[4] *Id.*

and sick, the expanded opportunities for health coverage available to them through the Marketplace mark an important achievement of the ACA.

KCC members have seen patients thrive as a result of receiving access to the clinical benefits of being insured for the first time or by having insurance that fully covers all Essential Health Benefits. There are a variety of reasons that patients with kidney disease benefit from or require access to the Health Insurance Marketplace. Many of kidney patients have no other insurance options, while some make informed decisions to elect commercial coverage instead of, or in addition to, government coverage. Commercial coverage has significant benefits for patients with kidney disease, including the following data points:

- Access to transplants is almost three times higher under commercial coverage than under Medicare and is 14 times higher for African Americans under commercial versus Medicare coverage;[5]
- Patients with commercial insurance have fewer hospitalizations and lower mortality rates than patients with Medicare fee-for-service;[6] and
- Patients have greater access to pharmaceutical benefits with commercial coverage over Medicaid, due to prescription drug caps on Medicaid plans.[7]

These demonstrable clinical benefits represent only a few of the many reasons why individuals with kidney disease may elect to enroll in Marketplace coverage.

Unfortunately, some Marketplace issuers have adopted policies that discriminate against individuals with kidney disease when it progresses and requires these individuals to commence dialysis treatments. The most common practices involve denying enrollment to Medicare-eligible individuals, requiring attestation that the enrollee is not receiving charitable assistance, limiting dialysis coverage to 42 treatments/three months, and sending investigators to patient's homes asking why the patient has Qualified Health Plan (QHP) coverage. A case in point of these discriminatory practices is the refusal of some issuers to accept third party payments from a nonprofit public charity, the American Kidney Fund (AKF), which helps cover the Marketplace plan premiums of individuals with ESRD. Such policies discourage or prevent individuals with ESRD from retaining their Exchange-based coverage if they wish to do so rather than enrolling in Medicare when they become Medicare-eligible. There are other policies discussed in the RFI that would have the effect of preventing or discouraging Medicaid beneficiaries from accessing Marketplace coverage, even when such coverage would be appropriate for them. In order to

---

[5] Reeves, Daniel, *et al.*, "Ethnicity, medical insurance, and living kidney donation," CLINICAL TRANSPLANT 498 (July-Aug. 2013), *available at http://www.ncbi.nlm.nih.gov/pubmed/23781870.*

[6] Afendulis CC, Chernew ME, Kessler DP. *The Effect of Medicare Advantage on Hospital Admissions and Mortality*. Working Paper 19101. Cambridge, MA: National Bureau of Economic Research; June 2013.

[7] Dayaranta, Kevin, "Studies Show: Medicaid Patients Have Worse Access and Outcomes than the Privately Insured," *Heritage Foundation Backgrounder #2740* (Nov. 2012), *available at http://www.heritage.org/research/reports/2012/11/studies-show-medicaid-patients-have-worse-access-and-outcomes-than-the-privately-insured#_ftn15.*

help prevent individuals with kidney disease from being needlessly deprived of these valuable choices for themselves and their families, KCC presents the detailed discussion below and strongly urges CMS to give it fair consideration in view of the need to protect the very individuals for which the ACA's protections were designed.

II. RFI: Questions Raised

The RFI raises questions about potential inappropriate steering of people eligible for Medicare or Medicaid to the Individual Market. These questions, the underlying assumptions, and the policies suggested by the RFI would also result in discrimination against, and harm to, patients with kidney disease.

A. Unjustified Targeting of Patients with Kidney Disease

As a preliminary matter, it is essential to understand that patients with kidney disease, the vast majority of whom are very poor and sick, are the exact set of people that the ACA was designed to assist. The ACA has provided many of these individuals the opportunity to purchase insurance without discrimination due to their disease state. These participants in the Individual Market deserve fair treatment and continued opportunities to access high-quality health care coverage options that meet the needs of themselves and their families. Because there are currently unforeseen issues arising with respect to the risk pools, CMS is justified in seeking to address these issues.

One of the concerns in the RFI is the provision of charitable premium assistance. Regarding kidney disease patients in particular, the AKF is the primary provider of charitable premium support for patients who receive individual coverage, either through the Marketplace or outside of the Marketplace. Altogether, this represents less than 0.05% of the estimated number of Marketplace enrollees in 2016.

The ACA expressly limits who is ineligible to enroll in the Exchange and state plans. Being a Medicaid enrollee is not a disqualification for enrolling.[8] However, the limitations on those who are eligible for tax subsidies to pay for an Exchange plan are more expansive.

B. Improper Assumptions

We are concerned that the RFI appears to make assumptions regarding the patients that receive care and the bases for the care is provided for them. We believe that it is important for CMS to consider the many reasonable factors that patients consider in selecting the most appropriate care to receive.

[8] The only qualifications necessary for an individual to enroll through an Exchange are that the individual be a resident of the state in which the Exchange exists, be lawfully present in the United States or a citizen, and not be incarcerated. 42 U.S.C. § 18032(f).

1. Medicare and Medicaid Patients Making Informed Choices

There are a number of reasons why a Medicare-eligible individual would make an independent and informed choice not to enroll in Medicare, or why a Medicaid-eligible individual would enroll in a Marketplace plan instead of or in addition to Medicaid. For instance, a consumer who wished to secure dependent coverage, supplemental benefits, and some out-of-pocket coverage may strongly prefer an Exchange-based plan to traditional Medicare.

Furthermore, Medicaid and Exchange plan benefits can differ significantly. For instance, the ACA requires non-grand fathered health plans in the individual and small group markets to cover essential health benefits (EHB), which include items and services in the following ten benefit categories: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care. HHS regulations (45 CFR 156.100) define EHB based on state-specific EHB benchmark plans – meaning the extent of the benefits covered within each of these categories can vary on a state-by-state basis. However, as CMS notes, prescription drugs, rehabilitative services, and certain preventive services are *optional* Medicaid benefits.[9] And much like with EHB, the extent of services covered under Medicaid are determined on a state-by-state basis, leaving room for significant variation across the country.

CMS's RFI discounts potential benefits of Marketplace coverage for these individuals. For instance, CMS asks only for information about "negative impacts on beneficiaries and enrollees" of third party premium assistance for an Individual Market plan for a Medicare- or Medicaid-eligible individual, apparently without considering that there could be positive impacts as well.[10] By focusing solely on the potential for undue influence by a health care provider on the beneficiary's choice and on potential harms to such an individual, CMS overlooks or omits the possibility that third party payments could provide significant benefits to individuals and that these individuals are capable of making independent, informed decisions about their own health care coverage.

CMS's underlying assumptions question these third parties' motives at the expense of respecting the dignity and ability of health care consumers to make well-informed decisions regarding their health insurance coverage options. Patients should remain in control of their ability to evaluate their options, consider the variety of factors involved, and choose an Exchange-based plan when it would best serve their needs.

[9] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/medicaid-benefits.html.*
[10] 81 Fed. Reg. at 57557.

2. Third Parties Providing Premium Assistance

The RFI appears to assume, incorrectly in the context of dialysis patients, that providers offering premium assistance do so solely for their own financial gain, and not to help their patients receive the best care for which they are eligible. Such assumptions are incorrect and fail to accurately consider various factors that go in to the election of health care treatment by Americans with ESRD.

As CMS states in the RFI, "[p]eople eligible for or receiving Medicare and/or Medicaid benefits should not be unduly influenced in their decisions about their health coverage options"—a sentiment CMS connects with the Agency's "goal … to protect consumers from inappropriate health care provider behavior" *without mentioning the need to protect consumers from inappropriate health insurance issuer behavior or to fairly evaluate health care provider conduct to ensure that lawful behavior is not punished.*[11] There are "bad actors" in every area of society, but the RFI is misdirected in assuming that health care providers direct patients to care at the expense of the patient's well-being.

3. CMS Has Overlooked Key Facts

We believe that CMS has overlooked the problematic, discriminatory behavior of some health insurance issuers that have been violating the ACA's nondiscrimination provisions and actively discouraging enrollments from individuals with ESRD. KCC has previously shared with the Center for Consumer Information and Insurance Oversight (CCIIO) multiple examples of unlawful practices of issuers that have been stating in various plan documents, for instance, that policyholders are eligible to be covered only if they are "[n]ot eligible for or enrolled in Medicare at the time of application" or that the plan "will calculate benefits as if [the member] had enrolled" in Medicare even if the member had not done so. Such statements are designed to deter or prohibit enrollments from individuals with ESRD who are eligible for Medicare but who may have very good reasons for wishing to stay in or select Exchange-based coverage. These practices directly violate Section 1557 of the Affordable Care Act and cause attendant harm to individuals with ESRD. In contrast, the vast majority of provider-affiliated organizations and health care providers providing premium assistance do so solely for the benefit of patients and, in doing so, help effectuate the patient freedom of choice and nondiscrimination purposes of the ACA.

C. Clarification of Law and Fact

1. Discussion of Section 1882 of the Social Security Act

The RFI states that "it is unlawful to enroll an individual in individual market coverage if they are known to be entitled to benefits under Medicare Part A, enrolled in Medicare Part B, or receiving Medicaid benefits."[12] This statement is inaccurate; it does not reflect the requirements established under

[11] *Id.* at 57556.
[12] *Id.* at 57556.

Section 1882 of the Social Security Act (SSA) and it fails to account for the express exemptions that apply to ESRD patients.[13] Notably, prior Agency guidance expressly exempted Exchange coverage from the Medicare anti-duplication statute. Specifically, with regard to Exchange coverage, CMS had previously clarified that: "Individuals with ESRD who do not *have* either Medicare Part A or Part B are eligible to enroll in individual market coverage *because the Medicare anti-duplication statute does not apply*; therefore, individual market guaranteed issue rights apply under the ACA."[14]

Furthermore, through the improper reference to standards established under SSA § 1882, the RFI suggests that Exchange coverage cannot be sold to individuals if it is "duplicative" of *Medicaid* coverage. However, the specific provision referenced by CMS in the excerpt above – and *directly* cited by CMS in the Agency's corresponding letter to providers[15] – merely prohibits the sale of *Medigap* policies to certain individuals who are eligible for benefits under Part A or enrolled under Part B of *Medicare*. Specifically, the section relied on by CMS states that:

> "[i]t is unlawful for a person to sell or issue *to an individual entitled to benefits under part A or enrolled under part B of* ***this title*** *[(i.e., title XVIII, or Medicare)]* (including an individual electing a Medicare+Choice plan under section 1851)… in the case of an individual not electing a Medicare+Choice plan, a *[M]edicare supplemental policy* with knowledge that the individual is entitled to benefits under another medicare supplemental policy or in the case of an individual electing a Medicare+Choice plan, a medicare supplemental policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under the Medicare+Choice plan or under another medicare supplemental policy."[16]

Elsewhere in this section of the statute, Congress provided that "[i]t is unlawful for a person to sell or issue *to an individual entitled to benefits under part A or enrolled under part B of* ***this title*** *[(i.e., title XVIII, or Medicare)]…* a health insurance policy with knowledge that the policy duplicates health benefits to which the individuals is otherwise entitled under this title *or title XIX*."[17] In other words, while the statute does establish a prohibition on the sale of an insurance policy that is known to be duplicative

---

[13] *See* SSA § 1882, codified at 42 U.S.C. § 1395ss.

[14] CMS, *Frequently Asked Questions Regarding Medicare and the Marketplace*, August 1, 2014, available at: *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf* (emphasis added).

[15] While the CMS RFI does not expressly cite Section 1882 of the Social Security Act, the corresponding letter from CMS to dialysis providers does. ("Moreover, in the case of an individual actually receiving Medicare and/or Medicaid benefits, as opposed to potentially eligible for such benefits, section 1882(d)(3)(i)(II) [*sic*] of the Social Security prohibits selling such a person insurance coverage knowing that it duplicates such Medicare and/or Medicaid benefits. Under section 1882(d)(3)(A)(ii), this act is punishable by imprisonment of up to five years and/or civil money penalties.") In turn, the RFI references language that mirrors the categories set forth under Section 1882.

[16] SSA § 1882(d)(3)(A)(i)(II) (emphasis added).

[17] SSA § 1882(d)(3)(A)(i)(I) (emphasis added).

of Medicaid benefits, it clearly limits this prohibition such that it applies only the subset of individuals who are first and foremost entitled to benefits under part A or enrolled under part B of Medicare.

In addition, CMS has previously stated that patients may not be simultaneously Medicaid-eligible *and receive tax credits or premium subsidies* for an Exchange policy—not that an individual who is Medicaid-eligible cannot *enroll* in an Exchange plan.[18] CMS states that "Qualified individuals who are Medicaid or CHIP eligible are allowed to purchase qualified health plans instead of receiving coverage through the Medicaid or CHIP programs. However, they are not eligible to receive advance payments of premium tax credits or cost-sharing reductions to help with the cost of purchasing qualified health plans through an Exchange."[19] This has been subsequently explained and understood by stakeholders – including, as we understand it, through CMS training – to mean that the only impact Medicaid eligibility has on an individual's ability to access a QHP is the limitation on the availability of subsidies – not the ability to actually purchase coverage. As noted, we understand that Navigators and brokers have been informed directly by CMS that patients who are enrolled in both plans with subsidies may remain enrolled in both policies, but they may not collect subsidies for their Exchange coverage; this is reiterated in guidance provided through Healthcare.gov.[20]

Moreover, CMS itself seems to recognize that Medicaid enrollment alone cannot obviate access to coverage under Exchange policies – and vice versa – given its ongoing willingness to approve State Medicaid waivers (*i.e.*, Section 1115 waivers) that permit the use of "premium assistance", or the state purchase of private market plans on behalf of Medicaid enrollees.[21] For example, the Medicaid and CHIP Payment and Access Commission explains that "[t]hrough Section 1115 research and demonstration waivers, Arkansas and Iowa are using Medicaid funds to purchase exchange plans for residents who are newly eligible for Medicaid."[22]

Furthermore, this broad sweeping statement by CMS (*i.e.*, that "it is unlawful to enroll an individual in individual market coverage if they are known to be… receiving Medicaid benefits") seemingly fails to acknowledge that there are, in fact, certain types of Medicaid coverage that are not considered "minimum essential coverage" (*e.g.*, pregnancy-related Medicaid). Enrollment in such Medicaid coverage would not disqualify individuals from receiving premium tax credits – let alone prohibit them from enrolling in a QHP.

Instead, what would truly be duplicative would be allowing an individual to receive subsidies for Exchange coverage both through Medicaid and through tax credits. However, that is not what is being

---

[18] *See* CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* (December 10, 2012).
[19] *Id.*
[20] *See, e.g.*, Healthcare.gov, *Cancelling a Marketplace plan when you get Medicaid or CHIP*, available at: *https://www.healthcare.gov/medicaid-chip/cancelling-marketplace-plan/.* ("If you still want a Marketplace plan after you're found eligible for Medicaid or CHIP, you will have to pay full price for your share of the Marketplace plan without premium tax credits or other cost savings.")
[21] *See, e.g.,* MACPAC, *Premium Assistance: Medicaid's Expanding Role in the Private Insurance Market (Ch. 5)*, March 2015, available at: *https://www.macpac.gov/wp-content/uploads/2015/03/Premium-Assistance-Medicaid%E2%80%99s-Expanding-Role-in-the-Private-Insurance-Market.pdf.*
[22] *Id.*

done with Medicaid enrollees who also enroll in Exchange plans — or at least that is not what is supposed to be done. To the extent that CMS is concerned that individuals are double dipping (e.g., receiving Medicaid and a tax subsidiary for a QHP), then the Agency could provide tools to providers to identify these instances. For instance, CMS could provide dialysis facilities with a list of individuals enrolled in both Medicaid and Exchange plans and tools to check if any of these individuals are receiving a tax credit for such Exchange coverage.

2. Coverage Options Before and After Transplant

Another critical inaccuracy in the RFI is the linkage of the statement that "[w]e 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" with the overbroad and somewhat misleading statement that "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."[23] The latter statement obscures the fact that patients may enroll in Medicare up to the day of transplant and receive full coverage for immunosuppressant drugs.[24] This is important because patients may delay enrollment in Medicare until they receive a transplant to ensure continuity of access to specialists, family coverage, or reduced cost-sharing. It is important to note that entitlement to Medicare continues only for the first three years following a patient's transplant, after which point the patient will no longer be eligible for Medicare. To that end, immunosuppressant drugs are covered under Medicare coverage for only these three years following transplant, yet those drugs are required for the rest of a patient's life to continue supporting the transplant. CMS's statement in the RFI does not recognize the possibility or benefits of staying in an Exchange plan until the transplant date.

This example appears to reflect an underlying and unsubstantiated assumption that patients who elect to enroll in Exchange plans despite their Medicare or Medicaid eligibility are necessarily subject to financial harm. By its language, the RFI overlooks important coverage-related nuances (such as the transplant example set forth above), the multiplicity of factors involved in health coverage choices, and individuals' abilities to evaluate these options for themselves based on their particular circumstances. Moreover, the RFI appears to overlook the fact that enrolling in the Exchange does not eliminate an individual's backup options of Medicare or Medicaid; eligibility in these programs is not lost through Exchange enrollment, and individuals can change their enrollments as required by their circumstances

[23] 81 Fed. Reg. 57555, 57556.
[24] CMS, "Medicare Coverage of Kidney Dialysis & Kidney Transplant Services" (rev. May 2016), *available at https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf; see* CMS, FAQ Regarding Medicare and the Marketplace (Aug. 2, 2014, updated Aug. 28, 2014), *available at http://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v21.pdf*, at 9 ("Individuals with ESRD are not required to sign up for Medicare; it is voluntary"; "Individuals with ESRD who do not have either Medicare Part A or Part B are eligible to enroll in individual market coverage because the Medicare anti-duplication statute does not apply; therefore, individual market guaranteed issue rights apply under the ACA").

(subject to enrollment period limitations). As it evaluates policy options moving forward, we urge CMS to consider the important nuances and the primacy of individual choice.

D. Discriminatory Effect of Proposals

The RFI appears to be hinting at policies that would effectively treat Medicare or Medicaid enrollment as a necessary follow-up to Medicare or Medicaid eligibility (at least for patients with ESRD), or that would in essence prohibit issuers from accepting third party payments on behalf of individuals with ESRD. Regardless of the reasons behind them, such policies would constitute *de facto* discrimination based on health status.

In addition to articulating above why CMS's assumptions are improper, we wish to underscore here that the results suggested by CMS (or that would follow as a logical consequence of CMS's proposals)—i.e., requiring individuals with ESRD to drop Exchange-based coverage and enroll only in Medicare or Medicaid, and prohibiting Marketplace plans from accepting third party payments on behalf of individuals with ESRD—would violate Section 1557 of the ACA. To avoid this unintended outcome, the Agency should carefully consider all implications of its proposals, and ensure that its steps to protect consumers and enhance the Marketplace do not inadvertently violate the ACA's nondiscrimination provisions. We are confident that CMS will carefully consider this information and formulate policies within the bounds of the law.

E. Better Ways to Address Problems

We believe that the RFI springs from CMS's desire to address concerns about risk pools—a desire that is legitimate given the unanticipated imbalance seen in the risk pools. Unfortunately, the RFI is built on a set of fundamentally flawed assumptions that could, without correction, result in policies that severely discriminate against sick, poor patients who the ACA was enacted to protect. Such discriminatory policies would not only harm vulnerable patients, but would also violate Section 1557 of the ACA while simultaneously failing to correct the underlying problems in the risk pools. The proposals in the RFI should be stepped away from in order to prevent such discrimination.

Fortunately, the ACA has already provided a variety of tools that would enable CMS to address issues with the risk pools. These tools include: continuing to strengthen risk adjustment, risk corridors, and reinsurance policies; establishing more special enrollment periods; encouraging more efficient and coordinated care; protecting charitable premium assistance; and making other efforts to encourage younger and healthier people to enroll. By using these tools, CMS will follow the arc of the ACA and help protect patient freedom of choice while also enhancing Marketplace options.

III. ESRD Facility Compliance with Governing Authorities

The discussion below is intended to clarify the current state of the laws governing Medicare- and Medicaid-eligible individuals' choices to enroll in Marketplace coverage, ESRD facilities' responsibilities for patient education, and third party premium assistance. In all respects, KCC believes that dialysis providers have been compliant with applicable laws.

A. Medicare Eligibility Versus Enrollment: Existing Guidance Effectuates the ACA's Nondiscrimination Provisions

On several occasions, CMS has issued guidance stating that that individuals with ESRD may not be discriminated against in the selection of a health insurance plan. In 2014, CMS clarified in regulatory guidance that individuals with ESRD may enroll in Healthcare Marketplace plans and that they may not be turned away by virtue of their kidney disease.[25] CCIIO reaffirmed this principle in 2015 when discussing how CMS will evaluate health plans for compliance with relevant nondiscrimination rules. CCIIO stated, "[w]e also remind issuers that individuals under age 65 with end stage renal disease (ESRD) are not required to sign up for or enroll in Medicare."[26] Not only has CMS clarified this critical distinction between Medicare eligibility and enrollment in order to protect patients' freedom of choice, but the Department of the Treasury has also issued similar guidance.[27]

These guidance documents underscore that ESRD makes a person *eligible* for Medicare but does not require a person to *enroll* in Medicare, and also indicate that such a person remains eligible for subsidies for private health insurance under the ACA. These guidance documents also cohere with the letter and intent of the ACA, as both the ACA and the guidance are premised upon the view that patients deserve freedom of choice regarding health care coverage—including whether or not to enroll in Medicare upon becoming eligible for Medicare—and that issuers may not discriminate against individuals based on health status. Furthermore, this guidance is consistent with the Medicare Secondary Payer laws,

---

[25] *See* CMS, FAQ Regarding Medicare and the Marketplace (Aug. 2, 2014, updated Aug. 28, 2014), *available at http://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v21.pdf*, at 9 ("Individuals with ESRD are not required to sign up for Medicare; it is voluntary"; "Individuals with ESRD who do not have either Medicare Part A or Part B are eligible to enroll in individual market coverage because the Medicare anti-duplication statute does not apply; therefore, individual market guaranteed issue rights apply under the ACA").

[26] CCIIO, *Final 2016 Letter to Issuers in the Federally-facilitated Marketplaces* (Feb. 20, 2015), at 36, *available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015-R.pdf*. Guidance on the Medicare.gov website currently confirms the same important principle: "[T]here are a few situations where you can choose a Marketplace private health plan instead of Medicare: … If you're eligible for Medicare but haven't enrolled in it. This could be because: … You have a medical condition that qualifies you for Medicare, like end-stage renal disease (ESRD), but haven't applied for Medicare coverage." Healthcare.gov, "*If you have Medicare*," available at: *https://www.healthcare.gov/medicare/medicare-and-the-marketplace*.

[27] *See* IRS Notice 2013-41, *Eligibility for Minimum Essential Coverage for Purposes of the Premium Tax Credit*, available at *https://www.irs.gov/pub/irs-drop/n-13-41.pdf* (noting that "[a]n individual is eligible for minimum essential coverage under… [certain programs including Medicare Part A] for purposes of the premium tax credit only if the individual is enrolled in the coverage.").

which state that beneficiaries may choose to keep their private coverage for up to 30 months before enrolling in Medicare.[28]

B. Current Rules on Tax Credits and Medicaid Enrollment: Supportive of the ACA and Also Reflected in CMS's Waivers

While the RFI states that an individual enrolled in Medicaid may not enroll in a Marketplace plan, CMS has clarified on other occasions that the true limitation is on Medicaid beneficiaries' ability to receive subsidies for Marketplace coverage. Specifically, the ACA provides, and the Administration has stated, that individuals are prohibited only from accessing Medicaid (or other minimum essential coverage) *and* receiving tax credits toward their Marketplace premiums.[29] This rule coheres with the underlying intent of the ACA, since one of its core purposes was to expand the availability of high-quality coverage options for low-income individuals, and it also avoids running afoul of the anti-duplication intent by prohibiting two government subsidies per individual. Moreover, in such situations, the Exchange coverage would need to be designated primary and the Medicaid coverage secondary, which would protect federal and state governments from incurring inappropriate costs and ensure beneficiaries have access to the broadest array of services.

Not only do CMS's existing rules allow this, but CMS has also explicitly approved waivers for states seeking to purchase Exchange coverage for Medicaid beneficiaries. Arkansas, for instance, received a Section 1115 waiver to purchase Exchange coverage for individuals from the traditional Medicaid expansion population. Iowa, likewise, previously received a Section 1115 waiver allowing the state to provide Medicaid premium assistance to allow certain individuals to purchase Exchange plans. More recently, CMS approved New Hampshire's Section 1115 waiver to transform its existing Medicaid expansion program into a Marketplace premium assistance model, under which Marketplace coverage would be purchased for newly-eligible adults. In approving these waivers, CMS has recognized the potentially significant benefits of expanding Marketplace enrollment to Medicaid-eligible consumers.

We recognize that CMS's concerns about Medicaid-eligible individuals' enrollment in Exchange-based plans could relate to the possibility that these individuals could be high-cost patients and, as such, could skew the risk pools. While it is certainly a valid consideration, the conclusion is by no means warranted. Some insurers—including non-Medicaid plans—have employed strategies to manage high-cost patients and thereby experience success in the Marketplace. In fact, CMS recently launched a series of plan outreach and engagement efforts, designed to highlight "success stories come from all across the country and from diverse types of insurers and markets" and "describe strategies around consumer

---

[28] SSA § 1862(b)(1)(C).

[29] *See*, e.g., IRS Notice 2013-41, *Eligibility for Minimum Essential Coverage for Purposes of the Premium Tax Credit,* available at: *https://www.irs.gov/pub/irs-drop/n-13-41.pdf*. ("Under § 36B and § 1.36B-2 of the Income Tax Regulations, in general, an individual (who may be the taxpayer claiming the premium tax credit or a member of the taxpayer's family) may receive health insurance coverage subsidized by the premium tax credit only for months the individual is enrolled in a qualified health plan through an Exchange and is not eligible for other minimum essential coverage.")

engagement, provider contracting, and care coordination models tailored by population data."[30] It is widely reported that the Agency is in turn developing a toolkit that CCIIO Director & Marketplace CEO Kevin Counihan hopes issuers can use to replicate these successful strategies across the country and entice issuers to return to or remain in the Marketplaces."[31] KCC applauds these plans' successes and appreciates CMS's forthcoming efforts to encourage and expand such strategies.

C. Patient Education: Dialysis Providers' Legal Obligations and Important Work with Patients

Insurance education, without influence, has long been a pillar of the services provided by dialysis providers. In fact, insurance education is required by the Dialysis Patients' Bill of Rights and Responsibilities.[32] As such, patients in a dialysis facility are fully educated on the insurance choices available and all assistance programs available to them, from government programs to nonprofit foundations. Social workers in dialysis facilities provide the requisite insurance education, in addition to performing a variety of other functions such as evaluating patients' psychosocial needs.[33] These social workers must meet specified education and training requirements that prepare them to meet the unique and wide-ranging needs of dialysis patients.[34] Of critical importance, dialysis facility social workers do not sell insurance or have financial relationships with insurers. Their conversations about insurance coverage with dialysis patients are designed to inform patients about their financial responsibilities under various coverage options, and if requested by patients, social workers may provide assistance with completing insurance forms. CMS's presumption that patient steering is occurring in dialysis facilities simply attacks these social workers' character, professional responsibility, and level of commitment to their patients—without provocation. We agree with CMS that "[e]nrollment decisions should be made, without influence, by the individual based on their specific circumstances, and health and financial needs,"[35] and we believe that education provided by social workers to dialysis patients in dialysis facilities is facilitating, not hampering, these patients' abilities to make enrollment decisions in their best interests.

Moreover, whereas CMS voices concern that "[p]eople 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,"[36] we wish to clarify that patients who are steered in *any* direction, either towards *or away from* Exchange coverage, may face a disruption in

---

[30] *https://blog.cms.gov/2016/05/09/improving-the-marketplace-through-innovation/.*
[31] Lotven, Amy, Inside Health Policy, *Counihan Confident Plans Will Return To Exchanges For 2018* (Aug. 31, 2016), available at: *http://insidehealthpolicy.com/daily-news/counihan-confident-plans-will-return-exchanges-2018.*
[32] National Kidney Foundation, *Dialysis Patients' Bill of Rights and Responsibilities* (2013), *available at https://www.kidney.org/sites/default/files/11-65-1639_dialysisbillrights.pdf.*
[33] *See, e.g.,* 42 C.F.R. § 494.80(a)(7).
[34] 42 C.F.R. § 494.140(d).
[35] 81 Fed. Reg. at 57555.
[36] *Id.* at 57556.

coverage if their continuity of care is not carefully considered. Steerage can create disruption, which is why holistic patient education that enables patients to make the insurance decisions that are best for them is a critical support for patients on dialysis. Regardless of the type of insurance dialysis patients ultimately select as their primary and/or secondary coverage, these patients need support in completing a thorough review of the network of physicians, pharmaceuticals, and ancillary benefits that are available, whether they are selecting coverage for the first time or making a change in coverage. The education provided by social workers in dialysis facilities can help provide these invaluable forms of support.

The multifaceted work of social workers is one example of how dialysis providers have patients' best interests at heart and work in a wide variety of ways to serve their patients' needs. Additionally, dialysis providers, pursuant to their education requirement, think holistically about patient well-being, and provide social workers or other trained resources to consult with patients individually to help each patient understand the benefits and drawbacks of all available options based on the patient's specific circumstances before that patient makes a coverage decision. In doing so, dialysis facility social workers and other trained resources satisfy their obligations under the Dialysis Patients' Bill of Rights and Responsibilities, and patients benefit from the opportunity to gather and evaluate information required for an informed and independent decision.

Should CMS believe that a change in the *Dialysis Patients' Bill of Rights and Responsibilities* is needed, then the Agency should address that specifically and work with the ESRD community to come up with appropriate modifications. Dialysis providers are compliant with the law and what the Agency itself has told providers to do on many occasions.

D. History of Working with CMS to Support the Agency's ACA Implementation Efforts

KCC has worked consistently with CMS since passage of the ACA to ensure that individuals with ESRD had the same, equal access to QHP coverage as individuals with other chronic conditions, or any other eligible citizen for that matter. Our member companies requested and were granted multiple meeting opportunities with CCIIO in 2012 and in 2013, leading to the publication of guidance and FAQs that established QHP access rights for individuals with ESRD, regardless of their eligibility for Medicare. In at least one instance, we were asked to assist our patients in making informed coverage decisions and in QHP/Exchange enrollment – a request we took seriously and implemented during the first and subsequent open enrollment periods under the ACA. Since then, we have met with CMS and CCIIO to draw attention to problematic issuer conduct, like access denials, detailed *supra*, that we believe is discriminatory.

IV. Importance of Charitable Premium Assistance Payments

A. Consistent with the ACA: Helping the Poorest, Sickest Individuals

Protecting the opportunity for charitable premium assistance is critical because the primary recipients of these subsidies are low-income individuals, often facing significant health conditions—the very people whom key provisions of the ACA were enacted to help. While we agree with CMS about the need for guardrails around third party charitable assistance payments, it is imperative that CMS recognize exactly who will be harmed by broad restrictions. Especially in the case of premium assistance subsidies on behalf of patients with kidney disease, these subsidies provide valuable insurance options for a disproportionately poor, sick, and minority populations. To deny these people the opportunity for premium assistance for Exchange coverage would not only be detrimental to their well-being, but would also constitute discrimination based on their health status, contrary to the nondiscrimination provisions of the ACA.

This discrimination is magnified by the existence of the Ryan White HIV/AIDS program, which is permitted to provide premium assistance subsidies for Exchange plans on behalf of individuals with HIV/AIDS. Much like HIV/AIDS, ESRD is a long-term health condition that presents individuals with significant health care costs. Moreover, given that patients subsidized by Ryan White will be allowed to remain in the Exchange plans, the notion of prohibiting ESRD patients subsidized by third party charitable organizations from remaining in Exchange plans does not make economic sense. Ryan White-subsidized patients, along with the Medicaid-eligible, subsidized patients from state waiver plans, who are enrolled in Exchange plans together could skew the risk pool significantly more than the comparatively very small number of subsidized ESRD patients enrolled in Exchange plans. Further, there are tools available to plans that can help them manage high-cost patients, and CMS should devote its energy toward identifying, supporting, and communicating these tools among plans instead of removing important health coverage options from poor, sick, minority populations.

B. Need for Well-Designed Guardrails

As part of ensuring the continued availability of charitable premium assistance subsidies for ESRD patients and other low-income, sick individuals, CMS should adopt clear and carefully designed guardrails. These guardrails are needed on two fronts: (1) identifying the specific charities or third party entities that are permitted to provide the subsidies; and (2) specifying which organizational practices are acceptable. With respect to the organizations that should be allowed to subsidize Exchange premiums, we believe that CMS should require issuers to accept payments from any nonprofit charitable organization that existed prior to the ACA's enactment, that has been favorably reviewed by an Office of Inspector General Advisory Opinion, and that provides at least one year of assistance to enrollees. Regarding organizational practices or behaviors, the guidelines should specify the charity's obligations for due diligence, the individual recipient's income level, and the organization's reporting requirements to insurers and CMS, among other things. These rules will help ensure that subsidies are going to

individuals who need and deserve extra assistance, while also protecting against improper use of such programs to drive patients into certain products or plans.

Moreover, the dialysis provider community stands ready to help CMS monitor and enforce these guardrails. Likewise, ESRD facilities are ready and willing to assist CMS with its concerns that there could be some individuals receiving both tax credits and Medicaid subsidies for Exchange coverage. Our patient education already includes an explanation to individuals that such a situation is not permissible, and we are not in fact aware of any ESRD patients violating these rules. However, if CMS has information or tools that can be given to providers to enable us to check or confirm that our patients are not simultaneously receiving tax credits and Medicaid subsidies for Exchange plans, we will work with the Agency to address these concerns.

V. Conclusion: Call for Fidelity to the Letter and Spirit of the ACA

KCC shares CMS's concerns about aggressive or unethical behaviors by any individual or entity that may result in harm to health care consumers or federal health care program beneficiaries. Further, KCC believes that CMS is, like KCC member companies, fully committed to the nondiscrimination principles of the ACA as well as to ensuring the availability of high-quality, affordable, accessible medical care that meets the needs of individuals with ESRD, who are some of the most vulnerable health care consumers. As such, KCC believes that the potential ACA Section 1557 violations that could result from some of CMS's proposals in the RFI are unintentional. KCC, accordingly, appreciates this opportunity to raise these concerns to CMS and to encourage the Agency to ensure that any next steps it takes to enhance the Marketplace also support the nondiscrimination provisions of the ACA and cohere with existing CMS guidance.

KCC agrees wholeheartedly with CMS that there is no place in high-quality, patient-centered treatment for "undue influence" from providers or decisions for the provider's financial gain at the expense of patients and that "enrollment decisions should be made based on an individual's particular financial and health needs."[37] At the same time, we urge CMS to realize that such instances of bad conduct, if identified, are by no means the norm. Moreover, we exhort CMS not to undo the important work it has already accomplished through prior Agency guidance which helps protect individuals with ESRD from issuers' discriminatory practices. Instead, we encourage CMS to proceed carefully, seek and evaluate a more robust set of data regarding provider *and issuer* behavior, and craft narrow policies that prohibit only bad conduct, not good conduct that could be improperly perceived as bad conduct if viewed through the lens of extreme bias against health care providers. As CMS itself recognized in the RFI, "[i]ndividuals eligible for Medicare and/or Medicaid benefits are not required to enroll in these programs," and the Agency must ensure that its future policy decisions do not effectively nullify this critical patient protection principle to the detriment of some of the poorest, sickest Americans.[38]

---

[37] *Id.*
[38] *Id.* at 57555.

Thank you for your attention to these matters. Please contact Colin Roskey at (202) 239-3436 or me at (202) 744-2124 should you wish to discuss these matters further or if KCC can be of any assistance to CMS in the Agency's ongoing efforts to enhance the Marketplace and protect health care consumers from discrimination in accordance with the ACA.

Respectfully Submitted,

Cherilyn T. Cepriano
President

Kidney Care Council Member Companies 2016

American Renal Associates
Atlantic Dialysis Management Services
Centers for Dialysis Care
DaVita Healthcare Partners
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Northwest Kidney Centers
Renal Ventures Management
The Rogosin Institute
Satellite Healthcare
U.S. Renal Care

EXHIBIT 7

DaVita, Inc.
2000 16th Street
Denver, CO 80202

September 22, 2016

Submitted electronically through Regulations.gov.

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-6074-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: *Request for Information, Steering of Individuals Eligible for or Receiving Medicare or Medicaid Benefits to Individual Market Plans*

Dear Mr. Slavitt:

Please allow this letter to serve as DaVita Kidney Care's (DaVita) response to the Request for Information (RFI) you issued on August 18, 2016. We appreciate the opportunity to demonstrate that our processes comply with not only the letter, but also the spirit of federal law and regulations.

As discussed in more detail below, DaVita's focus is on enabling its patients to make well-informed choices, based on the patient's circumstances, needs and preferences. DaVita does not steer patients towards any particular insurance option or plan. DaVita educates its patients so that they are able to make informed decisions that are in their best interest. Moreover, DaVita does not pay patients' health insurance premiums. Charitable assistance provided to end stage renal disease (ESRD) patients by the American Kidney Fund's (AKF) Health Insurance Premium Program (HIPP) is sufficiently separate from provider contributions to the AKF and provides invaluable support to patients most in need. To limit ESRD patients' access to such charitable premium assistance as suggested in the RFI would unduly burden this already financially disadvantaged patient population. Instead, access to charitable assistance for ESRD patients, such as provided by the AKF under the long-standing guardrails of the OIG opinion, should be explicitly protected by CMS.

Our response is presented in four sections to address: (1) the unique nature of ESRD and the existing regulatory framework concerning the provision of renal dialysis services; (2) the interdisciplinary services we provide to our patients pursuant to this regulatory framework; (3) dialysis patients and the Affordable Care Act (ACA); and (4) the impact on the individual risk pool. We respond to the specific questions raised at the end of the RFI in Addendum A, attached to this letter.

I. Unique Nature of Renal Dialysis and the Existing Regulatory Framework

Congress and CMS have long recognized the unique nature of dialysis patients. This recognition has come in the form of specific regulatory provisions that create a unique balance between the protection of the patient and the financial impact of these chronically ill patients on the healthcare system. Maintaining this balance is particularly important as this patient group is predominately made up of racial minorities and financially disadvantaged individuals.

A. ESRD Patients and Unique Medicare Eligibility Qualification

In 1972, Congress amended the Social Security Act to create a special eligibility for Medicare for individuals under the age of 65 suffering from ESRD who met certain eligibility requirements. This eligibility was not age based, but rather a result of the ESRD diagnosis and entitled a qualifying individual to Medicare coverage after three months from the ESRD diagnosis (hereafter "ESRD Medicare Eligibility").[1] While the ability to enroll is an enormous benefit to many, Congress and CMS appreciated that ESRD Medicare Eligibility may not be considered a benefit by all, so they did not require a patient to enroll in Medicare. The provision allows a patient with ESRD Medicare Eligibility to remain on primary commercial coverage for 30 months before Medicare becomes primary. The statutory provision governing ESRD Medicare Eligibility has been amended several times over the years to protect patients, providers, and the insurance carriers, but the fundamental premise remains the same – patients qualifying for ESRD Medicare Eligibility have the *choice*, but are not required, to enroll. Specifically, unlike individuals who qualify for Medicare based on age, individuals who qualify for Medicare based on their ESRD diagnosis are not required to enroll in Medicare, and they incur no penalty if they chose to delay Medicare enrollment.

[1] To qualify for Medicare under the age of 65, individuals with ESRD and on dialysis must (a) have worked the requisite amount of time under Social Security, the Railroad Retirement Board, or as a government employee, or (b) must be eligible for Social Security or Railroad Retirement Benefits, or (c) be the spouse or dependent child who meets the requirements of (a) or (b). 42 U.S.C. §426-1.

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

ESRD is the only disease state for which these special conditions exist.

B. Dialysis Providers Required to Provide Interdisciplinary Support to ESRD Patients

CMS also enacted unique rules as to how these patients should be treated by dialysis providers. For example, in April 2008, CMS published new Conditions for Coverage for Renal Disease Facilities.[2] The stated purpose of the new rules was to emphasize a more patient-centric, outcome-oriented approach to dialysis treatment, with a focus on interdisciplinary, integrated care that would educate each individual patient on the full range of their rights and responsibilities at the onset of treatment, and better enable that patient to cope with their kidney disease.[3]

In the Dialysis Patient Bill of Rights and Responsibility, CMS outlines that dialysis patients are entitled to rights that include:

- The right to be treated with respect
- The right to be told about my health in a way that I understand
- The right to be told about and choose my treatment options
- The right to be told about services offered at the center
- The right to be told about any expenses they may have to pay for that are not covered by insurance or Medicare, and
- The right to be told about any financial help available to me.[4]

II. DaVita's Interdisciplinary Support Services

DaVita provides interdisciplinary support that is consistent with CMS regulations. The fundamental principle behind DaVita's interdisciplinary support is that all decisions are made by the patient and the patient's choice is paramount. DaVita does not steer patients in their treatment options or to any particular type of insurance coverage, plan or provider. Instead, DaVita provides comprehensive, accurate information that allows our patients to make informed choices on the various clinical and financial decisions dialysis patients face, based on their individual circumstances and preferences.

---

[2] *73 Federal Register 20370, 4/15/2008.*
[3] *73 Federal Register at 20371, 20387, 4/15/2008.*
[4] *Dialysis Facility Patient Rights, at https://www.medicare.gov/dialysisfacilitycompare/#resources/patients-rights.*

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

Responsibility for the balanced education of our patients rests with an interdisciplinary team that includes social workers and insurance counselors, as well as the members of the patient's medical care team. The interdisciplinary team conducts regular assessments that include, among other things, psycho-social evaluations, evaluations of the patient's financial capabilities and resources, and evaluations of the patient's insurance options.[5] The interdisciplinary team has ongoing communications with the patients on these issues.

If a patient has multiple insurance options, DaVita seeks to ensure the patient receives balanced, comprehensive information presented in a straightforward way to enhance the patient's understanding, including the short and long-term implications of each option. Many of the insurance issues these patients face are unique to dialysis (*e.g.*, ESRD Medicare Eligibility) and many are impacted by local factors (*e.g.* state differences). In order to properly educate patients on the wide range of insurance issues and options, DaVita social workers and insurance counselors undergo rigorous training on the available insurance options and requirements for coverage available to patients in each state. The DaVita team, whenever possible, seeks to include family members in the education process along with the patient. We provide multiple opportunities to discuss issues to avoid a rushed decision. To help ensure an unbiased presentation of information to the patients, the DaVita interdisciplinary team has no outcome incentives. In addition, the team does not have knowledge of specific contract terms or rate agreements between DaVita and the commercial payors.

As a result of each of these mechanisms, we are confident that our patients' choice of coverage is driven by their needs and preferences.

III. Dialysis Patients and the ACA

DaVita's obligations to its patients under the Conditions of Coverage and the other applicable regulatory provisions did not change with the advent of the ACA. What changed was that some of our patients now have a new option, namely to obtain or retain healthcare coverage under an individual market plan. Where applicable, and with the explicit encouragement of CMS officials,[6] this option was presented by the interdisciplinary team consistent with DaVita's overall structural guardrails.

---

[5] CMS ESRD Surveyor Training Interpretive Guidance, 10/3/2008, page 187, available at https://www.medicare.gov/dialysisfacilitycompare/#resources/patients-rights.

[6] *In numerous meetings, CMS officials repeatedly requested that DaVita and other dialysis providers ensure patients were provided information about, and had the opportunity to enroll in, individual marketplace insurance plans.*

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

Under the ACA, a dialysis patient has the opportunity to enroll in an individual market plan if the patient (1) is a citizen or lawfully present in the U.S, (2) is not incarcerated, and (3) meets the applicable residency standards.[7] A qualified individual may choose to enroll in any qualified health plan available.[8]

A. Patients with ESRD Medicare Eligibility and the ACA

The ACA did not revise or impact the ESRD Medicare Eligibility provisions – specifically, the patient still has the right to choose whether to enroll. An individual who selected and enrolled in an individual market plan and then was diagnosed with ESRD is governed by the ESRD Medicare Eligibility provisions that provide enrollment in Medicare is voluntary. Indeed, CMS specifically provided that "individuals with ESRD who do not have either Medicare Part A or Part B are eligible to enroll in individual market coverage . . . individual market guaranteed issue rights apply under the ACA."[9] Healthcare.gov also recognizes that an individual can choose an exchange plan instead of Medicare.[10] As such, individual market plan patients who qualify for ESRD Medicare Eligibility face the same choice as patients on group health plans and do not incur any penalties for late enrollment.[11] DaVita educates these patients on their choices consistent with the interdisciplinary support framework discussed above.

For these patients, who often are still working or trying to remain in the work force, factors they consider when deciding whether to continue with their individual market plan coverage or enroll in Medicare are both clinical and financial. The following are examples of such considerations:

- The benefit of continuity of coverage by remaining on the same individual market plan;
- The fact that many providers do not accept **new** Medicare patients;[12]

---

[7] *45 C.F.R. §§155.305(a), 155.315.*

[8] *42 U.S.C. §18032(a).*

[9] *CMS FAQs Regarding Medicare and the Marketplace, as updated 8/28/2014, Q. B.2, available at https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf.*

[10] *https://www.healthcare.gov/medicare/medicare-and-the-marketplace/.*

[11] *Because patients with ESRD would incur financial consequences if they elected to withdraw a Medicare application to join an individual market plan, DaVita did not educate patients on this option and did not assist with any such transition.*

[12] *The Texas Medical Association reported over a recent two year period that the percentage of physicians accepting new Medicare patients dropped from 66% to 58%. (https://www.texmed.org/template.aspx?id=24764) "Secret shopper" surveys of physicians who are included on lists as accepting Medicare were proven to be largely inaccurate in Oregon and in Tallahassee Florida; the Florida survey revealed that while a majority of area physicians were reported to accept Medicare; 60% of those physicians either accepted no **new** Medicare patients, or capped the number of patients they would accept. (http://www.oregonlive.com/finance/index.ssf/2015/10/medicare_2015_more_doctors_rej.html; http://www.consultant360.com/articles/milestone-or-millstone-medicare-access-midsize-metros.)*

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

- The potential inability to enroll in Medicare Advantage plans;
- The potential additional costs involved with applicable premiums, deductibles and co-insurance responsibilities in light of the need to enroll in Medicare Parts A, B, and D;
- Additional costs of having to purchase separate insurance coverage for the patient's family;
- The inability to obtain Medi-Gap insurance in some states for ESRD patients under 65;
- Limitations on the ability to obtain coverage for ancillary services through Medicare such as dental or vision coverage, which may be vital for patients considering a transplant;[13]
- Enrollment in Medicare Part A means individuals will lose any premium tax credits (PTC) or cost-sharing reductions (CSR) they presently receive under an exchange plan;
- Individuals on a current transplant list could potentially lose their place on the waiting list if the transplanting facility or provider does not accept Medicare;
- An individual who enrolls in Medicare due to ESRD cannot later change their mind and "opt-out" of Medicare enrollment without significant financial risk for amounts expended by Medicare during the period of enrollment.

As has been the case for over 30 years, patients who become Medicare eligible due to the onset of ESRD evaluate these various clinical and financial factors to make the decision that is best for them. Patients can only do this effectively if they are informed about their rights and the options available to them. The RFI focuses on the potential harm to patients in enrolling in individual market plans but seems to ignore the multitude of benefits patients derive from enrolling in the individual market plans. DaVita's patients make choices based on these benefits.

B. Medicaid Patients and the ACA

The opportunity for Medicaid patients to enroll in individual market plans was greatly enhanced by the ACA. Contrary to the letter written to dialysis facilities in connection with the RFI,

[13] *Dental infections are a leading obstacle to kidney transplant eligibility, so for some dialysis patients dental coverage is a necessity.*

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

Medicaid patients have the right under the current regulations to enroll in an individual market plan.[14]

Indeed, CMS recognizes in its training materials that a Medicaid beneficiary is eligible to enroll in an exchange plan.[15] As stated in a March 2016 training, when individuals have access to an exchange plan, but also are Medicaid eligible, the role of the broker/agent is to "inform" the patient that "they should consider their individual circumstances and health care needs before deciding which coverage is best for them."[16] Thus under the current regulations, patients eligible or enrolled in Medicaid are permitted to enroll in an individual market plan while retaining their Medicaid coverage. Where state Medicaid plans and programs coordinate coverage, DaVita informs Medicaid patients of this choice as part of its education.

In certain situations Medicaid patients may choose to enroll in an individual market plan and have Medicaid coverage secondary. These decisions are based on a variety of clinical and financial considerations including, for example:

- Limitation on the network of available providers if Medicaid only -- according to a Kaiser Family Foundation Report from October 2015, only 67% of primary care providers treat Medicaid patients and only 44% of those accept **new** Medicaid patients;[17]
- The ability to access specialists or transplant providers;
- The opportunity for family coverage;
- Access to required medications not covered by Medicaid;

---

[14] *The letter states that "section 1882(d)(3)(A)(i)(II) of the Social Security prohibits selling [a person receiving Medicaid benefits] insurance coverage knowing that it duplicates such Medicare and/or Medicaid benefits." Section 1882 of the Social Security Act, however, is specific to the sale of Medicare Supplemental Health Insurance Policies, not individual or exchange plans. Even if, arguendo, CMS intended to cite to subsection (d)(3)(A)(i)(I), and wanted to read subsection I as outside of the title of Section 1882, and applying to sales broader than just Medicare Supplemental Policies, the subsection cannot be isolated from the introductory phrase: section (d)(3)(A)(i) in its entirety* ***only*** *applies to sales of insurance policies to individuals entitled to benefits under Medicare Part A, enrolled in Medicare Part B, or who have elected Medicare+Choice plans - not to Medicaid beneficiaries. If read in this manner, the citation to Title XIX in subsection I is easily explained as a reference to Medicare beneficiaries who are dually eligible and thus receive secondary coverage from Medicaid under Title XIX.*

[15] CMS Training, *Assisting Consumers with Complex Situations, Tips for Agents and Brokers Assisting Consumers in the FFM,* 3/30/2016, page 26.

[16] *CMS Training, Assisting Consumers with Complex Situations, Tips for Agents and Brokers Assisting Consumers in the FFM, 3/30/2016, page 26.*

[17] http://kff.org/medicare/issue-brief/primary-care-physicians-accepting-medicare-a-snapshot/.

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

- The ability to travel out-of-state as most dialysis patients need treatment three times/week and most Medicaid programs will not provide coverage for healthcare services obtained out of state.

Medicaid patients enrolling in individual plans is not unique to dialysis. Indeed, more than 30 states operate programs that provide premium assistance to Medicaid beneficiaries to enable the Medicaid beneficiaries to obtain commercial insurance, including several programs specific to obtaining individual market plans. Arkansas estimates that close to 300,000 Medicaid-eligible individuals obtained health insurance coverage through an exchange plan with Arkansas covering the cost of premiums.[18] New Hampshire also implemented a program to support the purchase of coverage for Medicaid beneficiaries through the purchase of individual market plans in the exchange market. The goal of the New Hampshire program was to provide the patient with services not covered by Medicaid, and have Medicaid provide what it terms "wrap" benefits, not covered by the individual market plan, including limited vision and dental services, non-emergency medical transportation and free access to family planning services.[19] Washington, Colorado, Iowa, Missouri, and multiple other states also tout the benefits of their programs to have Medicaid beneficiaries obtain primary insurance through individual coverage, employer plans or COBRA, especially for those with chronic conditions, because of the ability to access services not covered by Medicaid, to get family members covered, and to maintain Medicaid as secondary insurance.[20]

C. Dialysis Patients and PTC and CSR

With respect to the tax credits and subsidies, when educating Medicaid beneficiaries or Medicare Part A beneficiaries interested in considering enrollment in an individual market plan, DaVita explicitly advises the patients that they would be ineligible for PTC or CSR. DaVita, however, does not have a mechanism to ensure the patient does not receive any PTC or CSR as we are not involved with every application process or preparing the patient's tax returns. We believe that certain plans protect against the possibility in the enrollment process. For example, one plan requires that individuals applying for exchange plans who have minimal essential coverage

---

[18] *Arkansas Health Care Independence Program, Private Option, Interim Report, June 2016, available at* http://www.achi.net/Content/Documents/ResourceRenderer.ashx?ID=357.

[19] *New Hampshire Health Protection Program Premium Assistance Section Fact Sheet, page 1; NHHPP: Marketplace Premium Assistance Program Overview, available at* http://www.dhhs.nh.gov/ombp/pap/documents/overview.pdf.

[20] http://myarhipp.com/wp-content/uploads/2013/01/ARHIPP-BROCHURE_V3.pdf; ttps://www.colorado.gov/pacific/hcpf/health-insurance-buy-program. http://dss.mo.gov/mhd/participants/pages/hipp.htm; http://dhs.iowa.gov/ime/members/medicaid-a-to-z/hipp.

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

submit the application by paper, as opposed to on-line.[21] The federal health care exchange application, however, does not appear to have a section for the applicant to indicate whether they are asking to be considered for PTC or CSR.[22]

If patients are, in fact, inappropriately receiving PTC or CSR, DaVita is open to working with CMS to identify any such patients and to rectify and resolve any such situations. DaVita also is open to working with CMS to adopt changes in the exchange application process to prevent any such future occurrences.

IV. Impact on the Individual Market Risk Pool

The RFI raises concerns and seeks input relating to the impact "of potential steering activities" on the individual market risk pool. To be clear, DaVita does not steer patients and, therefore, our activities do not present such risk to the individual market risk pool. DaVita recognizes, however, that ESRD patients have high healthcare needs so their participation in the individual market likely would have an impact, especially if an insufficient number of healthy patients enrolled in the individual market.

A. ACA Planned for Dialysis Patients

The ACA accounted for dialysis patients in its genesis and three-year implementation in several ways. First, the benchmark plans contain 30 months of dialysis coverage as an essential health benefit. By regulation, plans in the individual and small group markets must be "substantially equal" to benchmark plans with regard to limitations on coverage, benefit amount, duration and scope.[23] Therefore, the historical costs of covering dialysis patients were factored in at the front end of risk calculations for the exchange plans, and should not be unduly impacting ultimate costs.

Second, because the purpose of the ACA was to increase health insurance options for the uninsured and underinsured, processes were instituted using risk pool adjustments and transitional reinsurance programs, to account for the costs of an influx of chronically ill enrollees. Those programs appear to working because during the period from 2014-2015 per-enrollee costs in the broader health insurance market grew by at least 3% as compared to the per-

[21] *Of note, this bifurcated process also demonstrates that the plans are aware that patients with minimum essential coverage are applying for individual policies.*
[22] *https://marketplace.cms.gov/applications-and-forms/marketplace-application-for-family.pdf*
[23] *45 CFR 156.115(a)(1)(ii).*

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

enrollee costs in the individual market, which actually fell by .1%.[24] In addition, the 2016 marketplace premiums were between 12%-25% **lower** than initially predicted.[25]

Third, it was known and anticipated that individuals with minimal essential health coverage, including beneficiaries of government health, might enroll on the individual market. For example, as discussed above, at least one large health insurer implemented a separate application process for individuals with minimal essential health coverage, another specifically asked whether applicants were presently covered by Medicaid.

We recognize that the individual market plans are relatively new and that CMS, and the states, are actively reviewing and addressing changes to the risk adjustment and reinsurance programs.[26] DaVita agrees with CMS that the goal of any changes to the risk adjustment process should be in keeping with the goal of the ACA itself: to foster a stable market "in which insurers are rewarded for providing high-quality, affordable coverage, not for offering plans designed to attract the healthy and avoid the sick."[27]

B. Charitable Premium Assistance for ESRD Patients

The RFI also questions the impact of charitable premiums assistance broadly on the individual market risk pools. While DaVita recognizes the very legitimate concern associated with reports that some providers are directly paying premiums for short periods of time to bill for expensive treatments. That is not the situation with dialysis patients. Through the American Kidney Foundation (AKF), state Medicaid HIPP programs, and other organizations, the charitable premium assistance offered to ESRD patients is akin to other programs which CMS already protects, such as the Ryan White program. These ESRD assistance programs offer long-term assistance (*e.g.*, annual grants) based exclusively on financial need. Importantly, there is nothing to suggest that ESRD patients who receive charitable support have a disproportionate effect on the risk pool as compared to chronically ill individuals who receive support from CMS protected programs. Since charitable premium assistance for dialysis patients in its current form has existed for nearly 20 years, the impact of charitable assistance to ESRD patients also is included in the benchmark plans.

---

[24] *Building on Premium Stabilization for the Future, by Kevin Counihan, CMS Blog, 8/11/2016.*
[25] *Id.*
[26] *Id; CMS Discussion Paper, HHS-Operated Risk Adjustment Methodology Meeting, 3/24/2016.*
[27] *CMS Discussion Paper, HHS-Operated Risk Adjustment Methodology Meeting, 3/24/2016, page 1.*

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

Charitable programs whose mission it is to support and protect the chronically ill serve an important public purpose and any limitation on such programs should be carefully considered because the very sick people the programs help are typically in need of the most protection. The AKF, for example, exclusively provides support to low income patients and its beneficiaries are predominately racial minorities. Indeed, the system should protect against payors use of prohibitions on charitable premium assistance as a means to adversely select and avoid enrolling the poor and chronically ill. In the ESRD setting, such prohibitions would be disproportionately discriminatory on racial minorities and the poor.

The Office of Inspector General for the U.S. Department of Health and Human Services (OIG), has addressed the question of when a charitable entity can properly provide assistance to a Medicaid/Medicare beneficiary, including charities funded by provider donations, and not violate provider-related conflict of interest laws. Since the issuance of its first Advisory Opinion in 1997, through the issuance two Special Advisory Bulletins, the latest published in May 2014[28], OIG has published information on the guardrails it believes necessary to ensure the integrity of patient assistance programs, including those that pay insurance premiums on behalf of patients. The OIG has published information on the guardrails it believes appropriate to ensure the integrity of patient assistance programs, including those that pay insurance premiums on behalf of patients.

The OIG has repeatedly found that adoption of these safeguards is sufficient to separate any provider donations from the award of charitable premium assistance, and protect against providers' improper steering of patients to a particular provider, product or service.

Public policy clearly supports charitable programs that provide assistance to some of the most vulnerable in our society. Therefore, the goal should be to develop the right safeguards to protect against the concerns raised in the RFI. For example, CMS could expand the existing regulations, or issue an FAQ, that requires insurers to accept premium assistance from any governmental program or from a *bona fide* 501(c)(3) charity that meets the OIG safeguards. Use of these safeguards would protect the option that exists for individuals to obtain individual insurance coverage where appropriate while protecting against concerns of improper steering.

Importantly, any restriction on charitable premium assistance based on minimum essential coverage would be uniquely discriminatory to ESRD patients that qualify for Medicare soley

[28] https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf *and* *https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf*

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

DaVita

based on their ESRD diagnosis. Congress clearly and unequivocally has provided these patients the right to choose between coverage for 30 months and that should not be rescinded now.

V. Closing

Thank you for this opportunity to provide information addressing the issues raised in the RFI. In summary, DaVita does not steer its patients towards any particular insurance option, but educates its patients on their available insurance options so that each patient can make informed choices that best meet their individual needs. DaVita also does not pay patients' health care insurance premiums, but believes that charitable assistance programs such as the American Kidney Foundation's HIPP serve an important public service that should be protected. DaVita believes that the guardrails already established and operationalized by HHS-OIG for such programs provide the necessary protections against improper provider steering. Most importantly we encourage you to consider the benefits to patients who selected to retain or obtain individual market plans.

In addition to this information, we have also provided responses to the specific questions raised in the Addendum A. We welcome the opportunity to continue a dialogue with you on these issues.

Sincerely,

Philipp H. Stephanus
Senior Vice President

cc: Shantanu Agrawal, M.D.,
Deputy Administrator and Director
CMS Center for Program Integrity

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

ADDENDUM A: CMS Questions and Answers

CMS asked a number of specific questions in its RFI. DaVita provides the following responses.

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

   Theoretically, anytime a provider interacts with current or prospective patients, that provider could be in a position to engage in inappropriate steering – just as anytime a plan interacts with current or prospective members, that plan could be in a position to engage in inappropriate steering. Yet at the same time, both providers and plans have a duty to interact with and educate their patients and members, respectively. Therefore, the question whether providers and plans in fact do engage in steering, can only answer this question for our organization: through our values, our systems, and our teammates, we are highly committed to provide appropriate education to our patients about all the options available to them, in order to enable the patient to choose the option that is best for them based on their own individual needs and preferences. We do not steer.

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

   The impact of any patient population on the risk pool depends on that population's healthcare needs. Some members that could be covered, or used to be covered, by other government programs but now choose to seek coverage in an individual market plan have high medical needs. This is the case, for example, in the various state high-risk programs, which were meant to be replaced by the ACA. Those members were enrolled in ACA plans as the state high-risk programs were largely shut down. At the same time, a key goal of the ACA is to attract younger, healthier people who previously had not signed up for any coverage – a process that has taken longer than expected. To what extent these younger, healthier members are eligible for coverage under other government programs is not known. The risk adjustment and reinsurance mechanisms of the ACA were intended to address the challenge of pricing individual market risk in the initial years of the ACA, when plans did not have the benefit of extensive underwriting

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

history. We expect pricing for individual market plans to stabilize, as a result of three factors: first, multiple years of underwriting history that is now available to plans; second, the price adjustments that have already been made to align premiums with actual experience; and third, the continuing addition of healthier individuals to the individual market plans.

3. *Are there examples of steering practices that specifically target people eligible for or receiving Medicare and/or Medicaid benefits to enroll in individual market plans? In what ways are people eligible for or receiving Medicare and/or Medicaid 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.*

   DaVita does not engage in any such practices. Instead, DaVita's efforts in patient education are organized around a single principle: to enable patients to make the clinical and financial decisions that are best for them based on their own individual needs and preferences. As for other providers, either in dialysis or other healthcare sectors, we are not in a position to assess their practices.

4. *Is the payment of premiums and cost-sharing commonly used to steer individual 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 insurers 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?*

   On payment of premiums and cost-sharing: DaVita does do not engage in either practice, and we are not in a position to comment on whether other providers do. We are, however, aware of such practices deployed by some individual plans, which offer to directly pay or reimburse a member's Medicare premium, in an attempt to incentivize the member to sign up for Medicare coverage, which would reduce the individual plan's coverage obligation. While portrayed as a benefit, this practice is potentially harmful to patients, who have no guarantee that the individual plan will continue to cover the

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

Medicare premium once the member has signed up for Medicare. We believe this practice is also discriminatory when targeted specifically at patients that have particular diseases, such as ESRD. We have brought examples of this practice to CMS' attention.

On "provider-affiliated organizations": CMS has not defined what it means to be a "provider-affiliated organization." We suggest that any organization that the federal government has recognized as a *bona fide* independent 501(c)(3) organization operated by independent management and an independent board of directors, should not be so classified. Thus, the American Kidney Fund (AKF), under the OIG Advisory Opinion 97-1, would not constitute a provider-affiliated organization.

On actions CMS might consider to add transparency to third party payments: when DaVita receives cost-sharing payments from patients, we do not ask the patient to state the source of the funds used to meet those obligations. We consider such inquiries not only unnecessary, but a violation of a patient's right to privacy. Whether a patient pays their obligations with funds from their own or their spouse's employment, from financial support provided by a relative, from their savings, or from any other source, including charitable assistance, should be up to the patient and not subject to scrutiny by providers, plans, or the government.

5. *How are enrollees impacted by the practice of a health care provider or provider-affiliated organizations enrolling an individual into an individual market plan and paying premiums for that individual, 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 wide-spread or varied than we have identified.*

DaVita does not "enroll patients in individual plans." Instead, we educate our patients on the entire set of options available to them, and it is up to the patient to make a decision based on his/her own needs and preferences. If enrollment in an individual plan is a permissible option (e.g., not enrolled in Medicare) for a patient and may have specific benefits – either clinical or financial – then we include that option in our education.

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

Based on the specific healthcare needs of ESRD patients and the specific rules of coverage options available to them (such as the ESRD entitlement in the Social Security Act, coupled with the explicit provision that patients are not required to enroll), we find that while most of our patients choose to enroll in government coverage that is available to them, some patients choose to stay in, or enroll in, a commercial group or individual plans. Patients make these choices based on differences in their individual needs and circumstances, such as:

- continuity of coverage they already have
- access to particular providers and services
- coverage of their medications
- financial patient responsibility (premiums, deductibles, co-insurance, out-of-pocket limits, etc.)
- availability of secondary insurance options
- ability to maintain coverage for their family
- other clinical and quality-of-life goals and considerations (such as qualifying for a kidney transplant)

In addition, we encourage our patients to consult other sources of information, such as educational materials provided by CMS, and to make their decisions in active consultation with their family members or other caregivers. As a result, the decisions our patients make are truly based on their own needs and preferences, and the coverage of their choice – whether it is a government or a commercial plan – frequently creates substantial patient benefit, rather than causing patient harm, as supposed in the question.

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

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

obligations of enrollees, such as increased copayments and deductibles where the enrollee's chosen provider is out-of-network to the individual market plan.

DaVita's comprehensive education includs both the costs and benefits of each option available to the patient. Examples of potential costs for patients eligible for Medicare or enrolled in Medicaid, who are considering enrollment in an individual market plan, include late-enrollment penalties where applicable, loss of PTC or CSR, lack of coordination of benefits between Medicaid and the QHP and interruption of continuity of care. As a result, where DaVita patients select an individual market plan, it is because the patient made that election understanding the potential costs and benefits.

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

   DaVita believes that CMS' focus should be on protecting patient choice, consistent with the ACA's principles.

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

   DaVita cannot comment on a third party payor's screening processes.

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

   DaVita does not offer premium assistance. In explaining potential resources to its patients, DaVita does reference the AKF HIPP program, and social workers or insurance counselors, as renal professionals, may help a patient apply to the program. However, consistent with the framework approved by the OIG, the determination of patient

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

eligibility for assistance and of the amount of any HIPP grant are entirely made by AKF, and there is a clear separation between the AKF and DaVita.

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

    DaVita does not make offers of premium assistance or routine cost-sharing waivers to our patients.

    Medicare eligibility as a result of the diagnosis of ESRD is different from Medicare eligibility based on age. Congress and CMS have long recognized this distinction and have specifically protected the ability of individuals whose eligibility is based solely on the diagnosis of ESRD to maintain their commercial coverage for 30 months. As such, any policy that would broadly prohibit Medicare eligible patients from receiving charitable assistance would directly and disproportionately hurt ESRD patients. The impact of such a policy would be directly negative because it would turn the advantage of Medicare eligibility based on ESRD diagnosis into a disadvantage of losing access to charitable premium assistance. In doing so, it would disproportionately force such patients, who are predominately poor, into Medicare. This would be contrary to the long-established principle that such patients have the option, but are not required, to enroll in Medicare merely as a result of the ESRD diagnosis. We believe such a policy would have discriminatory effect on the ESRD population. If CMS were to implement such a policy, it should exclude patients whose Medicare eligibility is based solely on a diagnosis of ESRD in order to be consistent with the Social Security Act.

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

    We are unaware of any providers who enroll patients in plans, or manipulate enrollment in plans. DaVita does not steer patients to any particular insurance. DaVita would be opposed to any restrictions which have the effect of inhibiting the rights of patients to select the insurance options that best meet their individual needs.

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

Inappropriate provider behavior, such as billing for services not provided or abusive care, is already regulated by federal and state legal authority and enforced by state and federal prosecutors. Billing for services not provided is a form of theft that can be prosecuted under any state criminal code, and state regulatory authorities pursue complaints involving quality of care by health care providers.

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

    Providers are not in a position to collect and report information as to manner in which patients pay their health insurance premiums or patient responsibility payments. Premium assistance could include payments made by family, friends, church groups and a variety of charitable entities. The scope and amount may often not be known by providers unless the provider itself is making the payment. As a result, any such policy would be very difficult to comply with and, arguably, would be an invasion of the patient's privacy.

    Moreover, DaVita does not offer routine waiver of cost-share for any classification of patients. Consistent with existing policies and Medicare bad debt requirements, DaVita examines each patient's individual circumstances to make case-by-case determinations in relation to forgiveness of patient debt. There is no legitimate basis to require any reporting of these individual, case-by-case determinations.

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

    We believe CMS should allow market forces to determine prices for healthcare services in the individual market, in the same way they are determined in the group market. The dynamics of competition among plans (for members) and the competition among providers (for network inclusion) produce a better balance between competitive contracted rates and adequate and attractive provider networks.

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

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

Introducing such policies, would inevitably be fraught with ambiguity and questions about due process. Such policies would also invite plans to allege "inappropriate steering" whenever a high-cost patient chose to enroll in the plan. Ultimately, permitting plans to make retroactive payment adjustments could have the effect of discouraging providers from providing appropriate and much-needed education to their patients on the full range of options available to them, as it would expose providers to potential financial harm anytime a patient were to makes a choice that results in higher payment for the provider and higher cost for the plan. It would also create a pattern of plans routinely questioning patients about their choices, in the hope of making an accusation of inappropriate steering.

DaVita has already heard anecdotal information from patients about insurers who have aggressively questioned patients about their insurance choices, including sending investigators to their homes, intimating that the patient committed some sort of fraud, demanding information about whether the patient receives charitable assistance even when such assistance is not prohibited by the plan, and even suggesting that the patient will be in trouble if they do not withdraw from the insurance plan.

Instead, we believe sufficient mechanisms already exist to deter inappropriate behavior. For example, if a provider were to recruit patients with an inappropriate inducement, clear rules, standards, and enforcement mechanisms already exist and could be applied.

2000 16th Street, Denver, CO 80202 | P (888) 484-7505 | F (310) 536-2675 | DaVita.com

EXHIBIT 8

U.S. RENAL CARE

September 22, 2016

Filed Electronically

Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Rm 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-6074-NC – U.S. Renal Care, Inc. Comments Regarding Request for Information: "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans"

Dear Acting Administrator Slavitt:

U.S. Renal Care, Inc. (USRC) writes in response to the Request for Information issued by the Centers for Medicare and Medicaid Services (CMS) on August 23, 2016, titled "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans" (RFI). USRC appreciates the opportunity to comment on the RFI, since the issues raised by CMS deeply concern USRC and could negatively impact USRC's patients' access to quality health insurance and access to care.

The RFI appears to presume that USRC's patients, persons with end-stage renal disease (ESRD), should not have access to health coverage through Exchange Plans available through the Marketplace (Marketplace Plans). We unequivocally disagree. The Affordable Care Act (ACA) ensures open access to commercial insurance to almost all Americans, including those afflicted with serious, chronic health conditions, like ESRD. The ACA established new options for quality coverage to very sick people who previously were barred from purchasing health insurance from commercial insurers because of their pre-existing conditions and health status. It allows persons with ESRD who are eligible for Medicare or enrolled in Medicaid to enroll in Marketplace Plans. While a small percentage of USRC patients are currently enrolled in Marketplace Plans, Marketplace Plan coverage provides a viable alternative to Medicare and Medicaid coverage for some persons with ESRD. Consequently, USRC urges that CMS refrain from enacting any policy reforms designed to restrict ESRD patient access to commercial insurance through the Marketplace Plans or otherwise undermine the mandate of the ACA.

Dialysis facilities must disclose all available health insurance options to their patients in compliance with the Medicare Conditions for Coverage. Accordingly, USRC dialysis facilities openly discuss health insurance options, including employer-sponsored health coverage, Medicare, Medicaid, Medigap, Marketplace Plans, and other coverage options, with their patients. USRC supports CMS issuing additional regulatory guidance requiring all providers that discuss health insurance with their patients to adopt procedures ensuring that patients receive full disclosure of their health insurance options. USRC also agrees that it should be the patient's decision to enroll in the health care coverage that best suits the patient's (and their families) financial and health needs. If certain providers or insurers engage in conduct designed to mislead or restrict patient access to health insurance, those situations should be reviewed under CMS's existing regulatory authority.

Finally, USRC is concerned that the RFI seeks insurers' input as to whether their risk pools are being adversely affected by the enrollment of individuals in Marketplace Plans who may have access to other governmental coverage or are receiving charitable premium assistance – namely sick, disabled, and low-income individuals. Sick, disabled, and low-income individuals should have unrestricted access to the Marketplace as required by federal law. Since the advent of the Marketplace, some commercial health insurers have engaged in a variety of efforts to deny or diminish persons with ESRD full access to Marketplace Plan coverage and benefits. They have done so by adopting plan designs that restrict dialysis benefits and refusing to accept third-party premium payments from bona fide charities, like the American Kidney Fund (AKF). We ask that CMS take immediate action to investigate insurers that purposely discriminate against persons with ESRD and that refuse to accept third-party premium assistance from the AKF, so Marketplace Plan coverage remains open and accessible to persons with ESRD.

We thank CMS in advance for reviewing our submission below and are available to meet with CMS for further discussions regarding the issues raised in the RFI.

A. Who Is U.S. Renal Care and What Is End Stage Renal Disease (ESRD)?

USRC is a dialysis provider that serves people living with chronic and acute renal disease. We serve more than 23,000 patients across 31 states and the Territory of Guam at our 306 dialysis clinics. We provide in-center and at-home hemodialysis and peritoneal dialysis services, focusing on treating individuals with ESRD. USRC also manages several acute dialysis programs through contracts in conjunction with local community hospitals.

ESRD is an irreversible medical condition in which a person's kidneys cease functioning on a permanent basis. Currently, there are more than 650,000 Americans who have ESRD. Millions of Americans are at risk for ESRD due to kidney disease, diabetes, and high blood pressure.

Persons who suffer from ESRD require a regular course of long-term dialysis or a kidney transplant in order to survive. Dialysis is a medical procedure that removes toxins from the blood, as well as harmful waste, extra salt, and fluids that build up in the body due to kidney failure. Persons with ESRD require dialysis treatments multiple times per week. Patients who receive hemodialysis dialyze at a facility or at home three times per week. Patients who receive peritoneal dialysis typically treat at home, seven times per week.

ESRD patients are also often afflicted with multiple pre-existing co-morbidities, meaning they suffer from other acute and chronic diseases, such as diabetes, hypertension, and congestive heart failure that require medical care from an array of providers. Consequently, the health care provided to ESRD patients can be costly.

A. Federal Law Requires That Marketplace Plans Remain Available for Persons with ESRD.

Prior to the passage of the ACA, many persons with ESRD were unable to purchase commercial health insurance to pay for their care, since they had pre-existing conditions requiring expensive treatment. They were uninsurable and struggled to pay for their treatments out-of-pocket if they could not obtain comprehensive health insurance coverage. The passage of the ACA in 2010 and implementation of the ACA Marketplace removed the barriers that in many cases had previously blocked persons with ESRD from acquiring commercial insurance coverage by prohibiting insurer discrimination based on health status and by eliminating insurer pre-existing condition bans. Persons with ESRD are now guaranteed access to commercial insurance.

ACA eligibility rules established that "each health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every … individual in the State that applies for such coverage."[1] Insurers selling Qualified Health Plans (QHPs) through the Marketplace must accept all individuals who enroll, so long as they meet U.S. citizenship and residency requirements and are not incarcerated.[2] The only other eligibility restriction is that QHPs cannot be sold to Medicare beneficiaries enrolled in Part A and/or Part B due to the Medicare anti-duplication provisions in the federal Medigap statute.[3]

CMS has repeatedly recognized that persons with ESRD are permitted to sign up for Marketplace coverage and forego or delay enrollment in Medicare. That is because even though a person with ESRD may be eligible for Medicare, Medicare entitlement does not occur until the individual files an application for Medicare coverage with the Social Security Administration. For instance, in a publication titled "Frequently Asked Questions Regarding Medicare and the

[1] 42 U.S.C. § 300gg-1(a).
[2] 45 C.F.R. § 155.305(a).
[3] 42 U.S.C. § 1395ss.

Marketplace,"[4] which CMS issued initially on August 1, 2014 and has periodically updated, CMS answered the following questions:

> *B.1. Are Individuals with ESRD required to sign up for Medicare?*
>
> No. Individuals with ESRD are not required to sign up for Medicare; it is voluntary. In order to get Medicare coverage, the individual must meet the necessary eligibility requirement and apply. If you don't apply, you do not get Medicare coverage.
>
> *B.2. Are individuals with ESRD who do not have Medicare coverage eligible to enroll in a Marketplace Qualified Health Plan (QHP)?*
>
> Individuals with ESRD who do not have either Medicare Part A or Part B are eligible to enroll in individual market coverage because the Medicare anti-duplication statute does not apply; therefore, individual market guaranteed issue rights apply under the ACA. In order to enroll in a QHP through the Marketplace, the individual must meet the eligibility requirements for enrollment (i.e., criteria related to citizenship, lawful presence, incarceration, and residency).
>
> * * *
>
> *C.5 Can I choose Marketplace coverage instead of Medicare?*
>
> Generally, no. … But there are a few situations where you can choose a Marketplace private health plan instead of Medicare: … [if] you are eligible for Medicare but haven't enrolled in it …because [y]ou have a medical condition that qualifies you for Medicare, like end-stage renal disease (ESRD), but haven't applied for Medicare coverage.

Importantly, persons with ESRD who are entitled to premium-free Part A are not subject to late enrollment penalties for Parts A or B if they defer enrolling in Medicare Part A and Part B in favor of Marketplace Plan coverage.[5] Nor are persons with ESRD who delay Part A and Part B necessarily barred from receiving Medicare coverage of immunosuppressant transplant drugs if they do not enroll in Medicare when first eligible. They can enroll in Medicare Part A and Part B before receiving the transplant and the immunosuppressant transplant drugs will be covered. Further, persons with ESRD who defer Medicare Part A and B enrollment may qualify for federal premium tax credits to help pay for Marketplace Plan premiums, depending on their income.[6]

---

[4] https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_4-28-16_v2.pdf.
[5] *See* https://www.ssa.gov/pubs/EN-64-107.pdf.
[6] *See* IRS Notice 2013-41 at https://www.irs.gov/pub/irs-drop/n-13-41.pdf.

CMS has also acknowledged that persons with ESRD may choose to maintain both Exchange coverage and Medicaid coverage:

> *If you still want a Marketplace plan*
>
> You can have both Marketplace coverage **and** Medicaid or CHIP, but you are not eligible to receive advance payments of the premium tax credit or other cost savings to help pay for your share of the Marketplace plan.[7]

This is consistent with the Medigap statute's anti-duplication provisions, which do not prohibit a person with Medicaid coverage from purchasing a commercial insurance policy.[8] Further, individuals with dual Marketplace Plan and Medicaid coverage may not be subject to commercial cost-sharing obligations.[9]

B. Dialysis Facilities Are Required to Discuss Insurance Options with Patients.

CMS requires dialysis facilities to counsel ESRD patients on their health insurance options. The agency's Medicare Conditions for Coverage (CFCs) for ESRD Facilities Interpretive Guidance states that dialysis facilities will provide "information and help[] patients apply for Medicare, Medicaid and other insurance benefits to assure payment for care, and locat[e] resources to assist in payment for adequate nutrition, housing, and medications."[10] Further, Medicare.gov informs persons with ESRD that dialysis facility social workers "are trained to handle health insurance and payment questions" and "usually know of programs to help patients pay for prescription drugs."[11] USRC dialysis facilities comply with the CFCs by discussing health insurance options with USRC patients.

USRC encourages patients to evaluate their health insurance options to determine which plans best meet their needs (and the needs of their family), provides the greatest access to care and coverage, and limits their out-of-pocket medical costs. Some health insurance options for ESRD patients include:

> ***Employer-Sponsored Group Health Plans (GHPs)*** – This commercial health coverage is available through employers who sponsor health plans for their employees and their dependents. GHPs may not discriminate against persons with ESRD and are generally

---

[7] https://www.healthcare.gov/medicaid-chip/cancelling-marketplace-plan/.
[8] 42 U.S.C. § 1395ss.
[9] *See* 42 C.F.R. § 447.20(a)(1).
[10] Conditions for Coverage, ESRD Surveyor Training-Interpretive Guidance (Final Version 1.1, October 3, 2008).
[11] https://www.medicare.gov/dialysisfacilitycompare/#resources/patient-checklists.

required by federal law to provide 33 months of primary health coverage to persons with ESRD, even if the employee is eligible for or enrolled in Medicare.[12]

Pros: Historically offered robust coverage and benefits for serious illness.

Cons: Coverage and benefits have eroded in recent years, requiring beneficiaries to pay more out-of-pocket expenses; benefits differ based on employer; coverage is contingent on employment status.

Commercial Insurance and Exchange Plans – Standard commercial insurance was generally unavailable to persons with ESRD before the ACA and the establishment of the Marketplace in 2014.

Pros: Supposed to mimic coverage available in small group employer market; cover essential health benefits, including chronic disease and prescription drugs; government premium subsidies may be available for Marketplace Plans; out-of-pocket costs capped at $6,850 for 2016 for an individual.
Cons: Limited enrollment periods; plans differs by locality; may not cover dialysis.

Medicare Parts A, B & D – Persons with ESRD may enroll in Medicare Parts A, B & D before they turn 65-years old when they are diagnosed with ESRD, so long as they are also entitled to social security benefits.

Pros: Covers dialysis treatment, transplants, and prescription drugs.
Cons: Persons with ESRD are subject to waiting periods;[13] premiums required for Part B & D coverage; Medicare does not cover all medical costs associated with ESRD, namely Part B coinsurance and Part D copayments.

Medicare Advantage – Medicare managed care for Medicare beneficiaries. Persons with ESRD are generally prohibited from enrolling in Medicare Advantage plans unless they meet an exception identified under 42 C.F.R. § 422.50(a).

Pros: Offers a managed care option for Medicare beneficiaries.
Con: Persons with ESRD generally are prohibited from enrolling; may have continuing out-of-pocket medical costs.

[12] 42 C.F.R. § 411.162.
[13] 42 C.F.R. § 406.13.

Medigap – Medigap supplemental policies are commercial insurance policies underwritten to cover the health care costs that Original Medicare does not cover.

Pros: Provides "wrap" coverage to insure against out-of-pocket costs that Medicare does not pay for.
Cons: Only available if already enrolled in Original Medicare; expensive premiums; federal law *does not* guarantee that persons with ESRD who are under 65 can obtain Medigap coverage;[14] many states do not require that insurers sell Medigap policies to persons with ESRD who are under 65;[15] does not cover prescription drugs costs.

Medicaid – Persons with ESRD may enroll in Medicaid only if they meet stringent eligibility criteria and financial means testing.

Pros: Covers dialysis treatment; very low out-of-pocket expenses for patients.
Cons: Enrollees, particularly ones with Medicaid managed care, sometimes have inadequate access to health care providers[16] and pharmaceuticals. Eligibility for Medicaid may fluctuate month-to-month based on changes in income.

USRC strives to discuss the full array of health insurance options with patients, including Marketplace coverage. We try to help the patients understand all of their choices and which insurance options will provide the most comprehensive coverage and minimize their out-of-pocket costs.

Marketplace Plans can offer health insurance options to persons with ESRD who have gaps in their health insurance coverage. For instance, newly diagnosed persons with ESRD who do not have employer-sponsored health insurance and who are not eligible for Medicare may choose to enroll in a Marketplace plan to pay for their medical treatment. Other persons with ESRD who are eligible for Medicare, but not enrolled, may decide to maintain Marketplace coverage instead of enrolling in Medicare, because they may have less out-of-pocket expenses based on Marketplace coverage and federal caps on out-of-pocket expenses for QHPs. Individuals with Medicaid may decide to enroll in commercial health coverage to increase their access to health care providers and pharmaceuticals (which are limited by many state Medicaid programs).

Ultimately, health coverage decisions for persons with ESRD are patient-specific. Considerations may also include weighing the various coverage and financial factors. It is the patient's choice related to each of the myriad options to select the health coverage that best meets

[14] 42 U.S.C. § 1395ss.
[15] https://www.medicare.gov/supplement-other-insurance/when-can-i-buy-medigap/when-can-i-buy-medigap.html#collapse-2239.
[16] *See* OIG Report, Access to Care: Provider Availability in Medicaid Managed Care (Dec. 2014), https://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf.

the patient's needs. As noted, only a small percentage of USRC's patients are enrolled in Marketplace Plans.

If CMS is aware of health care providers providing false and misleading information to patients regarding their health insurance options, USRC supports CMS taking action under its existing enforcement authority against those providers.[17]

C. Charitable Premium Payments and the American Kidney Fund

Persons who have ESRD often suffer severe financial strain; 70% of those stricken with the disease have to stop working as a result of ESRD and other comorbidities. That is one reason USRC and CMS direct persons with ESRD who are in economic distress to the AKF.[18]

The AKF is a bona fide, independent charitable organization that was established 45 years ago to provide financial assistance to persons with ESRD. It provides much needed support to persons with ESRD who require financial assistance to obtain health care coverage necessary to pay for their medical treatment. Current AKF programs include financial assistance with health insurance premiums, grants for children with ESRD, disaster relief grants, transportation costs, prescription medications, and other expenses related to care. Poverty and financial distress are unfortunate consequences of ESRD; 60% of the patients AKF assists have annual incomes under $20,000 per year.[19] Consequently, AKF premium payments are a lifeline to many patients who are in financial distress and who must rely on AKF to maintain health insurance and to cover the cost of medical treatments

The AKF Health Insurance Premium Program ("HIPP") has been in existence for almost 20 years. It operates in accordance with HHS OIG Advisory Opinion No. 97-1[20] and independently of USRC and other dialysis and non-dialysis health care providers. AKF donor funding is provided to AKF without any restrictions or conditions whatsoever and help is provided to individuals with ESRD based on their financial need, regardless of the dialysis provider with whom they treat, their health condition, or the patients' choice of health insurance. The AKF does not help individuals select their health insurance, nor does it discriminate in funding persons with ESRD who participate in HIPP in any way. HIPP funding is available for Medicare Part B coverage, Medicaid (for states that require premium payments), Medigap, commercial plans (including Marketplace plans), employer group health plans, and COBRA plans.[21]

[17] *See, e.g.*, 45 C.F.R. § 155.285.
[18] *See* https://www.medicare.gov/people-like-me/esrd/esrd.html.
[19] http://www.kidneyfund.org/advocacy/third-party/patients/.
[20] https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf.
[21] http://www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/.

While USRC does donate to the AKF, the AKF and USRC maintain systems that wall off provider donation information from the AKF's determinations of premium assistance grant eligibility.

The AKF makes its decisions without input from USRC. Moreover, when the AKF makes a decision to provide premium assistance, it continues that assistance for an entire policy year, not based on episodes of sickness or care. If a patient wishes to continue assistance after a plan year, he or she must recertify his or her need to the AKF.

Tens of thousands of ESRD patients rely on HIPP funding to obtain health insurance coverage. However, since the advent of the Marketplace in 2014, we have seen some health insurers take aggressive steps to block ESRD patients receiving HIPP funding from maintaining coverage on their Marketplace Plans. These insurers are blocking HIPP funding to push the sickest, poorest individuals out of their plans. They are doing this by (i) refusing to accept AKF premium payments, (ii) demanding that patients sign affidavits that they have not received any third party premium assistance, and (iii) terminating insurance coverage for individuals receiving third-party premium assistance mid-year. Their conduct has had a negative impact on a vulnerable patient population, causing undue and unneeded stress on vulnerable ESRD patients who receive AKF premium support. These insurers claim their conduct is permissible as a result of "guidance" from CMS. In reality, we believe this conduct is highly discriminatory and deliberately designed to push sick patients off of their Marketplace Plans on to governmental plans, like Medicare and Medicaid.

USRC urges CMS to take action to protect ESRD patients receiving AKF HIPP assistance from insurer discrimination in the Marketplace. We request that CMS amend 45 C.F.R. § 156.1250 and add the AKF to the list of entities from which Marketplace Plans must accept premium and cost-sharing payments. Or in the alternative, CMS issue new regulations or guidance requiring insurers to accept third party premium assistance from bona fide charities, like the AKF, that register with CMS, grant premium assistance without provider or insurer influence, base decisions solely on patient financial need, and offer assistance for an entire year.

C. USRC Opposes Any Reduction in Reimbursement by Marketplace Plans.

Lastly, the RFI asks whether CMS should permit Marketplace Plans to limit their payments to providers to Medicare-based amounts for particular services and items of care. USRC is against this proposal. The reimbursement paid by Marketplace Plans to USRC are commercial, arms-length transactions that CMS should not (and may not have the authority to) regulate. CMS does not regulate the payments Medicare Advantage plans make to their contracted network providers. It should not do so in the Marketplace.

If CMS were to endorse the reduction of Marketplace Plan reimbursement to Medicare-based payments, it would undermine the essential health benefits package that Marketplace Plans must offer, likely resulting in Marketplace Plans offering essential benefits that fall well short of the

actuarial value of assigned benchmark plans, violating the ACA.[22] It would also discourage providers from contracting with Marketplace Plans.

CMS would also be validating a discriminatory practice that some insurers have adopted to discourage persons with ESRD from enrolling in their Marketplace Plans. It includes adopting a plan design that requires that the Marketplace Plan pay secondary to Medicare, not only for individuals who are currently covered by Medicare, but also for those who are eligible for Medicare coverage, but not currently enrolled. The result is that some persons with ESRD who are enrolled in these plans receive almost no health care coverage and face enormous out-of-pocket expenses, even though they enrolled in QHPs that represent that they cover dialysis treatment. The conduct is discriminatory[23] and we understand that CMS is currently investigating these practices.[24]

USRC objects to CMS permitting any reduction in reimbursement by Marketplace Plans.

* * *

We thank CMS for providing us with an opportunity to address the important issues raised in the RFI. USRC puts ESRD patients, their care, and their needs first. It is paramount that ESRD patients continue to have access to Marketplace Plans, as contemplated by the ACA.

Sincerely,

U.S. RENAL CARE, INC.

J. Christopher Brengard
Chief Executive Officer

[22] 45 C.F.R. Part 156, Subpart B.
[23] *See* FAQs Regarding Medicare and the Marketplace, D.7. at https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_4-28-16_v2.pdf (CMS stating that modifying a benefit design based on the "theoretical possibility of a person's enrollment" in Medicare eligibility could be considered discriminatory in violation of 45 C.F.R. § 147.104(e), § 156.125, and § 156.200(e)).
[24] *See* HHS Notice of Benefit and Payment Parameters for 2018, 81 Fed. Reg. 61455, 61465 (Sept. 6, 2016).

EXHIBIT 9

American Kidney Fund®

DPC DIALYSIS PATIENT CITIZENS
Improving Life through Empowerment

National Kidney Foundation™

September 22, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-6074-NC: "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans"

Dear Acting Administrator Slavitt:

On behalf of the dialysis patients we represent, the American Kidney Fund (AKF), Dialysis Patient Citizens (DPC), and the National Kidney Foundation (NKF) appreciate the opportunity to provide comments on the Request for Information entitled "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans" (RFI). More specifically, we are writing to ask you to protect the rights of individuals living with kidney failure to retain private insurance once they require dialysis treatments.

We agree that the practice of steering any patient toward one type of health plan versus another is inappropriate. Such practices should be prohibited not only at the provider level, but also when health plan issuers undertake such activities. The role of the federal government is to protect individuals' rights to select the health plan that best meets their needs. No provider or issuer should be permitted to take that right away from any individual, including individuals who have kidney failure and require dialysis treatments to live. Therefore, as you review the information submitted under the RFI, we ask that you protect individuals – especially patients with kidney disease – above all others, including private insurance plan issuers.

Individuals living with kidney failure, also known as End Stage Renal Disease (ESRD), are in the unique position of being eligible for Medicare three months after they are diagnosed with the disease. The Federal government, however, has made it clear that individuals living with ESRD have the right to retain their private health insurance, despite being eligible for Medicare. While most issuers comply with the Federal law, others have designed or are designing plans that make it difficult, or in some instances impossible, for these individuals to retain private insurance. We remain deeply troubled that given the unique health care needs of these individuals,

some health plan issuers, especially those offering coverage through the Marketplaces, are implementing policies that steer these individuals into Medicare and/or Medicaid, eliminating their right to choose.

One of the most egregious practices in which issuers have engaged is refusing to allow dialysis patients to accept assistance from 501(c)(3) charities to pay coinsurance obligations. Despite the outcry from some of the issuers of Exchange plans, the dialysis patients receiving such assistance represent a tiny fraction – only 0.05 percent – of the more than 12.7 million Americans currently enrolled in health plans. While it is true that dialysis patients may incur higher costs than healthier patients, these costs were included in the actuarial valuation of Exchange plans and the Agency has developed risk adjusters to account for these costs (and is proposing to update and improve these adjusters in the most recent Notice of Benefit and Policy Parameters proposed rule).

By undertaking these actions, these issuers are actively discriminating against dialysis patients, contrary to the guarantee issue requirements. We have asked the Office for Civil Rights to investigate these practices. In violating the requirements of Section 1557, these issuers are conducting discriminatory policies in a way that unfairly target poorer African American patients. According to the NKF statistics, the number of Blacks and African Americans living with kidney failure is three times higher rate than that of Caucasians.[1] Thus, we ask that CMS exercise its authority and protect these individuals by prohibiting issuers from implementing policies that discriminate against dialysis patients and require these issuers to accept assistance from charities that meet the guardrails set forth in this letter on behalf of dialysis patients who qualify for such assistance.

I. The Congress and CMS Have Historically Protected the Rights of Dialysis Patients To Select the Health Plan of Their Choice.

Dialysis patients hold a unique position within our health care system. When the Congress created the Medicare ESRD benefit, it made a commitment to maintain a safety net to ensure that all Americans who required dialysis would be able to access this life-sustaining treatment through the Medicare. However, it did not require all dialysis patients to rely upon Medicare for coverage. Instead, it required – and continues to do so to this day – all group health plans to allow enrollees to maintain their insurance even three months after a diagnosis of ESRD, making Medicare coverage secondary.[2]

The Administration has maintained this commitment to allow dialysis patients to select the health plan that best meets their needs. Regulations issued by

[1] *See,* https://www.kidney.org/news/newsroom/factsheets/African-Americans-and-CKD.
[2] 42 U.S.C. § 1395y.

the Internal Revenue Service (IRS) affirm that dialysis patients may be eligible for tax credits and subsidies as long as these individuals do not affirmative enroll in Medicare. A similar policy applies to Medicaid beneficiaries, as most recently noted in CMS's guidance to brokers. CMS has also indicated that dialysis patients have a right to select and maintain non-Medicare coverage unless they are actively enroll in Medicare.

For Medicaid, some States have received waivers that allow eligible patients to enroll in Exchange plans as an alternative to Medicaid. Other States have expanded Medicaid to include individuals who may be 150 – 200 percent above the poverty level. These patients may also have the choice to enroll in an Exchange plan rather than Medicaid.

II. Private Insurance May Be the Best Option for Some Patients.

The affirmation of the right of individuals with dialysis to select the coverage of their choice is critically important. ESRD patients have much to consider when selecting insurance and should have the same right as every other American to select their coverage that best meets their needs. While Medicare may work for many patients, it is not always the right option. In a survey of its members, DPC found that 77 percent of patients rate their private health insurance as the "best health insurance plan possible."

Dialysis patients may prefer private coverage for many reasons. For example, private plans may offer better coverage and lower coinsurance obligations. Private plans may also offer more care coordination and chronic care management options, which is especially important to individual with dialysis who are under 65 years old because they are prohibited by statute from enrolling in Medicare Advantage (MA) plans.

Additionally, in approximately half of the States, dialysis patients who are under 65 years old and qualify for Medicare due to their ESRD diagnosis are prohibited from obtaining Medigap supplemental coverage. Even if a State allows dialysis patients to purchase Medigap plans, some States only require plans to offer the most basic Medigap Plan A, which fails to cover the services they may need. Medigap Plan A does not cover Part A and B deductibles and does not have an out-of-pocket max. Of the 6,900 patients in the Exchange plans who are currently receiving charitable assistance through the AKF, about 1,600 (25 percent) of them live in states where Medigap under age 65 is not required. ESRD patients without Medigap have trouble filling in the gaps in Medicare coverage to treat their disease. While there are efforts to expand Medigap coverage for all dialysis patients, the problem remains.

Similarly, Medicaid may not always provide the coverage that a dialysis patient seeks. Many States do not require coverage for prosthetics, fistula placement, podiatry, physical therapy, and optometry. Often, drug coverage may also not be as comprehensive as private plan options. As with Medicare, not all dialysis patients are required to enroll in Medicaid and chose not to do so because of the coverage differences.

Other dialysis patients rely on private insurance because of their families. Neither Medicare nor Medicaid covers family members. If a dialysis patient is forced to accept coverage from Medicare or Medicaid, his/her family will be required to have different plans. This requires the family to duplicate its coinsurance obligations (two sets of premiums, two different sets of deductibles, etc). Thus, dialysis patients with families may seek to maintain their private coverage to multiple plans and to avoid higher out-of-pocket expenses.

Deciding to remain in private insurance rather than to enroll in Medicare or Medicaid does not automatically mean that a patient will be harmed. During the MSP period, dialysis patients retain the right to remain in their private coverage without risking a penalty to maintaining this coverage. Some patients may also qualify for Medicare through their status of being disabled and would also not be subject to an enrollment penalty if they maintained private coverage for a period after their diagnosis of ESRD. Additionally, some dialysis patients may actually be more likely to receive a transplant if they remain in private insurance.[3]

In the end, it is the right of every dialysis patient to have the opportunity to examine all of their options and select the plan – whether private or governmental – that best meets their needs. It is wrong for any provider or issuer to steer patients toward one option over another. CMS should protect the patient's right to chose, not the issuers who are steering patients away from their products.

III. Patients Need Accurate and Complete Information To Exercise Their Rights To Select a Health Plan that Is Best for Them.

To make informed choices, dialysis patients need accurate information and someone to help guide them through the complexities of evaluating health insurance plans. To this end, dialysis patients have been very active in shaping the educational and social service requirements of the Medicare ESRD Conditions of Coverage. Current law requires dialysis facilities to provide dialysis patients – even before they are enrolled in Medicare – with access to social workers or other members of the dialysis facility's interdisciplinary team to assess all aspects of their ability to cope with the disease, including insurance coverage.[4]

---

[3] AM Reeves-Daniel, AC Farnety, *et al.*, "Ethnicity, medical insurance, and living kidney donation," 27 *Clin Transplant.* E498-503 (2013).
[4] 73 *Fed. Reg.* 20370, 20424 (Apr 15, 2008).

The average individuals who are diagnosed with ESRD enter a dialysis facility relying upon their previous health insurance – unless they were already Medicare or Medicaid beneficiaries – for at least the first three months of their dialysis treatments. During the initial months, these individuals receive a comprehensive patient assessment and plan of care. The assessment includes reviewing their insurance options, many times with a licensed social worker. The social worker reviews their insurance and other potential options, as well as any financial assistance for which they might qualify as required by CMS.[5] This information should also include information about different dialysis modalities, transplant options, and the impact of coverage in accessing various aspects of care.

The information provided at this time is critically important to dialysis patients and must be complete and accurate, presenting the benefits and potential detriments of the various insurance options available to each patient. Empowered with this information, each dialysis patient can make the choice of which plan is best for him/her. If anything, patients would like to see more education. They do not want these services to be confused with steering and taken away.

IV. CMS Should Protect Patient Choice By Preventing Issuers from Steering Dialysis Patients Away from Private Coverage.

In light of our multiple conversations with CMS during the last three years, we are disappointed that the RFI accuses providers of inappropriate steering while ignoring the specific examples of issuers steering patients that we have shared with the Agency and others in the Administration. We ask that CMS examine the practices of issuers, some of which we summarize below, and stop the issuers using these tactics from discriminating against dialysis patients.

Several issuers refuse to recognize premium payments made on behalf of dialysis patients by the AKF. They ignore the OIG's Advisory Opinion that clearly states that there is a firewall between contributors to the AKF and the patients who receive the assistance. Instead, issuers have accused providers and indirectly the AKF of using this charitable assistance to steer patients to private plans. These accusations reflect a complete misunderstanding of the structure and processes of the AKF. Simply put, there is no connection between a dialysis facility's contribution and the decision to support a patient through the AKF's assistance program.

These policies also appear to single out dialysis patients. Issuers continue to accept third party payer assistance for HIV/AIDS and cancer patients, while

[5] *CMS, "Dialysis Facility Patient Rights," available at https://www.medicare.gov/dialysisfacilitycompare/#resources/patients-rights.*

rejecting such assistance for dialysis patients, the vast majority of whom are African American.

As the history of the AKF clearly indicates, it has been providing assistance to dialysis patients to maintain group health plans and/or Medigap policies for nearly 45 years. Nothing of substance in the way patient assistance grants are evaluated and awarded has changed. The only thing that has changed is the fact that dialysis has been designated an essential benefit under the Affordable Care Act (ACA) and issuers in the Exchange are required to provide coverage without regard for the fact that a patient requires dialysis.

We appreciate the difficulties that health plans have experienced during the initial years of the ACA. We also recognize that it may be difficult to distinguish between a legitimate patient-centered charity, like the AKF, and other charities that have been formed to take advantage of the new ACA coverage. To that end, our organizations, along with the broader kidney care community, have recommended that CMS establish clear guardrails that would distinguish such entities. More specifically, we have recommended that to provide premium or other coinsurance assistance, an entity must:

- Provide assistance for at least one full plan or calendar year (and not merely to secure temporary coverage for short-term or one-time procedures or conditions);

- Have procedures that protect patient choice and prohibit any direction that the patient use only certain insurers or providers and provide assistance for a full range of insurance products including but not limited to: Medicare Part B, Medigap, QHP and other commercial, Medicaid, EHGP and COBRA plans;

- Be a bona fide, publicly or privately funded, 501(c)(3) charitable organization run by independent Board of Directors;

- Have uniform procedures that include an application process, independent determination of financial need by the charity's employees, and geographic diversity;

- Have uniform procedures that sever any nexus between insurer or provider donations to the charity and the beneficiary's receipt of grant assistance, including procedures prohibiting providers from limiting use of their donations to certain patients other than for financial need, and procedures prohibiting providers or insurers from having any input in the assessment or approval of patient applications;

- Meet the requirement CMS finalized in NBPP (e.g., notice requirements 45 CFR § 156.1250(b)); and

- Comply with other applicable federal, state, and local laws.

We believe that these guardrails, which we have shared in various venues during the past year, address the specific concerns raised by issuers. If CMS feels that these guardrails are not sufficient, we ask the agency to work with our organizations to refine them so as to protect patient access to this critical assistance.

In addition to refusing to accept charitable assistance on behalf of dialysis patients, issuers have begun modifying their plan designs in ways that discriminate against dialysis patients and steer them away from private coverage toward Medicare and/or Medicaid. While our organizations continue to work with State Insurance Commissioners to try to stop these policies, they persist. For example, some plans intentionally mislead individuals with dialysis by writing in their plan descriptions that federal law requires individuals with ESRD to enroll in Medicare four months after having been diagnosed with the disease. Other plans tell individuals with dialysis that if they enroll in Medicare, the plans will pay their Medicare coinsurance amounts on their behalf. Still others seek to incentivize individuals with dialysis to enroll in Medicare directly by stating that effective the first day of the fourth month of dialysis, the plan will pay for renal dialysis services at a designated percentage of the Medicare allowable amount. This places the enrollee requiring dialysis in the position of having to pay the remaining amount that is above the Medicare rate but consistent with the amount negotiated between the plan and the provider.

While we again do not condone providers steering patients toward one plan or another, we urge CMS to also actively police the activities of issuers and stop them from doing the same. Individuals requiring dialysis should be presented with complete and accurate information to make their own informed choices without having to navigate coercive and deceptive policies imposed by anyone.

V. CMS Can Address Issuer Concerns by Implementing Appropriate Risk Mitigation Policies.

The concerns expressed by health plan issuers appear to be grounded more in the inadequacies of the current risk mitigation policies, rather than in providers "steering" dialysis patients into private insurance. Dialysis is an essential health benefit and, as such, these patients are included in the actuarial valuation of the plans, as noted already. Improvements can and should be made to risk pools. While we continue to evaluate the proposed modifications to the risk adjustments related to dialysis patients in the Notice of Benefits and Payment Parameters proposed rule, they appear to move in the right direction. We ask that CMS protect patients and,

rather than accept misguided allegations of steering, implement appropriate risk adjusters similar to those used for MA plans. CMS should not endorse affirmatively or tacitly the actions of health plan issuers that discriminate against patients or vilify providers because these issuers do not want to provide coverage to a group that the Congress mandated as part of the essential health benefits.

VI. Conclusion

On behalf of the patients we serve, AKF, DPC, and NKF appreciate the ongoing engagement with us and our members on the problems that dialysis patients continue to experience with issuers in the Exchange plans. However, it is now time to protect patients. We are sincere in our commitment to work with CMS to ensure that legitimate charitable assistance is provided in an appropriate and fair manner. We also ask that CMS stop issuers from rejecting this assistance and implementing other policies that discriminate against dialysis patients by steering them into Medicare or Medicaid. It is time that CMS clarify its policy to protect dialysis patients from such actions.

Sincerely,

LaVarne A. Burton
President and CEO
American Kidney Fund

Hrant Jamgochian, J.D., LL.M.
Executive Director
Dialysis Patient Citizens

Tonya Saffer

Tonya L. Saffer
Senior Health Policy Director
National Kidney Foundation

EXHIBIT 10

C ID

The is a Comment on the **Centers for Medicare Medicaid Services** (CMS) Proposed Rule: **Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans**

For related information, **Open Docket Folder**

Comment Period Closed
Sep 22 2016, at 11:59 PM ET

ID: CMS-2016-0145-0690

Tracking Number: 1k0-8s17-kx5d

Comment

I am commenting on the request for information released on August 23, 2016, file number CMS-6074-NC. having the choice to have private insurance coverage is important to ESRD patients.

Access to private coverage is important for end stage renal disease (ESRD) patients. Being on limited incomes, ESRD patients need the lower out of pocket costs this provides.

It helps the ESRD patient find a provider of choice as some doctors may not take Medicare. It also provides access to additional benefits that may not be included in Medicare such as diabetic testing supplies, access to psychological services or dental care. Insurance choice is important to kidney disease patients and their ability to access care.

Document Information

Date Posted:
Oct 5, 2016

RIN:
0938-ZB31

Show More Details

Submitter Information

Country:
United States

State or Province:
ID

EXHIBIT 11

C MN

The is a Comment on the **Centers for Medicare Medicaid Services** (CMS) Proposed Rule: **Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans**

For related information, **Open Docket Folder**

Comment Period Closed
Sep 22 2016, at 11:59 PM ET

ID: CMS-2016-0145-0691

Tracking Number: 1k0-8s17-nw1r

Tweet Share Email

Comment

I am commenting on the request for information released on August 23, 2016, file number CMS-6074-NC.

I am a 64-year-old male with end-stage chronic kidney disease. I have been on the University of Minnesota's Kidney Transplant List for one year as of September 17, 2016. Minnesota's average wait time for a kidney transplant is six years. I am seeking a living donor to shorten my time on dialysis and to obtain a more optimum transplant outcome.

My wife has a generous, but expensive, family healthcare plan through her employer. Through the University of Minnesota's hospital and Fairview Clinics, we have access to the best medical care available in this region. Each year we hit maximum out-of-pocket deductibles early, and run through the remainder of the year with no copays and no fears of losing access to continuing care for my dialysis needs or the needs of my wife and our 13- and 14-year-old daughters.

If I were forced off of my wife's family coverage, we would have to pay for a separate insurance policy for me, even as we would have to maintain the original policy for my wife and kids. Why should we have to carry the extra insurance burden, a burden that carries unlimited copays and no maximum out-of-pocket expenses? We are just staying afloat with our current insurance plan (whose premium has already skyrocketed due to the misnamed "Affordable Care Act"). We could not afford to pay for an additional insurance policy, so how would I get the care I need?

Moreover, having "insurance coverage" is NOT the same thing as having "medical care." As an example, when my parents wanted to move from their rural homestead in northern Minnesota to the Minneapolis area in order to be closer to family caregivers, we were not able to get them any closer than Faribault, because there were no doctors in the Twin Cities who were willing to accept new Medicare patients. They had insurance, but they had no access to care.

It is worse under the misnamed "Affordable Care Act," whose Obamacare participants often find themselves mere pawns in a bureaucratic shell game.

We would all be better off if government backed off and allowed the free-market to be free. Do not even suggest that the free-market failed in healthcare, because government regulation has acted constantly to ensure that it has not been a free market. With mandates for coverage and access limited to state-approved policies, there has been nothing free about it at all. Government has stated its purpose to destroy the free market and replace it with its own single-payer tax-funded healthcare system. That will be the death of hundreds of thousands of citizens.

Document Information

Date Posted:
Oct 5, 2016

RIN:
0938-ZB31

Show More Details

Submitter Information

Country:
United States

State or Province:
MN

EXHIBIT 12

KS

The is a Comment on the **Centers for Medicare Medicaid Services** (CMS) Proposed Rule: **Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans**

For related information, **Open Docket Folder**

Comment Period Closed
Sep 22 2016, at 11:59 PM ET

ID: CMS-2016-0145-0697

Tracking Number: 1k0-8s17-m235

Comment

I am commenting on the request for information released on August 23, 2016, file number CMS-6074-NC.

I am one of the younger ESRD patients and have been dealing with ESRD/CKD since 2008. I was 32 at the time of diagnosis and am now 40. Being wrongfully terminated from my job that provided me benefits and not being able to work a full time job with benefits due to ESRD and the physical challenges that come with the disease- as a single, never been married female with no dependents; having the option available of the AKF, or NKF to off set the out of pocket premium cost, is a huge blessing to me personally as an ESRD patient. Medicare does provide some coverage; but it's not enough.

Having ESRD is literally, a day to day lifestyle. Sometimes, it's even a half day to half day lifestyle. Fatigue is just about 90% of the disease. It's an out of control fatigue that knocks you down. Anything am ESRD patient does physically- for example, a load of laundry, cooking a meal, running an errand or 2, even taking a shower is physically exhausting. I have to sit down and rest about 15 minutes after I take a shower. Fatigue is one aspect of why I personally cannot endure a full time job.

With the recent changes to Medicare, there have been several, if not many Dr's that have dropped their patients as they are no longer accepting Medicare.

Having AKF assist with premium coverage costs, helps me in the additional services that I need as an ESRD patient, such as emotional or psychological counseling. There is a lot to deal with emotionally, having a chronic illness. Another additional service, is dental. Having dental clearance is one of the primary qualifications to be be positively evaluated to receive a kidney transplant. This has to do with any infections such as a cavity; can interfere in a very negative way, possibly death with the anti-rejections drugs that are admitted post a kidney transplant, or even any organ transplant.

One last benefit to me, having AKF assist with the premium coverage cost is the lower out of pocket costs. Not having a full time job with benefits, is a financial burden enough. So, to have lower out of pocket costs for medical; is a huge blessing. I'm surviving by paying rent for a roof over my head; keeping my weakened immune system nourished with food, car payments and fuel in my car to be able to attend my weekly Dr and clinic appointments, and having a cell phone to receive calls from the Dr's offices, an being available so the transplant team can call me for my kidney transplant.

Thank you for taking time to read my story. I'm one of hundreds of ESRD patients. I speak on behalf of them. Please put yourself in the patient's shoes when evaluating this important life changing decision involving Medicare. I'll leave you with this last thought: what if your spouse, or sister or brother, or parent, or even a child was diagnosed with ESRD? How would this effect your decision about eliminating charitable assistance?

Document Information

Date Posted:
Oct 5, 2016

RIN:
0938-ZB31

Show More Details

Submitter Information

Country:
United States

State or Province:
KS

EXHIBIT 13

C FL

The is a Comment on the **Centers for Medicare Medicaid Services** (CMS) Proposed Rule: **Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans**

For related information, **Open Docket Folder**

Comment

As a current dialysis patient of 9 years, patient advocate, ESRD Network 7 patient advisory committee member, Dialysis Patient Citizen and former health care professional, I feel it's my duty as well as my well earned right to address this matter of CMS 6074_NC with you and your colleagues. I've been placed in a position where I've needed the assistance of organizations to provide help with the costs of insurance premiums, necessary medications, and medical visit travel vouchers & gas cards. I never would have thought that I having worked in social & human services as well as the hospital, I'd be so needful and dependent on the generosity of these fine organizations. The very healthcare provider I was employed by is refusing to cover items necessary for my life. I've gone through my meager savings in the first 4 years of my illness, that I was able to put away as a single mother of two children who are now young adults. Now at age 56, I've got nothing and am fighting to save my home from foreclosure while trying to receive a kidney transplant. But, of course the IViG therapy I need to provide a greater probability of non rejection of the donor organ has a co-payment cost of $4616 for the treatment. That's my 20% co-payment before the insurance will cover it. I've waited 4 years to finally get this close to move up the list and now can't afford to stay on. Without the IViG treatment I have NO HOPE OF NOT REJECTING THE ORGAN. It's unfair, that I'm willing to work but can't because no employer's insurance will cover me. And the coverage I have isn't enough to provide for the healthcare needs. I haven't been to a dentist for 3 years because I can't afford it. Each month I have to chose which of my 12 prescriptions I can afford this month, as I pay my house mortgage, utilities, medical copays, vehicle costs for my 12yr old car on it's last leg as I travel 600 miles every 3 months to my transplant center, food, clothing, house maintenance & repair, house & car insurance, all on $1300 SSDI. But keep in mind, I worked my first job in 6th grade at the local YWCA during the summer teaching the babies in summer camp.So yes, I have paid into the system. During the open enrollment period in November for medicare insurance.... I've tried unsuccessfully to change insurance providers.NONE will take me because of ESRD in the state of Florida. Yes, I've spoken to medicare and the state insurance agency; but the insurance companies have a RIGHT OF REFUSAL. Or the coverage they do provide is so poor that none of the doctors accept it or you have to travel outside your county for healthcare visits. For most ESRD persons, we live or die on the whims/ votes/ regards/ thoughts & opinions of those who've not taken a step in our shoes. WE need ACCESS to better PRIVATE healthcare options. Medicare doesn't cover the majority of the needs we face.Our out of pocket costs are completely OUTRAGEOUS!!! Where do we have an extra $4K or $8K hidden away for one medication or medical test. For those that do, guess what??? Your nest egg of $20-$50 thousand dollars dwindles away rather quickly. Then what? I have watched more than 30 persons (my friends and chairmates) including my only (40year old younger) brother and nephew (25 year old) die on dialysis along with my 78yr old mother who was diagnosed with kidney failure and died 1 year after her diagnosis; all while I've been on dialysis. The youngest person was only 19. I ask you how many more lives much be lost? How many productive citizens, how many future politicians, business leaders, astronauts, scientists, doctors, heads of state, contributors to society must we allow to die because to the barriers to excellent healthcare for all American citizens. When my children were born my former husband and I, worked hard to provide everything they needed regardless of our own needs. Because we wanted better for them, better that we had growing up poor. We taught them to do well in school, love and care for others less fortunate that you because you never know who has the potential for greatness besides you. We thought that our family could in some way benefit mankind. I believe that of those who serve our country through the legislative branches of our government. You run for office believing you're the right choice to better the society. Those that voted for you believed the same, even if they weren't or aren't on the same financial, social or educational level as you. I implore you and your colleagues to consider passing legislation demanding the citizens have a choice and opportunity to excellent private insurance coverage in addition to medicare & medicaid. And the penalize those who abuse the system both as consumers and providers. Please be reminded of my situation and the hundred thousands others like as you make your choices. Please share my concerns with your colleagues. Thank you.

Comment Period Closed
Sep 22 2016, at 11:59 PM ET

ID: CMS-2016-0145-0708

Tracking Number: 1k0-8s18-zpch

Tweet Share Email

Document Information

Date Posted:
Oct 5, 2016

RIN:
0938-ZB31

Show More Details

Submitter Information

Country:
United States

State or Province:
FL

EXHIBIT 14

C TX

The is a Comment on the **Centers for Medicare Medicaid Services** (CMS) Proposed Rule: **Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans**

For related information, **Open Docket Folder**

Comment

See attached file(s)

Attachments (1)

Letter to CMS

View Attachment: DOC PDF

Comment Period Closed
Sep 22 2016, at 11:59 PM ET

ID: CMS-2016-0145-0729

Tracking Number: 1k0-8s1a-gbus

Tweet Share Email

Document Information

Date Posted:
Oct 5, 2016

RIN:
0938-ZB31

Show More Details

Submitter Information

Country:
United States

State or Province:
TX

To Whom It May Concern,

My name is Jason, and I have ESRD. I am a 28 year old male living in Allen, Texas with my brother, sister-in-law and their two children. Previously, I was a nursing student living independently in Houston, working at a hospital with the expectation of working there post-graduation. I have lived with type 1 diabetes for 20 years and it finally took my kidneys along with any semblance of independence along with them. I took leave from work when my kidneys started to fail, then had to stop all together the day before my 27th birthday. Soon after I lost my apartment and then my car.

I want to share my story pertaining to insurance and third party payers. I started peritoneal dialysis (PD) the day after Labor Day, 2015. I was already on a Marketplace insurance after losing my health insurance through my employer, and when it came time for dialysis, at least I had that checked off the list. Aetna had been great up until then. Paying for all of my doctor's office visits, diabetes supplies and medications for all of my laundry list of health problems.

I would like to say that I am a fairly educated, experienced consumer of health information and insurance. Knowing that dialysis would probably mean switching to Medicare, I quickly did my research. I plugged in all of my medications, researched the Medicare supplement plans from A to N, debated over Medigap versus Medicare Advantage plans and had made some decisions. Fast forward to my talk with an extremely patient-oriented counselor at DaVita a few months later when open enrollment began for 2016. The counselor told me about all my insurance options and let me know that the American Kidney Fund might be able to help me with whatever kind of insurance I chose. I was not steered away from Medicare or Medicaid. The counselor also let me know it was up to me to choose the healthcare plan I thought was best for me.

Apparently, only Medigap policy A is available to Texas Medicare patients under the age of 65. Then I moved on to part D, the medications. Let's just say, thousands of dollars for the first few months, known as the "donut hole" then only a mere $450 every month for the rest of the year, what's referred to as "catastrophic".

I understand that private insurance companies aren't in the business to save lives. They are businesses and businesses are "in the business" of making money. I am not some naïve soul who thinks that the world is full of nothing but good people and good intentions. But as these private insurances are in the business of making money, I am in the business of staying alive and doing it while not completely destitute. If I can maintain a private insurance through the Marketplace for $343 a month while meeting that $6,500 out-of-pocket max for the year, I will certainly do that instead of thousands in medications alone, not to mention the barebones coverage of a supplemental Medicare plan that isn't covered by the original Medicare 80%.

Through my discussion with my insurance counselor Valerie, she also notified me of a blessing in disguise. The American Kidney Fund (AKF) would assist with paying my insurance premiums and some of my medications cost while struggling to stay afloat on dialysis. This caused quite a stir in the beginning of 2016, and is still ruffling some feathers from what I hear. I was a consumer who dealt with this first hand, scrambling from person to person office to office to ensure I wasn't dropped from my insurance and left uninsured. Many weren't as fortunate as

me to have a brother who can shell out $700 for two months of premium payments until the insurance company decided to take third-party payments on behalf of patients directly from the AKF. Insurance companies are jumping ship left and right, pulling out of the Marketplace due to "consumers being sicker than they expected".

And I am asked "Why are you not on Medicare? They can assist you, and Medicaid is also available. Have you tried Medicare and Medicaid?" First, as I have explained previously, Medicare doesn't cover everything that I unfortunately have to deal with in terms of healthcare. Also, Medicaid has denied me a stunning 4 times. Every time I apply for a Marketplace insurance or get another form of government assistance, my application is sent to Medicaid and I am denied. And I have worked in medical offices before. A large amount of doctor's offices hate taking Medicare patients because of their low profitability through reimbursements, let's not even talk about combined Medicare/Medicaid recipients. Finding a quality doctor with Medicare or Medicare/Medicaid is a difficult task to accomplish. Not saying they don't exist, but it is almost a full-time job hunting one down. Do not get me wrong, if I had no other options, I am thankful Medicare is there to lend assistance. But I am thankful that I have options and I would like to continue to have those options.

EXHIBIT 15

C OK

The is a Comment on the **Centers for Medicare Medicaid Services** (CMS) Proposed Rule: **Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans**

For related information, **Open Docket Folder**

Comment Period Closed
Sep 22 2016, at 11:59 PM ET

ID: CMS-2016-0145-0755

Tracking Number: 1k0-8s1r-w21l

Document Information

Date Posted:
Oct 5, 2016

RIN:
0938-ZB31

Show More Details

Submitter Information

Country:
United States

State or Province:
OK

Comment

I am commenting on the request for information released on August 23, 2016, file number CMS-6074-NC.

I am a 58 year old male and I'm in poor health, due to End Stage Renal Failure. I got sick in 1983 from glomerular nephritis and was on hemo dialysis for about 2 months. I received a living donor kidney transplant in April of 1983. That transplanted kidney worked fine and lasted for about 32 years.

From 2010 to 2014, I had Arteriosclerosis Disease, most likely due to dialysis and the build up of Phosphorus and Potassium in my system. I had 3 different vascular surgeries in this timeframe and the surgeons placed 8 different Heart Stints in my vascular system.

When my transplanted kidney finally failed, I started on Peritoneal Dialysis in 2012 and was on that mode of dialysis for about 3 years. Then I got Paratonitis in 2015 that started out as E.Colie and progressed to Vancomycin Resistant Enterococcus (VRE). I was in the hospital and Rehab Center for about 1 month, from these infections.

From 2010 to 2015, I received several Blood Transfusions and had Anemia, from reduced Red Blood Cells in my system.

I understand that Insurers are trying to kick ESRD patients off their plans in the health exchanges by refusing to accept charitable assistance for insurance premiums from organizations like the American Kidney Fund.

I am writing this correspondence to CMS, to plead, to allow us dialysis patients the right to have private insurance.

I am begging CMS, to please do not cave into insurers demands. Help us protect patient choice for insurance coverage.

Having the choice to have private insurance coverage is important to ESRD patients, like me. I don't fully understand the intricacies of insurance, but I believe having private insurance would provide us ESRD patients to have lower out of pocket costs for dialysis and the associated treatments and medications. My current dialysis bill is about $80,000 each month. My medications cost about $500 per month. My Medicare monthly premium is about $104 dollars and my Medigap insurance is about $350 per month.

Additionally, my Plan D insurance for the required medications, is about $75 per month. One of my more expensive medications is called Epogen and costs about $1,400 per month.

With out private insurance, I would not be able to afford all the dialysis related cost and would surely die. Im not trying to be overly dramatic, but I'm trying to portray how us ESRD Patients lives totally rely on insurance. I estimate my monthly dialysis costs are about $82,000.

Additionally, I'm on the National Kidney Transplant list and my medical team had estimated that surgery will cost between $150,000 to $200,000. Also, the monthly Transplant anti-rejection drugs will cost over $4,000.

My goal is to survive the medical complications and general pain of going to the dialysis clinic 3 days a week, get a kidney transplant, and finally to become a contributing member of our society.

Additionally, I financialy support my wife and live-in grandson. I'm also a US Army veteran, but don't qualify for veterans benefits, because I was honorable discharged, due to my kidney disease. Without private Insurance, I would not be able pay both my dialysis costs and my families daily living cost. Without insurance, I would lose my house and me and my family would become homeless.

In closing, please, please do not allow the Big Insurance Companies to kick us ESRD patients off their

plans. ESRD patients all over the United States, like me, have worked their entire careers and contributed to making the United States the greatest country on the earth. Us ESRD patients can't help that we have kidney disease, and we did not do anything, like smoking or drinking to exess, to bring on the kidney disease. As American citizens, we have worked our entire adult lives, and deserve insurance, to allow us to beat this life robbing disease and to re-enter society and become contributing citizens, once again.

Finally, I want to sincerely thank the CMS organization for supporting us ESRD patients for all these years. Without CMS, we would certainly die at an early age and never become contributing members of our society.

Thank you...

EXHIBIT 16

PA

The is a Comment on the **Centers for Medicare Medicaid Services** (CMS) Proposed Rule: **Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans**

For related information, **Open Docket Folder**

Comment

I am commenting on the request for information released on August 23, 2016, file number CMS-6074-NC. As an individual with End Stage Renal Disease, I am fortunate to have my private health insurance premiums paid by the American Kidney Fund. Without this support I would not be able to afford the 20% of my lifesaving care that is not paid by Medicare. Also Medicare does not pay for dental,vision, diabetic supplies etc necessitating the need for private insurance. For private insurance this is a win/win. Money is money no matter where it comes from. Barring third party payers is discrimination pure and simple against those of us that need insurance to pay for treatments to save our lives.

Comment Period Closed
Sep 22 2016, at 11:59 PM ET

ID: CMS-2016-0145-0803

Tracking Number: 1k0-8s1w-6rfd

Document Information

Date Posted:
Oct 5, 2016

RIN:
0938-ZB31

Show More Details

Submitter Information

Country:
United States

State or Province:
PA

EXHIBIT 17

KIDNEY CARE PARTNERS

September 22, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-6074-NC: "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans"

Dear Acting Administrator Slavitt:

On behalf of Kidney Care Partners (KCP), I appreciate the opportunity to provide comments on the Request for Information entitled "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans" (RFI). As you know, KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both CKD and irreversible kidney failure, known as ESRD.[1]

We reiterate our continued disappointment that CMS has not protected dialysis patients who wish to remain in their Exchange plans and must rely upon charitable assistance to do so. These patients have the same rights as those who can afford such coverage directly. The number of patients with kidney failure relying on charitable assistance in Exchange plans is extremely small. According to the American Kidney Fund (AKF), which operates under an Advisory Opinion from the Office of the Inspector General (OIG), there were only 6,400 patients in 2015 with kidney failure who receive AKF assistance to meet their Exchange plan coinsurance obligations. This number constitutes 0.05 percent of the 12.7 million Americans currently enrolled in Exchange plans. As we describe in detail in the letter, these patients' rights to remain in the plan of their choice should not be limited merely because they need charitable assistance.

At the outset, we also wish to echo the concerns outlined in the RFI stating that it is not appropriate to steer individuals toward or away from certain health insurance plans. KCP and our members do not condone any activity that seeks to direct patients to health insurance plans that may not be appropriate for them. As we have noted in previous letters, KCP strongly supports efforts to ensure that

[1] A list of KCP members is provided in Appendix A.

dialysis patients receive accurate and complete information about their plan options so that they can select the plan that best meets their needs, as well as the needs of their families. In light of our ongoing concerns, we are troubled that the RFI fails to seek information about behaviors that health plan issuers have undertaken to steer dialysis patients away from private insurance options. Because it is equally important that issuers, as well as providers, empower individuals to allow them to select their own plans, we also provide updated information about documented issuer behaviors that discriminate against patients with kidney failure and make specific recommendations as to how CMS can stop the inappropriate steering in which some issuers are engaging.

In sum, we ask that CMS protect the right of all patients, as promised them by the President, to select the health plan that best meets their needs. This means that not only providers, but also issuers, who are found to have inappropriately steered patients toward or away from certain plans for the provider's or issuer's benefit should be prohibited from doing so.

I. CMS should distinguish between educating individuals about insurance options from "steering" individuals toward or away from certain plans.

A. CMS should not confuse educational and charitable practices with steering.

While KCP condemns practices by any entity – including issuers – meant to steer individuals toward or away from certain plans, it is important to distinguish legitimate educational and charitable practices from steering.

Under the Conditions for Coverage, dialysis facilities are required to convene interdisciplinary teams. This team "is responsible for providing each dialysis patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care." It includes not only health care providers, but also social workers.[2] The social worker is responsible evaluating a patient's psychosocial needs, as well as his/her family and other support systems.[3] In the preamble to the 2008 Final Rule updating the Conditions for Coverage, CMS acknowledges in the preamble that social workers, or other members of the interdisciplinary team, may perform a variety of tasks, including assisting with insurance coverage.[4] When working with patients, this assistance includes providing educational information about a patient's health insurance options so that the patient can make an informed decision about what insurance plan is right to

[2] 42 C.F.R. § 494.80.
[3] *Id.*
[4] 73 *Fed. Reg.* 20370, 20424 (Apr 15, 2008).

meet his/her needs and, when appropriate, the needs of his/her family members. The obligation is echoed in the CMS Patient Rights documents also emphasize that patients must be told about any financial assistance available to them.[5] Despite accusations from some issuers, providing this information in a balanced and accurate manner is not steering and should not be considered as such. Also, informing an individual that he/she has access to charitable or other types of financial assistance should not be conflated with the concept of steering.

In addition, it is not steering when an individual seeks to obtain charitable assistance so that he/she may retain existing private insurance. As CMS has noted in various regulatory contexts, eligibility for Medicare coverage due to a diagnosis of ESRD does not require enrollment in Medicare. There is no question that individuals who can afford to pay their coinsurance obligations are allowed to maintain their existing coverage, or even to change their insurance policies by remaining in the group or individual market. Patients who may not have the same financial resources but with assistance from a not-for-profit, 501(c)(3) charitable organization operated, consistent with federal law could make a similar choice, should be allowed to do so.

Conversely, it is steering when issuers undertake specific actions that require or incentivize individuals with ESRD to drop their private coverage or place it as secondary to Medicare and/or Medicaid before these individuals are required to do so. KCP members have documented the following activities undertaken by specific Exchange plan issuers with the intent of dropping individuals from coverage based on their health status:

- **Misleading patients:** Some plans mislead enrollees by suggesting that federal law requires individuals with ESRD to enroll in Medicare four months after having been diagnosed with ESRD.

- **Incentivizing patients to shift to Medicare:** Some plans will pay the Medicare coinsurance amounts or other cost-sharing obligations on behalf of the individuals if they shift their coverage to Medicare.

- **Increasing patients' coinsurance obligations:** Some plans increase individuals' coinsurance obligations by dropping the plans' payments to providers to rates at or slightly above the Medicare rates, placing individuals in the position of being responsible for paying the remainder of the rates plans negotiated with providers.

These behaviors are discriminatory and seek to push these patients into Medicare and, thus, should be prohibited.

---

[5]CMS, "Dialysis Facility Patient Rights," *available at* https://www.medicare.gov/dialysisfacilitycompare/#resources/patients-rights.

B. Individuals with kidney failure have the same right to select a plan that best meets their needs – even if it is not a Medicare or Medicaid plan.

While the kidney care community remains supportive of the unique status of patients with kidney failure in that most have the ability to enroll in Medicare prior to turning 65 years old, this unique status does not under current law eliminate their right to exercise the same choice that other Americans under 65 years old have to select a health care plan that best suits their needs and those of their families. These patients are not necessarily "more vulnerable" to steering because of their disease status, but some could inappropriately view these patients as not needing the same choices as other individuals because they have Medicare and/or Medicaid as a default option for coverage. Such a conclusion is false because while Medicare and/or Medicaid can be beneficial to many patients with kidney failure, it does not meet every patient's needs—especially when considering the complex health issues that most kidney failure patients face, it is particularly important that they be afforded the same choice as other Americans in selecting an appropriate health plan.

As the Congress has repeatedly recognized by extending the Medicare Secondary Payer (MSP) provisions that apply to all group health plans,[6] Medicare is not necessarily the best fit for all patients. For example, patients with other family members who require coverage may wish to retain their private coverage rather than duplicate cost sharing requirements across two different plans. Other patients may wish to enroll in plans with better chronic care management benefits, which Medicare patients under 65 years old cannot access. Currently, Medicare patients who enroll based on their diagnosis of ESRD are prohibited from selecting Medicare Advantage. In about half of the States, patients who qualify for Medicare because of a diagnosis of ESRD may not be able to access Medigap plans and, therefore, wish to rely upon private insurance, which may have more favorable cost-sharing obligations or expanded coverage. Whatever the reason, patients with kidney failure have the same right as all Americans to select the health plan that works best for them and their families. It should not be assumed that Medicare is always the right choice for every such patient.

Similarly, there are a small number of Medicaid eligible individuals who may wish to retain their Exchange coverage or retain Medicaid as secondary coverage. Current law does not prohibit such individuals from retaining their Exchange coverage, but it does prohibit them from receiving a subsidy or tax credit if doing so. There are also valid reasons an individual may seek to retain private insurance rather than enroll in Medicaid. For example, it can be difficult for individuals to find

[6] 42 U.S.C. § 1395y.

health care providers who will accept Medicaid enrollees.[7] Similar to Medicare, Medicaid coverage in many states is limited to an individual, leaving their family members to have to find another option for insurance. Perhaps most importantly, individuals who rely upon Medicaid have a *de facto* barrier to being able to travel. Many Medicaid program will not cover treatments provided in noncontiguous States. Such restrictions can be particularly difficult for individuals with family members in other States. Additionally, 30 State Medicaid programs also provide assistance to certain Medicaid eligible, but not enrolled, individuals to allow them to obtain private insurance.[8] As long as these individuals are able to legitimately meet their coinsurance obligations, they should be permitted to do so. In fact, some States have established programs approved by CMS through its waiver process to encourage some Medicaid eligible individuals to retain their private coverage. Patients with kidney failure should not be prohibited from participating in these waiver programs simply because of their medical condition.

We agree that CMS should ensure that there is not duplicative coverage; however, the solution is not to allow the issuer to decide that the patient must enroll in a government program, but rather to allow the patient to make that choice and have CMS provide the information necessary to issuers, providers, and others about each patient's enrollment status.

C. AKF's HIPP program does not increase the risk of steering.

As we have written in many previous letters and discussed with your staff, patients with kidney failure have come to rely upon AKF to assist them as they battle kidney failure. AKF plays a critical role in helping the nation's dialysis patients maintain their access to health insurance coverage. Established in 1971 by patients for patients, the AKF seeks to help patients retain their autonomy to select the health plan of their choice and now provides direct assistance to patients in all 50 states, the District of Columbia and every U.S. territory. As the Department of Health and Human Services (HHS) OIG concluded: "AKF is a bona fide, independent, publicly-funded, 501(c)(3) charitable organization whose charitable purposes include aiding ESRD patients and their families."[9]

---

[7]For example, the Kaiser Family Foundation has reported that only 44 percent of primary care providers accept new Medicaid patients. Kaiser Family Foundation, "Issue Brief: Primary Care Physicians Accepting Medicaid, A Snapshot" *available at* http://kff.org/medicare/issue-brief/primary-care-physicians-accepting-medicare-a-snapshot/ (Oct. 2015).

[8]For example, Arkansas is one State that provides such assistance in this way through a CMS-approved waiver. Other States providing such programs include Colorado, Iowa, and Missouri, as well as many others. Illinois specifically provides assistance to patients with certain chronic conditions, including cancer, HIV/AIDS, and kidney disease. *See* http://www.dhs.state.il.us/page.aspx?Item=19229.

[9] OIG, Advisory Opinion 97-1, at 6.

AKF's HIPP program began serving patients with kidney failure in 1997, many years before the enactment of the Affordable Care Act (ACA). When the ACA came online, AKF offered assistance for ACA plans in the same way it historically offered assistance for the full spectrum of insurance products.

Patients who are in the Exchanges and receive assistance make up less than 10 percent of all of the patients the AKF assists. Of these 6,400 Exchange patients, one-quarter relies upon the assistance because they live in States that prohibit them from purchasing Medigap policies. The vast majority of the patients who receive this assistance are minority patients, particularly African Americans. To qualify for this assistance, they must meet strict low-income requirements.

The AKF process for awarding patients with year-long assistance grants is completely separate from any of the entities who provide donations, as the OIG has recognized in writing. This process relies upon the financial information provided by the patient. As with most charities, AKF does not have the resources to confirm each applicant's insurance status.

Given the long and positive history of the AKF in administering funds to support patients with kidney failures in all types of health insurance – not only Exchange plans – KCP continues to be perplexed that CMS has not clarified that a program such as AKF with the guardrails placed upon it by the OIG should be permitted to provide assistance to patients seeking to exercise the choice guaranteed them in the ACA. This assistance allows those who are otherwise marginalized – particularly minority patients – to exercise their choice. Issuers should not be permitted to discriminate against these patients merely because they rely upon a 501(c)(3) charity for assistance rather than an employer, family member, or other individual who can support them. It is also disappointing that patients with kidney failure have been singled out for such treatment, when patients with cancer or HIV/AIDS are allowed to rely upon such third party assistance to remain in the health insurance plan of their choosing.

D. The Congress and Administration have concluded that eligibility does not mean enrollment for purposes of selecting a health plan.

KCP also is concerned that the RFI contains language that suggests that the decisions by the Congress (through the MSP provision), the Internal Revenue Services (IRS, through the tax credit and subsidies regulations), and even CMS (through previous Notice of Benefit and Payment Parameter regulations) should now not apply for purposes of Exchange plan coverage. In each of these contexts, federal policy-makers have concluded that the unique status of patients diagnosed with ESRD being eligible for Medicare does not eliminate their right to retain existing private coverage or even obtain new private coverage. While issuers may wish to eliminate their responsibility for these patients, patients have been very

clear over the years that they support policies that promote patient choice in selecting their coverage options.

Eliminating this right to select their coverage would have an immediate negative impact on individuals with kidney failure. As noted earlier in the letter, Medicare and/or Medicaid are not always the right option for individuals and their families. Forcing them into a Medicare- or Medicaid-only option could increase their financial burden, reduce their access to providers of their choice (especially for their family members), cause disruption in their care management (especially for other chronic diseases they may be managing), and even reduce their chance for a transplant.

The RFI particularly raises a question about the potential impact on patients receiving transplant. As noted previously, selecting the right coverage is a highly personal decision even when transplant is involved. For example, a recent study found that particularly for minority patients with kidney failure, private insurance increased their chances of receiving a kidney transplant. Researchers looked at the relationship between transplant status (both deceased donors and living kidney transplantation (LKT)) and the recipients' health insurance status. They found that "a higher proportion of patients with private insurance, relative to those without private insurance, received LKT." African American patients were 11 times more likely to receive a transplant if they had private insurance than if they were enrolled in Medicaid. The researchers concluded that **"**[r]ecipient insurance status is associated with LKT, positively with private insurance and negatively with Medicaid."[10] Given these findings, CMS should not assume that Medicare, and especially Medicaid, will always be the best choice for every patient with kidney failure.

Medicare may also not be the best option for transplant patients because once a patient receives a transplant, he/she can no longer remain in Part A and retain Part B only for purposes of receiving their immunosuppressive medications. In light of concerns about care coordination and maintaining provider relationships, there are clearly reasons why some patients with kidney failure would want to try to retain their private coverage for purposes of receiving a transplant and the follow-up care.

Additionally, patients with kidney failure are equally unique in that they are not subject to late enrollment penalties during the MSP 30-month period. Given the MSP statutory requirements, as well as the IRS and CMS decisions that clearly state that eligibility does not require enrollment, they are in a different place with regard to enrollment timing. In addition, the individual patient should have the ability based on accurate and complete information to decide whether he/she prefers

[10]AM Reeves-Daniel, AC Farnety, *et al.*, "Ethnicity, medical insurance, and living kidney donation," 27 *Clin Transplant.* E498-503 (2013).

Exchange coverage versus Medicare, even if the penalty were to apply. Issuers and the government should not paternalistically make that decision for the patient.

E. CMS should be clear that actions that discriminate against individuals with kidney failure, as well as the act of providing inaccurate or incomplete information to steer individuals toward or away from particular plans, are prohibited.

In previous letters, KCP has strongly supported the antidiscrimination provisions in the MSP statute, as well as the Section 1557 requirements more recently implemented by the Office of Civil Rights (OCR) and the Department of Labor requirements related to employer plans. Patient organizations have filed complaints with both OCR and the Department of Labor seeking to enforce the existing laws and to stop issuers from discriminating against individuals with kidney failure. We encourage CMS to work with these patient organizations to identify and stop discriminatory practices that steer individuals with kidney failure away from Exchanges plans.

We also recognize that some providers could also engage in behaviors that are not appropriate. To that end, we could support policies that would require all entities discussing insurance options with beneficiaries to provide accurate and complete information about plan design, coinsurance obligations, any potential penalties for late enrollment in Medicare, and the right for Medicare eligible individuals with kidney failure to postpone enrollment into these programs. Issuers should be required to accept third party payer assistance from organizations, such as the AKF, which meet specific guardrails that we have identified in previous letters. In previous letters and discussions, KCP has recommended the following guidelines:

- Provides assistance for at least one full plan or calendar year (and not merely to secure temporary coverage for short-term or one-time procedures or conditions);

- Has procedures that protect patient choice and prohibit any direction that the patient use only certain insurers or providers and provide assistance for a full range of insurance products including but not limited to: Medicare Part B, Medigap, QHP and other commercial, Medicaid, EHGP, and COBRA plans;

- Is a bona fide, publicly or privately funded, 501(c)(3) charitable organization run by independent Board of Directors;

- Has uniform procedures that include an application process, independent determination of financial need by the charity's employees, and geographic diversity;

- Has uniform procedures that sever any nexus between insurer or provider donations to the charity and the beneficiary's receipt of grant assistance, including procedures prohibiting providers from limiting use of their donations to certain patients other than for financial need, and procedures prohibiting providers or insurers from having any input in the assessment or approval of patient applications;

- Meets the requirement CMS finalized in NBPP (*e.g.*, notice requirements 45 CFR § 156.1250(b));

- Complies with other applicable federal, state, and local laws.

In addition, CMS could give providers with easy to search information to allow them to assist in preventing patients already enrolled in Medicare and who are not eligible for other coverage from mistakenly enrolling in an Exchange or another plan. Similarly, providers could assist with identifying patients who are not eligible for tax credits or subsidies from seeking those as well. Given the existing obligations on providers to assist patients with a variety of issues, including insurance coverage, providers would be well positioned to help address any problems that may arise.

These recommendations would protect patient rights, while also establishing a framework to protect against steering.

II. CMS should address issuers concerns about covering individuals with kidney failure by addressing the risk adjusters rather than allowing issuers to discriminate against such individuals.

Dialysis treatments were among the original essential health benefits contemplated when the ACA was implemented. As such, the cost of individuals relying on these treatments was incorporated into the actuarial valuation of the plans. Thus, it is no surprise that patients requiring dialysis have enrolled in Exchange plans. More importantly, the valuation incorporated these individuals into the planning and issuers should have taken that into account when developing their plan products.

Even so, KCP understands that issuers need effective tools and mechanisms to address the needs of complex patients with chronic diseases. To that end, we continue to recommend that CMS address the needs of issuers through appropriate risk adjustment policies rather than allowing issuers to avoid having to cover individuals with kidney failure. While we continue to review the recently released Notice of Benefit and Payment Parameters (NBPP) proposed rule, we believe that adding ESRD-specific risk adjusters and providing options for identifying higher-

cost patients that improves the transfer of resources are important first steps to addressing the very real problems issuers have had in managing the Exchange population. CMS should work closely with providers and issuers to make sure the risk adjustment policies are appropriate and avoid placing patients with kidney failure in the losing position of not being able to fully exercise their choice when selecting a health plan. It is also important that CMS work with insurers to promote enrollment by health individuals to help balance the risk pool.

Eliminating charitable assistance will not solve the issuers' problems. As noted, in 2015 there were only 6,400 patients with kidney failure who receive charitable assistance to remain in Exchange plans. They constitute only 0.05 percent of all Exchange enrollees. Therefore, KCP strongly opposes any policies that would prohibit issuers from accepting charitable assistance to individuals with kidney failure when the appropriate guardrails are in place.

In fact, to prohibit discrimination and treat patients with kidney disease in the same manner as patients with HIV/AIDS, CMS should require issuers to accept such payments.

III. CMS, not issuers, should enforce statutory and regulatory requirements.

Finally, KCP once again urges CMS to enforce the statutory antidiscrimination requirements through its existing authority and Section 1557 to protect individuals with kidney failure from being steered away from Exchange plans by issuers. We also ask that CMS work with providers to establish clear and accurate guidelines for providing information to patients, consistent with the ESRD Conditions for Coverage requirements, to ensure that patients receive the information they need to make appropriate decisions about the health insurance plan that best meets their needs. We oppose allowing issuers or any other nongovernmental entity implementing penalties or seeking payment adjustments from providers, just as we would oppose allowing providers to retroactively bill claims that issuers inappropriately failed to pay because they steered individuals away from Exchange plans and into Medicare and/or Medicaid.

Similarly, we oppose allowing issuers to apply Medicare rates or rates similar to Medicare rates when the patients involved are patients with kidney failure. As KCP has noted in comment letters since 2010, the current Medicare methodology for determining the ESRD prospective payment system rates is flawed in terms of the methodology used to establish the case-mix adjusters. MedPAC has raised similar concerns even in its most recent letter on the system. These concerns suggest that it would not be appropriate to apply these rates outside of the Medicare program. However, even if the methodology were corrected, the rates do not cover the cost of providing dialysis services. The Moran Company has documented year

after year that ESRD Medicare margins are negative. Most recently, it predicted that by 2018, 77 percent of all dialysis facilities would have negative Medicare margins. Given the inadequacy of this rate, it would be inappropriate to apply it to other insurance categories. Perhaps most importantly, issuers are extremely sophisticated organizations that negotiate rates with all types and sizes of providers on a regular basis. They have enormous market power. The marketplace should be allowed to work in terms of establishing rates.

IV. Conclusion

KCP appreciates the opportunity to provide a response to the RFI. As noted, we would welcome the opportunity to develop real-world, practical solutions to stop bad actors – both providers and issuers – from discriminating against individuals with kidney failure in a way that prevents them from exercising their right to select the health plan that best meets their needs. Please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com with any questions that may arise.

Sincerely,

Frank Maddux, M.D.
Chairman
Kidney Care Partners

Appendix A: KCP Members

AbbVie
Akebia Therapeutics, Inc
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
AstraZeneca
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners Inc.
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medicare Care Renal Therapies Group
Greenfield Health Systems
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical, Inc.
Renal Physicians Association
Rogosin Institute
Sanofi
Satellite Health Care
U.S. Renal Care

EXHIBIT B

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

DIALYSIS PATIENT CITIZENS, *et al*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No._____
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al*.	)	
	)	
Defendants.	)	

AFFIDAVIT OF HRANT JAMGOCHIAN IN SUPPORT OF
PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER

1. My name is Hrant Jamgochian. I am the Chief Executive Officer of Dialysis Patient Citizens ("DPC"). I have personal knowledge of the facts set forth herein or believe them to be true based on my experience at DPC or upon information provided to me by others. If asked to do so, I could testify truthfully about the matters contained herein.

2. DPC is a non-profit educational and social welfare organization operating under section 501(c)(4) of the Internal Revenue Code. Its purpose is to improve the quality of life of patients with kidney disease--both those with End Stage Renal Disease ("ESRD") and those with chronic kidney disease ("CKD")--through advocacy and education. We do this by empowering kidney disease patients and helping to elevate their voice with policymakers.

3. More than 500,000 people in the United States have ESRD. When someone has ESRD, his kidneys, which remove waste products and excess fluid from the blood, have stopped working. In order to survive, therefore, a person with ESRD must either obtain a new kidney through a kidney transplant or undergo dialysis, a mechanical process which cleans the blood, approximating the process of a functioning kidney. The standard dialysis treatment requires the

patient to be hooked up to a machine in a dialysis center for approximately four hours, three times a week, although more convenient methods of dialysis have been and are continuing to be developed.

4. CKD includes many different conditions that cause some loss of kidney function. CKD may or may not progress to ESRD. It usually gets worse slowly, and symptoms may not appear until the kidneys are badly damaged. There are approximately 26 million people with CKD in the U.S.--almost one in twelve Americans.

5. DPC's membership is restricted to kidney disease patients and their family members. We have more than 28,000 total members. Our 2016 Membership Survey found that 87% of our members with kidney disease are on dialysis, that 11% have had kidney transplants, and that 2% have CKD that is likely to progress to ESRD.

6. Our Membership Survey also found that the average DPC member with ESRD has been on dialysis for 6.7 years, and that 19% have been on dialysis for more than 10 years. One-third of our members who have not received transplants are on a transplant waiting list. The average waiting time for a transplant is between 3 and 7 years.

7. Fifty-three percent of our members are white, 30% are African-American, and 4% are Hispanic. Fifty-two percent are retired, and 26% are unemployed. That is to be expected, since although there have been advances in dialysis treatment in recent years, dialysis for most people remains a process that saps their energy and makes it very difficult to hold a full-time job. As a result, a large proportion of our members have very little income. Two-thirds have received some form of financial assistance to help make ends meet, including Social Security Disability payments, food stamps, pharmaceutical assistance programs, and charitable assistance.

8. Depending on their economic status, age, where they live and other factors, DPC members may have multiple insurance options to choose from, including Medicare--whether or not they're over 65--Medicaid and, since the guarantee-issue and non-discrimination provisions of the Affordable Care Act took effect in 2014, private coverage. Twenty-three percent of DPC members with ESRD--more than 6,000--have received funding to help pay their premiums, including premiums for both Medicare and private coverage, from the American Kidney Fund ("AKF").

9. DPC is a patient-led organization. Its by-laws require that the President, Vice President and 51% of the Board be current dialysis patients. For the past several years, the non-dialysis patients serving on the Board have been former dialysis patients with kidney transplants.

10. I have been the CEO of DPC since April 2011. I previously served as the Director of Health Policy for the United Way Worldwide, as Director of Congressional and State Relations for the American Pharmacists Association, and as Director of Field and State Operations for the American Psychological Association. I have a law degree (J.D.) from Catholic University, and a Master of Laws (LL.M) in Global Health Law from Georgetown.

11. While I have a family history of kidney disease, I never had any symptoms myself. However, a few months after joining DPC I was diagnosed with IgA Nephropathy, a form of CKD. I have had some recent troubling test results, which I discuss briefly below. I live in Bethesda, MD, with my wife Lenna and my three-year old son, Xander.

DPC's interest in and concern about CMS's Interim Final Rule ("IFR") regarding third-party payment

12. The Centers for Medicare and Medicaid Services ("CMS") is a component of the U.S. Department of Health and Human Services ("HHS"). On December 14, 2016 CMS published an Interim Final Rule (the "IFR"), to be made effective 30 days thereafter, that

contains two parts. The first part would require dialysis companies to explain to dialysis patients their various insurance options, the coverage each option provides, and what it will cost the patient; to explain whatever premium assistance may be available for private coverage; and to disclose the payment the company would receive from the insurer if the patient elects private coverage.

13. DPC believes that it is in the best interests of ESRD patients to receive comprehensive information about their insurance alternatives, and also about the compensation providers will receive if the patient elects each alternative. Notably, the rates the insurers negotiate with the dialysis companies are higher than those the government sets for Medicare and Medicaid. As a result, dialysis companies have an economic incentive to have dialysis patients covered by private insurance. Conversely, insurers have an economic incentive to disenroll dialysis patients, or to avoid insuring them in the first place, because dialysis patients cost them a great deal of money.

14. If the IFR stopped with the first part of the rule DPC would not be challenging it. But it does not stop there. Rather, it includes a second part that will cause low-income DPC members with ESRD who currently have AKF-funded private coverage to lose their insurance.

15. The second part of the IFR prohibits any dialysis company participating in Medicare or Medicaid--which as a practical matter is all dialysis companies--from paying the health insurance premiums of ESRD patients, or contributing to any organization that does so such as AKF, unless the patient's insurance company agrees to accept such payment. Because insurers have a strong economic incentive to avoid dialysis patients, and because the rule permits insurers to reject payment by dialysis-company-funded organizations like AKF on behalf of dialysis patients at any time and for any reason, the second part of the rule necessarily would result in the

elimination of AKF funding of private coverage for dialysis patients. If the IFR is permitted to take effect, therefore, DPC members who currently rely on AKF funding for private insurance and who cannot afford to pay their premiums themselves will lose their current health insurance.

16. DPC is vitally interested in and concerned about the IFR because it will adversely affect our members as well as more than 26 million other people with kidney disease--both CKD and ESRD--throughout the United States. Unfortunately, although CMS asserts in the IFR preamble that it is promulgating this rule without notice and the opportunity for the public to comment in order to prevent harm to patients, for the reasons discussed below the IFR will actually create harm to patients. CMS asserts that the IFR is necessary in order to protect patients seeking a transplant, to prevent unnecessary costs, and to prevent disruptions to patient care. In fact, however, as I explain below, the IFR will harm patients seeking a transplant, will create unnecessary costs, and will cause disruptions to patient care.

17. In this statement I first explain why CMS's promulgation of the IFR is unfair to dialysis patients in general and to DPC and its members in particular. I then explain the harm that this rule would cause to DPC members, both those with ESRD and those with CKD, if it is permitted to take effect.

The IFR v. HHS Guidance

18. The IFR directly contradicts guidance which CMS has published after the Affordable Care Act ("ACA") was enacted in March 2010, which DPC has relied on in advising its members. It is fundamentally unfair for CMS to now adopt a policy--and even more so to adopt it, as CMS has in the IFR, without notice and an opportunity for public comment--that penalizes DPC and its members for following exactly the advice CMS has given it. A few examples follow.

CMS guidance makes clear that ESRD patients who are eligible for Medicare also have the option of private insurance

19. In a publication intended for ESRD patients that was updated only a few months ago, CMS stated unequivocally that "Individuals with ESRD are not required to sign up for Medicare; it is voluntary." CMS, "Medicare Coverage of Kidney Dialysis & Kidney Transplant Services" (rev. May 2016), available at https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf.

20. Further, CMS has made a point of reminding insurers that ESRD patients are not required to sign up for Medicare. CCIIO, Final 2016 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 20, 2015), at 36, available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015- R.pdf.

21. HHS has also made clear that ESRD patients can obtain both private coverage and Medicare, and that doing so can reduce the patient's costs: the booklet Financial Help for Treatment of Kidney Failure, published in June 2014 (NIH Publication No. 14-4765), at page 5 informs ESRD patients that "Having Medicare Part B plus another health plan can limit what a person pays out-of-pocket for health care."

22. Notwithstanding the above, by authorizing insurers to refuse to accept third-party payment and mandating disclosure of information that facilitates such refusals, the IFR would preclude ESRD patients who are eligible for both Medicare and private coverage but cannot afford to pay premiums themselves from obtaining private coverage. It would force them to rely exclusively on Medicare, even when private coverage would provide them with more extensive benefits than would Medicare.

CMS guidance makes clear that Medicaid-eligible ESRD patients are also eligible for private coverage as long as they forego government subsidies

23. In a Frequently Asked Question at the CMS website, CMS states that "qualified individuals who are Medicaid or CHIP eligible" are "not eligible to receive advance payments of premium tax credits or cost-sharing reductions" if they buy on the Exchange, but that they "are allowed to purchase qualified health plans instead of receiving coverage through the Medicaid or CHIP programs." See CMS, Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid (December 10, 2012), available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/exchanges-faqs-12-10-2012.pdf.

24. Nevertheless, by authorizing insurers to refuse to accept third-party payment, the IFR would preclude ESRD patients who are eligible for both private coverage and Medicaid from obtaining private coverage. It would force them to rely exclusively on Medicaid, even when private coverage would provide them with more extensive benefits than would Medicaid alone.

HHS has told ESRD patients who can not afford to pay private insurance premiums that the AKF may be able to pay those premiums for them, and has encouraged them to contact the AKF

25. The National Institutes for Health (NIH), a component of HHS, tells insureds at its website that "The American Kidney Fund has grants to help pay health plan premiums. A social worker can help a person apply for assistance."

26. The NIH booklet Financial Help for Treatment of Kidney Failure is even more expansive and encouraging regarding AKF funding for ESRD patients. At page 9, it contains the following language:

> "What private organizations can help? Private organizations include charities and foundations. A few exist specifically to help people with kidney disease and kidney failure, such as the ***American Kidney Fund**. The American Kidney Fund gives small grants to U.S. dialysis and transplant patients based on need. The American Kidney Fund has grants to help pay health plan premiums. A social worker can help a person apply

for assistance. The American Kidney Fund depends on donations, so there may be times when funds are low. More information can be found at www.kidneyfund.org."

27. The CMS Patient Rights documents also emphasize that patients must be told about any financial assistance available to them. CMS, "Dialysis Facility Patient Rights," available at https://www.medicare.gov/dialysisfacilitycompare/#resources/patients-rights.

28. The IFR would prevent dialysis patients from receiving assistance from AKF to pay their premiums even though HHS has consistently encouraged dialysis patients to obtain assistance from AKF to pay their premiums. That is fundamentally unfair.

How the IFR will injure DPC and its members

29. Of the more than 6000 DPC members who have AKF-funded health coverage, some have obtained private coverage through AKF assistance. Were the IFR to take effect, there is a significant risk that those members will face coverage disruptions. Some examples follow.

30. Medicare has no out-of-pocket limit, while private coverage does. The IFR will thus cause DPC's Medicare-eligible members with ESRD who have AKF-funded private coverage to lose that coverage, thus pushing them into Medicare with its lack of an out-of-pocket limit. In 23 states ESRD patients under the age of 65 do not have a right to purchase a Medigap policy--a policy paying some of the costs that Medicare does not cover--so in those states under-65 ESRD patients will have unlimited liability for the 20% of their costs that Medicare does not cover. Because ESRD patients not only must undergo dialysis but also often have such conditions as diabetes, anemia, hypertension, and congestive heart failure, under-65 ESRD patients on Medicare in states where they can not buy Medigap will likely be unable to afford to pay the 20% that Medicare does not cover. As a result both their finances and their health are likely to deteriorate.

31. I am aware of one member under 65 years of age in California, which is one of the states in which ESRD patients under 65 cannot buy Medigap coverage, who has been on dialysis since December 2014. She has had Blue Cross Blue Shield individual coverage since approximately 2012, and her premiums are currently paid by AKF. She is barely able to afford the costs of the $6,500 out-of-pocket limit on her policy, and is currently behind on her payments. Because she is unable to work full-time, she would be unable to cover both the out-of-pocket costs and premiums under her current policy. She would prefer to stay on her private coverage, but if AKF did not cover her premiums as a result of the IFR, she would struggle to do so. If she had Medicare instead of private insurance, she would likely have a 20% coinsurance requirement, which for a dialysis patient is likely to be many thousands of dollars more.

32. Even in the 27 states in which ESRD patients do have a right to purchase a Medigap policy, they typically have only a right to purchase the most basic Medigap Plan, which still leaves a substantial portion of their expenses uncovered. In those states, too, therefore, under-65 ESRD patients on Medicare would likely see both their finances and their health deteriorate.

33. The IFR will cause DPC's Medicaid-eligible members with ESRD who have AKF-funded private coverage to lose that coverage, thus leaving them with Medicaid exclusively. Less than half of all primary care physicians accept new Medicaid patients--44%, according to the Kaiser Family Foundation--and even fewer specialists accept new Medicaid patients, since Medicaid pays them so much less than either private insurance or Medicare. Dialysis patients often need multiple specialists, including nephrologists, vascular surgeons, and cardiologists. The IFR thus subjects DPC's Medicaid-eligible members with ESRD who now have AKF-funded private coverage to a substantial likelihood that they will have to find at least one and perhaps multiple new doctors, which could disrupt their care and adversely affect their health.

34. Medicare covers only the ESRD patient, not dependents. The IFR therefore will cause DPC's Medicare-eligible members with ESRD who have AKF-funded private coverage which also covers their dependents to lose that coverage. The IFR will thus result in the dependents of those DPC members losing their coverage (and will also force the ESRD patient himself to rely exclusively on Medicare and thus to suffer the injury described in paragraph 30, above).

35. Research shows that ESRD patients with private coverage are almost three times as likely to obtain a transplant as those on Medicare, and that African-American ESRD patients with private coverage are approximately 14 times as likely to obtain a transplant as those on Medicare. By preventing low-income ESRD patients, including low-income African-American patients, from obtaining private coverage, the IFR makes it substantially less likely that DPC's low-income members with ESRD who are seeking to receive transplants will receive them, and particularly less likely that DPC's low-income African-American members with ESRD who are seeking to receive transplants will receive them.

36. In some cases, private insurance covers drugs or devices that both Medicare and Medicaid do not cover. For example, a DPC member in Boynton Beach, FL who has AKF-funded private insurance is also a diabetic. She can control her blood sugar most effectively by using the Omnipod insulin pump along with the Dexcom continuous glucose monitoring system. Neither Medicare nor Medicaid cover either the Omnipod or Dexcom devices, but her private insurance covers both. Were the IFR to take effect, and thus eliminate her ability to maintain her private insurance coverage, she would lose coverage for both devices that enable her to most effectively control her blood sugar.

The perverse incentives the IFR creates for insurers

37. If the IFR takes effect insurers will have an incentive to accelerate the deterioration of the health of their low-income insureds with kidney disease rather than to prevent that adeterioration. That is because patients with ESRD, but not CKD before it progresses to ESRD, qualify for Medicare, and because under current law private insurers must continue to insure patients with ESRD for 30 months after they qualify for Medicare.[1] To avoid paying for 30 months of dialysis treatments, therefore, under current law the insurer has an incentive to keep its insureds with CKD as healthy as possible for as long as possible. Low-income patients on dialysis, however, can pay their premiums only through the assistance of the AKF. If the insurer can refuse to accept such payment--as the IFR authorizes it to do and essentially guarantees that it will do--the insurer can jettison any of its low-income patients as soon as they are diagnosed with ESRD, thus making Medicare solely responsible for the cost of 30 months of dialysis treatments. Were the IFR to take effect, therefore, it would be in the insurer's interest to have the health of its low-income patients with CKD decline to ESRD status as soon as possible, so that the insurer can get them and their costs off its books as soon as possible.

38. Moreover, the IFR would create an incentive for insurers to deny coverage for effective but expensive procedures not just to its low-income insureds but to potentially all its insureds. That is because even CKD patients who can today pay their premiums themselves because they work full time are likely not to be able to afford to do so if their health declines and

[1] Under the Medicare Secondary Payer law, 42 U.S.C § 1395y, group health plans must continue to provide coverage to ESRD patients for 30 months after they become eligible for Medicare. § 1395y(b)(1)(C). In providing such coverage the insurer cannot take into account that its insureds with ESRD are entitled to or eligible for Medicare. § 1395y(b)(1)(C)(i). And the insurer cannot "differentiate in the benefits it provides" ESRD patients and other insureds on the basis of the existence of ESRD, the need for dialysis, or "in any other manner." § 1395y(b)(1)(C)(ii). Those requirements also apply to individual coverage sold on the Exchange operating in Texas, as well as in other states, because such coverage must include the same benefits as any of the state's three largest small group, state employee, or FEHBP plans, or of the state's leading HMO, and all those plans cover dialysis treatments for ESRD patients. See 45 C.F.R. § 156.100; https://www.cms.gov/cciio/resources/data-resources/ehb.html.

they are forced to go on dialysis and can no longer work full time. Data from our October 2016 Membership Survey bear this out: 55% of DPC members were employed when they started on dialysis, but only 8% of those now on dialysis are still employed full-time, with another 6% working part-time. Thus, an employed CKD patient with the means to pay his premiums himself may well become an unemployed ESRD patient without the means to pay his premiums once his kidneys fail. The IFR thus creates a system where insurers have an incentive to establish a two-track system of care: one for people who will be able to pay their own premiums after their kidneys fail, and one for those who won't.

39. Patients with kidney disease are particularly vulnerable when their insurer's economic interest conflicts with their own interest in maximizing their health status, because procedures are available that can minimize the adverse effects of dialysis or even avoid dialysis entirely, but they are very expensive. For example, the research clearly shows that patients with declining kidney function who receive pre-emptive kidney transplants--transplants before they need to go on dialysis--have better outcomes than those who receive post-dialysis transplants. They are less likely to reject the kidney; have a higher survival rate; are more likely to avoid infections; and can avoid the dietary restrictions and health complications of dialysis. It is clearly in such a patient's interest, therefore, to obtain a pre-emptive transplant. With the IFR in effect, however, the insurer would have a strong economic incentive not to approve such a transplant for a patient who is likely to need financial assistance to pay his premiums--which according to our Membership Survey includes the large majority of patients on dialysis. Instead, it would have an incentive to allow the patient's condition to deteriorate until he must go on dialysis, at which point he qualifies for Medicare. With the patient unable to pay his private

insurance premiums without financial assistance, Medicare would pay for the transplant and the private insurer would be absolved from doing so.

40. As I mentioned in para. 12 above, dialysis providers and insurers have opposite economic incentives regarding patients with kidney disease. Dialysis companies have an economic interest in getting paid as much as possible for treating dialysis patients, and insurers have an economic interest in avoiding dialysis patients entirely and in disenrolling them if they happen to end up with them. Dialysis providers and insurers also have opposite incentives regarding the longevity of dialysis patients: dialysis providers have an interest in keeping dialysis patients alive because they get paid as long as they're alive, whereas insurers have the opposite interest because they must make payments on behalf of the dialysis patients they insure for as long as they're alive. An insurer's incentive not to maximize the lifespan of its insured exists with respect to any patient on whose behalf the insurer pays out in claims more than it takes in in premium--that is an unavoidable effect of our health insurance system. But rather than seeking to minimize that incentive, the IFR exacerbates it. That doesn't mean than every insurer will seek to accelerate the decline of every patient with kidney disease who cannot afford to pay his own health insurance premium. But it does necessarily make that type of behavior more likely.

41. I am particularly concerned about the perverse incentives the IFR would create for insurers because as I noted in paragraph 11 above, I have CKD myself--in particular, a condition known as IgA Nephropathy, which reduces the ability of the kidneys to filter wastes from the blood. The test to determine the progression of IgA Nephropathy measures the level of the protein albumin, normally present in the blood, that has leaked into the urine. The normal level is between 0.0 and 17.0 micrograms per millileter (ug/mL). When I was first diagnosed, in

October 2012, my microalbumin test result was 248.1 ug/mL; my most recent test result, in July 2016, was 996.9.

42. I am hopeful that I can slow the progression of my kidney disease, as I have started to take medications (ACE inhibitors) to reduce some of the pressure on my kidneys. But if my kidney function continues to decline my wife has volunteered to donate her kidney to me so that I can obtain a pre-emptive transplant. I currently have a health insurance plan offered through the Washington DC Exchange by CareFirst, that covers me and my three-year old son. I am fortunate to be working at DPC, which pays for 90% of the employee premium and 75% of the dependent premium. Because of my current position with DPC, and because my wife and I have the means to pay unsubsidized health insurance premiums, I am hopeful that CareFirst would not resist authorizing a pre-emptive transplant for me. But for people who do not work for an organization dedicated to advocating for the rights of patients with kidney disease, and who don't have the luxury of another income and moderate savings as my wife and I do, the insurer's calculation would be different: it clearly would find it in its economic interest, if the IFR were in effect, to seek to avoid paying for a pre-emptive transplant for its insured and to push him into dialysis so that Medicare would pay for a post-dialysis transplant, even though the former option is better for the insured.

43. Notably, although HHS claims that third-party payment exposes ESRD patients to "a significant risk of a mid-year disruption in health care coverage," it is HHS which is creating the situation that produces that disruption, by authorizing the insurer to refuse to accept third-party payment. HHS could have prevented the disruption the IFR is creating and could have eliminated harm to ESRD patients by requiring the insurer to accept third-party payment. Moreover, HHS could have at least reduced disruption and harm to patients if it had permitted

insurers to reject third-party payment but had required them to make their decisions effective at the beginning of the next calendar year and had also required them to provide adequate notice to patients of their decisions and their effective dates. The patient would then at least have had time to try to make other arrangements to ensure that there would be no disruption in her care. The IFR, however, leaves ESRD patients in the worst possible position: it subjects them to the possibility that their care can be disrupted at any time, since it allows the insurer to refuse to accept third-party payment at any time and for any reason. The IFR thus does not eliminate an imminent hazard but rather creates one.

The effect of the IFR on insurer efforts to avoid or disenroll ESRD patients

44. Some insurers have sent private investigators to the homes of some DPC patients to ask them why they had private coverage.

45. Some insurers have stated in plan documents that policyholders are eligible to be covered only if they are "[n]ot eligible for or enrolled in Medicare at the time of application."

46. Some insurers have told DPC members that federal law requires them to enroll in Medicare four months after they've been diagnosed with ESRD.

47. Some insurers have demanded that ESRD patients sign an affidavit under penalty of perjury attesting that they have not and will not pay their premiums with money obtained from a third party, and threatening them with legal consequences without stating any legal basis for doing so. These letters appear to be designed to scare patients into dropping coverage they are satisfied with and are legally entitled to, and which they must maintain to be eligible for a kidney transplant. An example of such a letter is attached.

48. Because the IFR now mandates disclosure of information about a patient's use of third-party premium assistance, the IFR will inevitably embolden insurers to continue engaging

in the above-described conduct, which will inevitably have the effect of forcing some DPC members with AKF-funded private insurance into coverage that provides them less generous benefits than their current coverage.

49. It would also have the effect of forcing DPC to spend more time challenging insurance company efforts to have state insurance departments authorize insurers to blanketly reject third-party payments on behalf of ESRD patients, or even to authorize insurers to inquire into the source of the funds ESRD patients use when they pay their own premiums. And it would force DPC to spend more time and effort educating its members as to how to maximize their ability to obtain health coverage.

I, Hrant Jamgochian, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 6th day of January, 2017, in Washington, DC.

Hrant Jamgochian

Attachment A

UnitedHealthcare

May 24, 2016

via overnight delivery

Member:

Carrier Name: All Savers Insurance Company
Policy #:

Dear

Thank you for your payment in the amount of $777.45 on May 18, 2016, for the above medical policy.

Our records show that the American Kidney Fund may have improperly paid your premiums in the past. Your medical policy does not allow a party like the American Kidney Fund to pay your medical premium.

We need to make sure that you paid your premium with your own money. We also need to make sure you do not expect to be reimbursed for this payment from a party like the American Kidney Fund.

What do I need to do?

We want to ensure that you get the help you need. Please sign the attached document and send it back in the envelope we have provided by **June 3, 2016.**

What happens if I don't send back the document?

If you don't sign and return the document, we will not be able to accept your payment. We will return any payment received and you will not have coverage.

What happens if I did *receive* money from American Kidney F and to pay my premium?

Please call us right away. You will need to make your payment from your own money.

Do I have any other options?

- You may be eligible to enroll in Medicare if you have End-Stage Renal Disease. We have nurses available to talk to you about this option and other aspects of managing your care. Please call us toll-free at 866-561-7518, TTY 711. We will help you understand all of your options.
- You may be eligible to enroll in Texas Medicaid coverage. Please contact the Texas Medicaid Health and Human Services Commission to discuss whether you can access the care you need through their program. Call toll-free **1-800-252-8263**, TTY 711.

DECLARATION

Under penalty of perjury, I hereby state that the following information is true and correct to the best of my knowledge and belief, as of the date that I signed this document

1. I am over the age of majority, suffer from no legal disabilities, and have personal knowledge of the information contained in this Declaration.

2. I am the policyholder listed on Policy Number issued by All Savers Insurance Company (the "Policy").

3. I applied for the Policy of my own free will after considering available options.

4. I am aware that the Policy states that I must pay my own premium unless payment is made by one of the following parties:

    a. Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act;
    b. Indian tribes, tribal organizations or urban Indian organizations; or
    c. State and Federal Government programs.

5. I hereby certify that the funds used to make the payment on May 18. 2016, in the amount of $777.45, were not supplied to me (and will not be reimbursed to me) by any third party entity other than one listed in 4 above. Further, I will not pay any future premium for the Policy with funds received front (or reimbursed by) a prohibited third party entity.

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

Executed , 2016, at

DATE CITY STATE

SIGNATURE

EXHIBIT C

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS, *et al*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No._____
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al*.	)	
	)	
Defendants.	)	

AFFIDAVIT OF ANNE BAILEY

1. I, Anne Bailey, respectfully submit this affidavit in support of Plaintiffs' Motion for an Emergency Temporary Restraining Order and Preliminary Injunction. I make this affidavit based upon my knowledge of the facts stated herein.

2. I am Group Vice President, Patient Support and Insurance at DaVita Inc. ("DaVita"). In this role, I have responsibility for patient education and patient admissions, including insurance coverage.

3. I assumed my current position in October 2014. Before then, I was Vice President with responsibility for helping patients remain working and insured. I have been with DaVita since October 2009.

4. In my position, I have extensive experience with patient education and admissions that enables me to be very familiar with the needs of DaVita's patients, with the various health insurance options available to them, and with the consequences for those patients who are unable to receive premium assistance from charitable organizations.

5. Based upon my personal knowledge, my review of relevant records and of information provided to me in my capacity as Group Vice President, information provided to me in connection with the submission of this Affidavit, and my knowledge of the kidney dialysis industry, I am familiar with the information in this Affidavit, including the harms that DaVita itself will suffer as a result of the CMS's interim final rule (IFR) amending the Conditions for Coverage of ESRD facilities. I have read and analyzed the provisions of the IFR.

6. DaVita is a leading provider of kidney care in the United States, delivering dialysis services to patients with chronic kidney failure and end stage renal disease (ESRD). As of November 30, 2016, DaVita operated or provided administrative services at 2,418 outpatient dialysis centers spread across 46 states and the District of Columbia, serving approximately 187,000 patients.

7. As a dialysis provider and participant in the Medicare and Medicaid programs, DaVita is subject to rules and regulations promulgated by the Department of Health and Human Services (HHS). Within HHS, the Centers for Medicare & Medicaid Services (CMS) has been charged with Medicare-related rulemaking. This includes requirements, known as Conditions for Coverage or CfCs, with which dialysis providers must comply to receive Medicare funds.

8. CMS conducts regulation and enforcement activities to ensure that Medicare dialysis facilities comply with the Conditions for Coverage. It also administers a survey and certification program. This program is a joint effort of the federal and state governments. State survey agencies audit dialysis facilities' compliance with the Conditions for Coverage and investigate complaints made against dialysis providers.

I. OVERVIEW OF HEALTH INSURANCE OPTIONS AVAILABLE TO ESRD PATIENTS

9. ESRD is the last stage of chronic kidney disease. At this stage, the kidneys can no longer filter and clean blood. The most common causes of ESRD are diabetes and high blood pressure, although it may also be caused by a variety of other conditions, such as lupus and nephrotic syndrome. A person suffering from ESRD will die within a short period of time if that person does not receive kidney dialysis or a kidney transplant.

10. Dialysis is a process of artificially cleaning the blood and removing excess fluid from it, essentially simulating working kidneys. The process involves removing blood from the body and filtering it through a man-made membrane called a dialyzer, or artificial kidney, and then returning the filtered blood to the body. It is accomplished using specialized equipment in a specialized facility, such as a DaVita center, or at home under the periodic care of a renal professional. While the time needed for dialysis varies depending on the patient's physical characteristics, in-center hemodialysis treatments typically last about four hours and is done at least three times per week.

11. ESRD patients are some of the most vulnerable in the country. Many are of extremely limited means, and many are minorities. For example, data from organizations like the National Institutes of Health's National Institute of Diabetes and Digestive and Kidney Diseases has shown that ESRD is about 3.7 times more prevalent in African Americans than Caucasians, 1.5 times more prevalent in both Hispanics and Asian Americans than Caucasians, and 1.4 times more prevalent in Native Americans than Caucasians. *See Hispanics and Kidney Disease*, National Kidney Foundation, *available at* https://www.kidney.org/atoz/content/hispanics-kd (last visited Jan. 5, 2017); *Kidney Disease Statistics for the United States*, National Institutes of Health, *available at* https://www.niddk.nih.gov/health-information/health-

statistics/Pages/kidney-disease-statistics-united-states.aspx (last updated December 2016). Approximately 65% of DaVita's patients are racial minorities.

12. Adjusted for race, kidney disease is two to three times more prevalent in low income individuals than higher income individuals. For instance, a 2012 study in the National Kidney Foundation's *American Journal of Kidney Diseases* found that African Americans who had incomes of between $20,000 and $35,000 per year had more than double the risk of kidney disease compared with African Americans earning more than $75,000. *Low Income Linked to Higher Levels of Kidney Disease*, National Kidney Foundation (Nov. 5, 2012), *available at* https://www.kidney.org/news/newsroom/nr/Low-Income-Linked-to-Higher-Levels-of-Kidney-Disease.

13. ESRD patients have a variety of insurance options available to them—from private insurance offered by an employer or purchased individually, to whole or partial public coverage through Medicare, Medicaid, and similar programs. The exact options available to a given patient depend on a number of factors, including, but not limited to, state of residence, age, and financial status.

A. ESRD Coverage Under Medicare

14. In 1972, Congress amended the Social Security Act to make individuals under the age of 65 suffering from ESRD eligible for Medicare, subject to certain requirements. Notably, while ESRD patients under the age of 65 are eligible for Medicare, they are not required to enroll in Medicare. Unlike patients over 65, they may defer enrollment without facing late enrollment penalties.

15. Patient choice is a key facet of the regulatory framework—a patient typically has the choice to maintain private health insurance for up to 30 months after diagnosis, after which the private insurance company is no longer obligated to pay as the primary insurer.

16. Traditional Medicare, or "Original Medicare," coverage can involve a number of distinct programs and parts, each with their own applicable premium, deductible, and coinsurance requirements. This includes:

a. Part A—or hospital insurance—covers inpatient hospital stays, skilled nursing facility care, hospice care, and some home health care. Part A coverage does not require most people to pay a monthly premium. It does, however, impose significant deductible and coinsurance costs. In 2016, for example, a Part A beneficiary had a $1,316 deductible for each benefit period. Coinsurance charges ranged from zero dollars to $658 per day, depending on the length of a hospital stay. *Medicare 2017 Costs at a Glance*, Medicage.gov, *available at* https://www.medicare.gov/your-medicare-costs/costs-at-a-glance/costs-at-glance.html (last visited Jan. 5, 2017).

b. Part B—or medical insurance—covers doctors' services, outpatient care, durable medical equipment, and preventative services. The standard Part B premium in 2017 will be $134 per month, however this number can vary significantly depending on the beneficiary's income. Individuals enrolled in Part B in 2017 will be required to pay a $183 deductible. Outside of the deductible, Part B beneficiaries typically must pay 20% of the cost of most doctors' services (although supplemental coverage for these costs may be

available to some). This coinsurance expense includes dialysis treatments. It is uncapped. *Id.*

c. Part D plans cover prescription drugs for beneficiaries enrolled in Part A, Part B, or both Parts. They are administered by Medicare-approved private insurers. Their premium, deductible, and coinsurance obligations vary by plan and beneficiary income level. *Id.*

17. To be eligible for Medicare, a person must (1) possess a certain number of work credits based on the patient's age, earned by working and paying Social Security taxes; and (2) maintain U.S. citizenship.

18. Medicare coverage is typically initiated on the first day of the fourth month of a patient's dialysis treatments. During the initial waiting period, patients need alternate coverage to remain insured.

19. Although other eligible individuals may face penalties for failing to enroll in Medicare, ESRD patients under the age of 65 may defer enrollment without penalty, with certain exceptions. DaVita counsels its patients extensively on avoiding late enrollment penalties, consistent with CMS regulations.

20. In lieu of "Original Medicare," some beneficiaries may elect to enroll in Medicare Advantage Plans (also known as Medicare Part C), which function as managed care plans providing all of the coverage provided by Medicare Parts A and B, and depending on the plan, Part D. ESRD patients are not eligible to enroll in Medicare Advantage plans unless they had already enrolled in a Medicare Advantage plan pre-diagnosis.

21. Medicare supplemental plans, known as Medi-Gap, supplement Medicare's out-of-pocket expenses for beneficiaries enrolled in both Parts A and B. Medi-Gap plans are

administered by Medicare-approved private insurers. Medi-Gap plans cover the out-of-pocket expenses—copayments, coinsurance, deductibles—that Original Medicare does not cover. Federal law sets general standards for Medi-Gap plans, and those standards are supplemented by individual state insurance laws.

22. Federal law does not require that Medi-Gap plans be offered to Medicare beneficiaries under the age of 65. As a result, 23 states do not require that Medi-Gap plans be made available to all Medicare beneficiaries in the state, regardless of age. The private insurers who administer the Medi-Gap plans in those states typically do not make their plans available to ESRD patients under age 65. ESRD patients under 65 in those states are fully liable for Medicare's 20% coinsurance expenses, and fully liable for incidental costs and out-of-pocket expenses not covered by Medicare at all.

B. ESRD coverage under Medicaid

23. Medicaid is another government-subsidized insurance plan. Eligibility for Medicaid is based on income, not health status or age. Each state's Medicaid program is administered by the individual state, and the states may individually determine the services Medicaid will cover and the applicable Medicaid-provider reimbursement rates. Coverage under Medicaid plans is typically more circumscribed than Medicare or private insurance. By law, Medicaid is the insurer of last resort, meaning that Medicaid beneficiaries may be covered by other insurance options that will pay primary to Medicaid.

24. Individuals that are eligible for or enrolled in Medicaid are permitted to enroll in a QHP or individual market plan while retaining Medicaid as secondary coverage.

C. The Affordable Care Act maintained ESRD patient choice

25. In 2010, Congress passed the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, collectively the Affordable Care Act ("ACA," known colloquially as "Obamacare"). DaVita's regulatory obligations did not change under ACA. Its patients, however, received broader access to insurance options on the individual healthcare market.

26. QHPs can be offered in up to four "tiers": Bronze, Silver, Gold, and Platinum. Each plan is required to offer 10 basic coverage areas, which include hospitalization, prescription drugs, and laboratory services. The plan's category dictates its co-pay and deductible amounts. For instance, Bronze plans charge lower premiums but cover only approximately 60% of a beneficiary's expenses, leaving a beneficiary responsible for approximately 40% of his or her out-of-pocket costs. Platinum plans, on the other hand, charge a much higher premium but cover approximately 90% of a beneficiary's medical costs.

27. Under the ACA, patients may be eligible for premium tax credits or cost sharing reductions, but availability is limited by a number of factors. For example, any patient *eligible* for Medicaid, regardless of whether they actually enroll, is not eligible for premium tax credits or cost sharing reductions. Patients who choose to purchase QHP coverage to access benefits not covered by Medicaid, therefore, must do so without the benefit of federal tax credits or cost sharing.

* * *

28. In sum, Congress has recognized the unique vulnerability of ESRD patients and has made options available to them, both public and private. But it has never required any

particular form of coverage, recognizing that different coverage options will be better for different patients.

II. DaVita Patients Make Their Own Educated Choices About Insurance

29. Consistent with this statutory and regulatory framework, DaVita focuses on enabling its patients to make well-informed choices regarding their health insurance options, based on their own circumstances, needs, and preferences.

30. CMS mandates providers to educate our patients. In 2008, for example, CMS amended the Conditions for Coverage. The stated purpose of this amendment was to emphasize a more patient-centric, outcome-oriented approach to dialysis treatment.

31. The 2008 revision focused on patient rights, education, and support. The revised Conditions for Coverage, therefore, require dialysis facilities to provide each patient with an individualized, multidisciplinary plan of care. They further entitle patients, among other rights, to the right to be fully informed of treatment options, the right to be fully informed of charges for services not covered under Medicare, the right to fully participate in all aspects of care, and the right to receive all information in a way that they can understand.

32. In compliance with these regulations and other guidance, DaVita provides comprehensive, accurate information that allows patients to make informed choices, based on individual circumstances and preferences, on the various clinical and financial decisions dialysis patients face.

33. For this purpose, DaVita employs an interdisciplinary team that includes social workers, insurance counselors, and members of each patient's medical care team. The team regularly assesses a patient's psychological well-being, financial capabilities and resources, and insurance options. The team communicates regularly with the patient on these issues.

34. DaVita insurance counselors help patients make informed insurance coverage decisions. This includes providing the information necessary to allow a patient to make an informed choice between Medicare, Medicaid, and private insurance. If a patient faces difficulty paying for coverage, insurance counselors also educate the patient on available financial assistance programs. Insurance counselors serve as the primary contact between patients concerning insurance, DaVita's billing office, and insurers to resolve patient insurance issues and concerns.

35. DaVita requires insurance counselors to complete a rigorous training program. This includes a month of training before they begin counseling patients on their own—two weeks of classroom sessions and two weeks shadowing more experienced counselors. Counselors must learn how every insurance option, both public and private, is structured, and they are educated on the rules that govern these options. They also receive a refresher on how to properly review all of a patient's coverage options with that patient, with the objective of fully educating a patient and allowing the patient and their family to choose the best insurance type for their needs. DaVita frequently updates this training.

36. Consistent with CMS's patient-oriented approach, DaVita educates patients on all available insurance options, both public and private. Thus, if a patient has multiple insurance options, DaVita social workers and insurance counselors provide balanced, comprehensive information on each option, including short- and long-term implications. DaVita's insurance counselors are also available to provide individualized insurance guidance to patients over the phone, in person, or via email.

37. DaVita social workers generally have a master's degree in social work and are licensed, if necessary, in the states in which they work. They work closely with patients on a

number of different areas, including emotional support, disease education, family and other support systems, goal setting and diet adjustment. Along with DaVita's insurance counselors, they help patients understand their insurance plan options and, if necessary, apply for premium assistance. By presenting a full picture of the patients' needs to the dialysis team, social workers help ensure the best decisions will be made regarding the patients' overall health and well-being.

38. DaVita's counseling is not limited to the initial stages of patients' treatment. DaVita social workers and insurance counselors educate patients about insurance options throughout the time they receive treatment. DaVita's insurance counselors and social workers guide patients through their insurance coverage options up to and after the point of transplantation. Patients who request assistance are not left to navigate the process on their own.

39. DaVita patients are not required to use its internal support system. Many patients conduct their own independent research and arrive at an insurance decision without the assistance of DaVita team members. DaVita possesses very little information about these patients, and in many circumstances knows only what is listed on those patients' insurance cards. On the other hand, when a DaVita team is actively involved in assisting a patient who is evaluating insurance options, the team is very knowledgeable about that patient's financial resources, preferences, and coverage options.

40. The patient's ultimate insurance decision is the patient's alone. DaVita merely supports the patient in making his or her decision.

III. DAVITA'S RELATIONSHIP WITH CHARITIES THAT PROVIDE PREMIUM ASSISTANCE

41. Because of the high cost of dialysis treatment and the low income of many ESRD patients, a significant number of these patients cannot afford to pay their insurance premiums.

42. In response to this problem, charitable organizations, most notably the American Kidney Fund, have long provided premium assistance to eligible ESRD patients. Many of these charitable organizations have provided this assistance since the mid-1970s, and it has become a critical component of the ESRD treatment framework. DaVita has been donating to the American Kidney Fund for almost twenty years.

43. DaVita does not provide premium assistance directly to its patients. The vast majority of DaVita's patients who receive charitable premium assistance receive that assistance from the American Kidney Fund's Health Insurance Premium Program (HIPP).

44. The American Kidney Fund publically discloses that it receives donations from a variety of sources, including dialysis providers such as DaVita. DaVita does not provide any suggestion as to how its contributions should be used. In other words, DaVita does not tie its contributions to the American Kidney Fund to the total amount of premium assistance that the American Kidney Fund gives to DaVita patients, DaVita's donations are made without any restrictions or conditions placed on the donation, and DaVita's donations are not earmarked for the use of DaVita patients.

45. Premium assistance is typically limited to patients receiving dialysis treatment. As described above, however, DaVita educates these patients who will no longer need to receive dialysis treatment based on a transplant on how to maintain insurance coverage. Patients have a number of options for ensuring continuous coverage:

a. Most commonly, an ESRD patient will enroll in Medicare at the time of transplant. Deferred enrollment enables the patient to keep the coverage they choose up until his or her transplant, along with 36 months of post-transplant coverage under Medicare. After that, assuming the patient is

not yet eligible for Medicare due to age, the patient will be positioned to re-enter workforce and obtain coverage through an employer group plan or purchase a QHP on his or her own.

b. Other patients are able to secure alternative sources of financial assistance. They maintain QHP coverage through these other sources until such time as they are able to re-enter the workforce and return to a group health plan or purchase a QHP on their own.

IV. MANY PATIENTS HAVE GOOD REASONS TO PREFER PRIVATE INSURANCE OVER MEDICARE AND MEDICAID

46. Patients are, of course, free to choose the type of health coverage that works best for them, and have differing options available to them, depending on variety of factors, such as financial means, age, and options available in their state.

47. The vast majority of DaVita's patients are insured by Medicare, Medicaid, or some combination of the two. As of October 2016, approximately 5,000 patients were on a QHP plan.

48. There are many reasons why these patients would prefer private insurance over Medicare or Medicaid. These reasons are not just financial—many go directly to patients' health, quality of life, quality of care, and, for some, whether they have any insurance at all.

A. Ineligibility for Medicare or Medicaid

49. Most critically, over 1,000 DaVita patients are entirely ineligible for either Medicare and Medicaid. These patients either have not earned the required number of work credits to qualify for Medicare, cannot meet Medicare's citizenship requirement, do not have sufficiently a low income to qualify for their state's Medicaid program, or cannot meet other

eligibility requirements. The only insurance available to these patients is through the private market.

50. In Texas, we estimate that approximately 78 DaVita patients receiving charitable premium assistance on QHPs are ineligible for government insurance. Without charitable premium assistance, these patients will incur significant financial expense, either from covering their own premiums or from becoming uninsured. Those who become uninsured may lose access to the dialysis treatments that keep them alive.

B. Specific Benefits of Private Insurance Over Medicare

51. There are many reasons a patient might prefer private coverage to public options. A patient is potentially exposed to higher out-of-pocket costs on Medicare than on an QHP. For example, Medicare Part B beneficiaries must make out-of-pocket coinsurance payments of 20% of the cost of doctors' services. Coinsurance costs can be significant for ESRD patients. In addition to regular dialysis treatments, which are both frequent and expensive, they must also commonly receive treatment for ESRD co-morbidities such as diabetes, anemia, and hypertension. In contrast, coinsurance expenses are capped under a QHP. This difference can amount to thousands of dollars in extra expenses for Medicare beneficiaries, as illustrated in the attached example. *See* Figure 1 at Addendum.

52. While Medi-Gap *can* cover these out-of-pocket expenses, it generally is not available to ESRD patients under 65 in 23 states. Therefore, patients in these states face uncapped out-of-pocket expenses on Medicare. Approximately 250 DaVita patients are currently receiving charitable assistance for QHPs in states that do not give ESRD patients under 65 access to Medi-Gap.

53. Commercial insurance also usually produces significantly better health outcomes on average than public options. ESRD patients covered by commercial insurance have a lower risk of death, lower rates of hospitalization, and higher rates of transplantation than ESRD patients covered by Original Medicare. By way of analogy, Medicare Advantage—which is administered by private insurers and is more analogous to a commercial plan than to Original Medicare—leads to better health outcomes than Original Medicare. Medicare Advantage patients have a single year mortality rate of 1.8%, compared to a rate of 6.8% for Original Medicare patients. Hospital stays are 19% shorter on average for Medicare Advantage patients than Medicare Fee-For-Service patients, and Medicare Advantage patients have a 27% lower hospital readmission rate. Medicare Advantage patients utilize emergency services and receive ambulatory surgery at 20% lower rates than Original Medicare patients.[1] See Jon Kaplan et al., *Alternative Payer Models Show Improved Health-Care Value*, BCG Perspectives (May 14, 2013), *available at* https://www.bcgperspectives.com/content/articles/health_care_payers_providers_alternative_payer_models_show_improved_health_care_value/?chapter=3; Jeff Lemiuex et al., *Hospital Readmission Rates in Managed Plans*, American Journal of Managed Care (Feb. 27, 2012), *available at* http://www.ajmc.com/journals/issue/2012/2012-2-vol18-n2/Hospital-Readmission-Rates-in-Medicare-Advantage-Plans; Bruce E. Landon et al., *Analysis Of Medicare Advantage HMOs Compared With Traditional Medicare Shows Lower Use Of Many Services During 2003–09*, Health Affairs (Dec. 2012), *available at* http://content.healthaffairs.org/content/31/12/2609.short.

[1] Although Medicare Advantage generates more successful health outcome than Original Medicare, as mentioned above, few ESRD patients are enrolled in Medicare Advantage. The exceptions for ESRD patients are narrow. To have access to Medicare Advantage, an ESRD patient must have been covered by a Medicare Advantage plan pre-diagnosis or live in an area that offers a Medicare Special Needs Plan for people with ESRD.

54. Most commercial plans also include case management programs, which generally lead to better health outcomes. A 2011 DaVita study found that patients in its Health Case Management program had a 13% central venous catheter (CVC) rate, compared to a 22% benchmark rate. A higher CVC rate leads to greater rates of patient infection, thrombosis, hospitalization, and death.

55. It is important for ESRD patients to retain access to the primary-care providers and specialists that they have built relationships with, and to have access to the full spectrum of preventative care and medication that their private plan provides. That may not be possible if the patient switches to public insurance. This is particularly important to ESRD patients under 65, who are more likely than older patients to have minor children and Medicare-ineligible dependents. Medicare will not cover these dependents unless they are independently eligible. As the following studies show, patients on Medicare typically have restricted access to physicians and specialists as compared to patients on private insurance:

a. While 89% of primary-care physicians will accept new commercial patients, only 73% will accept new Medicare patients. *See, e.g.,* Esther Hing & Susan M. Schappert, *Generalist and Specialty Physicians: Supply and Access, 2009-2010,* 105 NCHS Data Brief at 3 (Sept. 2012), a*vailable at* https://www.cdc.gov/nchs/data/databriefs/db105.pdf.

b. One in five specialists and one in three primary-care physicians are restricting the number of Medicare patients accepted in their practices. This disparity is even more pronounced in certain markets. *See, e.g., AMA Online Survey of Physicians: The Impact of Medicare Physician Payment on Seniors' Access To Care*, American Medical Association

(May 2010), *available at* http://www.cathmed.org/assets/files/AMA,%20Participation%20in%20Medicare,%20May%202010.pdf.

c. The Texas Medical Association reported over a recent two year period that the percentage of physicians accepting new Medicare patients dropped from 66% to 58%. *See, e.g.*, *Drop in Physician Acceptance of Medicaid, Medicare Patients*, Texas Medical Association (July 9, 2012), *available at* https://www.texmed.org/template.aspx?id=24764.

d. A "secret shopper" survey of physicians in Tallahassee, Florida who were included on a list of physicians who accepted Medicare revealed that 60% of physicians either accepted no new Medicare patients or capped the number of Medicare patients they would accept. *See, e.g.*, Jesse G. O'Shea et al., *Milestone or Millstone? Medicare Access in Midsize Metros*, 21 Clinical Geriatrics 12 (Mar. 2, 2015), *available at* http://www.consultant360.com/articles/milestone-or-millstone-medicare-access-midsize-metros..

56. Part D plans also typically include an initial coverage limit, beyond which the insurer's obligations are limited up to the beneficiary's out-of-pocket limit. Between the initial coverage limit and the out-of-pocket cap limit is a coverage gap, sometimes called a "donut hole." In this gap, the beneficiary typically pays coinsurance of 40% to 60%. The gap can be very costly for ESRD patients, who can have up to twenty different drug prescriptions. In 2016, Medicare beneficiaries in that gap were responsible for paying 45% of the plan's cost of covered brand name prescription drugs, and 58% of the cost of generic drugs. For ESRD patients, many

of whom must take more than ten prescriptions per day, a QHP likely offers better drug coverage at a lower cost.

C. Specific Benefits of Private Insurance Over Medicaid

57. There are also a number of treatment-related reasons why QHPs might be preferable to Medicaid.

58. Many providers do not accept *any* Medicaid patients. Medicaid typically reimburses providers at much lower rates than commercial plans (and even Medicare), so providers are reluctant to give up the higher profits generated by commercially insured patients. Only 67% of primary care providers treat Medicaid patients, and only 44% of those providers accept new Medicaid patients. *See, e.g.,* Cristina Boccuti et al., *Primary Care Physicians Accepting Medicare: A Snapshot*, The Henry J. Kaiser Family Foundation (Oct. 30, 2015), *available at* http://kff.org/medicare/issue-brief/primary-care-physicians-accepting-medicare-a-snapshot/. These numbers vary across the country, but low Medicaid reimbursement rates cause providers to accept far fewer Medicaid patients than commercially insured patients in every state.

59. This, in turn, means that QHPs provide broader access to specialists and transplant providers. For instance, an ESRD patient with epilepsy who cannot safely travel will not be able to receive neurological treatment if no neurologists in the area accept Medicaid. If the patient lives in a large state such as Texas, that patient may have to travel great distances to find a necessary neurologist who does accept Medicaid. Because specialists accept commercial insurance at a higher rate, the patient is much more likely to receive much-needed local epilepsy treatment if that patient can obtain a commercial plan.

60. In addition, some types of state Medicaid programs may only cover a single individual, while QHPs provide the opportunity for family coverage.

61. Furthermore, in many cases, QHPs provide access to required medications not covered by Medicaid.

62. QHPs also provide more geographic flexibility, allowing patients to travel out of state. Most Medicaid programs will not provide coverage for services obtained out of state, because each state has its own Medicaid plan.

D. Benefits Of Private Insurance For Patients Seeking Kidney Transplants

63. A patient with private coverage, including with a QHP, is more likely to receive a kidney transplant—and receive it more quickly—than a patient on either Medicare or Medicaid.

a. According to a 1998 study, individuals covered by private insurance were 24% more likely than those without private insurance to be listed for kidney transplantation before dialysis.

b. A 2013 study of kidney transplant candidates found that 22% of patients with private insurance received a living kidney, compared to 7.6% of patients without private insurance. African Americans with private insurance were 14 times more likely to receive a living kidney transplant than those without private insurance.

c. A total of 374 DaVita QHP patients have received a transplant since 2014, a 4% transplant rate in less than three years, well below the average time spent by ESRD patients on transplant waitlists. By comparison, Medicare patients have a 3% transplant rate and Medicaid patients have a less than 2% transplant rate over an average of five to seven years.

d. A 2016 DaVita Clinical Research study showed that patients with commercial insurance were up to 8 times more likely to receive a transplant than patients on government insurance.

64. Of the 374 DaVita QHP patients who have received a transplant since 2014, just 3 have been readmitted to DaVita for dialysis treatment.

65. Furthermore, certain transplant centers will not accept Medicare or Medicaid. And some Medicaid plans will not pay for live transplant surgery, the type of surgery with the highest success rate.

66. For example, dental coverage is typically a prerequisite to kidney transplant eligibility because dental infection threatens the viability of the transplant. Most QHPs provide access to oral specialists, while many Medicare and Medicaid plans do not.

E. The Majority of ESRD Patients Receiving Private Insurance Would Be Harmed If They Lost That Coverage

67. Given all this, the majority of ESRD patients would not benefit from moving from a QHP to public health insurance.

68. Medicare eligible patients who are ineligible for Medicaid and who reside in states that do not make Medi-Gap coverage available to ESRD patients face significant financial costs. As stated above, unlike QHPs, Medicare has no cap on out-of-pocket expenses. These patients will be required to pay Medicare's 20% coinsurance for treatment, which typically amounts to $7,200 per year (*see* Figure 1), until they have exhausted their savings to the point they become eligible for Medicaid.

69. For patients who are ineligible for Medicare—which includes ESRD patients who do not meet the years-worked requirement and non-citizens—the situation becomes even more

dire. Some may be eligible for Medicaid in a state whose Medicaid program provides minimum essential coverage, although that coverage will be limited and they will lose access to important ancillary treatment that may compromise their health or deprive them of the opportunity to secure a kidney transplant. Others would have something less than the minimum essential coverage, and many would be left with no coverage at all. For these patients, all non-emergency health care costs would have to be paid out of pocket.

70. Approximately 2,500 DaVita patients have already elected a marketplace plan for 2017. If their insurers begin rejecting third-party premium payments, those receiving charitable assistance will be forced to cover their own costs until the three-month Medicare enrollment period has run, or until they reduce their savings sufficiently to qualify for Medicaid. Three months of costs can be significant for ESRD patients.

V. THE INTERIM FINAL RULE WILL CAUSE DAVITA SEVERE AND IRREPARABLE HARM

71. On December 14, 2016, CMS promulgated the IFR. The IFR becomes effective 30 days from publication in the Federal Register. It was published on December 14, 2016, which means that DaVita must comply by January 13, 2017 or risk violating the rule.

72. The IFR will cause irreparable harm to DaVita in the following four ways: (1) the loss of income due to patients switching from private to public insurance will make it financially infeasible for many DaVita facilities to continue operations; (2) DaVita is unlikely to be able to comply with the IFR's vague and unworkable requirements, and the likely result of failure to comply would be the termination of those facilities' participation in Medicare, causing DaVita potentially catastrophic financial injury; (3) for DaVita to attempt compliance, the costs will be significant and substantial; and (4) DaVita's business relationships and reputation are likely to suffer significant harm.

A. The Interim Final Rule Will Cause Many DaVita Facilities To Become Financially Unsustainable

73. The cost to DaVita of treating a patient covered by Medicare and Medicaid is more than the reimbursement DaVita receives from the government for that treatment. As is common throughout the dialysis industry, DaVita subsidizes these costs with the reimbursements it receives from private insurers.

74. Government dialysis-related payments in the United States are determined by federal Medicare and state Medicaid policy. Absent action by Congress, the base Medicare reimbursement rate is automatically updated annually by a formulaic inflation adjustment. Increases in DaVita's operating expenses, however, typically outpace Medicare rate increases. On the other hand, commercial reimbursement rates are the result of negotiations between DaVita and insurers or third-party administrators. Accordingly, these rates are generally significantly higher than government rates.

75. For some DaVita facilities, these costs would not cover operating expenses if a significant number of patients moved from private insurance to Medicare and Medicaid or become uninsured.

76. The IFR will cause a significant number of DaVita's patients to switch from private insurance to Medicare or Medicaid, or lose insurance entirely, because they will lose needed charitable premium assistance. This will result in a number of DaVita facilities becoming financially unsustainable. Based on recent financial analysis, for example, as many as six DaVita facilities in Texas alone—located in Cypress, Dallas, Denton, Carrollton, Raymondville, and Webster—would suffer an adverse financial impact should patients currently

receiving HIPP assistance for QHPs be forced to move to a government program or become uninsured.

77. As a result of this financial impact, DaVita may have to close these facilities and lay off employees. If facilities are closed, patients of these facilities will be forced to travel 20 miles or more to receive treatment at the closest outpatient dialysis facility, significantly impairing their ability to receive critical care.

B. Uncertainty Regarding Compliance With The Interim Final Rules Presents A Significant Risk Of Termination From Medicare And Insolvency

78. Medicare participation is critical to DaVita's business. As stated above, a majority of DaVita patients is insured by Medicare. As a result, DaVita relies on Medicare reimbursement as a critical source of income. In fact, almost 60% of the total reimbursement received for patient care in 2016 was paid by the Medicare program. In addition, many insurers require that the facility be Medicare-certified in order to participate.

79. Due to this reliance on Medicare, if CMS terminated DaVita dialysis facilities from the Medicare program based on noncompliance with the Rule, the results would be devastating. At a minimum, termination from Medicare as a result of failure to comply with the IFR would likely require the closure of affected dialysis facilities and employee lay-offs.

80. Should termination from Medicare be sufficiently widespread, due to, for example, a company-wide inability to meet the IFR's requirements, DaVita risks insolvency.

81. Put simply, DaVita cannot afford to violate the IFR, even for a limited period of time, and thus the company is taking all necessary steps to come into compliance.

82. Nevertheless, DaVita faces substantial, and perhaps insurmountable, obstacles in complying with the IFR's disclosure requirements, as follows:

1. DaVita cannot identify every patient who receives charitable premium assistance

83. DaVita does not necessarily know whether a patient is receiving premium assistance from a third party, or even what third-parties might be providing such assistance.

84. Specifically, DaVita does not know which patients have secured assistance on their own. Nor does DaVita know all of the charitable organizations that might be providing such assistance to these patients.

85. Just by way of example, DaVita has historically donated to various United Way chapters. It is possible that, unbeknownst to DaVita, some of these chapters run programs that provide charitable premium assistance to DaVita patients. For example, although DaVita has not recently donated to the United Way of the Greater Triangle, publicly available information shows that that chapter provides premium assistance in the Durham, North Carolina area for Blue Cross Blue Shield of North Carolina insurance plans. DaVita is in no position to know every charity that might provide similar assistance, or which of its patients might receive it.

86. Because the IFR does not define the reasonable steps a provider must take to ensure that payments are not made by a charitable organization to which the provider contributes, and because it has provided no guidance on the issue, DaVita's failure to identify these patients and receive assurance regarding their coverage is a potential violation of the rule.

2. DaVita will likely be unable to receive timely assurance from insurers

87. Nor is there sufficient time to receive the necessary assurance from insurers.

88. As a preliminary matter, DaVita does not necessarily know which of its patients successfully enrolled in a QHP for 2017. That process typically requires communication and confirmation from the insurer that can last well into the first quarter of the year.

89. In any event, DaVita has been in communication with some insurers regarding their plans for 2017. To date, those insurers have taken inconsistent and varied positions in response.

90. For example, one responded by saying that, because the IFR demonstrates that DaVita has an "undisputed financial conflict of interest," it "will not accept premium payments from DaVita or [the American Kidney Fund] in 2017."

91. Another sent letters directly to patients, asserting that HHS has "instructed insurance companies to reject premium payments received from third parties on behalf of individual customers, except in certain circumstances." This insurer is requiring these patients to provide proof, through a cancelled check, bank statement, or credit card statement, that a third party is not paying their premiums.

92. One insurer responded that it "continue[s] to develop [its] process to support" the IFR, but that it "expects you will comply with the rule and send [the insurer] notice for every enrollee, as required, prior to you, or a third party you support, providing premium assistance."

93. Given the inconsistency in the positions taken by the insurers that have responded thus far, and the practical difficulty in sending and tracking assurance requests for thousands of individual patients, DaVita will be unable to secure the assurance required under the IFR by the rule's effective date, which is just one week from today.

3. Compliance will cause DaVita to violate the OIG Advisory Opinion

94. Even if DaVita could identify all the patients receiving charitable premium assistance and secure the required assurance from insurers, compliance with the IFR would be inconsistent with and arguably violate specific provisions of the HHS Office of Inspector

General ("OIG") Advisory Opinion No. 97-1 (OIG Advisory Opinion), leaving it without the significant and longstanding protection afforded by the guidance.

95. First, the OIG Advisory Opinion expressly prohibits providers from "disclos[ing] directly or indirectly to individual patients they refer [to the American Kidney Fund] that such members have contributed to the American Kidney Fund to fund the grants."

96. In direct conflict with that prohibition, the patient disclosure provisions require DaVita to disclose to patients that it makes charitable contributions to the American Kidney Fund.

97. CMS's has already instructed state surveyors to expressly ask a "facility administrator or designated personnel," among other questions, whether "the facility provides all patients with current information regarding the facility's or parent organization's overall contributions to date made to patient's or third parties supporting enrollment in individual market health plans." *See* Memorandum re: Notice of Interim Final Rule (IFR) Third Party Payment and Information on Implementation Plan (Dec. 16, 2016), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-16.pdf. A "no" response would "indicate non-compliance" with the IFR. *Id.*

98. Second, the OIG Advisory Option prohibits providers from earmarking contributions for the use of a particular beneficiary or groups of beneficiaries

99. Contrary to that provision, the IFR requires DaVita to seek to halt the grant of premium assistance to specific patients whose insurers refuse to accept third party payments. In other words, the IFR requires DaVita to dictate which beneficiaries may or may not receive

charitable assistance, in direct conflict with OIG's requirement that contributions not be earmarked for the use of a particular beneficiary or groups of beneficiaries.

100. The purpose of the OIG Advisory Opinion, and subsequently issued guidelines establishing standards for compliant charitable assistance programs, is to permit health providers like DaVita to donate to independent charities and provide health care services to patients receiving premium assistance from those charities, without running afoul of federal healthcare laws.

101. Thus, the IFR places DaVita in the untenable position of choosing between adhering to the OIG standards but facing Medicare termination for violating the requirements of the IFR, or adhering to the IFR but violating the OIG standards and potentially subjecting itself to significant liability under other laws.

4. Discontinuing all charitable donations to charities providing premium assistance will harm patients

102. Simply ceasing to donate to charities that provide premium assistance to DaVita patients is not an option, for several reasons.

103. First, as already explained, DaVita is not in a position to know every charity that provides assistance to its patients.

104. Second, even for charities DaVita does know about, such as the American Kidney Fund, DaVita cannot instruct the American Kidney Fund to use its contributions for Medicare patients only. As stated above, under existing OIG requirements, DaVita cannot earmark contributions to the American Kidney Fund. Further, the Preamble to the IFR expressly states that "the 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." 81 Fed. Reg. 90,211, 90,219 n.16 (Dec. 14, 2016).

105. Thus, DaVita would have to cease making any contribution to the American Kidney Fund. Ceasing contributions to the American Kidney Fund, however, would result in the loss of a source of critical funding for not only those patients receiving support of QHPs, but for those receiving any assistance, including assistance for Medicare or Medi-Gap premiums.

106. Given all this, DaVita cannot be sure it can comply with the IFR by January 13, 2017, and if the IFR becomes effective, DaVita faces termination from Medicare, significant harm to its business, and potential bankruptcy.

C. The Interim Final Rule Imposes Substantial Compliance Costs

107. The compliance costs imposed by the IFR are substantial, especially given the compressed period for coming into compliance. DaVita will be forced, among other things to develop and implement several new compliance systems and disclosure materials and retrain many employees, all before the IFR's January 13, 2017 effective date, at an estimated cost of over $11 million.

108. DaVita estimates that it will cost over $500,000 to attempt compliance with the IFR's insurer disclosure requirements. It must retrain employees who assist patients in submitting applications to the American Kidney Fund on how to identify whether an insurer will accept charitable assistance, how to identify patients whose charitable assistance is likely to be denied, and how to educate patients on the implication of their insurer's decision. It must also retrain employees to monitor communications with insurers, to monitor those insurers' charitable assistance rules, and to apply that knowledge to patient insurance education.

109. DaVita must also develop new tracking systems that will record insurer rules and guidance, track patient insurance decisions, and ensure that DaVita complies with HIPAA in all respects when interacting with insurers about patients' information. DaVita must also develop compliance systems to ensure that it consistently follows the IFR's requirements.

110. DaVita estimates that it will cost $10.5 million to attempt compliance with the IFR's patient disclosure requirement. The IFR requires DaVita to develop a number of new training programs and tracking systems. It must increase its staff to account for the IFR's more robust patient-education requirements, and it must train that new staff. It must develop new education materials, such as area-specific pamphlets, to assist patients in making insurance decisions. Finally, it must devote substantially more employee time to assist all of its patients with their insurance decisions during the Open Enrollment period.

D. The Interim Final Rule Will Substantially Harm DaVita's Business Relationships and Reputation

111. The IFR will harm DaVita's business relationships and reputation in at least two ways. First, it will cause patients to leave DaVita for providers who do not donate to organizations that provide charitable assistance, and thus will not be required to disclose patients' use of assistance to insurers. Second, it will harm DaVita's relationships with its patients.

1. DaVita will lose business to providers who do not need to comply with the IFR

112. The IFR applies only to providers who donate to organizations that provide third-party assistance. If a provider does not donate to the American Kidney Fund or other organizations providing assistance, it need not disclose to insurers that its patients receive such

assistance. Patients of these facilities will be able to continue to use charitable premium assistance.

113. Because QHPs have significant advantages—both financial and in terms of health outcomes—over public insurance, many patients are therefore likely to leave DaVita for another provider if they can keep their QHP coverage.

2. Compliance with the IFR will harm DaVita's relationship with patients

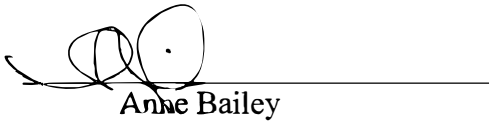
114. The IFR requires DaVita to disclose how patients are paying for their private insurance. The fact that a patient cannot afford insurance premiums, and thus must receive charitable assistance, is private, sensitive information. Patients trust DaVita to keep that information private, and DaVita will breach that trust by disclosing the information to insurers.

115. That breach of trust will not only violate patients' expectations of confidentiality and privacy, but also will cause a number of patients to lose vital private coverage that is in many ways much more beneficial than government coverage, from both a financial and health outcome perspective. Patients are likely to blame DaVita for that loss of coverage, which will doubtless harm Provider Plaintiffs' goodwill with their patients.

* * *

116. My statements above are true and accurate to the best of my knowledge.

Executed this 6th day of January, 2017, in Denver, CO.



Anne Bailey

ADDENDUM

FIGURE 1: SAMPLE TEXAS ESRD PATIENT POTENTIAL HEALTH INSURANCE COSTS

Type of plan	Individual Marketplace Plan (Low Premium)	Individual Marketplace Plan (BCBS TX - Gold)	Medicare, no Supplement	Medicare, with Medi-Gap Supplement
Premium	$436.78	$784.36	Part A - Free	Part A – Free
			Part B - $121	Part B - $121
			Part D - $50	Part D - $50
				Supplement - $400*
Deductible	$7,150	$1,415	Part A - $1316	Part A – $0
			Part B - $183	Part B - $0
			Part D - $400 (avg)	Part D - $400
Out-of-pocket annual maximum	$7,150	$4,850	Part A - $1316	Part A – $0
			Part B - 20% uncapped ($7200 avg)	Part B - $0
			Part D - $1240	Part D - $1240
Total Annual Costs without Charitable Premium Assistance	$12,391.36	$14,258	$11,652	$8,492
Total Annual Costs with Charitable Premium Assistance	$7,150	$4,850	$10,179	$1,640

* Average with Charitable Premium Assistance in 2014

EXHIBIT D

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No._____
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al*.,	)	
	)	
Defendants.	)	

AFFIDAVIT OF LAVARNE A. BURTON IN SUPPORT OF
PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER

I, LAVARNE BURTON, do hereby declare as follows:

1. I am the President and Chief Executive Officer of the American Kidney Fund ("AKF") and have served in that role since 2005.

2. I submit this declaration in support the plaintiffs' application to temporarily restrain the Centers for Medicare and Medicaid Services' ("CMS") Interim Final Rule titled, "Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment," CMS-3337-IFC, published at 81 Fed. Reg. 90,211, *et seq*. (the "IFR"), filed in the above captioned action.

I. AKF and Its Mission

3. AKF is a 501(c)(3) charity that has served as the safety net for U.S. dialysis patients since we were founded in 1971.

4. AKF was founded to help one dialysis patient afford care, and our mission ever since has been to help people fight kidney disease and live healthier lives.

5. AKF fulfills its mission by providing a complete spectrum of programs and services, including top-rated health education materials and programs, free kidney disease screenings, and need-based financial assistance.

6. Over the past 45 years, in addition to providing an array of programs and services to educate the public about kidney disease prevention and treatment, we have helped more than one million low-income end-stage renal disease ("ESRD") patients to access healthcare—including dialysis, transplantation, and other healthcare services—through our various grant programs.

7. Through our Health Insurance Premium Program ("HIPP"), we provide grants to low-income people living with ESRD to allow them to pay premiums for the health insurance that best suits their individual circumstances.

8. We also offer Safety Net Grants for expenses that insurance does not cover, such as transportation to and from dialysis treatment, free medications to treat common side effects of kidney failure, summer camp scholarship grants for children with kidney disease, and disaster relief grants for dialysis patients living in communities affected by natural disaster. (Recently in September 2016, for example, we assisted Louisiana ESRD patients affected by historic flooding with more than $50,000 in disaster relief grants.)

9. We spend 97 cents of every donated dollar on programs that directly serve and educate patients and the public.

10. The nation's leading charity watchdog organizations—including Charity Navigator, Consumer Reports, CharityWatch, and the Better Business Bureau Wise Giving Alliance—have consistently recognized AKF as one of the nation's most trusted and respected charities.

II. HIPP Enables the Most Vulnerable Patients to Choose and Maintain Insurance Coverage Best Suited to Their Needs

11. People confronted with an ESRD diagnosis face life-altering challenges, including reduced ability to work and care for themselves and their families, the burden of needing regular dialysis treatment, a decline in health and capacity, and the corresponding financial impact of living with and treating ESRD.

12. By providing financial assistance to qualifying low-income patients with kidney disease to help pay health insurance premiums, HIPP allows these patients to receive comprehensive medical care, including dialysis, medications, and preventative care.

13. In 2015 alone, AKF provided HIPP assistance to more than 79,000 low-income dialysis patients in all 50 states—that is, *we help nearly one out of every five dialysis patients in the U.S. to afford their healthcare*.

A. *HIPP Serves the Most Vulnerable*

14. For nearly 20 years, AKF has worked effectively to remove significant barriers to maintaining coverage for the low-income, chronically ill population we serve.

15. Fully 70% of the patients we serve are unemployed, while another 20% work only part-time—reflective of the fact that the dialysis treatment regimen makes it difficult to stay employed.

16. To qualify for HIPP assistance, a patient's monthly household income may not exceed reasonable monthly expenses by more than $600, and 60% of the patients we assist have annual household incomes under $20,000.

17. At the same time, our nation's ESRD patients have average annual out-of-pocket medical expenses of close to $7,000.

18. Kidney failure also disproportionately impacts racial and ethnic minority populations. African Americans and Hispanics develop kidney failure at higher rates than Caucasians (more than one in three kidney failure patients living in the United States is African American). These groups, which have been underserved historically, are thus also disproportionally affected by barriers to maintaining health coverage.

19. Over half of our HIPP grant recipients are people of color (38% African American, 15% Hispanic).

B. *HIPP Exists to Allow Disadvantaged Patients to Afford the Coverage Best for Them*

20. The core mission of HIPP is to allow low-income ESRD patients to maintain the healthcare coverage best suited to their needs when they otherwise could not afford to do so.

21. Over 60% of our HIPP grants fund premiums for government program coverage such as Medicare Part B and Medigap.

22. HIPP also helps a smaller number of recipients pay premiums for employment group health plans ("EGHPs"), COBRA plans, and qualified health plans ("QHPs") and other individual marketplace plans offered pursuant to the Patient Protection and Affordable Care Act (the "ACA") ("individual market plans").

23. However, our HIPP grants to assist patients with individual market plans constitute a small fraction of our overall grant assistance—indeed, as of 2015, only 6,400 HIPP grant recipients, representing approximately 7% of our total HIPP grant recipients, and a tiny fraction (.05%) of the total 12.7 million individual market coverage enrollees, receive HIPP assistance to pay for individual market coverage.

24. HIPP exists to preserve each eligible low-income ESRD patient's ability to choose and maintain the coverage that is best for them, no matter what that coverage option is.

25. A patient begins the process of applying for HIPP *after* selecting the health plan that best meets their financial and medical needs, following consultation with his or her social worker or other advisor provided through his or her renal care provider.

26. By providing assistance for the full range of insurance options and otherwise staying independent from patients' choices regarding provider and coverage, we ensure that our grant decisions cannot steer patients toward any particular type of coverage.

C. *Individual Market Coverage Is Best for Some ESRD Patients*

27. A range of healthcare coverage options are available to people living with ESRD, options that have only expanded with the ACA.

28. Each coverage option has its own unique benefits and drawbacks, just as each ESRD patient's personal circumstances are unique. For that reason, each patient will have a coverage option best suited to him or her.

29. Our commitment to funding all types of insurance reflects our mission. We firmly believe that it is our obligation not only to provide premium assistance to ESRD patients, but also to provide them the ability to choose and maintain the healthcare coverage that they believe is best for them.

30. Most relevant to the IFR, while only a small percentage (7%) of our beneficiaries receive grants for individual market coverage (as compared with the majority who receive assistance for Medicare and other government-based coverage plans), there are compelling reasons why individual market coverage is better than a government-based plan for certain patients.

31. For instance, ESRD patients are different from other Medicare beneficiaries—both demographically and with respect to coverage rights and options.

32. One key consideration is that Medicare covers only the ESRD patient, not dependents. ESRD patients are younger than the typical Medicare beneficiary, and are often supporting families.

33. Medicare also leaves recipients with substantial cost-sharing obligations—including a 20% coinsurance requirement that can be financially crushing for individuals with chronic conditions like ESRD.

34. For individuals who do not meet the stringent eligibility requirements for the various "Medicare Savings Programs" designed to defray such cost-sharing obligations for the lowest-income beneficiaries, Medigap policies sold by private insurance companies may be available to help cover the annual deductible and coinsurance obligations under Medicare. And HIPP grants also fund premiums for those plans.

35. However, the federal government does not require carriers to offer Medigap to ESRD patients under 65, and regulations vary from state to state.

36. Only 27 states mandate that insurance carriers offer Medigap to ESRD patients under age 65, leaving patients in the other 23 states without access to this important supplemental insurance.

37. Also, while Medicaid provides healthcare coverage for a number of individuals living with ESRD, it may not be the ideal choice for those who are eligible.

38. The severe shortage of providers accepting Medicaid, especially in rural areas and among specialists, can jeopardize access to care for ESRD patients.

39. By contrast, an individual market plan covering an ESRD patient's entire family may be preferable. Individuals with ESRD may wish to have the same coverage—with the same network of physicians and other providers, and the same cost-sharing requirements—for all members of their family, including a spouse or child who does not qualify for Medicare or Medicaid.

40. For example, an individual with ESRD may find that her child's pediatrician's practice group is not enrolled in Medicare or is not taking new Medicare patients but is in-network for an individual market plan in the area. Choosing Medicare for such a patient would make it impossible for her to choose one group provider for her and her child.

41. Individuals may also be motivated by differences with respect to plan benefits, provider access, and/or quality of care.

42. Individual market plans often offer better integration of medical, prescription, and dental coverage compared to what is offered through Medicare alone, or through Medicare with Medigap wrap-around coverage.

43. Additionally, compared with Medicaid plans in most states, individual market plans typically offer greater access to providers, especially specialists.

44. Lack of access is a problem that impacts all Medicaid recipients, but is particularly challenging for patients with ESRD. An ESRD patient has to find not just a dialysis center that accepts Medicaid, but also a cadre of other providers such as cardiologists, endocrinologists, and pulmonologists.

45. ESRD patients may not be able to find specialists in the Medicaid network close by, or if they can, there can be unreasonable waits to get an appointment. For dialysis patients, this lost time can have a significant impact on their health.

46. Individual market plans may also offer better prescription drug benefits than either Medicare or Medicaid. Most Medicare drug plans have a coverage gap (also called the "donut hole"). In 2016, for example, beneficiaries were responsible for paying 45% of the plan's cost for covered brand name prescription drugs and 58% of the cost for generic drugs while the beneficiary is in the coverage gap. For ESRD patients who take multiple medications, an ACA plan may offer better drug coverage at lower cost.

47. Also, many state Medicaid programs have limited formularies or caps on the number of prescriptions that can be filled per month, which can lead to patient non-adherence and additional costs on the healthcare system.

48. Limited prescription benefits under Medicare and Medicaid can even force some patients to make the impossible decision of choosing between their medications and groceries.

49. Dialysis patients often need numerous prescriptions to manage their various conditions. We have seen patients with more than 20 prescriptions who are able to get only 10 filled at any one time, due to prescription drug caps under their state Medicaid program. These patients must then ration prescriptions and determine which ones they will fill. After moving to an individual market plan, these patients are able to fill all prescriptions and maintain better outcomes.

50. In addition, individual market plans may provide coverage that Medicare or Medicaid plans do not offer, may have lower coinsurance obligations, and may have features to better assist ESRD patients with the full range of their healthcare needs, including preparing for and obtaining a kidney transplant.

51. Individual market plans often offer wellness programs, preventive care, health coaching, and other services not provided by traditional Medicare or Medicaid programs.

52. Evidence indicates that ESRD patients with commercial coverage have better health outcomes, including higher transplant rates, fewer infections, and lower hospitalization rates.

53. For instance, research has shown that access to transplants is almost three times higher under commercial coverage than with Medicare, and 14 times higher for African Americans.

54. In carrying out our mission, we work with real patients facing day-to-day decisions about how they can manage their ESRD while having enough money to pay their bills and support their families as best they can.

55. For some patients, after weighing the costs and benefits of their coverage options, obtaining an individual market plan simply gives them the best access to care and the medications they need at the lowest overall cost to them—cost savings that make an enormous difference in their lives.

III. Health Insurers' Concerted Effort to Keep Individuals Living with ESRD Off Their Rolls Under a Pretextual Objection to Charitable Third-Party Payments

56. From the time the ACA prohibited health insurers from denying coverage or charging more by discriminating against people with preexisting conditions, major health insurers have attempted to exclude from coverage groups with a specific condition or disability by virtue of the fact that such groups receive third-party premium assistance from a charitable program focused on that disability.

57. In 2014 for example, the three health insurers in Louisiana's ACA marketplace announced that they would refuse to accept most premium assistance, including

from the federal Ryan White Program enacted to help low-income people living with HIV and from AKF.

58. As grounds for refusing premium assistance, the insurers cited purported concerns about fraud and abuse, tied to third-party payments, affecting the insurance markets.

59. In response to a class action lawsuit filed on behalf of Ryan White fund recipients, brought under the anti-discrimination provisions of the ACA and state contract and insurance law, a federal court restrained the insurers from implementing their plan.

60. Shortly thereafter, the Department of Health and Human Services ("HHS") published an interim final rule requiring insurers to accept third-party payments for Ryan White fund recipients and certain other beneficiaries of government programs, adopted at 45 C.F.R. § 156.1250.

61. More recently, insurers have focused their efforts on excluding low-income ESRD patients from their rolls.

62. Some states, including North Carolina and Louisiana, have encouraged or required insurers to accept third-party premium assistance from charities including AKF.

63. However, the insurance industry has pursued its efforts on all fronts, including bringing litigation against certain dialysis providers, and lobbying the federal and state governments to seek approval to refuse third-party premium assistance based on the contrived narrative that dialysis providers are improperly steering patients from government plans to individual market plans and using HIPP grants to cover the patients' costs.

64. To be clear, AKF has provided premium assistance for private commercial individual health care plans (as well as private COBRA plans and EGHPs) since 1997, long before passage of the ACA.

65. Commercial insurance companies never raised purported concerns about patient steering or abuses of third party payments until after enactment of the ACA, when they could no longer discriminate against ESRD patients by charging higher premiums based on a preexisting condition.

66. Despite the insurance industry's far-reaching campaign, it has yet to provide us information about a single verified instance of inappropriate patient steering or related collusion between AKF and any insurance provider.

67. Nevertheless, on August 23, 2016, CMS, which is headed by Andy Slavitt, a former executive of one of the country's largest health insurance companies, UnitedHealth Group, published a request for information regarding "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans" (the "RFI").

68. In the RFI, CMS explained that it had heard unspecified reports that health care providers and affiliated organizations were steering people who were eligible for Medicare or Medicaid to individual market plans so that the providers would receive higher reimbursements. The RFI asked for public comments about the alleged steering and what impact it had. The RFI also asked for suggestions about how to limit the alleged steering.

69. CMS received 829 comments within the RFI's short 30-day window to respond, including more than 600 comments from individuals describing the value of charitable premium assistance in supporting patient choice and avoiding reliance on taxpayer assistance for their care.

70. On behalf of AKF, I also submitted a comprehensive response to the RFI. A true and accurate copy of that response is attached here as Exhibit A.

71. The hundreds of comments, including AKF's submission, described in detail the importance of charitable premium assistance to ESRD and other patients, including concrete and particularized reasons for why providing access to individual market coverage for patients who could not otherwise afford it is critically important to the health and wellbeing of those patients for whom that coverage best addresses their economic and health care needs.

IV. CMS Promulgated the IFR Without Following Required Procedural Safeguards and Based on Pretextual Rationale for Doing So

72. On December 14, 2016, CMS published the IFR.

73. The IFR establishes new "Conditions for Coverage" standards for Medicare-certified dialysis facilities.

74. The new standards would apply only to 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)."

75. The IFR appears to consider a dialysis facility's charitable contribution to a non-profit organization like AKF as the "payment of premiums" by that facility—notwithstanding the HHS Office of the Inspector General's ("OIG") conclusion in its 1997 advisory opinion (the "'97 Advisory Opinion") that such contributions "should not be attributed" to dialysis facilities that contribute in accordance with the guidelines set forth in that opinion. The IFR does not acknowledge, or attempt to reconcile, this discord with prior federal guidance.

76. The IFR would require dialysis facilities subject to the rule to: (i) provide comprehensive information to patients regarding their insurance options and the coverage- and cost-related consequences associated with choosing one type of insurance coverage over another; (ii) inform patients about the availability of premium assistance and the "limitations and any

associated risks of such assistance," and provide current information about the facility's premium assistance contributions to patients or to third parties like AKF; (iii) disclose such contributions to the applicable insurers and obtain assurances that the insurer will accept such payments for the duration of the plan year; and (iv) if such assurances are not provided, avoid making any premium assistance payments and "take reasonable steps to ensure such payments are not made by the facility or by third parties to which the facility contributes."

A. *CMS Adopted the IFR Without the Required Notice and Comment Period and Without a Valid Basis*

77. AKF has had productive conversations with CMS officials, and we looked forward to further discussions and a fulsome notice and comment period to provide further input on any rule that CMS would propose regarding charitable third-party premium assistance.

78. However, the IFR dispensed with any formal notice and comment period and is rushing to implement this rule on January 13, 2017.

79. The IFR's stated bases for dispensing with a meaningful notice or comment period are that, if the rule is not implemented, (i) patients' ability to be determined ready for a kidney transplant could be negatively affected, (ii) patients could be exposed to additional costs, and (iii) patients could be exposed to a "significant risk of a mid-year disruption in health care coverage."

80. However, in my several discussions with CMS officials, CMS did not focus on these concerns but rather stated multiple times that their primary concern was promoting stability of the marketplace.

81. As to its specific rationales, the IFR vaguely references anecdotes from unidentified commenters about confusion surrounding transplant readiness and continuity of

coverage, but entirely ignores the empirical evidence cited by AKF that access to transplants is almost three times higher under commercial coverage than with Medicare.

82. The IFR also ignores the fact that Medicare for ESRD patients also winds down after a patient receives transplant. Just like AKF, Medicare also accounts for the fact that transplant recipients typically regain the ability to work and obtain private sector health insurance, and thus resources can be better diverted to those who most need help paying for their care.

83. The IFR states that individual market coverage "is financially disadvantageous for some patients with ESRD." AKF does not disagree. But AKF provided well-documented bases for why individual market coverage is *advantageous* for some patients—evidence the IFR completely ignored.

84. AKF believes that it is the complex and varied benefits and drawbacks of *all* coverage options that make it important to provide patients the means to select the best option for them, and that underscore how important a notice and comment period is to properly consider appropriate rulemaking to account for these complexities.

85. Finally, the IFR voices the concern that patients may face a mid-year disruption in coverage if an insurer learns that they are receiving third-party premium assistance and consequently drops those patients from coverage, and that those patients will then be discharged.

86. First, the IFR does not state that CMS has any basis to believe that providers would actually discharge patients if they were dropped from coverage.

87. Second, the IFR presumes that insurers' policies of refusing third-party premium assistance disproportionately, and sometimes expressly, directed at ESRD patients do

not violate the ACA's anti-discrimination provisions and other law, but does not address the legality of such policies or acknowledge that similar policies were halted by a federal court in recent years.

88. Third, the IFR states that CMS has consistently discouraged insurers from accepting payments directly from health care providers—purportedly supporting CMS's contention that issuers might refuse third-party payments mid-year—but fails to acknowledge its policy dating back to February 7, 2014 that CMS's concerns with third-party payments do *not* include payments from private not-for-profit foundations if made based on defined criteria based on financial status where the premium assistance lasts for the entire policy year, like HIPP.

89. In light of CMS's standing policy, if CMS were truly concerned about mid-year coverage loss, it could have required insurers to keep grant recipients on their rolls for the entire policy year, consistent with its policy as to not-for-profits.

B. *The IFR's Broader Stated Impetus Behind the Rule Is Unsupported While the Harms from Discriminating Against ESRD Patients and Their Ability to Pay Their Premiums Are Well Documented*

90. AKF also has serious concerns about the broader stated impetus of the IFR, namely, that dialysis providers are improperly steering patients from government plans to individual market plans when they are not in patients' best interest.

91. The IFR supports its main rationale by only stating in the abstract the financial interest dialysis providers have in seeking reimbursement from individual market plans over government plans, and with a small number of unidentified commenters' anecdotes centered on incomplete information about aspects of coverage provided by certain dialysis social workers.

92. The IFR's anecdotes are anonymous, none are published in their entirety but are paraphrased and assembled with incomplete quotations and ellipses, and none states a

specific instance of a patient being steered or moved to an individual market plan when that plan was not in the patient's best interests.

93. In contrast to the IFR's vague and anonymous comments, numerous individuals and their family members submitted comments stating the importance of third-party premium assistance for patients for whom individual market coverage best suits their needs.

94. The IFR gave those specific comments little weight, and ignored AKF's and other patient groups' detailed submissions supporting the benefits of individual market coverage for certain patients.

95. The IFR also disregarded AKF's detailed discussion of how HIPP operates with the express approval of, and under guidance from, the OIG.

96. Specifically, in 1997, AKF, together with six dialysis providers, requested an advisory opinion from the OIG, seeking approval of, and guidance regarding, continued operation of HIPP while allowing providers to donate to the program.

97. At that time, AKF described for the OIG in detail how AKF had been operating its patient assistance program.

98. In providing its '97 Advisory Opinion, the OIG reviewed the information provided and concluded that continuation of AKF's operating procedures in an expanded HIPP program—that allowed for dialysis providers to voluntarily contribute funding for the program—would enhance patient choice with regard to dialysis providers and ensure that provider contributions would not be used to influence patients.

99. In approving the '97 Advisory Opinion, the Inspector General stated that "the interposition of AKF, a bona fide, independent, charitable organization, and its administration of HIPP provides sufficient insulation so that the premium payments should not

be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of HIPP assistance their patients receive bears any relationship to the amount of their donations. Indeed, the Companies are not guaranteed that beneficiaries they refer to HIPP will receive any assistance at all. . . . Simply put, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice."

100. The '97 Advisory Opinion remains published on the OIG's website at: https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/

101. The '97 Advisory Opinion was the first of its kind, and featured hallmarks that set the standard for all of the OIG's similar opinions to follow:

a. AKF is an independent 501(c)(3) organization.

b. Providers are not required to contribute to HIPP in order for their patients to receive assistance.

c. AKF has complete discretion to determine applicant eligibility, based on AKF-established criteria of financial need.

d. Assistance from AKF does not restrict patients' choice of provider.

e. Grants follow patients, regardless of providers chosen, and as a result, these grants increase patient choice instead of restricting it.

102. Ever since then, HIPP has consistently aligned with the '97 Advisory Opinion and its guidance:

a. All contributions to HIPP are always voluntary.

b. Donor funding is provided to AKF without any restrictions or conditions whatsoever—funds go into one funding pool, and from that pool AKF administers the program, providing grants to

eligible low-income dialysis patients on a first-come first-served basis to pay for their insurance premiums.

c. Our Board of Trustees is independent and includes a subcommittee with responsibility for oversight of HIPP. Our Trustees are volunteers who are not compensated and have a wide range of backgrounds and expertise. Membership on the HIPP subcommittee excludes anyone associated with a dialysis center, including employees, officers, shareholders, or owners of such centers.

d. Using voluntary donor funding, we provide help to patients solely on the basis of their financial need. We do not consider a patient's health status in awarding financial assistance.

e. We carefully review each applicant's financial status and require that they meet specific income-to-expense criteria in order to qualify for assistance.

f. As part of the application process, the patient must complete and sign a detailed statement of income, assets, and expenses.

g. We provide financial assistance without regard to the type of insurance a patient has, where they live, who their dialysis provider is, or whether their dialysis provider is a contributor to our program. In fact, most of our beneficiaries are enrolled in government health insurance programs.

h. Patients choose their health insurance coverage with no input from AKF. While we support providing patients with the information they need to make an informed choice about their health insurance, AKF is not involved in helping patients find new insurance and does not advocate that patients keep or switch insurance.

i. Patients may change their health insurance coverage—and their provider—at any time, and AKF will continue to help them until their grant period expires. Their grant period is at least equal to their full health insurance premium year so long as the patient continues to meet qualifying criteria. (Patients who so change are of course eligible, like all other AKF grant recipients, to apply for a new grant at the end of the grant period.)

j. Many dialysis providers with patients being assisted by our program do not contribute to AKF. In fact, almost 40% of the referring providers do not make voluntary contributions to the pool at all.

k. Our staff responsible for processing and approving grants is barred from accessing information about which providers have contributed to HIPP.

l. Donors' contributions to AKF are not contributions made on behalf of individual patients. By participating in HIPP, providers agree that there is no "earmarking" of contributions to specific patients within the HIPP pool.

m. There is no guarantee that the patients referred by donors to the HIPP program will receive assistance.

n. The decision to provide assistance is at all times subject to the sole and absolute discretion of AKF—there is no "right" to a grant of financial assistance, regardless of the amount or frequency of donations by the referring provider.

103. In addition to demonstrating in detail the firewalls in place to ensure AKF's independence in its grant making, AKF's RFI response also outlined our ongoing efforts to promote patient education and choice, and to mitigate the potential for steering toward a particular type of coverage or provider—considerations CMS again appeared to not include in promulgating the IFR.

104. Subsequent to submitting the RFI response, I met with CMS officials to outline in more detail the enhancements that AKF proposed to increase patient education and guard against the potential for steering. I offered that AKF would work with CMS to ensure that patient choice of insurance plan would be protected. CMS never responded to the offer.

V. The IFR Will Irreparably Harm AKF and its Beneficiaries if it Takes Effect

A. *The IFR Will Irreparably Harm AKF's Ability to Carry Out its Mission to Enable Patient Choice and Thus its Beneficiaries*

105. The IFR's requirement that providers disclose to insurers when a patient is applying for HIPP assistance, and seek the insurers' permission therefor, will devastate AKF's ability to provide a level playing field for low-income ESRD patients to select the coverage that is best for them, but rather will completely chill our beneficiaries' ability to make any real choice, and irreparably injure our relationship with our beneficiaries.

106. The IFR invites and emboldens insurers to refuse ESRD patients at the very moment they are making their coverage decision, notwithstanding the ACA's prohibition barring insurers from discriminating against applicants on the basis of their disability.

107. We are already hearing accounts of insurers invoking the IFR and advising stakeholders that they will be refusing any request to accept an ESRD patient for coverage if they are receiving third-party premium assistance.

108. This dynamic eliminates our applicants' freedom of choice and forces anyone who cannot pay their own premiums onto government plans, even if that is not the best option for them.

109. We expect that the requirement that providers disclose a patient's need for financial premium assistance will by itself chill our applicants' desire to seek our help at all, keeping patients from applying for HIPP assistance even for other coverage options such as Medicare Part B or Medigap.

110. We are already feeling the effects of the IFR on our relationships with patients and our ability to carry out our charitable mission.

111. By issuing the IFR just two days before the December 15, 2016 deadline for January 1, 2017 exchange coverage, CMS introduced confusion and great uncertainty for (i) ESRD patients who selected an ACA plan prior to December 13, 2016; and (ii) ESRD patients who felt an ACA plan was best for them, but had not yet selected a plan as of December 13, 2016.

112. Numerous patients have called our toll-free hotline, distressed and confused about the IFR. Some of their dialysis providers have not referred them to AKF because the dialysis providers were unsure of the impact of the IFR. Accordingly, those patients are now

being forced into Medicare, Medicaid, or other state-based programs for 2017, even though they had an ACA plan for 2016 that they liked and that best met their needs.

113. In fact, of the 3,800 patients who applied for premium assistance with respect to an ACA plan in the first 45 days of open enrollment in late 2015, only 220 (6%) have applied for ACA coverage in the same period in late 2016. That means that nearly all previous HIPP beneficiaries have not reapplied for assistance for an ACA plan.

114. We believe that many of these patients have been scared into selecting Medicare or Medicaid or have foregone insurance entirely.

115. We are also seeing the potential for the IFR to destroy our mission to provide financial assistance entirely. While only a small percentage of our beneficiaries seek individual market plans, we are already seeing insurers emboldened by the IFR and moving to refuse third-party premium assistance for other coverage plans such as COBRA. We anticipate that insurers will continue to invoke the IFR as providing authority to discriminate against ESRD patients seeking assistance for Medigap, COBRA, and EGHPs under the pretext that third-party premium assistance from a *bona fide* charity is somehow improper. If the dynamic fostered by the IFR is allowed to unfold, AKF's core mission will be halted and tens of thousands of low-income individuals living with ESRD will have no option but the most basic Medicare or Medicaid coverage, funded 100% by taxpayers, with no way to pay for the thousands of dollars in additional, uncovered costs for their care.

B. *The IFR Will Irreparably Harm AKF's Relationships with Its Donors*

116. The extreme threat to our provider donors of running afoul of Medicare conditions for coverage regulations like the IFR will immediately and irreparably harm our longstanding relationships with our donors and infringe our basic right to association.

117. Forcing providers to disclose its patients who are seeking our assistance and to seek insurers' permission will inevitably cause donors to refer fewer patients to seek our help.

118. Notwithstanding the '97 Advisory Opinion's longstanding approval of providers' donations to HIPP and our operation of HIPP more broadly, and notwithstanding donor's fundamental rights to associate with and provide charitable donations to AKF, our donors may simply not wish to risk the consequences of some perceived non-compliance with the IFR and may stop associating with AKF altogether.

119. We have already heard from providers considering these options.

120. At the same time, compliance with the IFR raises its own potential legal hazards that further chill providers' relationship with AKF. Under the '97 Advisory Opinion, for instance, providers are not to track the amount of HIPP assistance provided to their patients and they are prohibited from advising patients that they have contributed to HIPP. These providers are understandably concerned that compiling a list of HIPP applicants and disclosing that to insurers, as well as disclosing to patients their donations to HIPP, as required by the IFR, will violate the '97 Advisory Opinion and related laws.

121. AKF is already experiencing the IFR's chilling effect on its vital relationships with its donors.

122. As a result of the uncertainty surrounding the IFR, AKF has, since mid-November 2016 amassed a shortfall in its HIPP pool of $13.5 million.

123. If other contributors do not make up the difference soon, AKF may not be able to fund its premium assistance grants for patients with all types of insurance—including more than 60% of beneficiaries who are enrolled in government program coverage such as Medicare Part B and Medigap.

124. For Medigap and group health plans, a missed or late payment will result in patient's insurance coverage being terminated.

125. The IFR thus will have an effect opposite of its stated goal that resources would still be available for assistance for government program coverage.

126. Overall, by putting into jeopardy the very existence of our HIPP program, the IFR will harm nearly one out of every five dialysis patients in the U.S. who rely on the program to afford their healthcare.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 5th day of January, 2017.

LaVarne A. Burton

Exhibit A

American Kidney Fund®

September 22, 2016

BY ELECTRONIC SUBMISSION
Attn: Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201
http://www.regulations.gov

Re: U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans, RIN 0938-ZB31 (File Code: CMS-6074-NC)

Dear Mr. Slavitt:

The American Kidney Fund, Inc. ("AKF") submits the following response to the request from the U.S. Department of Health and Human Services ("HHS") Centers for Medicare & Medicaid Services ("CMS") for information regarding "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans" (the "RFI").

AKF is the nation's leading nonprofit organization working on behalf of the 31 million Americans with kidney disease. Our mission is to help people fight kidney disease and live healthier lives, and we fulfill that mission by providing a complete spectrum of programs and services: top-rated health education materials, including brochures, fact sheets, and webinars; free kidney disease screenings in more than 20 cities nationwide; and need-based financial assistance enabling one in five U.S. dialysis patients to access lifesaving medical care, including dialysis and transplantation. Our award-winning website educates more than three million people each year about the prevention and treatment of kidney disease, and our toll-free HelpLine provides live support to people who need health information. We invest in clinical research to improve outcomes for kidney patients, and we work on Capitol Hill for legislation and policies supporting the issues that are important to the people we serve. We provide these critically needed services while maintaining the top rating (4-stars) from Charity Navigator, the nation's leading charity watchdog agency. We spend 97 cents of every donated dollar on programs that directly serve and educate patients and the public.

We are a member of Kidney Care Partners ("KCP") and work closely with various patient advocacy organizations. In addition to our response below, we support and are signing on to the letters that KCP and the joint advocacy groups are submitting in response to the RFI.

INTRODUCTION

We thank CMS for its concern regarding improper steering of patients away from the health care coverage best suited to their and their family's individual circumstances. AKF is similarly concerned about any actions that would infringe upon a patient's right to choose their health care coverage. Indeed, the core mission of AKF's Health Insurance Premium Program ("HIPP") is to allow low-income kidney patients with end-stage renal disease ("ESRD") to maintain the health care coverage best suited to their needs when they otherwise could not afford to do so.

People confronted with an ESRD diagnosis face life-altering challenges relating to their serious medical condition, including reduced ability to work and care for themselves and their families, the burden of needing regular dialysis treatment, a decline in health and capacity, and the corresponding financial impact of living with and treating ESRD. These challenges have prompted federal law to recognize ESRD as a disability. Fortunately, there exists a range of health care coverage options for people living with ESRD, options which have only expanded with the Patient Protection and Affordable Care Act ("ACA").[1] The benefits and drawbacks of each coverage option are as varied as the choices themselves. And because each ESRD patient's personal circumstances are likewise unique, each will have a coverage option best suited to his or her needs. This may be coverage under Medicaid, Medicare—including with Medigap or other supplemental coverage—an employer group health plan ("EGHP"), a COBRA plan, a qualified health plan ("QHP") offered under the ACA's health insurance marketplaces (each a "Marketplace"), or other individual market coverage.

None of these options comes without a cost to the patient. HIPP exists to preserve each eligible low-income ESRD patient's ability to choose and maintain the coverage that is best for them, no matter what that coverage option is. That is why AKF is gratified to see the RFI's repeated emphasis on maintaining individuals' rights to make coverage decisions "based on their specific circumstances, and health and financial needs."[2]

AKF shares CMS's concerns surrounding improper steering of patients, since improperly influenced enrollment driven by the financial incentives of health care providers rather than by the specific circumstances and needs of individual patients would be antithetical to AKF's mission of ensuring patient choice. Because HIPP provides premium assistance for patients enrolling in individual market plans, along with every other form of coverage (Medicare, Medigap, COBRA, EGHP, and other commercial plans), AKF is eager to address any HIPP-

[1] Pub. L. 111-148 (2010).
[2] *See, e.g.*, RFI at p. 6.

related concerns that CMS may have, and AKF looks forward to working with CMS and all interested parties to the extent that there are HIPP issues requiring further attention.

In response to the RFI, AKF provides information detailing its longstanding institutional and operational safeguards and procedures—designed in consultation with, and approved by, the HHS Office of the Inspector General ("OIG")—allowing AKF to operate HIPP while permitting dialysis providers to join the thousands of donors supporting AKF's mission. AKF has operated HIPP continuously since 1997 under these federally approved guidelines designed to wall off provider-donors from HIPP's operations and to prevent any undue influence or patient steering in selecting a dialysis provider through HIPP. AKF also responds to the RFI with specifics about its more recent improvements to its policies and procedures, including enhancements currently under way, further designed to eliminate any risk of improper patient steering by providers whose patients are applying for or receiving HIPP funding. AKF also addresses its position on specific instances of alleged misconduct by market actors. In short, AKF takes allegations of misuse or abuse of its programs extremely seriously, and AKF is working, and will continue to work, to ensure that providers, insurers, their employees, and other market participants are not taking advantage of HIPP or its patient beneficiaries for their own financial gain.

AKF also describes how the safeguards and procedures that it follows, those it is additionally implementing, and a robust approach to incidents of alleged misconduct, provide the best path forward for addressing concerns about the possibility of improper steering of ESRD patients, without undermining consumer choice. AKF has serious concerns that health insurance companies do not want expensive-to-insure ESRD patients on their insurance rolls and are concertedly exaggerating discrete, anecdotal allegations of misconduct in an attempt to lobby for broader regulation that would cut off coverage options for low-income people with chronic health conditions, including those with ESRD. In the event that specific instances of inappropriate conduct have occurred, they should be addressed directly, rather than penalizing an entire class of disabled persons from choosing and paying for one or more forms of insurance coverage that may be best for their particular situation, including individual market plans. Indeed, while the RFI is limited to concerns about improper steering of patients into individual market plans—and any resulting regulatory action or guidance presumably would not apply to Medigap, EGHP, COBRA, or other types of commercial plans—the ACA's guaranteed-issue and anti-discrimination provisions and enabling regulations make clear that ESRD patients, like all other Americans, have every right to enroll in an individual market plan, including a QHP, if they determine that is best for them.

More broadly, AKF submits that certain health insurance companies are unfairly steering patients away from their plans in an effort to keep people living with ESRD off their rolls. This practice constitutes undue influence and undermines patient choice in the same way as improperly steering patients from Medicare or Medicaid coverage to individual market plans. One very overt way health insurance companies are dropping ESRD patients from their rolls is by attempting to refuse premium assistance from AKF and other charities. The same dynamic

was at play shortly after the ACA's implementation, when Louisiana's three Marketplace health insurance companies announced that they were refusing premium assistance payments from the Ryan White HIV/AIDS Program (the "Ryan White Program") on behalf of low-income people living with HIV. The insurance companies then, like now, raised unspecific allegations of fraud and abuse and rote arguments about the risk pool as their rationale for refusing premiums from people living with HIV—which, like ESRD, is a federally recognized disability.[3] In response to a class action lawsuit filed on behalf of Ryan White Program recipients, brought under (among other laws) the ACA's anti-discrimination provisions—the very provisions guaranteeing ESRD patients equal access to choice of coverage—a federal court restrained the insurers from implementing their plan.[4] Shortly thereafter, HHS published an interim final rule *requiring* insurers to accept such third-party payments, adopted at 45 C.F.R. § 156.1250. Because turning away premium payments from disabled people living with ESRD constitutes unlawful discrimination in the same way, AKF urges CMS to step in to protect these disabled Americans as it did for Ryan White Program recipients.

Beyond refusing to accept charitable premium payments on behalf of their members, some insurers have taken other actions that appear designed to direct ESRD patients to Medicare or Medicaid for primary coverage. Some plans offer to pay the Medicare coinsurance amounts if members will change their primary coverage to Medicare. Some plans have suggested to ESRD patients that federal law requires them to enroll in Medicare four months after an ESRD diagnosis. Such practices constitute steering and interfere with patients' ability to freely choose the plan that is in their best interests.

* * *

Because AKF serves in a unique role for ESRD patients in comparison to, for example, dialysis companies, renal social workers, health insurance companies, and other relevant participants, AKF is not positioned to answer all of the RFI's specific queries. Rather, the following response is directed to the RFI's principal inquiries focused on (1) maintaining the integrity of patient choice and (2) preventing improper patient steering. To that end, we ***first*** provide the historical and regulatory background of AKF's decades-long charitable mission to assist low-income people living with kidney disease, including the condition of AKF beneficiaries that underscores their need for assistance. This context—particularly the OIG's 1997 Advisory Opinion approving and setting the guidelines for HIPP in the form in which it substantially operates to this day[5]—is critical to understanding AKF's longstanding commitment to the independent administration of HIPP, free from improper influence. ***Second***, we explain the

---

[3] *See Fiscus v. Wal-Mart Stores, Inc.*, 385 F.3d 378, 382 (3d Cir. 2004) (finding that ESRD is a physical impairment that substantially limits one or more major life activities and therefore meets the definition of "disability" under the Americans with Disabilities Act).

[4] *East v. Blue Cross and Blue Shield of Louisiana, et al.*, No. 3:14-cv-115, 2014 WL 8332136 (M.D. La. Feb. 24, 2014), Exhibit 1; *see also* Complaint, *East v. Blue Cross and Blue Shield of Louisiana, et al.*, No. 3:14-cv-115, (M.D. La. Feb. 20, 2014), ECF No. 1, Exhibit 2.

[5] '97 Advisory Opinion, Exhibit 3.

current patchwork of insurance coverage options for people living with ESRD and provide background on critical considerations they face in choosing the coverage option best for them, including, in some cases, an individual market plan. *Third*, we detail AKF's policies and procedures—old, new, and forthcoming—designed to prevent fraud, abuse, and undue influence, and specifically those focused on providing patients with complete and balanced information about their coverage options and preventing improper patient steering. *Fourth*, we call to CMS's attention the improper patient steering occurring in the other direction—that is, health insurance companies dissuading or discriminating against disabled ESRD patients in efforts to keep them off their plans even when such plans are in the patients' best interests.

We again thank CMS for its efforts to ensure the integrity of patient choice. AKF is committed to working with CMS to establish a lasting regulatory framework protective of charitable third-party assistance, which establishes clear guardrails to eliminate the potential for improper steering, and that, at the same time, cannot be used by health insurers as a pretext for discrimination against, or improperly limiting choice of coverage for, Americans living with a particular disability.

I. BACKGROUND ON AKF'S MISSION TO ASSIST KIDNEY PATIENTS IN MAINTAINING THE COVERAGE AND CARE BEST FOR THEM

AKF has been the safety net for U.S. dialysis patients since we were founded in 1971 to help one dialysis patient afford care. We have consistently taken a comprehensive approach to ensuring the integrity of our work on behalf of the ESRD patients we serve. Over the past 45 years, in addition to providing an array of programs and services to educate the public about kidney disease prevention and treatment, we have helped more than one million low-income ESRD patients to access health care—including dialysis, transplantation, and other health care services—through our various grant programs. Our grant programs include not only the HIPP program, but also Safety Net Grants for expenses that insurance does not cover, such as transportation to and from dialysis treatment, free medications for low-income dialysis patients to treat common side effects of kidney failure, summer camp scholarship grants for pediatric kidney patients, and disaster relief grants for dialysis patients living in communities affected by natural disaster. For example, over the past month, we have assisted Louisiana ESRD patients affected by historic flooding with over $50,000 in disaster relief grants. Our donors include more than 63,000 individuals from all 50 states, as well as corporations and foundations. We receive no government funding and consistently receive the highest possible ratings from the nation's top charity watchdog groups for our stewardship of each donated dollar.

A. AKF's Longstanding Operation of HIPP Under Federal Guidance

HIPP is a critical part of the nation's health care safety net for ESRD patients. The program was established according to our own high standards and those approved by the federal government. Through HIPP, AKF provides grants to low-income people living with ESRD to

allow them to pay premiums for the health insurance that best suits their individual circumstances.

In 1997, AKF, together with six dialysis providers, requested an advisory opinion from the OIG, seeking approval of, and guidance regarding, continued operation of HIPP while allowing providers to donate to the program. Prior to seeking the OIG's opinion on HIPP, AKF had for some time been operating a program to help patients with their medical expenses, including payment of health insurance premiums. When AKF sought the OIG's advisory opinion in 1997, AKF described for the OIG in detail how AKF had been operating its patient assistance program.

In providing its advisory opinion (the "'97 Advisory Opinion"), the OIG reviewed the information provided and concluded that continuation of our operating procedures in an expanded HIPP program—that allowed for dialysis providers to voluntarily contribute funding for the program—would enhance patient choice with regard to dialysis providers and ensure that provider contributions would not be used to influence patients' choice of providers. In approving the '97 Advisory Opinion, the Inspector General stated:

> In sum, the interposition of AKF, a bona fide, independent, charitable organization, and its administration of HIPP provides sufficient insulation so that the premium payments should not be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of HIPP assistance their patients receive bears any relationship to the amount of their donations. Indeed, the Companies are not guaranteed that beneficiaries they refer to HIPP will receive any assistance at all. . . . Simply put, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice.[6]

The '97 Advisory Opinion was the first of its kind, and featured hallmarks that set the standard for all of the OIG's similar opinions to follow: (1) AKF is an independent 501(c)(3) organization; (2) Providers are not required to contribute to HIPP in order for their patients to receive assistance; (3) AKF has total discretion to determine applicant eligibility, based on AKF-established criteria of financial need; (4) Assistance from AKF does not restrict patients' choice of provider; and (5) Grants follow patients, regardless of providers chosen, and as a result, these grants increase patient choice instead of restricting it.

Ever since then, our program has consistently aligned with evolving federal standards for provider-funded assistance programs.

---

[6] *See* '97 Advisory Opinion, Exhibit 3, at pages 6-7.

In 2002, the OIG issued a special advisory bulletin on patient inducements.[7] That bulletin expressly highlights AKF's HIPP as the example of how a provider-funded assistance program can operate within federal law, because of two hallmarks: (1) the independent determination of patient financial need; and (2) the fact that a patient's receipt of assistance does not depend on the patient's use of any particular provider.

By 2005, the OIG was receiving numerous requests from charities wishing to establish patient assistance programs, particularly medication assistance programs under Medicare Part D. In the OIG's responsive bulletin, specifically focused on pharmaceutical programs, the OIG affirmed its longstanding policy first espoused in the '97 Advisory Opinion and noted specific concerns notably *not* applicable to programs with HIPP's design. This 2005 bulletin was notable for the clear guidance it provided to nonprofit organizations wishing to establish patient assistance programs. AKF's program, then and now, operates entirely free from the major concerns CMS elucidated. The 2005 bulletin:

- Expressed concerns with programs that were funded under the auspices of a single provider; **whereas** AKF's program receives funding from over 200 dialysis providers, ranging from small independent clinics to large dialysis organizations, and whereas many of our HIPP grant recipients are treated at providers who do not contribute to AKF at all;
- Declared that any patient assistance program must "sever the nexus" between patient grants and the providers; **whereas**, as explained below, AKF's protective firewalls ensure that there is no connection between donations and grants; and
- Identified a standard requiring that charities' aid be provided broadly and that all applicants for charitable assistance be treated alike; **whereas** AKF provides assistance to any financially qualified dialysis patient who applies, on a first-come first-served basis, and does not take into consideration the severity of a person's illness, where they are treated, or what kind of health insurance they have.

In 2014, the OIG further updated its 2005 guidance with a new special bulletin that similarly demarcated distinctions between programs that prompt concerns and the model represented by HIPP.[8] The bulletin:

- Voiced concern that the narrower the categories of patients who qualified for assistance, the greater the chance the assistance would steer patients to use a particular donor's product or service; **whereas** AKF's program is open broadly to all ESRD patients who depend on dialysis for survival, regardless of specific dialysis modality or provider;

[7] 70 Fed. Reg. 70623 (Nov. 22, 2005).
[8] 79 Fed. Reg. 31120 (May 30, 2014).

- Cautioned that assistance could not be narrowly defined in terms of a patient's stage within a disease, or need for a particular treatment; **whereas,** unlike pharmaceutical co-pay programs that help individuals who need a specific drug therapy, our program helps people who may need a full range of medical services through insurance, including everything from dialysis treatment, to cardiovascular care, to diabetes medications.

In short, HIPP has always operated within the guidance that the OIG has established (and continually refined) for charities wishing to operate provider-funded patient assistance programs. In practice, as detailed below, there are several core protective tenets and firewalls built into HIPP's operation, guided by the '97 Advisory Opinion, that we follow to this day to ensure the integrity and objectivity of the program:

Donations:[9]

- All contributions to HIPP are voluntary.
- Donor funding is provided to AKF without any restrictions or conditions whatsoever—funds go into one funding pool, and from that pool we administer the program, providing grants to eligible low-income dialysis patients on a first-come first-served basis to pay for their insurance premiums.
- Our Board of Trustees is independent and includes a subcommittee with responsibility for oversight of HIPP. Our Trustees are volunteers who are not compensated and have a wide range of backgrounds and expertise.[10] Membership on the HIPP committee excludes anyone associated with a dialysis center, including employees, officers, shareholders, or owners of such centers.
- The '97 Advisory Opinion states that HIPP is not to be publicly advertised by dialysis providers.

Grant Selection:[11]

- Using voluntary donor funding, we provide help to patients *solely on the basis of their financial need*. We do not consider a patient's health status in awarding financial assistance.
- We carefully review each applicant's financial status and require that they meet specific income-to-expense criteria in order to qualify for assistance.
- As part of the application process, the patient must complete and sign a detailed statement of income, assets, and expenses.

---

[9] *See* HIPP Guidelines, Rules and Procedures, http://www.kidneyfund.org/assets/pdf/financial-assistance/hipp-guidelines.pdf.

[10] *See* Instructions for Form 990, Internal Revenue Service, at 18-19, https://www.irs.gov/pub/irs-pdf/i990.pdf (setting forth requirements for independence of governing members of charitable organizations).

[11] *See* HIPP Guidelines, *supra* note 9.

- We provide financial assistance without regard to the type of insurance a patient has, where they live, who their dialysis provider is, or whether their dialysis provider is a contributor to our program.[12] In fact, most of our beneficiaries are enrolled in government health insurance programs.
- Patients choose their health insurance coverage with no input from AKF. While we support providing patients with the information they need to make an informed choice about their health insurance, AKF is not involved in helping patients find new insurance and does not advocate that patients keep or switch insurance.
- Patients may change their health insurance coverage—and their provider—at any time, and AKF will continue to help them until their grant period expires. (Patients who so change are of course eligible, like all other AKF grant recipients, to apply for a new grant at the end of the grant period.) Their grant period is at least equal to their full health insurance premium year so long as the patient continues to meet qualifying criteria.
- Many dialysis providers with patients being assisted by our program do not contribute to AKF. In fact, almost 40 percent of the referring providers do not make voluntary contributions to the pool at all. Critically, our staff responsible for processing and approving grants is barred from accessing information about which providers have contributed to HIPP.
- Donors' contributions to AKF are not contributions made on behalf of individual patients. By participating in HIPP, providers agree that there is no "earmarking" of contributions to specific patients within the HIPP pool.
- There is no guarantee that the patients referred by donors to the HIPP program will receive assistance. The decision to provide assistance is at all times subject to the sole and absolute discretion of AKF—there is no "right" to a grant of financial assistance, regardless of the amount or frequency of donations by the referring provider.

The nation's leading charity watchdog organizations—including Charity Navigator, Consumer Reports, CharityWatch, and the Better Business Bureau Wise Giving Alliance—have recognized AKF as one of the nation's most trusted and respected charities.[13] In fact, in 2015, Charity Navigator, the nation's premier charity evaluator, scored AKF a perfect 100 out of 100 on its "Accountability & Transparency" rating, and awarded AKF its "highest, 4-star" rating overall.[14] This is the 14th consecutive time AKF has received the 4-star rating from Charity

---

[12] While AKF does not condition eligibility for HIPP assistance on the type of insurance coverage (*e.g.*, Medicare/Medicaid, Medigap, EGHP, COBRA, or individual market coverage), HIPP is designed to provide premium assistance only in connection with primary and secondary health insurance coverage; thus, HIPP does not assist with tertiary coverage of any kind. *See* HIPP Guidelines, *supra* note 9.

[13] For links to and descriptions of the ratings and recognition AKF has received from these charity watchdog organizations, see the "Putting Your Donations to Work" section of AKF's website (http://www.kidneyfund.org/about-us/vision-and-mission/putting-donations-to-work.html).

[14] *See id*.

Navigator, placing AKF on Charity Navigator's list of the "ten charities [that] have earned the most consecutive 4-star ratings demonstrating an ongoing fiscal excellence."[15]

In recognition of the important role that AKF plays within the ESRD community, and reflecting its longstanding reputation as one of the nation's most trusted and respected charities, the National Institute of Diabetes & Digestive & Kidney Diseases—part of the National Institutes of Health within HHS—directs patients with ESRD to AKF for assistance.[16]

B. The Vital Importance of AKF's Premium Assistance to ESRD Patients in the U.S.

Under HIPP, in 2015 alone, AKF provided health insurance premium assistance to more than 79,000 low-income dialysis patients in all 50 states—that is, *we help nearly one out of every five dialysis patients in the U.S. to afford their health care*. More than 60 percent of our grants fund Medicare Part B and Medigap premiums. We also provide premium assistance to financially needy dialysis patients who are enrolled in QHPs, other individual market plans, COBRA, and EGHPs. Our grants to assist patients with QHPs constitute a small fraction of our overall grant assistance, as detailed below.

Importantly, patients begin the HIPP application process *after* selecting the health plan that best meets their financial and medical needs following consultation with the patient's renal professional. By providing assistance for the full range of insurance options and otherwise being independent of the decision-making process, we ensure that our grant decisions cannot steer patients toward any particular type of coverage. Our commitment to funding all types of insurance also reflects our mission. We firmly believe that it is our obligation not only to provide premium assistance to ESRD patients, but also to provide them the ability to choose and maintain the health care coverage that they believe is best for them.

Most often, we make premium payments directly to insurance carriers on behalf of patients. This ensures that no patient will lose coverage due to a late or incomplete payment, and also that the funds are used for their intended purpose. For nearly 20 years this process has worked effectively to remove significant barriers to maintaining coverage for the low-income, chronically ill population we serve, who often do not have the financial means to transact premium payments on their own behalf.

Fully 70 percent of the patients we serve are unemployed, while another 20 percent work only part-time—reflective of the fact that the dialysis treatment regimen makes it difficult to stay employed. To qualify for HIPP assistance, a patient's monthly household income may not exceed reasonable monthly expenses by more than $600. Indeed, 60 percent of the patients

---

[15] Charity Navigator, "10 Charities with the Most Consecutive 4-Star Ratings," https://www.charitynavigator.org/index.cfm?bay=topten.detail&listid=100 (last visited Aug. 18, 2016).

[16] *See* National Institute of Diabetes and Digestive and Kidney Diseases, "Financial Help for Treatment of Kidney Failure," https://www.niddk.nih.gov/health-information/health-topics/kidney-disease/financial-help-for-treatment-of-kidney-failure/Pages/facts.aspx (last visited Sept. 9, 2016).

we assist have annual household incomes under $20,000. At the same time, our nation's ESRD patients have average annual out-of-pocket medical expenses of close to $7,000. The patient population we serve is more advanced in age, with 48 percent above 60 years old, and 77 percent above 50 years old. Kidney failure also disproportionately impacts racial and ethnic minority populations that historically have been underserved. African Americans and Hispanics develop kidney failure at higher rates than Caucasians and so are disproportionally affected by any barriers to maintaining health coverage. Over half of our HIPP grant recipients are people of color (38 percent African American, 15 percent Hispanic).

In October 2015, we conducted a survey of renal social workers in North Carolina to further understand the unique challenges faced by our recipient population. As reported by social workers working directly with ESRD patients, our survey helps to clarify why payment of third-party premiums directly to insurers is so important. The survey found that the following conditions make it particularly difficult for our patient population, even if they are given or already have the funds, to conduct the transactions necessary to pay their own health insurance premiums:

- Many patients were living in assisted living or nursing homes, which meant they had more limited capabilities.
- Patients lacked bank accounts.
- Patients had low literacy.
- Patients struggled with limited or unreliable transportation, making it challenging to get to a bank or check-cashing business so they could obtain and send in an insurance premium payment.
- Patients tended to be reliant on others to help them with their finances and business transactions.

In addition to the high costs of obtaining health coverage, what may be to others the simple act of maintaining that coverage by paying bills in a timely fashion can be extraordinarily difficult for people with a debilitating disease. For many reasons, the patients with ESRD whom we serve are some of the most vulnerable in the country. The assistance that AKF provides is vital for their continued health and stability and potentially prevents them from needing additional federal and state financial assistance.

II. ANY FUTURE REGULATION SHOULD NOT IMPEDE PATIENT CHOICE

The ACA and the existing regulatory landscape—particularly as it relates to these vulnerable kidney patients—unmistakably reflect the strong public policy favoring and protecting patient choice. AKF fully supports CMS's efforts to ensure that patients' coverage choices are in no way being manipulated, and AKF is pursuing its own efforts to that end (*see* Part III below). At the same time, it is critical that CMS does not—in an attempt to rectify or prevent specific instances of alleged misconduct by individual actors—respond in a way that will

indiscriminately limit for an entire class of kidney patients the coverage and health care choices that best meet their needs but which have only been possible with the help of assistance from AKF. The longstanding statutory and regulatory policy of promoting choice for kidney patients, and the many and varied life-impacting reasons patients might chose an individual market plan for themselves and their families, underscore the imperative of ensuring that kidney patients' right to make their own health care choices is not infringed.

A. The Current Health Insurance Landscape For Kidney Patients

While Medicare and Medicaid provide health care coverage for many individuals living with ESRD, such government safety net programs are not the ideal choice for everyone. The premiums, deductibles, and co-insurance obligations under Medicare, for example, can be burdensome and often financially crushing for its beneficiaries, particularly because Medicare has no out-of-pocket limit. The severe shortage of providers accepting Medicaid, especially in rural areas and among specialists, can jeopardize access to care for ESRD patients. Fortunately, the insurance landscape that has developed in the past few decades, including, most importantly, through the introduction of the ACA, has resulted in a range of possible insurance coverage options and scenarios for individuals facing ESRD. HIPP is intended to help ESRD patients afford whatever option best meets their health and financial needs and preferences.

Recognizing the significant health and financial burdens faced by individuals living with ESRD, Congress in 1972 created a special Medicare benefit for individuals with ESRD, particularly in response to the growing incidence of the disease.[17] With this benefit, all individuals with ESRD who have earned a certain level of eligibility for Social Security benefits (or are dependents of those who have attained that level) are entitled to benefits under Medicare Part A and are eligible to enroll in Medicare Part B.[18]

While Medicare coverage is a critical component of the health care safety net for individuals with ESRD, it is not always the best option for every patient.

At the onset, it is important to note that ESRD patients are different from other Medicare beneficiaries—both demographically and with respect to coverage rights and options—and as a result they must consider even more factors when seeking to identify the insurance coverage that is best for them and their families. For example, the rules around eligibility for public programs and coordination of insurance with commercial plans, including those in Marketplace exchanges, are very complex and also different for patients with ESRD, as

---

[17] *See* 42 U.S.C.A. § 426-1.

[18] *See id*. In general, the waiting period for ESRD-based eligibility (*i.e.*, for individuals under age 65 who are not otherwise eligible for Medicare) is 3 months after initiation of dialysis. *See* 42 U.S.C.A. § 426-1(b)(1). During the 3-month waiting period, treatment is covered, if at all, by the individual's existing group or individual market plan (if any). Coverage can begin the first month of dialysis, for those able to undergo home-based treatment. *See* Medicare.gov, How to sign up for Medicare if you have End-Stage Renal Disease (ESRD), https://www.medicare.gov/people-like-me/esrd/getting-medicare-with-esrd.html#collapse-3170.

compared to other Medicare beneficiaries. Accordingly, patients must carefully evaluate the rules and options that apply to their individual situations before making a decision on insurance coverage.

One key consideration is that ESRD patients are younger than the typical Medicare beneficiary, and are often supporting families; Medicare covers only the ESRD patient, not dependents.

Medicare also leaves recipients with substantial cost-sharing obligations—including a 20 percent coinsurance requirement that can be financially crushing for individuals with chronic conditions like ESRD.[19] For instance, Medicare Part B payments on behalf of ESRD patients generally cover only 80 percent of the rate for Medicare-covered maintenance dialysis services, as well as 80 percent of physician services and certain ancillary services. In addition, most people must pay a monthly premium for Part B coverage (the standard premium for 2016 is $104.90 per month, although it may be higher based on income). Coverage is also subject to an annual deductible: the Part A deductible for 2016 is $1,288 per benefit period, while the Part B deductible is $166. The average patient living with ESRD covered by Medicare incurred $6,918 in annual out-of-pocket expenses in 2010.[20]

For those individuals who do not meet the stringent eligibility requirements for the various "Medicare Savings Programs" designed to defray such cost-sharing obligations for the lowest-income beneficiaries,[21] Medigap policies sold by private insurance companies may be available to help cover the annual deductible and coinsurance obligations under Medicare. However, the federal government does not require carriers to offer Medigap to ESRD patients under 65, and regulations vary from state to state. Only 27 states mandate that insurance carriers offer Medigap to ESRD patients under age 65, leaving patients in the other 23 states without access to this important supplemental insurance.[22] If a company does sell Medigap to individuals under 65, including ESRD patients, such policies will generally cost more than policies sold to people over 65.[23] Additionally, in many states, the only Medigap plan available to ESRD patients under 65 is Plan A, which is the most basic plan, does not cover Part A and B deductibles, and does not cover expenses such as skilled nursing facilities.

---

[19] Individuals with ESRD not only must undergo regular dialysis treatments (in addition to regular monitoring of laboratory values, diet, and medication regimens), but also commonly suffer from certain co-morbidities including diabetes, anemia, hypertension, and congestive heart failure.

[20] Juliette Cubanski, Christina Swoope, Anthony Damico, & Tricia Neuman, *How Much Is Enough? Out-of-Pocket Spending Among Medicare Beneficiaries: A Chartbook* (July 21, 2014), http://kff.org/report-section/how-much-is-enough-out-of-pocket-spending-among-medicare-beneficiaries-section-1/.

[21] To qualify, an individual generally must have a monthly income of less than $1,357 ($1,823 for a couple) in 2016, with total liquid assets of $7,280 or less ($10,930 or less for a couple). CMS, MEDICARE COVERAGE OF KIDNEY DIALYSIS & KIDNEY TRANSPLANT SERVICES 43 (May 2016), https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf.

[22] CMS, MEDICARE COVERAGE OF KIDNEY DIALYSIS & KIDNEY TRANSPLANT SERVICES 42 (May 2016), https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf.

[23] *Id*. at 42.

In short, Medicare, or Medicare with a Medigap supplemental plan, is not a one-size-fits-all coverage solution for our nation's ESRD patients and their families.

Before the enactment of the ACA—when health insurers could routinely deny or limit coverage for people with expensive-to-treat diseases like HIV/AIDS, cancer, or ESRD—people with pre-existing conditions could generally only access private insurance if they had coverage under employer- or union-sponsored plans. Individuals with ESRD who were fortunate enough to have such group health coverage could choose to enroll in Medicare, either in addition to or instead of their EGHP. In cases where an individual with ESRD is covered by both Medicare and an EGHP plan, federal law provides for a 30-month coordination-of-benefits period, during which time a patient may maintain the EGHP as the primary payor and Medicare as the secondary payor.[24] This Medicare Secondary Payer enactment, originally passed in 1981, secures for ESRD patients the choice to maintain their EGHP as primary—if, for example, continuity of care or family benefits are determinative priorities—for a substantial period after starting dialysis, even though they are eligible for Medicare. Over the years, Congress extended the maximum period of time that patients can retain their EGHP as primary coverage, setting it at its current 30 month-limit in 1996.

Now, thanks to the guaranteed-issue and other insurance market reforms implemented under the ACA,[25] ESRD patients who do not have access to an EGHP finally can obtain coverage for themselves and their families on the individual market, including subsidized coverage through a QHP offered in an ACA Marketplace. It is important to note that the ACA and its implementing regulations have clearly preserved the ability of ESRD patients to choose individual market coverage over Medicare. CMS, for example, has clarified that "[i]ndividuals with ESRD who do not have either Medicare Part A or Part B are eligible to enroll in individual market coverage"—including in QHPs offered through an ACA Marketplace—"because the Medicare anti-duplication statute does not apply; therefore, individual market guaranteed issue rights apply under the ACA."[26] Further, IRS guidance clarifies that ESRD patients under the age of 65 can qualify for tax credits and cost-sharing subsidies in connection with such QHP coverage.[27] There are many reasons why individual market coverage may be the

---

[24] 42 U.S.C. § 1395y(b)(1)(C).

[25] *See* 45 C.F.R. § 147.104(a) (requiring insurers offering coverage in the individual or group markets to "accept any individual or employer that applies" for coverage).

[26] *See* CMS Frequently Asked Questions Regarding Medicare and the Marketplace (Aug. 1, 2014), https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf. Similarly, people who are Medicaid-eligible are permitted to enroll in the exchange. They may or may not be eligible for subsidies depending on their individual circumstances, but they can buy full-priced plans. AKF's assistance allows Medicaid-eligible ESRD patients to afford a Marketplace plan if such a plan is better for them than Medicaid.

[27] *See* IRS Notice 2013-41, https://www.irs.gov/pub/irs-drop/n-13-41.pdf (stating that, for purposes of the premium tax credit, an individual whose Medicare eligibility is "based solely on a finding of disability or illness"—such as ESRD patients under the age of 65—is "eligible for minimum essential coverage under Medicaid or Medicare . . . only upon a favorable determination of eligibility"); *see also* Medicare.gov, Signing up for Medicare: special conditions, https://www.medicare.gov/sign-up-change-plans/get-parts-a-and-b/special-

preferred option for some individuals with ESRD—not unlike patients choosing to keep their EGHP coverage as primary—as detailed in Part II.B below. These policies advanced by the ACA and CMS clearly promote and protect equal access to individual market coverage for ESRD patients, if that is the best option for them.

Across this entire patchwork of insurance coverage options that a patient with ESRD may have over the course of his or her treatment, HIPP is the means by which ESRD patients can maintain the dignity of choosing the best health insurance option for their circumstances. With HIPP, choice in coverage under the law is not available only in the abstract—it is a reality for ESRD patients irrespective of their income. Without HIPP, only the nation's relatively wealthy ESRD patients would have access to the array of insurance options beyond Medicare and Medicaid.

B. Kidney Patients' Coverage and Care Options in Practice

In practice, one important option available to individuals with ESRD is coverage under an individual market plan if it best suits the patient's circumstances. Indeed, the ACA's express provisions barring discrimination based on preexisting conditions or disability (and ESRD is a disability under federal law) guarantee, in the very law providing for coverage through the Marketplaces, equal rights to such coverage for people living with ESRD.[28]

AKF shares the RFI's concerns about providers allegedly inappropriately "steer[ing] people eligible for or receiving Medicare and/or Medicaid benefits to individual market plans *for a provider's financial gain*."[29] AKF takes very seriously allegations of inappropriate steering or any other misconduct by health care providers, and it has longstanding institutional and operational safeguards and practices to prevent and combat improper use of HIPP—safeguards and practices that AKF is working to strengthen further today. *See* Parts I & III. But efforts to address alleged instances of abuse should not trump patients' rights to choose the best coverage for them, including if that plan is an individual market plan. Individual market coverage (including Marketplace coverage) may be preferable to Medicare or Medicaid for certain kidney patients, for any number of reasons—including some of the same reasons people choose to retain their COBRA or EGHP coverage as the primary payer throughout the 30-month coordination-of-benefits period, as discussed above. For example,

---

conditions/special-conditions.html#collapse-5277 (last visited Sep. 20, 2016) ("People with ESRD aren't required to sign up for Medicare. If you have ESRD and don't have either Medicare Part A or Part B, you can get a Marketplace plan. ***You may also be eligible for tax credits and reduced cost-sharing through the Marketplace***.") (emphasis added).

[28] 45 C.F.R. § 147.104 (requiring insurers offering coverage in the individual or group markets to "accept any individual or employer that applies" for coverage, and prohibiting such insurers from employing marketing practices or benefit designs that "will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage" or that otherwise discriminate based on an individual's "present or predicted disability" or other protected grounds including "expected length of life, degree of medical dependency, quality of life, or other health conditions"); *see* Part IV, *infra*.

[29] RFI at 9 (emphasis added).

individuals with ESRD may wish to have the same coverage—with the same network of physicians and other providers, and the same cost-sharing requirements—for all members of their family, including a spouse or child who does not qualify for Medicare or Medicaid. Taking one example, an individual with ESRD may find that her child's pediatrician's practice group is not enrolled in Medicare or is not taking new Medicare patients but is in-network for a QHP in the area. Choosing Medicare for such patient would foreclose her ability to choose one group provider for her and her child. While it would be wrong for a self-interested provider to "steer" such a person away from Medicare for the provider's own financial gain, it would be equally wrong for an insurer or regulator to "steer" the person away from a QHP for which they are otherwise eligible by denying their right to receive HIPP assistance to help pay their QHP premium.

Individuals may also be motivated by differences with respect to plan benefits, provider access, and/or quality of care. For example, individual market plans typically offer better integration of medical, prescription, and dental coverage compared to what is offered through Medicare alone, or through Medicare with Medigap wrap-around coverage. Additionally, compared with Medicaid plans in most states, individual market plans often offer greater access to providers,[30] especially specialists.[31] Lack of access is a problem that impacts all Medicaid recipients, but is particularly challenging for patients with ESRD. An ESRD patient has to find not just a dialysis center that accepts Medicaid, but also a cadre of other providers such as cardiologists, endocrinologists, and pulmonologists. ESRD patients may not be able to find geographically proximate specialists in the Medicaid network, or if they can, they must

[30] Studies show that less than half of Medicaid-enrolled physicians accept new patients. See KAISER FAMILY FOUNDATION & COMMONWEALTH FUND, Experiences and Attitudes of Primary Care Providers Under the First Year of ACA Coverage Expansion: Findings from the Kaiser Family Foundation/Commonwealth Fund 2015 National Survey of Primary Care Providers (2015), http://www.commonwealthfund.org/publications/issue-briefs/2015/jun/primary-care-providers-first-year-aca (noting that "[c]omparisons of the current survey with a similar study conducted in 2012 find that the reported rate of new patient acceptance among primary care physicians has declined slightly (89% to 83%), but [that] the share accepting new Medicaid patients remains about the same at 50 percent"). Even if a greater proportion of Medicaid-enrolled providers began accepting new Medicaid patients, the overall number of Medicaid-enrolled providers is limited in many states. In Florida, for example, there is a severe shortage of primary care physicians taking Medicaid patients. AKF knows of a patient in that state who went without a primary care physician for six years while on Medicaid, and after securing QHP coverage, was able to see a primary care physician within one week.

[31] Kevin D. Dayaratna, Ph.D., *Studies Show: Medicaid Patients Have Worse Access and Outcomes than the Privately Insured*, http://www.heritage.org/research/reports/2012/11/studies-show-medicaid-patients-have-worse-access-and-outcomes-than-the-privately-insured (noting that "academic literature has consistently illustrated that Medicaid patients—adults and children—have inferior access to health care," and observing that "it is becoming increasingly difficult for Medicaid patients to find access to primary and specialty care physicians"). Many states also prohibit out of state coverage for Medicaid recipients, which can cause isolation and temporary lack of coverage when a patient must travel to family or needs to move closer to caregiving family members.

wait extended periods of time to get an appointment; for dialysis patients, this lost time can have a significant impact on their health.[32]

Individual market plans may also offer better prescription drug benefits than either Medicare or Medicaid. Most Medicare drug plans, for example, have a coverage gap (also called the "donut hole"). In 2016, beneficiaries are responsible for paying 45 percent of the plan's cost for covered brand name prescription drugs and 58 percent of the cost for generic drugs while the beneficiary is in the coverage gap.[33] For ESRD patients who take multiple medications, an ACA plan may offer better drug coverage at lower cost. Similarly, many state Medicaid programs have limited formularies or caps on the number of prescriptions that can be filled per month,[34] which can lead to patient non-adherence and additional costs on the health care system. Limited prescription benefits under Medicare and Medicaid can even force some patients to make the impossible decision of choosing between their medications and groceries. Dialysis patients often need numerous prescriptions to manage their various conditions. AKF has seen patients with more than 20 prescriptions who are able to get only 10 filled at any one time, due to prescription drug caps under their state Medicaid program. These patients must then ration prescriptions and determine which ones they will fill. After moving to a Marketplace plan, these patients are able to fill all prescriptions and maintain better outcomes.

In addition, individual market plans may provide coverage that Medicare or Medicaid plans do not offer, may have lower coinsurance obligations, and may have features to better assist ESRD patients with the full range of their health care needs, including preparing for and obtaining a kidney transplant. QHPs often offer wellness programs, preventive care, health coaching, and other services not provided by traditional Medicare or Medicaid programs.

And notably, evidence indicates that ESRD patients with commercial coverage have better health outcomes, including higher transplant rates, fewer infections, and lower hospitalization rates.[35] For instance, research has shown that access to transplants is almost three times

---

[32] The access problem is particularly acute in rural areas; AKF has heard of ESRD patients in such areas who do not have access to a vascular surgeon to place a fistula, for example.

[33] *See* Medicare.gov, Costs in the coverage gap, https://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html.

[34] *See, e.g.*, National Health Law Program, Factsheet: Prescription Drug Coverage Under Medicaid, http://www.healthlaw.org/publications/factsheet-prescription-drug-coverage-under-medicaid (last visited Sept. 8, 2016).

[35] Research has shown that patients with commercial insurance have fewer hospitalizations and lower mortality rates than patients with Medicare fee for service insurance. *See* Jesse D. Schold et al., *Barriers to Evaluation and Wait Listing for Kidney Transplantation*, 6 CLINICAL J. AMER. SOCIETY OF NEPHROLOGY 1760 (2011), http://cjasn.asnjournals.org/content/6/7/1760.full (finding that "[o]lder age, lower median income, and ***noncommercial insurance*** were associated with decreased likelihood to ascend steps to receive a transplant") (emphasis added) (emphasis added); Tracy Sanders, OPTUM, MANAGING END-STAGE RENAL DISEASE: IMPROVING CLINICAL OUTCOMES AND REDUCING THE COST OF CARE FOR MEDICARE ADVANTAGE, MEDICAID AND COMMERCIAL POPULATIONS 5, https://www.optum.com/content/dam/optum/resources/whitePapers/managing-end-stage-renal-disease-wp.pdf (noting that "Medicare populations typically present higher risks than commercial plan memberships due

higher under commercial coverage than with Medicare, and 14 times higher for African Americans.[36]

The RFI raises the issue of delayed enrollment penalties for ESRD patients. AKF completely agrees that, before a Medicare-eligible individual with ESRD chooses individual market coverage, it is imperative that they fully understand the regulations surrounding Medicare enrollment and that they follow the correct procedures so that they avoid possible late enrollment penalties and coverage gaps.[37] If an individual determines that enrolling in or maintaining QHP coverage is best for them, even if doing so will result in a late enrollment penalty, that choice should be the individual's.

The issues surrounding choice of insurance coverage are complex for ESRD patients. Because dialysis providers are required by Medicare to employ social workers,[38] they institutionally and logistically are well positioned to help patients understand the complexities of Medicare enrollment, inform patients of the tradeoffs between Medicare/Medicaid and individual market coverage, and to help patients navigate the web of other coverage options referenced above, including Medigap, COBRA, and EGHPs. AKF is eager to work with the providers' social services units and the interested governmental actors and other stakeholders to formulate the clearest and most robust and balanced means of presenting ESRD patients with their coverage options. *See* Part III. At the same time, the potential benefits of an individual market plan over Medicare and Medicaid, as described above, are real and will be significant for certain kidney patients. AKF wants to ensure that any regulatory action does not impede patient choice or unduly influence patients against individual market coverage if that is the best option for them. It is also critical that regulatory action does not set off unintended consequences that more broadly harm ESRD patients' ability to pay for, with AKF's help, other forms of coverage that are best for them. The result would be *no choice* for low-income people living with ESRD.

III. ADDRESSING THE POTENTIAL FOR IMPROPER PATIENT STEERING

As the foregoing backdrop makes clear, empowering patients to maintain the coverage and care that is best for them and their families is central to AKF's mission. Accordingly, the phenomenon of patients being steered away from the coverage that is in their best interests is

---

to their relatively advanced age, increased co-morbidities, changes in cognition and memory, reduced resources (personal and financial), and limitations in transportation access and self-care capabilities").

[36] A.M. Reeves-Daniel, A.C. Farney, et al., *Ethnicity, medical insurance, and living kidney donation*, http://www.ncbi.nlm.nih.gov/pubmed/23781870; U.S. News & World Report, *Black Medicaid Recipients Less Likely to Get Living-Donor Kidney: Study* (June 26, 2013), http://health.usnews.com/health-news/news/articles/2013/06/26/black-medicaid-recipients-less-likely-to-get-living-donor-kidney-study.

[37] RFI at 7-8.

[38] *See, e.g.*, 42 CFR § 494.80 (requiring dialysis facilities to have an "interdisciplinary team consist[ing] of, at a minimum, the patient, . . . a registered nurse, a physician treating the patient for ESRD, *a social worker*, and a dietitian") (emphasis added); 42 CFR § 494.140(d) (requiring dialysis facilities to have a social worker meeting certain educational or training qualifications).

antithetical to AKF's mission, and so the concerns raised in the RFI are AKF's concerns. AKF has always operated its programs to protect patient choice, and we continuously evaluate and refine those programs to ensure that AKF meets evolving changes and challenges to achieving that goal. We detail below AKF's (A) longstanding program safeguards designed to prevent improper influence and misuse and abuse of HIPP, (B) the initiatives AKF has implemented (or will soon implement) to even further ensure the integrity of HIPP and to specifically protect patients' independent and informed decision-making, and (C) AKF's perspective on any specific instances of alleged individual misconduct.

A. AKF's Independent Operation Is a Key Component of Patient Choice

When the '97 Advisory Opinion was issued, it required firewalls that would prevent fraud and abuse, specifically in the form of beneficiary inducements or inappropriate patient "steering."[39] As the historical and regulatory background from Section I emphasizes, HIPP's model of insulating its operations from its donors, to which AKF has strictly adhered for nearly 20 years, remains recognized as the model for all such independent charitable third-party premium assistance programs. From this posture, AKF is well positioned, and has done so over the years, to respond quickly and effectively to any new concerns relating to alleged conduct that could undermine patient choice and exploit HIPP and its beneficiaries. Indeed, if independence is the cornerstone of our compliance model under the '97 Advisory Opinion, patient freedom of choice is the very heart of our mission.

We firmly believe that the answer to new challenges is not to limit third-party premium assistance for low-income people living with ESRD from *bona fide* charitable organizations like AKF, but to work within the structure that has been effective for two decades to make appropriate enhancements tailored to the new health insurance landscape. To that end, we have in the past proposed to CMS and to regulators in various states certain guardrails that we believe make it possible for legitimate charities to continue helping low-income patients pay for insurance, while also protecting against fraud and abuse:

- Bona fide 501(c)(3) charitable organization;
- Independent Board of Directors;
- Notification to or registration with a state agency such as the Department of Insurance;
- Procedures that include an application process, independent determination of financial need by the charity's employees, and geographic diversity;
- Procedures that completely wall off provider donation information from the charity's determinations of patient eligibility for grant assistance;

[39] *See generally* '97 Advisory Opinion, Exhibit 3; *supra* Section I.A.

- Procedures that protect patient choice and prohibit any direction that the patient use only certain insurers or providers, and provide assistance for a full range of insurance products;
- Assistance to cover the entire policy year (not short-term assistance);
- Annual certification of a uniform set of income and asset criteria used to determine eligibility; and
- Compliance with all other applicable federal, state, and local laws and regulations.

Like the safeguards discussed in Section I, these guardrails address charitable organizations' independence from their donor sources—what we believe to be the central tenet of the '97 Advisory Opinion and essential for the mission-focused and transparent operation of HIPP and any charitable organization that funds third-party premium assistance for a particular disease. However, these guardrails are not static, and we remain nimble in our own policies and procedures to ensure they are responsive to the evolving health care landscape, including the concerns now raised by CMS.

We have worked hard to establish measures to ensure that AKF could not influence the type of insurance a patient chooses. However, we also recognize that individuals must have access to complete and balanced information to make their own informed coverage choices, free from undue influence from other market participants. AKF recognizes and shares CMS's goal that patients must be enabled to make informed choices about their health insurance coverage, which, in the case of ESRD patients, includes information sufficient to weigh the pros and cons of each type of insurance against other options, which will involve varying considerations for different patients.

As the administrator of the HIPP program, which supports all forms of coverage, we are uniquely positioned to furnish patients with basic information about health coverage tailored to ESRD patients that is consistent, accurate, and balanced. While a charitable organization's own unique context will dictate the contours of the information provided, we believe that promoting patient choice and deterring inappropriate steering is best achieved by providing patients with accessible information at the appropriate time. We can also provide patients with information on objective, credible organizations and websites that may help in evaluating specific plans.

We have always endeavored to take an active but balanced role between being ESRD patient advocates and also ensuring that patients remain independent and autonomous in their decision-making, especially with respect to choosing health insurance and providers. In an ongoing effort to be responsive to the needs of our patient community as well as respond to CMS's concerns, we outline below the AKF initiatives either underway or soon anticipated that are designed to further strengthen patient choice while mitigating any opportunity for market participants to engage in inappropriate patient steering.

B. AKF's Ongoing Efforts to Promote Informed Patient Choice and to Mitigate Inappropriate Steering

AKF's longstanding mission has been to provide ESRD patients who otherwise would have limited or no choice in their health coverage with access to a full spectrum of coverage options. However, what makes AKF's assistance so valuable is when it is coupled with the knowledge necessary to make the choice that is *best for that individual*. As discussed above, AKF's institutional and operational policies and procedures ensure that AKF does not, through its administration of HIPP, unduly influence patients' decisions in choosing either their coverage or their provider. Today, however, AKF sees an opportunity to further its role as a patient educator and advocate, and it is pursuing several steps to that end. The following are enhanced procedures that we have developed and/or are currently developing in an effort to promote informed patient choice and to mitigate any inappropriate patient steering:

- AKF currently publishes a patient guidebook, which is available to the public on our website as well as at the dialysis centers.[40] It is written in plain language and contains important information about HIPP, including by outlining eligibility, confirming AKF's independence, clarifying that patients are free to choose their own provider and can change providers at any time, and highlighting that HIPP assistance will not continue past the end of the current policy payment period after a patient receives a kidney transplant.[41]
- We are currently adding to the patient guidebook a section entitled "Patients' Rights and Responsibilities," which will inform patients of their rights in selecting insurance that best suits their needs and in applying to HIPP for assistance. It will also list the patient's role and responsibilities in the process of selecting his or her own insurance and in the HIPP application process.
- To ensure that this information reaches any patient who is considering applying for HIPP assistance, we will require providers to furnish the patient with this information prior to the HIPP grant being approved. In the Patient Consent Form, signed by the patient, the patient will also initial that he/she has received these materials and understands the HIPP guideline that it is the patient's choice to select insurance from the available options. We also will be asking each patient's provider to certify to the best of their knowledge that the patient's request for HIPP assistance is accurate and that the selection of the insurance was the patient's.

---

[40] *See* Introduction to the American Kidney Fund, http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp.pdf.

[41] HIPP provides comprehensive coverage that pays for transplant workups for patients on the transplant waiting list, enabling them to stay on and possibly move up the list, and the HIPP-covered insurance pays for the transplant procedure itself. The conclusion of HIPP assistance *after* a transplant is a function of the fact that, after a transplant, kidney patients are usually able to go back to work and retain coverage from an employer. So, like Medicare, AKF winds down after an individual has had a transplant. 42 U.S.C.A. § 426-1(b)(2) (providing that coverage under the Medicare ESRD program "shall end, in the case of an individual who receives a kidney transplant, with the thirty-sixth month after the month in which such individual receives such transplant").

- We are developing a "Provider Code of Conduct," which will set forth standards of conduct, including pro-patient-choice and anti-steering provisions, for all dialysis professionals who refer patients to the HIPP program. We believe that such standards—which will be a required condition for providers' participation in HIPP—should also be provided to patients as a way to increase transparency and accountability by advising patients of the standards they should expect from providers.

AKF believes that these initiatives, on top of its current model designed to ensure independent operation of HIPP, will further promote complete and balanced patient choice of coverage and enhance existing measures to prevent any discrete instances of improper patient steering. At the same time, these expanded efforts on the part of AKF will help to ensure that patients will be provided information and education that they need to make informed choices. Furthermore, AKF remains willing to work with CMS and other market participants to implement other appropriate procedures to the end of supporting informed patient choice. AKF has formally requested a meeting with CMS to further explain its specific initiatives and to discuss any input that CMS may have.

C. AKF is Committed to Addressing Specific Instances of Potential Misconduct

AKF's charitable mission is to help low-income people living with ESRD. We operate programs in pursuit of this mission with the utmost efficiency and focus on stewardship over our resources. In fact, 97 cents of every dollar received go to fund those programs and services. We take any allegation of abuse of our limited resources extremely seriously.

We welcome the opportunity to address specific allegations of past or present abuse, although we think it is important to note several considerations in this context. First, while some insurers have suggested misuse of HIPP by certain dialysis providers, we have not received from any insurer a single specific complaint, information regarding, or example of such misuse that would support action on our part. The litigation surrounding supposed misuse pending in Florida provides a good example. AKF was provided no specific details or evidence of the purported misconduct alleged in the Florida complaint, and the most specific allegations central to the complaint's alleged scheme of patient steering are made "upon information and belief"—meaning that they are made with no evidence or first-hand information.[42] Obviously, if there are specific instances of misconduct involving a provider's interaction with the HIPP program—*e.g.*, if the Florida plaintiffs made the effort to provide AKF with actionable information of such misconduct—we would act on any proof that our funds or mission had been subverted. We want to be clear: AKF strongly rejects any claim or

[42] *E.g.*, *UnitedHealthcare of Florida, Inc., et al. v. American Renal Assocs. Holdings, Inc., et al.*, No. 16-cv-81180, First Amended Compl. (S.D. Fla.) ¶ 88 ("Upon information and belief, many patients were insured by the Medicaid program before ARA counseled them to enroll into United's plans, as described herein.").

implication that it has been somehow complicit, never mind an active participant, in illegal or unethical activity.[43]

The Florida case also raises some noteworthy considerations. The litigation demonstrates that, in the first instance, the most appropriate avenue for insurers to investigate and address purported instances of fraud and abuse by providers or policy-holders is by employing existing laws addressing specific alleged improper behavior within their relationships with the provider at issue. The '97 Advisory Opinion did not place any law enforcement duties on AKF to ensure that insurers and/or providers are not attempting to "game the system." Whether before the ACA or after, the insurers, providers, HHS, and law enforcement are best positioned and equipped to uncover, investigate, and ameliorate fraud and other misconduct. This is in contrast to an approach that would cut off one or more coverage options for an entire class of low-income and disabled HIPP beneficiaries in order to preemptively curtail an unknown number of alleged specific instances of alleged misconduct. Nonetheless, as noted, AKF is, at counsel's direction, conducting an independent, privileged investigation and review of the Florida allegations to ensure that AKF's mission has not been distorted by insurer or provider misconduct and to take appropriate steps if any improper conduct emerges.

More broadly, as outlined above, AKF is implementing procedures to increase accountability and transparency on the part of providers, and it fully intends to work with any market actor or governmental body to address known instances of fraud or abuse in relation to HIPP. To the extent any patient or other person communicates and provides documentation of a specific instance of steering or any other potentially inappropriate conduct by an insurer, a provider, or one of their employees or agents, we will document the communication and will directly refer the matter to the relevant entity's compliance department in writing and provide all of the relevant information we have. We will maintain a record of all such communications. To the extent we become aware of any improper conduct, such as lack of

---

[43] Health insurers, including the plaintiff in the Florida case, recently have attempted to imply by innuendo some impropriety simply in AKF's appeals for grant funding, pointing to, for example, AKF's HIPP Honor System, through which providers are asked to make "equitable" financial contributions to AKF and to contribute their "fair share." Of course AKF asks providers to make equitable contributions to HIPP—that is the *sine qua non* of the '97 Advisory Opinion. The '97 Advisory Opinion's allowance for provider donations necessarily entails AKF's requesting those donations, in order to continue its mission. The HIPP Guidelines, Rules and Procedures, recently misconstrued by insurance companies, underscore how, in accord with the '97 Advisory Opinion, (1) there is never any guarantee that patients of donor-providers will receive grant funding at all, (2) whether and how much providers donate is entirely voluntary, and (3) that AKF's only method to encourage equitable contributions is a moral one, *i.e.,* no patient will be considered differently based on whether the referring provider does or does not contribute. Further, about forty percent of the providers whose patients AKF assists *make no contribution at all to the HIPP funding pool*, and AKF has never turned away a needy patient on the basis of their being treated by a non-contributing provider, demonstrating the fact that charitable contributions are in no way tied to AKF's patient grants. AKF's motivation in requesting voluntary contributions is purely mission-focused: putting patients first and ensuring there are resources in the HIPP pool to support the 79,000 patients in the HIPP program. Nonetheless, we are redoubling our ongoing scrutiny of our charitable fundraising communications to ensure that they could not be misconstrued to suggest that our grants in any way tie to particular providers' contributions.

informed consent, undue influence, fraudulent documentation, or other behavior that undercuts patient choice, we will take action to redress the situation for the patient in each particular instance, and work with the responsible entities to halt the misconduct immediately.

We already correspond with our patients on a quarterly basis through a patient newsletter to ensure that we are available and in close contact for any patient questions or concerns. Going forward, we will place further emphasis on encouraging our patients to communicate to us any behavior in relation to HIPP that they perceive as inappropriate, whether by providers, insurers, or otherwise.

IV. INSURERS ARE UNDERMINING CHOICE OF COVERAGE FOR ESRD PATIENTS IN VIOLATION OF STATE AND FEDERAL ANTI-DISCRIMINATION LAWS

Whereas alleged incidents of patient steering away from public coverage appear to be isolated at the most, health insurance companies across the country have commenced an overt and forceful campaign to steer low-income ESRD patients off or away from their commercial plans—notwithstanding that such plans may be best for patients—by refusing or attempting to refuse patients' premium payments provided by AKF. In addition to impeding patient choice and freezing out countless low-income individuals from their coverage, this conduct implicates violations of federal and state law prohibiting discrimination on the basis of disability.

AKF's HIPP program plays a critical role in ensuring that ESRD patients can benefit from the full range of insurance options to which they are entitled under the law. Without HIPP, the choice of coverage options described above is an illusory one for far too many low-income ESRD patients who could not otherwise afford their premium payments or cost-sharing obligations, whether under Medicare, Medigap, COBRA, group coverage, or individual market plans. As noted in the '97 Advisory Opinion, the assistance provided by AKF "enhanc[es] patient freedom of choice in health care providers."[44]

Individual ACA market coverage comprises a very small fraction of the assistance provided through HIPP—indeed, only 6,400 HIPP grant recipients, representing approximately 8 percent of our total HIPP grant recipients, and a tiny fraction (.05 percent) of the total 12.7 million individual market coverage enrollees, receive HIPP assistance to pay for individual market coverage.[45] Nonetheless, supporting *all* applicable forms of coverage is an important part of AKF's mission to enhance patient freedom of choice. Notably, one of the goals of the ACA was to open doors to such coverage for millions of Americans with life-threatening and expensive-to-treat conditions like ESRD. Indeed, the ACA acts expressly to guarantee dialysis

[44] '97 Advisory Opinion, Exhibit 3, at 5.

[45] *See* HHS.Gov, "Fact Sheet: About 12.7 million people nationwide are signed up for coverage during Open Enrollment" (Feb. 4, 2016), http://www.hhs.gov/about/news/2016/02/04/fact-sheet-about-127-million-people-nationwide-are-signed-coverage-during-open-enrollment.html.

patients the right to choose their health plan and—according to the plain text of the ACA—not to be subject to discriminatory practices.

Unfortunately, some insurers have taken steps to deny premium assistance payments made by AKF for individual market coverage, undermining the choice of coverage for thousands of ESRD patients receiving HIPP assistance in certain states.

Insurance companies in some states are advising policyholders that they will be refusing premium assistance from any source other than the policyholder or other insurer-approved source, such as a family member or entity whose premium assistance federal regulation requires that insurers accept (*e.g.*, the Ryan White Program, Indian tribes and related organizations, and other government programs).[46] Insurers are setting policies that give themselves complete discretion to refuse premium assistance from charitable organizations that the insurer deems to be "[f]inancially interested"—if, for example, the organization receives a majority of its funding from entities with an interest in health insurance reimbursements.[47]

Such policies are transparently directed at charities focused on helping patients with specific disabilities and other conditions to pay for their coverage, and they blatantly violate basic principles of fairness in insurance contracting. Prior to the ACA, insurance companies for years were happy to accept third-party premium assistance payments, since the insurers could simply charge patients with ESRD and other disabilities higher premiums based on their conditions. After reaping those benefits for years, now that insurers can no longer discriminate in this way, they seek complete discretion to turn those same patients away *en masse*. Apart from the basic unfairness of this practice, its real world impact would be devastating not only for the 6,400 AKF beneficiaries with individual market coverage, but innumerable others as well. Depending on how insurance companies determine whether a charity is "financially interested"—a question on which the insurers make themselves the sole arbiter—untold numbers of low-income people with numerous disabilities and conditions could be summarily frozen out of their coverage. These include beneficiaries of the myriad charitable foundations that raise funds from industry donors whose missions also include premium and other cost-sharing assistance for low-income patients with particular conditions, such as the CancerCare Co-Payment Assistance Foundation, Leukemia and Lymphoma Society Co-Pay Assistance Program, National Multiple Sclerosis Society, A.L.S. Association, and American Transplant Foundation, among many others.[48] And specifically as

---

[46] *See, e.g.*, Letter from Blue Shield of California re: Notification of November 7, 2016 Updates to the Blue Shield Hospital and Facility Guidelines, Aug. 29, 2016, at 2, Exhibit 4.

[47] *Id.*

[48] Other potentially affected patients include beneficiaries of HealthWell Foundation; Patient Advocate Foundation Co-Pay Relief Program; The Assistance Fund; Patient Access Network Foundation; Patient Services, Inc.; National Organization for Rare Disorders; and Chronic Disease Fund. These nonprofit foundations also raise funds from the health care industry to provide financial assistance to patients suffering from countless serious health issues, including cancer; cardiovascular disease; endocrine conditions; immunodeficiency conditions;

to AKF, such a policy completely ignores the fact that HIPP operates with the help of provider funding with written approval from the OIG, which expressly concluded that HIPP's design insulates AKF from precisely the supposed conflicts on which these insurers purport to base their policies.

Relatedly, as health insurance companies have begun refusing third-party payments from reputable charities like AKF, we have had to change the method by which we provide charitable grant assistance. In instances where an insurance carrier will not accept a grant assistance check from AKF, we send the patient a charitable grant that will allow the patient to pay their insurance bill. As described above, the patients we serve often have challenges cashing their grant assistance check, as many do not have bank accounts. The patients often lose a portion of their grant in check cashing and money order fees, and thus jeopardize their ability to pay their premium. Some do not have reliable transportation to get to a bank or even to get to the post office to ensure that their payment is timely made. We believe that insurance carriers have adopted these third-party payment prohibitions in the hope that some patients will not be able to pay their premiums on time, giving the carrier justification to terminate coverage for non-payment. This is a form of adverse selection.

We also are very concerned about the question in the RFI that states: "Are issuers capable of determining when third party payments are made directly to a beneficiary and then transferred to the issuer?" Insurance carriers have implied that direct charitable assistance to nonprofits' constituents is somehow improper. At least one major carrier, United Healthcare, adopted an extremely restrictive policy for 2016, promising to terminate the QHP coverage of any member who receives direct charitable assistance from entities not mandated as third-party payors by the federal government. This carrier and its subsidiaries have sent letters to policyholders requiring them to sign attestations, under penalty of perjury, that they are not receiving charitable assistance to help them pay their premiums, and advising that their policy will be cancelled if they accept such assistance. Filings for 2017 Marketplace plans signal the expansion of this practice. Cigna, Healthnet, and subsidiaries of UnitedHealthcare are seeking to prohibit people from using direct charitable assistance to pay their insurance premiums. We believe it is a fundamental right of every American to receive charitable assistance and to use that assistance for important needs, including health coverage. In asking about sources of funding in the RFI, it is our hope that the federal government is not adopting a position antithetical to our nation's fundamental principles of free speech and freedom of association. The government must not permit health insurance carriers to dictate to Americans what they may and may not do with charitable assistance that they have received from recognized 501(c)(3) charities.

Wholly apart from the policy concerns articulated above with respect to fairness, freedom of choice, and the impact on ESRD patients and other recipients of charitable aid, such actions by

---

digestive and urinary conditions; bleeding disorders; infectious conditions; nervous system conditions; respiratory conditions; and others.

insurers raise serious legal concerns under anti-discrimination law. At the federal level, the ACA requires all insurers offering coverage in the individual or group markets to "accept any individual or employer that applies" for coverage, and it prohibits such insurers from employing marketing practices or benefit designs that "will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage" or that otherwise discriminate based on an individual's "present or predicted disability" or other protected grounds, including "expected length of life, degree of medical dependency, quality of life, or other health conditions."[49] Insurers offering plans through ACA Marketplaces are, by virtue of receiving federal funds (including via the tax credits and subsidies provided for under the ACA), subject to even broader non-discrimination requirements.[50] Individuals applying for or receiving coverage from such insurers must not, "on the basis of race, color, national origin, sex, age, *or* ***disability***, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination" in the "provision or administration of . . . health-related insurance coverage."[51]

An insurance company may not use a seemingly neutral classification—such as receipt of premium assistance payments by third parties—as a proxy to evade prohibitions on intentional discrimination.[52] Even if intentional discrimination could not be established in a particular case, the ACA forbids conduct that has an unjustifiable disparate impact on individuals in protected classes, regardless of the violating party's intent.[53] A *prima facie* case of disparate impact is established when a party can show that a facially neutral practice "operated more harshly on one group than another."[54]

It is significant in this context that ESRD has been recognized as a disability under federal law[55] and therefore constitutes one of the protected grounds under the ACA nondiscrimination provision.[56] Given the demographics of HIPP recipients, the refusal by an

---

[49] 45 C.F.R. § 147.104.

[50] *See* 42 U.S.C. § 18116(a); 45 C.F.R. § 92.101.

[51] 45 C.F.R. § 92.101*;* 45 C.F.R. § 92.4 (emphasis added). Notably, the anti-discrimination provisions apply to "all operations" of insurers offering coverage through an insurance exchange, and not just to an insurer's exchange line of business. *See* 45 C.F.R. § 92.4.

[52] *Cf., e.g., McWright v. Alexander*, 982 F.2d 222, 228 (7th Cir.1992) ("[A]n employer cannot be permitted to use a technically neutral classification as a proxy to evade the prohibition of intentional discrimination. An example is using gray hair as a proxy for age: there are young people with gray hair (a few), but the 'fit' between age and gray hair is sufficiently close that they would form the same basis for invidious classification.").

[53] *See, e.g.*, *Alexander v. Choate*, 469 U.S. 287, 299 (1985); *see also Kelly v. Boeing Petroleum Servs. Inc.*, 61 F.3d 350, 365 (5th Cir. 1995) (recognizing disparate impact as a valid basis for a claim under § 504 of the Rehabilitation Act of 1973, and thus under Section 1557 of the ACA, which provides that "the enforcement mechanisms provided for and available under . . . section 504. . . shall apply for purposes of violations of this subsection").

[54] *See Chance v. Rice Univ.*, 989 F.2d 179, 180 (5th Cir. 1993) (internal quotation marks omitted).

[55] *See Fiscus*, *supra* note 3, 385 F.3d at 382.

[56] *See* 45 C.F.R. § 92.4 (defining "disability" to mean "a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having

insurer to accept premium assistance payments from HIPP may also have an illegal disparate impact (*i.e.,* "operate more harshly") with regard to race and national origin.

For example, African Americans are more at risk for kidney failure than any other race.[57] More than one in three kidney failure patients living in the United States is African American.[58] Diabetes is the leading cause of kidney failure, causing nearly 40 percent of all cases of kidney failure in the United States.[59] African Americans get diabetes more often: they are almost twice as likely as whites to have diabetes.[60] About one in eight (13.2 percent) African American adults has diabetes.[61] High blood pressure is the second leading cause of kidney failure.[62] It causes about one out of four cases in the United States.[63] Like diabetes, high blood pressure is a serious problem for African Americans: almost half (over 42 percent) of African American adults have high blood pressure,[64] and African Americans are, on average, nearly six times more likely to get kidney failure from their high blood pressure than whites.[65] The statistics for Hispanics are similar, with Hispanics almost twice as likely as whites to have been diagnosed with diabetes.[66] Diabetes also leads to kidney failure more often in Hispanics than in non-Hispanic whites.[67]

Unfortunately, insurer discrimination against low-income, disabled people is nothing new. From the time the ACA first prohibited health insurers from denying coverage or charging more by discriminating against people with preexisting conditions,[68] certain health insurers have attempted to exclude from coverage groups with a specific condition or disability by virtue of the fact that such groups receive third-party premium or cost-sharing assistance from a charitable program focused on that disability. In 2014 for example, as noted above, the three health insurers in Louisiana's ACA Marketplace, including Blue Cross and Blue Shield of

---

such an impairment, as defined and construed in the Rehabilitation Act [] which incorporates the definition of disability in the ADA") (citations omitted).

[57] United States Renal Data System ("USRDS"), 2015 Annual Data Report: Epidemiology of Kidney Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, https://www.usrds.org/adr.aspx.

[58] Race, Ethnicity, and Kidney Disease (Mar. 5, 2014), https://www.niddk.nih.gov/health-information/health-communication-programs/nkdep/learn/causes-kidney-disease/at-risk/race-ethinicity/Pages/race-ethnicity.aspx (last visited Sep. 20, 2016).

[59] USRDS 2015 Annual Data Report, *supra* note 57.

[60] Treatment and Care for African Americans (Oct. 1, 2014), http://www.diabetes.org/living-with-diabetes/treatment-and-care/high-risk-populations/treatment-african-americans.html (last visited Sep. 20, 2016).

[61] *Id*.

[62] USRDS 2015 Annual Data Report, *supra* note 57.

[63] *Id*.

[64] High Blood Pressure Facts, (Feb. 19, 2015), http://www.cdc.gov/bloodpressure/facts.htm (last visited Sep. 20, 2015).

[65] USRDS 2015 Annual Data Report, *supra* note 57.

[66] *Id*.

[67] *Id*.

[68] *See* 42 U.S.C. §§ 300gg, 300gg–1, 300gg–3.

Louisiana ("BCBSL"), announced that they would refuse to accept most premium assistance, including from the federal Ryan White Program enacted to help low-income people living with HIV. BCBSL and the other insurers cited purported concerns about fraud and abuse, tied to third-party payments, affecting the insurance markets as grounds for refusing Ryan White premium assistance.[69] In response to a class action lawsuit filed on behalf of Ryan White Program recipients, brought under the anti-discrimination provisions of the ACA and state contract and insurance law, a federal court restrained the insurers from implementing their plan.[70] Shortly thereafter, HHS published an interim final rule *requiring* insurers to accept such third-party payments, adopted at 45 C.F.R. § 156.1250.[71] The vague complaints raised by insurers regarding HIPP reflect the same attempt to leverage generic policy concerns over fraud and abuse as a pretext to exclude an expensive-to-cover class of people with a disability—in this case, ESRD—from its insurance rolls.

Such systematic and discriminatory patient steering cannot stand, and CMS should act to protect people living with ESRD from such discrimination, just as it did to protect people living with HIV.

V. CONCLUSION

In sum, AKF takes the potential for improper use of HIPP, including improper patient steering, very seriously. We are committed to investigating and addressing allegations of improper conduct by providers and insurers, because such conduct tarnishes our well-earned reputation for excellence and transparency, undermines our charitable mission, and, most importantly, affects the patients we are committed to serving with the highest level of support. To further its continuing efforts toward these goals, AKF is:

- Maintaining its commitment to strict adherence to the '97 Advisory Opinion and the OIG's subsequent policy guidance affirming HIPP's operational design;
- Enhancing policies and procedures designed to ensure that patients receive clear and balanced information regarding their coverage options and that the choice of selecting coverage is theirs;
- Adopting a code of conduct for providers and professionals designed to preclude steering and other abuses, which will be furnished to patients for added accountability, and making providers' participation in HIPP strictly conditioned on adherence to the code of conduct's anti-steering and other provisions;
- As it relates to our HIPP program, we will consistently document patient and other complaints or concerns about steering or other abuses by both providers and insurers,

---

[69] *See, e.g.*, Ted Griggs, *Insurers Block Obamacare Coverage . . . Move Affects Poor HIV/AIDS Patients*, THE ADVOCATE, Feb. 13, 2014, at B8, Exhibit 5.
[70] *East,* 2014 WL 8332136, *supra* note 4, Exhibit 1; *see also* Complaint, *East, supra* note 4, Exhibit 2.
[71] *See* 79 Fed. Reg. 15240 (Mar. 19, 2014).

and we will formally communicate, in writing, any such complaints or concerns to the relevant entity's compliance department;

- Committing to address demonstrated, actionable allegations of misconduct and cooperating with the responsible party to investigate and eliminate any improper use of HIPP;
- Committing to work with CMS, beginning with our request for a near-term, formal meeting, to discuss these initiatives and any other areas in which AKF can assist CMS in promoting patient choice and in combatting improper steering and discrimination; and
- Continuing to notify CMS when AKF becomes aware of insurance carrier actions that are improperly steering patients away from a particular carrier and/or onto Medicare or Medicaid.

AKF fully supports the desire to have a robust commercial health insurance market. In keeping with the imperative of patient choice central to AKF's mission and the ACA's policy, this market must be one in which all eligible Americans, including Americans with disabilities, are welcome.

Thank you very much for your attention to this matter, and we very much look forward to a continuing dialogue in the days and weeks ahead.

Very truly yours,

LaVarne A. Burton
President & Chief Executive Officer
American Kidney Fund

Attachments

Exhibits to the American Kidney Fund's Response to
CMS Request for Information No. CMS-6074-NC

Table of Contents	
Tab	Document Description
1	*East v. Blue Cross and Blue Shield of Louisiana, et al.,* Temporary Restraining Order
2	*East v. Blue Cross and Blue Shield of Louisiana, et al.,* Complaint
3	97-1 OIG Advisory Opinion
4	Letter from Blue Shield of California re: Notification of November 7, 2016 Updates to the Blue Shield Hospital and Facility Guidelines, Aug. 29, 2016
5	Ted Griggs, *Insurers Block Obamacare Coverage . . . Move Affects Poor HIV/AIDS Patients* , The Advocate, Feb. 13, 2014

EXHIBIT 1

2014 WL 8332136
Only the Westlaw citation is currently available.
United States District Court,
M.D. Louisiana.

John EAST, et. al.
v.
BLUE CROSS AND BLUE SHIELD OF LOUISIANA, et. al.

Civil Action No. 3:14–cv–00115–BAJ–RLB.
|
Signed Feb. 24, 2014.

Attorneys and Law Firms

Harry A. Rosenberg, Bryan Edward Bowdler, Phelps Dunbar, New Orleans, LA, Amanda R. Phillips, Ropes & Gray LLP, Boston, MA, Anthony C. Biagioli, Ropes & Gray LLP, Washington, DC, Jeffrey J. Bushofsky, Nicholas M. Berg, Timothy R. Farrell, Ropes & Gray LLP, Chicago, IL, Kenneth D. Upton, Lambda Legal Defense & Education Fund, Inc., Dallas, TX, Scott A. Schoettes, Lambda Legal Defense & Education Fund, Inc., Chicago, IL, Susan L. Sommer, Lambda Legal Defense & Education Fund, Inc., New York, NY, for John East, et. al.

Charles A. O'Brien, III, Allison Nunley Pham, Baton Rouge, LA, Adam P. Feinberg, Anthony F. Shelley, Miller And Chevalier Chartered, Washington, DC, Brandon Kelly Black, Jones, Walker, Baton Rouge, LA, Richard John Tyler, Jones Walker LLP, New Orleans, LA, for Blue Cross and Blue Shield of Louisiana, et. al.

TEMPORARY RESTRAINING ORDER

BRIAN A. JACKSON, Chief Judge.

***1** Before the Court is putative class representative John East's ("East") **APPLICATION FOR A TEMPORARY RESTRAINING ORDER (Doc. 7) ("Application"),** requesting that the Court enjoin Defendants Blue Cross and Blue Shield of Louisiana ("Blue Cross"), Vantage Health Plan, Inc. ("Vantage"), and Louisiana Health Cooperative, Inc. ("Louisiana Health)" from changing their existing policies as they relate to Ryan White HIV/AIDS Program funds ("Ryan White Funds"), and/or implementing new policies related to Ryan White Funds, *(id.* at p. 4). East's Application is filed in accordance with Fed.R.Civ.P. ("Rule") 65 and this Court's Local Rules, *see* M.D. La. LR65. Defendants Blue Cross and Vantage each oppose East's Application. (Doc. 8; Doc. 17). Defendant Louisiana Health has not filed a notice of appearance, nor given any indication as to its position regarding East's Application.

For reasons explained below, the Court **GRANTS** East's Application as to all Defendants. In accordance with Rule 65, this Temporary Restraining Order shall be effective as of **6:00 p.m., Monday, February 24, 2014** and shall expire 14 days after the time of entry, unless otherwise ordered by this Court. *See* Fed.R.Civ.P. 65(b)(2)-(3). A hearing to determine whether a preliminary injunction shall supplant and/or follow this Order shall proceed at **12:00 p.m., Tuesday, February 25, 2014.**

Rule 65 provides, in relevant part:

> The court may issue a temporary restraining order without written or oral notice to the adverse party or its attorney only if:
>
> (A) specific facts in an affidavit or a verified complaint clearly show that immediate and irreparable injury, loss, or damage **will** result to the movant before the adverse party can be heard in opposition; and
>
> (B) the movant's attorney certifies in writing any efforts made to give notice and the reasons why it should not be required.

Fed.R.Civ.P. 65(b)(1). Additionally,

> Every temporary restraining order issued without notice must state the date and hour it was issued; describe the injury and state why it is irreparable; state why the order was issued without notice; and be promptly filed in the clerk's office and entered in the record.

Id. at 65(b)(2). Further, "[i]f the order is issued without notice, the motion for a preliminary injunction must be set for hearing at the earliest possible time, taking precedence over all other matters except hearings on older matters of the same character ." *Id.* at 65(b)(3). Finally, "[t]he court may issue ... a temporary restraining order only if

the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." *Id.* at 65(c).

Here, the Court is satisfied that East has met the requirements for the temporary relief he seeks. First, East has scrupulously adhered to Rule 65's procedural requirements. His Application is accompanied by an affidavit describing the nature of the "irreparable injury" that will result absent a temporary restraining order ("TRO"), (Doc. 7–2), as well as his attorney's certified description of the efforts that have been made to contact all Defendants in this case, including Defendant Louisiana Health, (Doc. 7–3). *See* Fed.R.Civ.P. 65(b)(1). Further, East's Application adheres to this District's requirements that: (1) the Application "be made in a document separate from the complaint"; and (2) "actual notice of the time of making the application" be included in the Application, (*see* Doc. 7–3 at p. 1). M.D. La. LR65.1.

***2** East has also satisfied Rule 65's substantive requirements. His affidavit (Doc. 7–2) and his Complaint (Doc. 1) each contain "specific facts" indicating that "immediate injury, loss, or damage will result" if a TRO is not issued. In particular, East states: (1) he is "an individual living with HIV," (Doc. 7–2 ¶ 2); he "take[s] two medications [each day] to treat [his] HIV," (*id.* at ¶ 4); his insurance provider, Blue Cross, has heretofore accepted full payment for his insurance premiums from "the Louisiana Health Insurance Program which receives funding from the Ryan White Program," (*id.* at ¶¶ 11–12, 19); East is otherwise unable to pay his monthly insurance premium of $1,306, (*id.* at ¶¶ 19, 24); Blue Cross and the other named Defendants—Vantage and Louisiana Health—recently decided "that they will no longer be accepting Ryan White assistance payments for health insurance premiums," (*id.* at ¶¶ 23, 26); this decision has caused East to miss his most recent payment, which means that he is "now without insurance coverage," (*id.* at ¶ 24); East does not otherwise qualify for health care assistance, (*id.* at ¶¶ 8, 10); and, finally, lacking insurance. East will "run out of ... essential medication," which will, eventually, result in his death, (see *id.* at ¶¶ 6, 30).

It goes without saying that Mr. East's eventual death is an irreparable injury. *See* Fed.R.Civ.P. 65(b)(2) ("Every temporary restraining order issued without notice must ... describe the injury and state why it is irreparable...."). Further, this result is hardly speculative given HIVs pathology, and the known consequences of discontinuity in its treatment. (*See* Doc. 1 at ¶ 56). Given the severe ramifications to Mr. East and other members of his putative class if their insurance coverage is allowed to lapse, the Court is convinced that this Order should be issued, thereby ensuring that the status quo is temporarily maintained, even in the absence of Louisiana Health's notice of appearance, and/or the opportunity for an evidentiary hearing on the issue. *See* Fed.R.Civ.P. 65(b)(2) ("Every temporary restraining order issued without notice must state ... why the order was issued without notice...."). [1]

Accordingly,

IT IS ORDERED that East's **APPLICATION FOR A TEMPORARY RESTRAINING ORDER (Doc. 7)** is **GRANTED.** Specifically,

1. Defendants are enjoined from changing their policies of accepting Ryan White HIV/AIDS Program funds ("Ryan White Funds") from current or prospective applicants to, or policy holders of, Defendants' health insurance plans;

2. Defendants are enjoined from implementing or executing their new policies of refusing Ryan White Funds from current or prospective applicants to, or policy holders of, Defendants' health insurance plans;

3. Given the nature of the issues and the parties involved, it is unnecessary for Plaintiffs to post a bond in this matter; and

***3** 4. This Order expires in 14 days or as modified by the Court.

IT IS FURTHER ORDERED that a hearing to determine whether a preliminary injunction shall supplant and/or follow this Order shall proceed at **12:00 p.m., Tuesday, February 25, 2014.**

All Citations

Not Reported in F.Supp.3d, 2014 WL 8332136

Footnotes

1 To the extent that East must satisfy the traditional 4–prong preliminary injunction test before a TRO may issue, see *Garcia v. United States,* 680 F.2d 29, 31 (5th Cir.1982) (indicating that "the requirements justifying a temporary restraining order" are equivalent to those justifying a "preliminary injunction"), the Court also finds that each of these requirements are met. First, East has made a preliminary showing that he is likely to succeed on the merits of his claim because the Affordable Health Care Act contains an express Nondiscrimination provision, requiring that "an individual shall not ... be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance," 42 U.S.C. § 18116; second, as explained, East has demonstrated a substantial threat of irreparable injury—specifically, declining health and eventual death—if his insurance is discontinued; third, this threat to East's well-being far outweighs any injury to Defendants because Defendants are simply required to maintain their existing policies of accepting Ryan White Funds paid on behalf of insureds in East's position; finally, the TRO serves the public interest because it ensures that insureds in East's position maintain their current health care coverage, thereby avoiding, among other things, additional costs resulting from lost health care coverage, such as emergency room treatment in lieu of regularly scheduled doctor appointments and medications. *See Texans for Free Enter. v. Tex. Ethics Comm'n,* 732 F.3d 535, 536–37 (5th Cir.2013) ("A preliminary injunction is an "extraordinary remedy" that should be granted only if the movant establishes (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.")(quotation marks omitted).

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA

JOHN EAST, individually and on behalf of all other persons similarly situated, Plaintiffs, v. BLUE CROSS and BLUE SHIELD of LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC., Defendants.	Civil Action No.: 14-115 Section Magistrate **COMPLAINT- CLASS ACTION** **JURY DEMANDED**

Plaintiff JOHN EAST, individually and on behalf of all other persons similarly situated (collectively, "Plaintiffs" or the "Plaintiff Class"), through his undersigned counsel, for his Complaint against Defendants BLUE CROSS AND BLUE SHIELD OF LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC., (collectively, "Defendants"), alleges the following upon knowledge as to his individual conduct and interactions and upon information and belief as to the conduct of others:

PRELIMINARY STATEMENT

1. This action seeks injunctive and declaratory relief to halt Defendants' abrupt and systematic policy of targeted discrimination on the basis of Plaintiffs' disability, *i.e.*, their

infection with the human immunodeficiency virus ("HIV"),[1] in violation of sections 1557(a) and 1311(c) of the Patient Protection and Affordable Care Act (codified at 42 U.S.C. §§ 18116(a) and 18031), and in contravention of Louisiana state law.

2. To ensure equal access to health care under the Affordable Care Act, Congress placed robust antidiscrimination requirements on health insurers that profit from the billions of federal dollars flowing into the health care insurance market and from the vast new market of health insurance consumers made available to insurers through the Affordable Care Act's health insurance exchanges.

3. One such safeguard is section 1557 of the Affordable Care Act, which expressly prohibits health insurers that receive federal funds, as do Defendants, as well as entities established under Title I of the Affordable Care Act, from discriminating against any individual on the basis of a disability for purposes of the individual's participation in or enjoyment of the benefits of health insurance coverage.

4. The "Plaintiff Class" consists of all Louisiana residents living with HIV who are qualified for health insurance premium assistance from the Ryan White HIV/AIDS Program.[2]

5. The Plaintiff Class includes a subclass of persons who have existing or past insured relationships with one or more Defendants ("Insured Plaintiffs").

6. The Plaintiff Class is fully eligible for coverage under Defendants' available plans. Insured Plaintiffs have been paying their premiums in full—some of them for decades—and all Plaintiffs are and remain ready, willing, and able to pay premiums with federal funds designed precisely for that purpose.

[1] HIV, when left untreated, causes AIDS.

[2] The Ryan White HIV/AIDS Program is a federal program that makes grants to states, cities, and non-profit organizations to provide people living with HIV with access to health care, including by assisting in the payment of health insurance premiums.

7. The Plaintiff Class benefits from health insurance premium assistance funded by federal grant money from the Ryan White HIV/AIDS Program, which is available exclusively for people living with HIV in need of financial assistance, and without which none of the Plaintiffs can afford individual health insurance premiums.

8. Defendants have routinely accepted funds from the Ryan White HIV/AIDS Program ("Ryan White Funds") for dozens of their policy-holders' health insurance premiums. Blue Cross and Blue Shield of Louisiana ("BCBS") has accepted Ryan White Funds since at least 2009, and upon information and belief, the other defendants have accepted such funds since each began offering health insurance in Louisiana and Ryan White HIV/AIDS Program premium assistance became available through the Louisiana Health Insurance Program.

9. In or around January 2014, however, BCBS took the position that it would no longer accept Ryan White Funds for premium payments and advised the Louisiana Health Insurance Program of this change to its longstanding policy of accepting these payments.

10. BCBS's new policy excludes Plaintiff class members from access to BCBS coverage, which Plaintiffs can afford only with Ryan White Funds, as surely as if BCBS had posted a sign saying "low-income people with HIV need not apply."

11. BCBS's abrupt policy change coincides with the open enrollment period of the Affordable Care Act's insurance exchange marketplace. BCBS's initial explanation for its dubiously timed policy change was guidance issued by the Centers for Medicare & Medicaid Services ("CMS," a lead federal agency administering the Affordable Care Act) on November 4, 2013 (the "November 2013 Regulatory Guidance"). This guidance discouraged insurers from accepting third-party premium payments from *hospitals, health care providers, and other commercial entities* that might fraudulently seek to attract health care consumers with promises

to make their premium payments, or to defray the costs of otherwise uncompensated care by paying the premiums of those whose coverage would soon lapse.

12. That guidance, however, did ***not*** discourage insurers from accepting payments from other sources, such as federal programs designed specifically to provide premium support. In fact, in a more recent statement, CMS expressly stated that its earlier guidance regarding third-party premium payments "does not apply to payments for premiums and cost sharing made on behalf of QHP [Qualfied Health Plan] enrollees by . . . state and federal government programs or grantees (such as the Ryan White HIV/AIDS Program)."

13. Even after CMS repudiated BCBS's sole justification for refusing these payments, BCBS did not acknowledge its misinterpretation—or mischaracterization—of the earlier guidance and did not resume its longstanding policy to accept Ryan White HIV/AIDS Program payments.

14. Instead, BCBS disregarded CMS' clarification and doubled-down on its discriminatory actions, thereby attempting to skew the Louisiana health insurance market in its favor. BCBS issued a statement on February 13, 2014 making clear that it was going ahead with its discriminatory policy, which would have the effect of keeping low-income individuals living with HIV from enrolling in a BCBS individual insurance plan.

15. In turn, the other state-wide insurers in Louisiana have followed BCBS's lead. Around the time that CMS issued its clarifying guidance, Defendant Louisiana Health Cooperative, Inc. ("Louisiana Health Cooperative") began informing enrollees that it too would no longer accept Ryan White HIV/AIDS Program third-party premium payments. Shortly thereafter, Vantage Health Plan, Inc. ("Vantage") announced that while it would continue to

accept such payments for the time-being, it would reconsider its policy if BCBS and the Louisiana Health Cooperative continued to refuse Ryan White Funds.

16. To avoid the costs associated with more people living with HIV on their insurance rolls, Defendants are intentionally discriminating against Ryan White Funds recipients.

17. Indeed, in an email that was recently made public, a Congressional staffer in Senator Mary Landrieu's office wrote that

> ***BCBS LA told me their decision was not due to the CMS [Centers for Medicare & Medicaid Services] guidance or any confusion (as we thought before) but was in fact due to adverse selection concerns.***

18. The National Association of Insurance Commissions defines adverse selection to include "insurance purchasing decisions based on [consumers'] own knowledge of their insurability . . . [including when] the applicant might have information about the risk that is not known to the insurer, or the insurer might have access to the information but be unable to incorporate it fully into the price of coverage, due to factors such as antidiscrimination laws." *Adverse Selection Issues and Health Insurance Exchanges Under the Affordable Care Act*, Nat'l Ass'n of Ins. Comm'rs (2011), *available at* http://www.naic.org/store/free/ASE-OP.pdf.

19. Against the backdrop of the Affordable Care Act prohibiting health insurers from incorporating applicants' pre-existing conditions into the price of coverage, BCBS candidly admitted that it was excluding a large group of expensive-to-insure individuals—Plaintiffs—for no other reason than to avoid adverse selection.

20. Due to the eligibility requirements of the Ryan White HIV/AIDS Program, which is designated to be a payor of last resort, Plaintiffs by definition do not have employer-provided insurance, are ineligible for Medicare, Medicaid, or other federal health care programs, and cannot afford private insurance on their own. Without Ryan White HIV/AIDS Program

assistance, Plaintiffs cannot obtain health insurance, without which Plaintiffs cannot maintain the continuous access to care and prescription medications that literally keep them alive.

21. Defendants' plans are Plaintiffs' only viable health insurance options.[3] Defendants' discriminatory policy of refusing to accept Ryan White Funds puts Plaintiffs in a situation that class representative John East describes as "a matter of life and death."

22. As a result of Defendants' unlawful discrimination in violation of sections 1557 and 1311 of the Affordable Care Act, hundreds—if not thousands—of low-income Louisianans with HIV face being dropped immediately from their health care coverage, and those who are currently uninsured will have no health care coverage option to which they can turn.[4]

23. As a result of Defendants' unlawful discrimination and refusal to accept Insured Plaintiffs' premium payments via the Ryan White HIV/AIDS Program, Defendants have violated their contractual obligations to Insured Plaintiffs, their duty of good faith and fair dealing, as well as other duties under state law.

---

[3] The residents of Jefferson Parish who are currently eligible for assistance through the Louisiana Health Insurance Program may be able to pay for a health insurance plan offered by Humana Medical Plan, Inc., using Ryan White Funds, though it is unclear whether that plan will adequately meet the health care needs of all of these individuals, cover the specific medications currently being prescribed to these individuals, or allow these individuals to remain with the physician currently providing them with care and treatment. Furthermore, unless the other insurers doing business in Jefferson Parish are prevented from discriminating against low-income people living with HIV and kicking them off their insurance rolls, Humana may have difficulty maintaining its position as the only insurer in Louisiana complying with the nondiscrimination mandates of the Affordable Care Act and providing these individuals with coverage.

[4] Through nondiscrimination provisions, and regulations promulgated thereunder, the ACA prohibits precisely the tactic Defendants are employing to rid their insurance rolls of people living with HIV. In addition to section 1557, section 1311 requires that participating health insurance plans not employ benefits designs or marketing practices that discourage people with significant health needs from enrolling, and regulations promulgated under section 1311 further elucidate these standards. *See, e.g.*, Section 1311(c)(1)(A) of the ACA provides that "to be certified, a plan shall, at a minimum (A) . . . not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs. . . ." *See* 42 U.S.C. § 18031. *See also, e.g.*, 45 C.F.R. § 147.104(e) (prohibiting insurers from "employ[ing] marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's . . . present or predicted disability . . . or other health conditions"); 45 C.F.R. § 156.125(a) ("[a]n issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's . . . present or predicted disability . . . or other health conditions"); 45 C.F.R. § 156.225(b) (prohibiting insurers from "employ[ing] marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs").

24. As a result of Defendants' longstanding practice of accepting and benefiting from Ryan White Funds, which induced Plaintiffs' reliance that Defendants would continue to do so, Defendants must also be estopped from taking their new position leaving Plaintiffs with no viable health insurance option.

JURISDICTION AND VENUE

25. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1343(a)(4) where this action arises under, *inter alia*, sections 1557 and 1331 of the Affordable Care Act and 29 U.S.C. § 794. The Court has jurisdiction over Plaintiffs' state law claims, which arise from a common nucleus of operative facts as Plaintiffs' federal claims, pursuant to 28 U.S.C. § 1367(a).

26. Venue is proper in this district pursuant to 28 U.S.C. § 1391 because, upon information and belief, Defendant BCBS resides in the Middle District of Louisiana and all Defendants are residents of Louisiana, and because all or a substantial part of the events giving rise to the claims in this action occurred and are occurring in the Middle District of Louisiana.

27. Declaratory relief is authorized pursuant to 28 U.S.C. § 2201 and 28 U.S.C. § 2202. A declaration of the law is necessary and appropriate to determine the respective rights and duties of the parties to this action.

NAMED PARTIES

PLAINTIFF

28. Plaintiff John East, a resident of Louisiana, has purchased insurance coverage from BCBS continuously since 1985. Mr. East is living with HIV. Despite working two jobs, in 2009 Mr. East's escalating health insurance premium costs became unaffordable, and he realized he soon would be unable to make his payment on his own. Because he is a low-income person

living with HIV, Mr. East qualified for and obtained Ryan White HIV/AIDS Program health insurance premium assistance.

29. Mr. East, whose coverage with BCBS began in 1985, never missed a premium payment and his coverage never lapsed. Since he became qualified for premium assistance in approximately 2009, BCBS has been accepting Ryan White Funds premium payments for Mr. East.

30. At the beginning of this year, however, BCBS advised that it would no longer accept Ryan White Funds, leaving Mr. East with no means to make his premium payments. After BCBS's announcement, Mr. East's next payment was due on February 15, 2014, and he now faces the loss of health insurance for the first time in 29 years. Mr. East has since learned that Defendant Louisiana Health Cooperative will no longer accept Ryan White HIV/AIDS Program premium payments. He has also learned that Vantage, his only other potential option for health insurance coverage paid for with Ryan White funds, will likely follow BCBS and Louisiana Health Cooperative and stop accepting Ryan White Funds in March 2014.

DEFENDANTS

31. Defendant BCBS is a Louisiana corporation, with headquarters in Baton Rouge, Louisiana. BCBS offers insurance policies to residents of every Parish in Louisiana through the federal healthcare exchange. Defendant BCBS is the administrator for the Federal Employees Health Benefit Plan in Louisiana. It also offers Health Maintenance Organization and Preferred Provider Organization insurance plans through the federal healthcare exchange, in connection with which it receives federal premium tax credits and cost-sharing subsidy payments directly from the federal government. Finally, Defendant BCBS has received federal money via the very program at issue here—the Ryan White HIV/AIDS Program.

32. Defendant Louisiana Health Cooperative is a non-profit health care company, with headquarters in Metairie, Louisiana. Defendant Louisiana Health Cooperative received a loan for $65,040,660 in 2012 from the Department of Health and Human Services Consumer Oriented and Operated Plan Loan Program to assist with establishing its health insurance business. Defendant Louisiana Health Cooperative is a "Consumer Operated and Oriented Plan" established under title I of the Affordable Care Act. It offers Health Maintenance Organization and Point of Sale insurance plans through the federal healthcare exchange, in connection with which it receives federal premium tax credits and cost-sharing subsidy payments directly from the federal government. Finally, Defendant Louisiana Health Cooperative has received federal money via the very program at issue here—the Ryan White HIV/AIDS Program.

33. Defendant Vantage is a Louisiana corporation, with headquarters in Monroe, Louisiana. It offers Point of Sale insurance plans through the federal healthcare exchange, in connection with which it receives federal premium tax credits and cost-sharing subsidy payments directly from the federal government. Vantage also receives federal funds to administer its Medicare Advantage health insurance plans. Finally, Defendant has received federal money via the very program at issue here—the Ryan White HIV/AIDS Program.

CLASS ACTION ALLEGATIONS

34. The named individual Plaintiff brings this action individually and on behalf of the Plaintiff Class pursuant to Federal Rule of Civil Procedure 23(a) and (b)(2). The class consists of all Louisiana residents living with HIV who are qualified for health insurance premium assistance from the Ryan White HIV/AIDS Program. The class includes a subclass of Plaintiffs who have existing or past insured relationships with one or more Defendants (defined above as "Insured Plaintiffs") who, by virtue of those relationships, are entitled to additional relief under state law.

35. Numerosity. The size of the class is indefinite, and includes at least 1400 individuals who are eligible to apply for and enroll in a health insurance policy offered by one of the Defendants—including a subset of individuals who have existing or past insured relationships with one or more Defendants—but whose premium payments will now be refused under Defendants' discriminatory policies, leaving the Plaintiff Class with no viable health insurance coverage option.

36. Adequacy of Representation. The named Plaintiff will represent fairly and adequately the interests of the class and subclasses defined above. Plaintiffs' attorneys include counsel experienced in insurance, health care, and civil rights matters who have litigated cases involving similar issues and claims, and have experience in class action litigation.

37. Common Questions of Law and Fact. Common questions of law and fact affecting the entire class are involved, including but not limited to questions of law and fact regarding Defendants' actions, such as adopting policies that discriminate against Plaintiffs on the basis of their disability.

38. Typicality of the Claims of Class Representatives. The named Plaintiff's claims are typical of the claims of the class as a whole, and of those of the Insured Plaintiffs subclass. The named Plaintiff is a member of the class and subclass defined herein and has suffered, and will continue to suffer, discriminatory denial of equal access to otherwise available health care coverage. The named Plaintiff alleges that he and the members of the class and subclass he seeks to represent are and will be subject to discrimination based on disability due to the conduct complained of in this action.

APPLICABLE LAW

39. Section 1557(a) of the Affordable Care Act, 42 U.S.C. § 18116(a), provides that "an individual shall not . . . be excluded from participation in, be denied the benefits of, or be

subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance" on the ground prohibited under, *inter alia*, section 504 of the Rehabilitation Act.

40. Section 504 of the Rehabilitation Act, 29 U.S.C. § 794, prohibits discrimination based upon disability. A "disability" under section 504 is "a physical or mental impairment that substantially limits one or more major life activities." 29 U.S.C. § 794(a); 29 U.S.C. § 705(20)(B); 42 U.S.C. § 12102(1)(A). "[A] major life activity . . . includes the operation of a major bodily function, including . . . functions of the immune system." 42 U.S.C. § 12102(1)(A) & (2)(B).

41. Section 1557 states that "[t]he enforcement mechanisms provided for and available under . . . section 504 . . . shall apply for purposes of [section 1557(a)]." 42 U.S.C. § 18116(a).

42. Section 504 may be enforced by "any person aggrieved by any act or failure to act . . ." according to the same "remedies, procedures and rights set forth in[, *inter alia*,] Title VI of the Civil Rights Act." 29 U.S.C. § 794(a)(2).

43. Section 1557 also prohibits discrimination on the basis of disability status by "any entity established under [title I of the Affordable Care Act] (or amendments)." 42 U.S.C. § 18116(a).

44. Section 1322 of the Affordable Care Act, 42 U.S.C. § 18042, establishes the Consumer Operated and Oriented Plan ("CO-OP") program.

45. Under section 1311(c)(1)(A) of the Affordable Care Act, a "qualified health plan" certified and offered on a federal exchange must "not employ marketing practices or benefit

designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs." 42 U.S.C. § 18031(c)(1)(A).

46. Section 2702(a) of the Public Health Services Act provides that "each health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every . . . individual in the State that applies for such coverage." 42 U.S.C. § 300gg-1.

47. Louisiana Revised Statute section 22:1964 ("section 1964") declares what are, in the insurance business, "[m]ethods, acts, and practices which are defined as unfair or deceptive." LA. REV. STAT. § 22:1964.

48. Section 1964(7) enumerates "unfair discrimination" as an "unfair or deceptive" practice. Section 1964(7) (incorporating Louisiana Revised Statute section 22:34) defines "unfair discrimination," *inter alia*, as

> unfair discrimination in favor of particular individuals or persons, or between insureds or subjects of insurance having substantially like insuring risk, and exposure factors, or expense elements, in the terms or conditions of any insurance contract, or in the rate or amount of premium charged therefor, or in the benefits payable or in any other rights or privileges accruing thereunder.
>
> LA. REV. STAT. § 22:1964(7).

49. Section 1964(14)(a) enumerates as an "unfair or deceptive" practice the act of "[c]ommitting or performing with such frequency as to indicate a general business practice any of the following: (a) Misrepresenting pertinent facts or insurance policy provisions relating to coverages at issue . . . " LA. REV. STAT. § 22:1964(14)(a).

50. Louisiana Revised Statute section 22:861 states that

> Any insurer may insert in its policies any provisions or conditions required by its plan of insurance or method of operation which are not prohibited by the provisions of this Code.
>
> LA. REV. STAT. § 22:861.

51. Louisiana Revised Statute section 22:880 states that

> Any insurance policy, rider, or endorsement hereafter issued and otherwise valid, which contains any condition or provision not in compliance with the requirements of this Code, shall not be rendered invalid, but shall be construed and applied in accordance with such conditions and provisions as would have applied had such policy, rider, or endorsement been in full compliance with this Code.

LA. REV. STAT. § 22:880.

FACTS

The Current State of Low-Income People Living with HIV in Louisiana

52. According to a study by the Centers for Disease Control and Prevention ("CDC"), Louisiana is the State with the second highest rate of HIV infection in the United States and the fourth highest rate of AIDS among adults and adolescents.

53. As of 2012 there were nearly 19,000 people living with HIV in Louisiana. As of 2009, there were 9,228 total HIV-related deaths among people living with HIV in the state.

54. HIV and AIDS disproportionately affect low-income populations, including in Louisiana. According to remarks by the Director of the CDC's National Center for HIV/AIDS, Dr. Jonathan Mermin, individuals with household incomes below $10,000 per year are 10 times more likely to have HIV than individuals with household incomes above $50,000 per year.

55. Twenty-two percent of people in Louisiana are living below the Federal Poverty Level, which is set at an annual income of $11,670 for an individual in 2014.

Critical Importance of Continuous Health Care Coverage for People Living with HIV

56. According to the CDC and many peer-reviewed articles, retention and continuity of health care for people living with HIV is directly linked to better health outcomes and a significantly decreased chance of transmitting HIV to others.

57. Continuity of care is critical for people living with HIV because it allows them to obtain and maintain a regimen of antiretroviral medication, reduce their viral load, and ultimately reduce mortality rates.

58. Viral load is a measurement of the amount of HIV in an individual's blood. It indicates the degree of infection and is used to determine treatment strategies. A health care provider will typically test an HIV patient's viral load every three to six months, and more often when changing or starting treatment.

59. Antiretroviral medications are the primary method of combatting HIV infection and reducing viral load. Antiretroviral medications work by interfering with the replication process of HIV. Standard antiretroviral treatment typically involves a combination of at least three drugs taken daily.

60. Consistent care and treatment, including access to antiretroviral medication, has been shown to greatly reduce illness and death attributable to HIV, particularly when introduced at an early stage of infection, and can lead to a reduction in viral load to undetectable levels.

61. Studies have shown that an undetectable viral load dramatically reduces the chance of HIV transmission and results in a life expectancy commensurate with individuals in the general population.

62. Unfortunately in Louisiana, late diagnosis and lack of medical care contributes to a rate of death from AIDS nearly double the national average.

63. In Louisiana, 25% of people who received an AIDS diagnosis between 2002 and 2006 died within 36 months of receiving their diagnosis. Nationally, over the same period, 17% of people receiving an AIDS diagnosis died within 36 months.

Health Insurance Options for Low-Income People Living with HIV in Louisiana

64. There are significant gaps in availability of affordable health care coverage for low-income people living with HIV in Louisiana.

65. Louisiana has not expanded Medicaid coverage to include all individuals with a household income at or below 133% of the federal poverty level, as contemplated by the Medicaid expansion provisions of the Affordable Care Act. Accordingly, low-income people living with HIV in Louisiana who are not yet eligible for Medicare may obtain health insurance coverage through Medicaid only under limited circumstances.

66. While the Affordable Care Act's new provision for private health insurance exchanges provides an opportunity for some low-income people living with HIV to obtain insurance, affordability remains a problem.

67. Indeed, according to a state health reform modeling project undertaken by the Harvard Law School, only 8% of Louisiana's Ryan White Funds-eligible clients will be eligible for health insurance subsidies under the Affordable Care Act. Individuals with a household income below 100% of the Federal Poverty Level do not qualify for premium assistance through the health care exchanges. For people living with HIV in this income group, purchasing private insurance on the exchange is impossible without the assistance of Ryan White Funds.

68. Even people living with HIV who qualify for a subsidy to purchase private health insurance on the exchange still need Ryan White Funds to assist them in meeting their remaining individual premium obligation.

69. Plaintiff John East is one such. Mr. East, who is currently under-employed, cannot afford the premiums for his legacy insurance policy without assistance from the Ryan White HIV/AIDS Program. While Mr. East also would be eligible to apply for a plan on the federal exchange, and he may qualify for a subsidy, any subsidy he would qualify for still would

not suffice to cover his premium payment, and he continues to need the Ryan White HIV/AIDS Program's assistance.

70. The good news is that, with the assistance of Ryan White Funds, Plaintiffs can obtain insurance under the Affordable Care Act's protections, because no health insurance plan offered on the exchange can discriminate in coverage or price of premium based on their condition living with HIV.

The Ryan White HIV/AIDS Program

71. The Ryan White HIV/AIDS Program is a critical bridge over the health insurance coverage gap for Plaintiffs, making it possible for these low-income individuals living with HIV to pay premiums for private health care coverage that they would not otherwise be able to afford.

72. In 1990, Congress passed the Ryan White Comprehensive AIDS Resources Emergency Act (Ryan White CARE Act), funding what is now the Ryan White HIV/AIDS Program. The Ryan White HIV/AIDS Program makes grants to states, cities, and non-profit organizations to provide people living with HIV with access to health care, including by assisting in the payment of health insurance premiums.

73. At the federal level, Ryan White Funds are administered by the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

74. In 2010, the U.S. government released the "National HIV/AIDS Strategy for the United States," reemphasizing the Ryan White HIV/AIDS Program's important role as part of the national HIV/AIDS prevention and treatment strategy. A critical goal of the "National HIV/AIDS Strategy for the United States" is to increase by 2015 the "proportion of Ryan White HIV/AIDS Program clients who are in continuous care (at least 2 visits for routine HIV medical care in 12 months at least 3 months apart) from 73% to 80% (or 237,924 people in continuous care to 260,739 people in continuous care)."

75. In Louisiana, the Louisiana Health Insurance Program administers the Ryan White HIV/AIDS Program. In fiscal year 2012, Louisiana received $50,704,888 in total funding for Ryan White Program activities.

76. Louisiana state and municipal grantees have been accepting and utilizing Ryan White Program Funds since 1991. These funds and the programs they support are central to Louisiana's strategy for combating HIV/AIDS.

77. Since 1994, the Louisiana Health Insurance Program has been assisting eligible individuals—Louisiana residents living with HIV who have a household income below 300% of the Federal Poverty Level—to make their individual health insurance premium payments.

78. The HIV/AIDS Alliance for Region II (the "HIV/AIDS Alliance") is the not-for-profit entity that administers the Louisiana Health Insurance Program's health insurance premium payment function.

79. Potential Ryan White HIV/AIDS Program premium assistance recipients apply through the HIV/AIDS Alliance. Once a recipient becomes enrolled, the HIV/AIDS Alliance sends premium checks to insurers on behalf of the participant.

80. The Health Resources and Services Administration HIV/AIDS Bureau, which is the Federal Administrator of the Ryan White HIV/AIDS Program, requires Ryan White HIV/AIDS Program Grantees to make payments directly to service providers and insurance companies. Grantees are not permitted to make direct payment to Ryan White HIV/AIDS Program beneficiaries.

81. Well before the Affordable Care Act's implementation, Insured Plaintiffs including John East, received Ryan White HIV/AIDS Program support to pay their premiums for health insurance plans purchased in the private marketplace from BCBS and Vantage, making

this a critically important means for low-income people living with HIV to obtain care and treatment.

82. With the implementation of the federally sponsored health insurance exchange in Louisiana beginning in October 2013, the federal government made clear that Ryan White HIV/AIDS Program premium support will play an equally important role in assisting low-income people living with HIV pay their private health insurance premiums for plans purchased through the exchange.

83. Indeed, the Health Resources and Services Administration has issued many policy statements providing guidance on the continued use of Ryan White Funds as premium assistance for eligible people living with HIV to purchase and maintain health insurance plans offered on the federal exchange.

Defendants' Past Acceptance of Ryan White Funds

84. Long before the implementation of the Affordable Care Act's health exchanges, Defendant BCBS, and upon information and belief Defendant Vantage, established an unequivocal pattern and practice of accepting Plaintiffs' Ryan White Funds premium payments.

85. BCBS has continuously and habitually accepted Ryan White Funds for its policy holders' premium payments at least since as early as 2009.

86. Vantage and Louisiana Health Cooperative also have received and accepted Ryan White Funds for its policy holders' premium payments.

87. Plaintiff John East's most recent BCBS insurance policy includes a section entitled "Due Date for Premium Payments," which states:

> 1. Premiums are owed by Subscriber. Premiums may not be paid by third parties unless related to the Subscriber by blood or marriage. Premiums may not be paid by Hospitals, Pharmacies, Physicians, automobile insurance carriers or other insurance carriers. Company will not accept premium payments by third parties unless required by law to do so. The fact that We may have

> previously accepted a premium from an unrelated third party does not mean that we will accept premiums from these parties in the future.

88. Despite this term in BCBS's recent written policy, when announcing its policy of refusing Ryan White HIV/AIDS Program and other third-party premium payments on February 10, 2014 and again on February 13, 2014, BCBS made no mention that such a term already existed in its insurance policies. Rather, BCBS made its announcements on February 10 and 13, 2014 as if no such term previously existed.

89. Despite this term in its recent written policy, BCBS announced on February 10 and 13, 2014 that the policy would not take effect until March 1, 2014, and that BCBS would continue honoring third-party premium payments up through February 28, 2014.

90. Despite this term in its recent written policy, BCBS went on to accept Mr. East's (and others') Ryan White HIV/AIDS Program premium payments after Mr. East undertook his most recent policy renewal.

91. Wanting to ensure that his coverage never lapses, Mr. East routinely called BCBS to ensure that BCBS had received his premium payment of Ryan White Funds and applied it toward his account. BCBS representatives always assured Mr. East that his Ryan White HIV/AIDS Program premium had been received and accepted like any other premium payment.

92. Defendants' policy, pattern, and custom of accepting Ryan White Funds caused Insured Plaintiffs to repeatedly renew their coverage in reliance on Defendants' prior practices, and based on their understanding that their only means of paying their premium in full—via Ryan White Funds—was acceptable to Defendants.

93. For instance, Plaintiff John East annually had the opportunity to renew his BCBS policy or shop for health insurance elsewhere. While Mr. East did make inquiries with other

health insurers, he always renewed his BCBS policy, largely based on his belief that there would be no issue with his Ryan White Funds payments being accepted by BCBS.

94. Defendant BCBS's longstanding policy, pattern, and custom of accepting Ryan White Funds persisted even after BCBS inserted boilerplate language in its insurance policies that it would not receive third party premium payments.

95. Defendants outwardly maintained their policy, pattern, and custom of accepting Ryan White Funds even on the eve of Defendants' changing that position, including at times when Defendants knew they would soon be changing that position, in furtherance of receiving and benefiting from Plaintiffs' Ryan White Funds premium payments.

Defendants' Abrupt Change of Policy and Purported Justification

96. In January 2014, BCBS abruptly advised state agencies and entities administering Ryan White funds, including the Louisiana Health Insurance Program and the HIV/AIDS Alliance for Region II, that it would no longer accept Ryan White Funds for Plaintiffs' premium payments.

97. At that time, healthcare advocates and case workers of HIV and AIDS support programs such as the NO/AIDS Task Force ("NO/AIDS") also learned that BCBS would be refusing Ryan White premium payments and that BCBS's explanation for its policy was that the November 2013 Regulatory Guidance prevented BCBS from accepting premium payments from third parties.

98. In mid-January, Plaintiff John East learned of BCBS's policy of refusing Ryan White funds from his case worker at NO/AIDS.

99. BCBS provided Mr. East himself with no such notice. However, BCBS did send Mr. East his premium bill as usual. If not for his conversation with NO/AIDS, Mr. East would

have continued to believe that BCBS would accept his Ryan White HIV/AIDS Program premium payments as it always had.

100. The November 2013 Regulatory Guidance that BCBS purportedly relied on addressed CMS' concern that private or commercial parties might distort the marketplace in attracting patients to consume their healthcare services, or in shifting the costs of uncompensated care, by paying those patients' premiums or cost-sharing payments.

101. To that end, the November 2013 Regulatory Guidance stated that "HHS [Department of Health and Human Services] discourages this practice and encourages issuers to reject such third party payments."

102. Consistent with its purpose of targeting the practice of third parties who seek to attract patients with offers to pay premiums and cost-sharing obligations, the November 2013 Regulatory Guidance was limited to discouraging the acceptance of third-party premiums paid only by "hospitals, other healthcare providers, and other commercial entities."

103. Nonetheless, BCBS announced publically in a February 10, 2014 media release that its policy of not accepting any third-party payments (including Ryan White Funds) was in response to the November 2013 Regulatory Guidance, which BCBS characterized as "strongly advising [insurers] not to take ***any*** third-party payments." (Emphasis added.)

104. In another media release on February 13, 2014, BCBS again offered only one justification for its policy—its purported concerns based on the November 2013 Regulatory Guidance that people or organizations might fraudulently seek to attract health care consumers with promises to make their premium payments or to defray the costs of otherwise uncompensated care by paying the premiums of those whose coverage would soon lapse.

105. BCBS has offered no justification for its refusal to accept Ryan White Funds from Plaintiffs, other than its claimed inapposite concerns over "fraud, waste and abuse" as discussed in November 2013 Regulatory Guidance.

The November 2013 Regulatory Guidance Never Supported BCBS's Only Purported Justification, and the Centers for Medicare & Medicaid Services Expressly Refuted BCBS's Incoherent Justification

106. BCBS's only justification for its refusal to accept Plaintiffs' Ryan White Funds premiums is a false pretext under which BCBS is attempting to keep what it perceives to be a more expensive class of insureds—people living with HIV—off its insurance rolls.

107. On February 7, 2014, very shortly after BCBS began advising that it would reject Ryan White Funds from Plaintiffs, CMS responded with clarifying guidance (the "February 2014 Regulatory Guidance"), in Question-and-Answer format, entitled, "Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces."

108. In response to the question whether the November 2013 Regulatory Guidance applied to "premium and cost sharing payments on behalf of [Qualified Health Plan] enrollees from . . . state and federal government programs or grantees (such as the Ryan White HIV/AIDS Program)," the February 2014 Regulatory Guidance stated that it did not apply:

> ***No. The November 4, 2013 FAQ does not apply to payments for premiums and cost sharing made on behalf of . . . state and federal government programs or grantees (such as the Ryan White HIV/AIDS Program). QHP issuers and Marketplaces are encouraged to accept such payments***.

(Emphasis added.)

109. The February 2014 Regulatory Guidance went on to confirm that earlier Health Resources and Services Administration guidance on the Ryan White HIV/AIDS Program "specifically describes how grantees can use grant funds to pay premiums and cost sharing for eligible individuals enrolled in QHPs."

110. BCBS's media releases of February 10, 2014 and February 13, 2014 each acknowledged the February 2014 Regulatory Guidance, but asserted that, in this more recent guidance, "CMS [Centers for Medicare & Medicaid Services] changed its position" and "issued a different communication."

111. BCBS supported its assertion that "CMS changed its position" by asserting that the earlier November 2013 Regulatory Guidance "strongly advis[ed insurers] not to take ***any*** third-party payments." (Emphasis added.)

112. The foregoing statements by BCBS on February 10 and 13, 2014, are deliberately false and misleading.

113. The November 2013 Regulatory Guidance did not discourage insurers from taking "any" third-party payments, but rather explicitly tailored its caution to those third-party payors that might actually seek to exploit patients with premium assistance for their own personal gain—"hospitals, other healthcare providers, and other commercial entities."

114. The November 2013 Regulatory Guidance certainly did not include federal Ryan White Funds or any other government program specifically designed to assist people living with HIV to pay their health insurance premiums.

115. Contrary to BCBS's assertion that "CMS changed its position" through its February 2014 Regulatory Guidance, the February 2014 Regulatory Guidance was ***consistent with*** the November 2013 Regulatory Guidance. Neither supports a policy of refusing federal funds to assist Plaintiffs to pay their health insurance premiums.

116. BCBS has not explained in any of its public statements how refusing Ryan White Funds premium payments from Plaintiffs, rather than refusing payments only from hospitals,

other healthcare providers, and other commercial entities, furthers BCBS's purported goal of safeguarding against patient-steering by private actors and other fraudulent activity.

117. BCBS's justification based solely on BCBS's characterization of the policy is unsupported by any regulatory guidance and is explicitly negated by the February 2014 Regulatory Guidance.

118. The vast majority of Blue Cross and Blue Shield affiliates across the country have not adopted this policy.

Defendants' True Motivation in Refusing Ryan White Funds Is to Exclude Individuals Based on Their HIV/AIDS Status from Defendants' Insurance Rolls

119. In reality, Defendants' policy is intended to exclude Louisianans living with HIV who cannot by themselves afford to pay the premiums for the health insurance offered by Defendants.

120. Defendants are motivated to keep people living with HIV off their insurance rolls and reduce the increased costs associated with paying for the care and treatment provided to people living with HIV.

121. This is demonstrated in an email made public via various news outlets, in which a Congressional staffer in Senator Mary Landrieu's office reported that,

> ***BCBS LA told me their decision was not due to the CMS [Centers for Medicare & Medicaid Services] guidance or any confusion (as we thought before) but was in fact due to adverse selection concerns.***

(Emphasis added.)

122. As defined by the National Association of Insurance Commissions:

> Adverse selection . . . occurs whenever people make insurance purchasing decisions based on their own knowledge of their insurability or likelihood of making a claim on the insurance coverage in question. This can happen in a variety of ways. For example, the applicant might have information about the risk that is not known to the insurer, or the insurer might have access to the

> information but be unable to incorporate it fully into the price of coverage, due to factors such as antidiscrimination laws . . .

Adverse Selection Issues and Health Insurance Exchanges Under the Affordable Care Act, Nat'l Ass'n of Ins. Comm'rs (2011), *available at* http://www.naic.org/store/free/ASE-OP.pdf.

123. People living with HIV have medical needs requiring regular doctor visits (preferably with an infectious disease specialist), periodic blood tests and other lab work, and uninterrupted access to the medications they take on a daily basis.

124. Without regular medical care and monitoring and continuous access to (often expensive) medications, people living with HIV face the strong likelihood of a deteriorating immune function, debilitating illness, and premature death.

125. In light of their pressing need for consistent medical care and their lack of sufficient resources to pay for such care out of pocket, Plaintiffs' need for health insurance is particularly high.

126. Pursuant to Affordable Care Act reforms effective January 1, 2014, Plaintiffs cannot be prevented from purchasing most private health insurance plans, including Defendants', from which they historically have been excluded based on pre-existing condition exclusions.

127. The Affordable Care Act's reforms also prevent insurers from denying claims or basing premiums on a person' pre-existing condition, such as HIV or AIDS.

128. Plaintiffs' elevated need for health care and correspondingly high demand for health insurance, combined with the Affordable Care Act's provisions preventing Defendants from discriminating against people living with HIV in coverage or in premium cost, is consistent with BCBS's admission to Senator Landrieu's aide that its policy not to accept Ryan White Funds is intended to exclude Plaintiffs and thereby avoid "adverse selection."

129. Defendants' sudden refusal to accept Ryan White Funds also has the ***effect of*** discriminating against people living with HIV.

130. By definition, all individuals eligible for Ryan White HIV/AIDS Program are living with HIV (or AIDS) and find themselves currently unable to afford private health insurance premiums without Ryan White Funds.

131. Accordingly, 100% of those affected by Defendants' refusal to accept Ryan White Funds are individuals with a disability as defined by the Rehabilitation Act, and 100% of those affected will be unable to purchase health insurance on the federal exchange or otherwise.

132. Tellingly, in its February 13, 2014 media release, BCBS specifically assured the public that Ryan White HIV/AIDS Program recipients were not the only individuals affected by its new policy of refusing third party payments.

133. BCBS, however, cited only one example, concluding that "some Louisiana universities pay for student athletes' premiums. This policy affects them as well."

134. Like its justification for its discriminatory policy, BCBS's conclusory attempt to paint its policy as one of general application appears wholly unsupported.

135. In fact, Louisiana State University, the largest public university in Louisiana, has stated that BCBS's policy does not affect it or its student athletes.

Defendants' Abrupt Change in Policy to Refuse Ryan White Funds Leaves Plaintiffs with No Access to Health Insurance

136. In early February 2014, after BCBS publicized its plan to refuse Ryan White funds, Defendant Louisiana Health Cooperative, announced it too would refuse Ryan White Funds. The remaining Defendant, Vantage, announced that it would reexamine its policy of accepting Ryan White Funds in the near future, signaling an intent to adopt positions similar to

BCBS's and Louisiana Health Cooperative's if those insurers are allowed to continue their practice.

137. The concerted effort by these three insurers to exclude Plaintiff Ryan White HIV/AIDS Program beneficiaries effectively freezes Plaintiffs out of the federal health insurance exchange—the only market offering affordable health insurance plans that cannot exclude Plaintiffs or charge more on the basis of their HIV or AIDS diagnosis.

138. BCBS, the Louisiana Health Cooperative, and Vantage, represent three out of the four Louisiana health insurers that offer plans on the federal health insurance exchange.

139. The fourth insurer offering health insurance through the federal insurance exchange offers policies in only Jefferson Parish.

140. According to BCBS's own media release, BCBS is the only "meaningful" state-wide insurance option offered in the federal exchanges in Louisiana:

> [BCBS] is the only insurer that is fully participating in the Marketplace, offering plans at every metal level in every parish and every ZIP code in the state. . . . Our competition has chosen, for the most part, not to participate in any meaningful way.

141. With Defendants' new discriminatory policy in place, there are no health insurance policies offered through the federal insurance exchange that cover the other 63 Parishes of Louisiana (besides Jefferson Parish) in which Plaintiffs could participate, because now no provider of such policies accepts Ryan White Funds premium payments.

142. As noted above, Plaintiffs fall into Louisiana's insurance gap of individuals who do not qualify for Medicaid, Medicare, or other federal health care programs, but who cannot afford private health care insurance on their own.

143. Beyond their need for Ryan White Funds to afford their insurance premiums, Plaintiffs are qualified to participate in and receive the benefits of their existing or prospective

health insurance plans. The lone obstacle to Plaintiffs retaining or obtaining insurance is Defendants' sudden refusal to accept Ryan White Funds.

144. The introduction of the Affordable Care Act's health insurance exchanges offered new and more favorable options to Insured Plaintiffs with existing policies, and finally offered to Plaintiffs currently without insurance an opportunity to secure insurance and not be turned away or gouged based on an HIV or AIDS diagnosis.

145. Plans purchased outside of an exchange are far less likely to be affordable because Plaintiffs will not be eligible for premium credits or cost sharing subsidies, as they will be in connection with plans purchased through an exchange.

146. Even the plans in the federal exchange, however, despite the availability of premium credits and cost-sharing subsidies, are still too costly for Plaintiffs to carry the premiums themselves, making Ryan White Funds essential for Plaintiffs to be able to participate in, and enjoy the benefits of, the new market of health insurance free of discrimination based on disability or pre-existing conditions. Defendants know this fact.

147. With the major market player, BCBS, refusing Ryan White Funds, and with ***all*** insurance options outside of Jefferson Parish doing likewise (or, as to Vantage, threatening to do so in the near future), Defendants' discriminatory policy freezes Plaintiffs out of any access to health care coverage.

148. Even Plaintiffs living in Jefferson Parish, from whom one insurer may accept Ryan White Funds, are frozen out of coverage from BCBS, who, by its own assertion, is the only health insurer "to participate [in the exchange] in any meaningful way."

The Effect of Defendants' Intentional Discrimination Could Mean Illness and Death for Plaintiffs Forced Off Their Insurance Coverage

149. The circumstances facing Plaintiffs due to Defendants' intentionally discriminatory policy could not be more dire.

150. Plaintiff John East described the effect of this policy as being a "matter of life and death."

151. As set forth above, most Plaintiffs must take a number of costly prescription drugs every day, in various combinations tailored to boost their individual immune systems.

152. These drugs literally keep Plaintiffs alive. As Plaintiff John East has stated, "I could die if I don't get my meds."

153. To ensure that the medications remain effective and that the virus has not mutated and developed a resistance to the particular medications being taken, Plaintiffs also must engage in routine doctor visits and regularly undergo blood work and other medical monitoring tests.

154. Without health insurance coverage, the Plaintiff class members, including Plaintiff John East, cannot afford any of the care that they need to remain healthy and, ultimately, to stay alive.

155. With Defendants' policy of refusing Ryan White Funds in place, premiums due this month will go unpaid, Plaintiffs' prescriptions will begin to run out, and Plaintiffs may be turned away from their health care providers if there is uncertainty as to whether their coverage remains in place.

156. In addition, the health effects of losing—or even the threat of losing—health coverage for Plaintiffs, who so desperately depend on it, substantially impair Plaintiffs' ability to work and support themselves and their families.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF- AS TO THE PLAINTIFF CLASS (Intentional discrimination in violation of section 1557(a) of the Patient Protection and Affordable Care Act)

157. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

158. Defendants meet the qualifications for being a "health program or activity, any part of which is receiving Federal financial assistance" under section 1557 of the Affordable Care Act.

159. Plaintiffs are "individual[s] with a disability" under section 504 of the Rehabilitation Act.

160. Plaintiffs are qualified to participate in and receive the benefits of their respective health insurance plans.

161. Defendants have violated and continue to violate section 1557(a) of the Affordable Care Act by intentionally causing Plaintiffs to "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance" based on their disability, which is a prohibited ground of discrimination under section 504 of the Rehabilitation Act.

162. Plaintiffs have been aggrieved by this violation of section 1557 of the Affordable Care Act and have no adequate remedy at law for Defendants' violation of their rights. Defendants' unlawful discrimination will irreparably harm Plaintiffs because they will be unable to obtain necessary medical care.

163. Declaratory and injunctive relief are required to define Plaintiffs' rights under section 1557 and related statutes, to remedy the Defendants' violation of section 1557 of the

Affordable Care Act, and to secure ongoing compliance with the antidiscrimination provisions of the Affordable Care Act and incorporated federal law

SECOND CLAIM FOR RELIEF- AS TO THE PLAINTIFF CLASS
(Disparate impact discrimination in violation of section 1557(a) of the Patient Protection and Affordable Care Act)

164. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

165. Even if Defendants did not act with discriminatory intent, Defendants' refusal to accept premium payments from third parties other than those CMS considers to be potentially problematic has a disparate impact on individuals with a disability, namely their HIV or AIDS diagnosis, who as a result of Defendants' policy necessarily will be denied meaningful access to, excluded from participation in, and denied the benefits of any health program or activity, any part of which is receiving Federal financial assistance, in violation of Affordable Care Act section 1557(a).

166. Plaintiffs' request that Defendants maintain the status quo and continue to accept Ryan White Funds—as they have for years—requests only a "reasonable accommodation" under, not a substantial modification to or fundamental alteration of, Defendants' insurance programs, to ensure Plaintiffs meaningful access to Defendants' health insurance.

167. Plaintiffs have been aggrieved by this violation of section 1557 of the Affordable Care Act and have no adequate remedy at law for the Defendants' violation of their rights. Plaintiffs will be irreparably harmed by Defendants' unlawful discrimination by being unable to obtain necessary medical care.

168. Declaratory and injunctive relief are required to define Plaintiffs' rights under section 1557 and related statutes, to remedy the Defendants' violation of section 1557 of the

Affordable Care Act, and to secure ongoing compliance with the antidiscrimination provisions of the Affordable Care Act.

THIRD CLAIM FOR RELIEF- AS TO THE PLAINTIFF CLASS
(Employment of unlawful marketing practice to discourage enrollment in health insurance plans by individuals with significant health needs in violation of section 1311(c)(1)(A) of the Patient Protection and Affordable Care Act)

169. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

170. Defendants offer "qualified health plans" on federal insurance exchanges established under the Affordable Care Act.

171. Defendants' refusal to accept Ryan White Funds is a "marketing practice[] . . . that [has] the effect of discouraging the enrollment in [Defendants' insurance plans] by individuals with significant health needs," namely individuals with HIV or AIDS.

172. Plaintiffs have been aggrieved by this violation of section 1311 of the Affordable Care Act and have no adequate remedy at law for the Defendants' violation of their rights. Plaintiffs will be irreparably harmed by Defendants' unlawful discrimination by being unable to obtain necessary medical care.

173. Declaratory and injunctive relief are required to define Plaintiffs' rights under section 1311, to remedy the Defendants' violation of section 1311 of the Affordable Care Act, and to secure ongoing compliance with the antidiscrimination provisions of the Affordable Care Act.

FOURTH CLAIM FOR RELIEF - AS TO THE PLAINTIFF CLASS
(Violation of the Guaranteed Availability requirements of section 2702 of the Public Health Service Act)

174. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

175. Defendants offer health insurance coverage in the individual and group markets of Louisiana.

176. By engaging in discriminatory marketing practices prohibited by section 1311 of the Affordable Care Act, Defendants refused to accept each individual in Louisiana who applied for coverage and thus violated the guaranteed availability requirements of section 2702 of the Public Health Service Act (42 U.S.C. § 300gg-1), as amended by section 1201 of the Affordable Care Act.

177. Defendants' refusal to accept Ryan White Funds is a "marketing practice[] . . . that [has] the effect of discouraging the enrollment in [Defendants' insurance plans] by individuals with significant health needs," namely individuals with HIV or AIDS.

178. Plaintiffs have been aggrieved by this violation of section 2702 of the Public Health Service Act and have no adequate remedy at law for the Defendants' violation of their rights. Plaintiffs will be irreparably harmed by Defendants' unlawful discrimination by being unable to obtain necessary medical care.

179. Declaratory and injunctive relief are required to define Plaintiffs' rights under section 1311, to remedy the Defendants' violation of section 2702 of the Public Health Service Act, and to secure ongoing compliance with the antidiscrimination provisions of the Affordable Care Act.

FIFTH CLAIM FOR RELIEF- AS TO THE PLAINTIFF CLASS
(Equitable Estoppel)

180. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

181. Defendants have, by their words and conduct, long represented that they will receive and accept Ryan White Funds as payment for health insurance premiums and that those payments will be treated no differently than any other health insurance premium payments.

182. Insured Plaintiffs have justifiably relied on Defendants' policy and custom of accepting Ryan White Funds.

183. Insured Plaintiffs have maintained, renewed, or applied for health insurance policies offered by Defendants, and have forborn from making alternative arrangements based on their justifiable reliance induced by Defendants.

184. As a result of Defendants' abrupt change in position that Defendants now will not accept Ryan White Funds, Insured Plaintiffs have been aggrieved, and have been and will continue to be irreparably harmed by being unable to obtain necessary medical care and medications.

185. Injunctive relief is required to equitably estop Defendants from changing their longstanding policy of accepting Ryan White Funds.

SIXTH CLAIM FOR RELIEF- AS TO INSURED PLAINTIFFS
(Breach of Contract)

186. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

187. A valid insurance contract exists between BCBS and Plaintiff John East, and exists or has existed as well as between one of more Defendants and all other Insured Plaintiffs.

188. Defendants are under an obligation to provide health insurance coverage to Insured Plaintiffs in exchange for receiving health insurance policy premium payments.

189. Plaintiff John East and Insured Plaintiffs have performed all the obligations required of them under their policies, and remain ready, willing, and able to continue performing, including allowing the continued payment of their health insurance premiums.

190. Any term in Insured Plaintiffs' insurance policy with Defendants relating to the refusal of third party payments is waived and modified by Defendants' past conduct.

191. Unfairly discriminating against individuals with like insuring risk in the terms or conditions of any insurance contract violates the Louisiana Insurance Code, including without limitation, section 22:1964(7)(c) and section 22:34.

192. Any term in Insured Plaintiffs' insurance policy with Defendants relating to the refusal of third party payments is void as against Louisiana public policy and must be read out of any insurance policy, rider, or endorsement issued by Defendants, pursuant to the Louisiana Insurance Code section 22:861(4) and section 22:880.

193. Defendants breached their contractual obligations by refusing to accept premium payments on Insured Plaintiffs' accounts, whether received from the Ryan White HIV/AIDS Program (via the Louisiana Health Insurance Program or the HIV/AIDS Alliance) or otherwise.

194. Defendants' refusal to accept Insured Plaintiffs' premium payments constitutes a unilateral repudiation of Defendants' contractual obligations to cover Insured Plaintiffs during the policy term so long as premium payments are made.

195. As a result of Defendants' breach of their agreement to provide health insurance coverage, Insured Plaintiffs have been aggrieved, and have been and will continue to be irreparably harmed by being unable to obtain necessary medical care and medicine.

196. Monetary damages are not adequate to remedy Defendants' breach of their contractual obligations.

197. Declaratory and injunctive relief are required to define Plaintiffs' rights under their insurance policies and to require specific performance by Defendants of their vital contractual obligations.

SEVENTH CLAIM FOR RELIEF- AS TO INSURED PLAINTIFFS
(Breach of the Duty of Good Faith and Fair Dealing)

198. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

199. Defendants owe a duty of good faith and fair dealing to Insured Plaintiffs, their insureds.

200. Defendants have breached their duties of good faith and fair dealing not to discriminate against individuals with like insuring risk in the terms or conditions of any insurance contract, pursuant to the Louisiana Insurance Code section 22:1964(7)(c) and section 22:34.

201. Defendants have breached their duties of good faith and fair dealing not to misrepresent to Insured Plaintiffs over a period of time that they would accept premium payments to induce Insured Plaintiffs to continue choosing Defendants' health insurance coverage when Defendants knew they later would not accept such payments, pursuant to the Louisiana Insurance Code section 22:1964(14)(a).

202. As a result of Defendants' breaches of their duties of good faith and fair dealing, Insured Plaintiffs have been aggrieved, and have been and will continue to be irreparably harmed by being unable to obtain necessary medical care and medicine.

203. Declaratory and injunctive relief are required to enjoin Defendants from their continued and ongoing breaches of their duties not to discriminate and not to mislead Insured Plaintiffs.

EIGHTH CLAIM FOR RELIEF - AS TO INSURED PLAINTIFFS
(Negligent Misrepresentation)

204. Plaintiff realleges and incorporates, as though fully set forth herein, each and every allegation contained above.

205. Defendants owe a duty of care to Insured Plaintiffs, their insured.

206. Defendants have a pecuniary interest in their relationship with Insured Plaintiffs insured by Defendants.

207. Defendants have long represented, for the guidance of Insured Plaintiffs, that Defendants will receive and accept Ryan White Funds as payment for health insurance premiums and that those payments will be treated no differently than any other health insurance premium payments.

208. Defendants carelessly maintained that guidance even after including in some of their insurance policies terms relating to the refusal of third party payments, continuing to induce Insured Plaintiffs' reliance in maintaining and applying for Defendants' health insurance plans.

209. Defendants carelessly maintained that guidance even immediately before Defendants announced their refusal to accept Ryan White Funds, continuing to induce Insured Plaintiffs' reliance in maintaining and applying for Defendants' health insurance plans.

210. Insured Plaintiffs justifiably relied on Defendants' policy and custom of accepting Ryan White Funds.

211. Insured Plaintiffs have maintained, renewed, or applied for health insurance policies offered by Defendants, and have forborn from making alternative arrangements based on their justifiable reliance induced by Defendants.

212. As a result of Defendants' longstanding practice of accepting Ryan White Funds followed by Defendants' abrupt change in position, Defendants breached their duty of care to

Insured Plaintiffs and Insured Plaintiffs have been aggrieved, and have been and will continue to be irreparably harmed by being unable to obtain necessary medical care and medicine.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the Court to enter an Order

(a) Certifying the proposed class and subclasses of Plaintiffs;

(b) With respect to the class:

(i) Enjoining Defendants from changing their policy of accepting Ryan White HIV/AIDS Program funds from current or prospective applicants to, or policy holders of, Defendants' health insurance plans;

(ii) Enjoining Defendants from implementing or executing their new policy of refusing Ryan White HIV/AIDS Program funds from current or prospective applicants to, or policy holders of, Defendants' health insurance plans; and

(iii) Declaring that Defendants' actions described above constitute discrimination in violation of section 1557 of the Affordable Care Act;

(iv) Estopping Defendants from taking the position of refusing to accept Ryan White HIV/AIDS Program funds for Plaintiffs' health insurance premium payments; and

(c) With respect to the subclass of Insured Plaintiffs:

(i) Requiring specific performance by Defendants of their contractual obligations to accept Ryan White HIV/AIDS Program premium payments from Plaintiffs currently insured by Defendants, and to maintain coverage so long as such premium payments are received;

(ii) Declaring that Defendants' actions described above constitute unfair discrimination in violation of Louisiana Revised Statute section 22:1964(7) and is therefore void pursuant to Louisiana Revised Statute 22:861(4) and section 22:880;

(iii) Declaring that Defendants' actions described above constitute a breach of Defendants' contractual obligations to Plaintiffs currently insured by Defendants;

(iv) Declaring that Defendants' actions described above constitute a breach of Defendants' duty of good faith and fair dealing to Plaintiffs currently insured by Defendants;

(d) Awarding reasonable attorneys' fees and costs; and

(e) Awarding other equitable and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs request a trial by jury on all issues so triable.

Respectfully submitted,

Dated: February 20, 2014

/s/ Harry Rosenberg

ROPES & GRAY LLP
Jeffrey J. Bushofsky (*pro hac vice pending*)
Timothy R. Farrell (*pro hac vice pending*)
191 North Wacker Drive, 32nd Floor
Chicago, IL 60606
Telephone: (312) 845-1200
Facsimile: (312) 845-5500
E-mail: jeffrey.bushofsky@ropesgray.com

-AND-

ROPES & GRAY LLP
Amanda R. Phillips (*pro hac vice pending*)
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
Telephone: (617) 951-7000
Facsimile: (617) 951-7050
E-mail: amanda.phillips@ropesgray.com

-AND-

ROPES & GRAY LLP
Anthony C. Biagioli (*pro hac vice pending*)
One Metro Center
700 12th Street, NW, Suite 900
Washington, DC 20005-3948
Telephone: (202) 508-4776
Facsimile: (202) 508-4650
Email: anthony.biagioli@ropesgray.com

-AND-

LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
Scott A. Schoettes (*pro hac vice pending*)
Kenneth D. Upton (*pro hac vice pending*)
Susan L. Sommer (*pro hac vice pending*)
120 Wall Street, 19th Floor
New York, NY 10005-3904
Telephone: (212) 809-8585
Facsimile: (212) 809-0055
E-mail:
sschoettes@lambdalegal.org

kupton@lambdalegal.org
ssommer@lambdalegal.org

-AND-

PHELPS DUNBAR LLP
Harry Rosenberg (Bar No. 11465)
Bryan Edward Bowdler (Bar No. 32097)
365 Canal Street, Suite 2000
New Orleans, LA 70130
Telephone: (504) 584-9219
Facsimile: (504) 568-9130
E-mail: harry.rosenberg@phelps.com
bryan.bowdler@phelps.com

Attorneys for Plaintiff John East and all others similarly situated

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

John East, individually and on behalf of all other persons similarly situated

(b) County of Residence of First Listed Plaintiff Orleans Parish
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
See attached.

DEFENDANTS

Blue Cross and Blue Shield of Louisiana, Louisiana Health Cooperative, Inc., and Vantage Health Plan, Inc.

County of Residence of First Listed Defendant East Baton Rouge Parish
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ❒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
42 U.S.C. 18116(a) and 18031

Brief description of cause:
Injunctive and declaratory relief to halt Defendants' abrupt and systematic policy of discrimination based on Plaintiffs' disability

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
02/20/2014

SIGNATURE OF ATTORNEY OF RECORD
/s/Harry Rosenberg

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

Print Save As... Reset

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

ATTACHMENT TO CIVIL COVER SHEET

Section I.
Attorneys representing Plaintiffs

Harry Rosenberg (#11465)
Bryan Edward Bowdler (#32097)
Phelps Dunbar, LLP
365 Canal Street, Suite 2000
New Orleans, LA 70130-6534
Telephone: (504) 566-1311
Telecopier: (504) 568-9130
harry.rosenberg@phelps.com
bryan.bowdler@phelps.com

-AND-

ROPES & GRAY LLP
Jeffrey J. Bushofsky (*pro hac vice pending*)
Timothy R. Farrell (*pro hac vice pending*)
191 North Wacker Drive, 32nd Floor
Chicago, IL 60606
Telephone: (312) 845-1200
Facsimile: (312) 845-5500
E-mail: jeffrey.bushofsky@ropesgray.com

-AND-

ROPES & Gray LLP
Amanda R. Phillips (*pro hac vice pending*)
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
Telephone: (617) 951-7000
Facsimile: (617) 951-7050
E-mail: amanda.phillips@ropesgray.com

-AND-

Ropes & GRAY LLP
Anthony C. Biagioli (*pro hac vice pending*)
One Metro Center
700 12th Street, NW, Suite 900
Washington, DC 20005-3948
Telephone: (202) 508-4776
Facsimile: (202) 508-4650
Email: anthony.biagioli@ropesgray.com

-AND-

LAMBDA Legal DEFENSE AND EDUCATION FUND, INC.
Scott A. Schoettes (*pro hac vice pending*)
Kenneth D. Upton (*pro hac vice pending*)
Susan L. Sommer (*pro hac vice pending*)
120 Wall Street, 19th Floor
New York, NY 10005-3904
Telephone: (212) 809-8585
Facsimile: (212) 809-0055
E-mail: sschoettes@lambdalegal.org
kupton@lambdalegal.org
ssommer@lambdalegal.org

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Louisiana

JOHN EAST, individually and on behalf of all persons similarly situated,

Plaintiff(s)

v.

BLUE CROSS and BLUE SHIELD of LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BLUE CROSS AND BLUE SHIELD OF LOUISIANA
c/o Its Registered Agent For Service of Process
Michele S. Calandro
5525 Reitz Avenue
Baton Rouge, LA 70809

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Harry Rosenberg
Bryan Edward Bowdler
Phelps Dunbar LLP
365 Canal Street, Suite 2000
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Louisiana

JOHN EAST, individually and on behalf of all persons similarly situated,

Plaintiff(s)

v.

BLUE CROSS and BLUE SHIELD of LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* LOUISIANA HEALTH COOPERATIVE, INC.
c/o Its Registered Agent For Service of Process
Rudolph R. Ramelli, Esq.
Jones Walker Waechter Poitevent Carrere & Denegre
201 St. Charles Avenue, Suite 5100
New Orleans, LA 70170

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Harry Rosenberg
Bryan Edward Bowdler
Phelps Dunbar LLP
365 Canal Street, Suite 2000
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Louisiana

JOHN EAST, individually and on behalf of all persons similarly situated,

Plaintiff(s)

v.

BLUE CROSS and BLUE SHIELD of LOUISIANA, LOUISIANA HEALTH COOPERATIVE, INC., and VANTAGE HEALTH PLAN, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* VANTAGE HEALTH PLAN, INC.
c/o Its Registered Agent For Service of Process
Robert Bozeman
130 Desiard Street, Suite 300
Monroe, LA 71201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Harry Rosenberg
Bryan Edward Bowdler
Phelps Dunbar LLP
365 Canal Street, Suite 2000
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

EXHIBIT 3

[Names and addresses of Requestors have been redacted]

Re: Advisory Opinion No. 97-1

Dear [Names have been redacted]:

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

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

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

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

I. FACTUAL BACKGROUND

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

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

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

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

B. Parties to the Proposed Arrangement

1. The Companies

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

2. American Kidney Fund

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

---

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

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

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

C. Health Insurance Premium Program

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

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

---

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

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

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

D. The Proposed Arrangement

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

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

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

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

II. LEGAL ANALYSIS

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

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

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

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

A. Donations By The Companies Do Not Constitute

---

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

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

Remuneration To An Eligible Beneficiary

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

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

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

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

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

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

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

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

III. LIMITATIONS

The limitations applicable to this opinion include the following:

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

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

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

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

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

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

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

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

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

Sincerely,

/S/

D. McCarty Thornton
Chief Counsel to the Inspector General

EXHIBIT 4

blue of california

August 29, 2016

Subject: **Notification of November 7, 2016 Updates to the Blue Shield *Hospital and Facility Guidelines***

Dear Provider:

We have revised our *Hospital and Facility Guidelines*. The changes listed on the following pages are effective November 7, 2016.

On that date, you can search and download the revised manual on Provider Connection at www.blueshieldca.com/provider in the *Provider Manuals* section under the *Guidelines & Resources* tab.

The *Hospital and Facility Guidelines* is referenced in the agreement between Blue Shield of California (Blue Shield) and the hospitals and other facilities contracted with Blue Shield. If a conflict arises between the *Hospital and Facility Guidelines* and the agreement held by the hospital or other facility and Blue Shield, the agreement prevails.

If you have any questions regarding this notice about the revisions that will be published in the November 7, 2016 version of this manual, please contact your Blue Shield Provider Relations Coordinator.

Sincerely,

Network Management
Blue Shield of California

UPDATES TO THE *HOSPITAL AND FACILITY GUIDELINES*

Section 1: Introduction

ENROLLMENT AND ELIGIBILITY

Added *the following new section regarding member premium payments:*

Premium Payment Policy

The member is responsible for payment of premiums to Blue Shield. Blue Shield does not accept direct or indirect payments of premiums from any person or entity other than the member, his or her family members or a legal guardian, or an acceptable third party payor, which are:

- Ryan White HIV/AIDS programs under Title XXVI of the Public Health Services Act;
- Indian tribes, tribal organizations or urban Indian organizations;
- A lawful local, State, or Federal government program, including a grantee directed by a government program to make payments on its behalf; and
- Bona fide charitable organizations and organizations related to the member (*e.g.*, church or employer) when all of the following criteria are met: payment of premiums is guaranteed for the entire plan year; assistance is provided based on defined financial status criteria and health status is not considered; the organization is unaffiliated with a healthcare provider; and the organization has no financial interest in the payment of a health plan claim. (Financially interested institutions/organizations include institutions/organizations that receive the majority of their funding from entities with a financial interest in the payment of health insurance claims, or institutions/organizations that are subject to direct or indirect control of entities with a financial interest in the payment of health insurance claims.)

Upon discovery that premiums were paid directly or indirectly by a person or entity other than the member or an acceptable third party payor, Blue Shield has the right to reject the payment and inform the member that the payment was not accepted and that the premiums remain due. Payment of member premiums by a Blue Shield contracted provider represents a material breach of the provider's agreement. Please note that processing any payment does not waive Blue Shield's right to reject that payment and future payments under this policy.

EXHIBIT 5

*Insurers block Obamacare coverage *** Move affects poor HIV/AIDS patients*

The Advocate (Baton Rouge, Louisiana)

February 13, 2014 Thursday, Main Edition

Section: B; Pg. 08

Length: 1035 words

Byline: TED GRIGGS

tgriggs@theadvocate.com

Body

Close to 2,000 poor Louisiana residents with HIV/AIDS won't be able to buy coverage under Obamacare because three of the four companies in the state offering coverage through the federal insurance exchange won't accept payments from a federal program that helps those patients pay their premiums.

The fourth company, Humana, accepts third-party payments from state and federal programs or grantees such as the Ryan White HIV/AIDS Program, spokesman Mitchell Lubitz said. However, Humana's offerings through the Obamacare marketplace are only available in Orleans Parish.

Scott Schoettes, HIV project director at Lambda Legal, said the insurance companies' actions completely defeat the purpose of the Affordable Care Act.

Schoettes said it's not surprising that other insurers respond when Blue Cross and Blue Shield of Louisiana, the state's largest insurer, skews the market by denying coverage to people the company knows have significant health needs. The other insurers will take whatever actions they can to avoid having those patients pushed onto their rolls, he said.

In the business, enrolling a disproportionately high percentage of high-cost individuals is known as "adverse selection."

Billy Justice, a spokesman for Vantage Health Plan in Monroe, said smaller health insurance companies have no choice but to follow Blue Cross's lead.

Eric Evans, advocacy coordinator at Shreveport's Philadelphia Center, said the Louisiana Health Cooperative has already informed some center clients the co-op will not accept third-party payments.

Officials with the cooperative could not be reached for comment.

Blue Cross spokesman John Maginnis said beginning March 1, the company will not accept third-party payments for individual members' premiums.

Blue Cross covers 1.4 million people in Louisiana, the vast majority through group policies. Only 139,000 are covered by individual policies.

Third-party payment recipients are a very small percentage of the company's individual policies, which are a very small percentage of the company's total business, Maginnis said.

"We realize that some organizations have directly paid premiums for members in the past .... Those organizations can still provide the members with financial support toward their premiums, but they must let the members make the premium payments directly for their health insurance policies," Maginnis said.

For example, the groups that now make the third-party payments could make grants to their clients, who could then use that money to pay health care premiums, he said.

The federal Health Resources and Services Administration, which oversees the Ryan White program, does not allow states, cities and nonprofits who receive funding to make payments to individuals.

"In no case may Ryan White HIV/AIDS Program funds be used to make direct payments of cash to recipients of services," the agency website says.

Maginnis said Blue Cross, which is the only insurer fully participating in the federal marketplace with plans at every level in every parish, developed the policy to prevent patient steering and other fraudulent activity.

Some providers and medical equipment suppliers will steer people to specific health plans and offer to pay the premiums so they can make more money by billing the insurance company for those patients' covered services, Maginnis said. This kind of activity can increase health care costs for everyone.

The insurer's policy affects more people than those receiving Ryan White funding, he said. Some Louisiana universities pay for student athletes' premiums.

LSU spokesman Michael Bonnete said Blue Cross's policy change does not affect LSU athletics.

According to the state Department of Health and Hospitals, as of Jan. 7, Louisiana used Ryan White funds to pay the insurance premiums for 1,355 people. An additional 493 were enrolled in the federally run Pre-Existing Condition Insurance Plan, which will stop offering coverage on March 31.

In addition, 329 individuals attempted to enroll in Blue Cross's Blue Plan with the intention of covering the premiums with Ryan White funds, according to DHH.

Schoettes said it's increasingly clear that Blue Cross is trying to avoid covering these high-cost patients.

The company made noises about preventing fraud or abuse, but CMS's most recent instructions make it clear third-party payments coming from the federal government are acceptable, he said.

Evans said the issue is much larger than rejecting third-party payments.

"This is them saying, 'We really don't want to insure people with HIV because there's no profit in it,'" Evans said.

The prescriptions for an HIV patient can cost $5,000 or $10,000 a month, Evans said. Those costs far outweigh the premiums patients pay, but insurance companies have known about this for decades.

America's Health Insurance Plans recently issued a brief noting: "The ACA's risk adjustment program is designed to spread risk among health plans to prevent problems associated with adverse selection. Under this program, health plans that enroll disproportionately higher risk populations (such as individuals with chronic conditions) will receive payments from plans that enroll lower risk populations."

People forget that the first two words in the Affordable Care Act's full title are "Patient Protection," Evans said. The law was designed to stop insurance companies from discriminating against people with pre-existing conditions.

Schoettes said Lambda is considering amending its complaint to include the other insurers who reject third-party payments.

The nonprofit group may also file a lawsuit, among other steps, if the complaint doesn't achieve the desired result, he said. Lambda hasn't set a deadline to file the lawsuit.

"Sooner rather than later because every day that goes by is another day where low-income people living with HIV don't know where to turn and don't know where they're going to get their insurance," Schoettes said.

Evans said the scary thing is that the full impact of Blue Cross's decision won't be seen until after March 1, just weeks before the Affordable Care Act open enrollment deadline of March 31.

"Then what are these people going to do for the next year?" Evans said. "It's very frustrating and very angering."

Classification

Language: ENGLISH

Publication-Type: Newspaper

Subject: AIDS & HIV (90%); AIDS & HIV POLICY (89%); ASSOCIATIONS & ORGANIZATIONS (89%); OBAMA HEALTH CARE REFORM (78%); NONPROFIT ORGANIZATIONS (78%)

Company: ANTHEM BLUE CROSS & BLUE SHIELD OF OHIO (83%)

Industry: INSURANCE (92%); HEALTH INSURANCE (90%); HEALTH INSURANCE MARKETPLACE (90%); INSURANCE POLICIES (89%); AIDS & HIV POLICY (89%); INSURANCE PREMIUMS (89%); OBAMA HEALTH CARE REFORM (78%); GOVERNMENT HEALTH INSURANCE (77%); HEALTH CARE (77%); DENIAL OF INSURANCE COVERAGE (72%)

Geographic: SHREVEPORT, LA, USA (79%); LOUISIANA, USA (94%)

Load-Date: February 26, 2014

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS, *et al*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No._____
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al.*	)	
	)	
Defendants.	)	

DECLARATION OF WILLIAM J. VALLE

1. I, William J. Valle, respectfully submit this declaration in support of Plaintiffs' Emergency Motion for a Temporary Restraining Order and Preliminary Injunction. I have personal knowledge of the facts set forth in this declaration based on my experience with FMCNA and my almost 30-years of experience in the dialysis industry generally.

2. I am an Executive Vice President of Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, a plaintiff in the above-captioned case. I am also President of Fresenius Kidney Care ("FKC"), the largest division of Fresenius Medical Care North America, which provides dialysis treatment and services to patients at facilities that Fresenius Medical Care North America's subsidiaries or affiliates own, operate, or for which they provide administrative services. Herein, I will collectively refer to Fresenius Medical Care North America and its subsidiaries and affiliates as FMCNA.

A. FRESENIUS MEDICAL CARE NORTH AMERICA

3. FMCNA is a corporation in good standing organized under the laws of the State of New York with its principal place of business located at 920 Winter Street, Waltham, Massachusetts 02451.

4. FMCNA is a premier health care company focused on delivering the highest quality care to people with renal and other chronic conditions.

5. Since its formation, FMCNA has grown into the largest vertically integrated dialysis provider in North America with more than 67,000 employees who are dedicated to the mission of delivering superior care that improves the quality of life for people with kidney disease, including end-stage renal disease ("ESRD"), better known as kidney failure.

6. In my capacity as EVP of FMCNA and President of FKC, I am responsible for the management of FMCNA's 2,381 in-center (outpatient) dialysis facilities, 410 inpatient dialysis programs, and 992 home therapies dialysis programs located in 48 states (including Texas), the District of Columbia, and Puerto Rico. FMCNA has a significant presence in underserved areas, with, based on CMS' data, more than 400 in-center dialysis facilities more than 10 miles from the nearest alternative and approximately 200 in-center facilities more than 20 miles from the nearest alternative.

7. Among its various operations, within the Eastern District of Texas, FMCNA owns, operates, or provides administrative services for 21 in-center dialysis facilities in the cities of Allen, Athens, Carthage, Center, Crockett, Frisco, Gilmer, Jacksonville, Lewisville, Liberty, McKinney, Mineola, Palestine, Paris, Plano, Sulphur Springs and Tyler. Within the Sherman division alone, FMCNA owns, operates, or provides administrative services for 7 in-center dialysis facilities in Allen, McKinney, Paris, Plano and Sulphur Springs.

8. FMCNA provides dialysis treatment and services to approximately 183,300 patients with ESRD across the country. Of those, approximately 1,600 ESRD patients receive dialysis treatment at FMCNA facilities in the Eastern District of Texas.

B. FMCNA IS REGULATED BY HHS AND CMS

9. FMCNA is regulated at both the state and federal level. As a participant in the Medicare and Medicaid program, FMCNA's dialysis facilities are subject to rules and regulations promulgated by the Department of Health and Human Services ("HHS") and they must comply with these rules and regulations in order to receive Medicare and Medicaid funds.

10. Within HHS, the Centers for Medicare & Medicaid Services ("CMS") is responsible for Medicare and Medicaid related rulemaking. CMS conducts regulation and enforcement activities to ensure that dialysis facilities comply with applicable standards for patient health and safety, and quality of care. It also administers a survey and certification program, through a joint effort of the federal and state governments. At the federal level, CMS establishes standards and regulations for the safe and effective operations of dialysis facilities, known as Conditions for Coverage, it develops guidelines and procedures for the operation of dialysis facilities, it provides training for conducting surveys, and it coordinates the survey activities of individual states.

11. Surveys are conducted prior to a dialysis facility's initial enrollment in Medicare and at periodic intervals to recertify the dialysis facility's compliance with the Conditions for Coverage, the timing of which depends on the particular state. Most states survey dialysis facilities for recertification at least once every three years, but some states resurvey as often as annually. Surveys also may occur in response to complaints or in connection with expansion, changes in location or ownership, or changes in services.

12. During a survey, surveyors cite any deficiencies identified, which must be corrected by the facility. Deficiencies may result in the facility's termination from Medicare coverage.

13. Providers are also subject to a variety of state rules and regulations promulgated by

state licensing boards, public agencies, and Medicaid administrators.

C. FMCNA'S PATIENTS AND THE DIALYSIS TREATMENT THEY RECEIVE

14. Nearly all of the more than 183,000 patients treated by FMCNA suffer from ESRD, which is the last stage of chronic kidney disease and is an irreversible medical condition.

15. The kidneys of individuals with ESRD are no longer able to filter and clean blood, and therefore, in order to survive, these individuals must receive ongoing dialysis or a kidney transplant. Dialysis is the process of artificially cleaning the blood by removing toxins, as well as harmful waste, extra salt, and fluids. FMCNA provides dialysis to its patients at its outpatient facilities, at home once a patient is properly trained on how to perform the process, or at inpatient acute facilities.

D. HEALTH INSURANCE OPTIONS AVAILABLE TO ESRD PATIENTS

16. ESRD patients have a variety of health insurance options available to them, ranging from private insurance offered by an employer or purchased individually, to whole or partial public coverage through Medicare, Medicaid, and similar programs. The options vary on the basis of state of residence, age, and financial status.

17. Although Medicare Coverage typically is available only to individuals who are 65 and older, Congress created a separate eligibility category for patients with ESRD, regardless of age, who have earned a certain level of eligibility for Social Security benefits.

18. ESRD patients also may be eligible for coverage under the Medicaid program, a joint federal-state program providing coverage to certain low-income persons, including disabled and other vulnerable populations. Unlike Medicare, there is no separate eligibility category for ESRD patients in Medicaid. While the Affordable Care Act created a new adult Medicaid eligibility category based solely on income, which has become an important vehicle for coverage

for many ESRD patients, many states, including Texas, have chosen not to expand their Medicaid programs to cover this group.

19. The vast majority (90%) of FMCNA's dialysis patients are insured by Medicare or Medicaid, either as primary or secondary coverage.

i. The Affordable Care Act Expanded ESRD Patient Choice

20. The Affordable Care Act (ACA) provided many ESRD patients with a new choice for their health insurance needs. Under the ACA, a dialysis patient now may enroll in an approved Qualified Health Plan ("QHP") from a new competitive health insurance marketplace, called the Exchange or the Marketplace, if the patient: (1) is a citizen or lawfully present in the United States; (2) is not incarcerated; and (3) meets the applicable residency standards.

21. The Affordable Care Act also expanded opportunities for patients with ESRD to obtain individual coverage outside the Marketplace by prohibiting insurers from discriminating against those with preexisting conditions, whether by denying coverage, charging different cost sharing amounts, limiting benefits, or other means.

22. When I use the term "individual coverage" or "individual plan," I am referring to plans purchased by individuals in or outside the Marketplace that are part of the same risk pool.

E. FMCNA ENABLES PATIENTS TO MAKE THEIR OWN CHOICE ABOUT THEIR INSURANCE COVERAGE

23. CMS rules and regulations, including the Conditions for Coverage for End Stage Renal Disease Facilities, set forth an array of requirements for dialysis facilities, including substantial obligations to provide holistic counseling services designed to treat the whole patient, and not merely the patient's ESRD.

24. Consistent with these rules and regulations, FMCNA's dialysis facilities have an "interdisciplinary team" to undertake "comprehensive assessment" of patient needs, including

"psychosocial needs," "evaluation of the patient's abilities, interests, preferences, and goals," and "evaluation of family and other support systems." This assessment informs an "individualized comprehensive plan of care that specifies the services necessary to address the patient's needs," including monitoring "psychosocial status" and providing "necessary monitoring and social work interventions to assist the patient in achieving and sustaining an appropriate psychosocial status."

25. FMCNA's dialysis facilities are staffed with not only nurses and other clinical personnel that provide patients with their dialysis treatment, but also social workers and dietitians all of whom are part of the interdisciplinary team that meets with and works with patients in an effort to support them and monitor their progress.

26. Social workers at FMCNA's dialysis facilities provide psychosocial services to both in-center and home dialysis patients and work with the health care team to promote positive adjustment, rehabilitation, and improved quality of life for FMCNA's patients. In collaboration with the interdisciplinary team, the social workers inform, educate, and support the staff in understanding the emotional, psychological and behavioral impact on the patient and family to ensure comprehensive quality care. They are charged with helping patients understand their rights, responsibilities, and the grievance procedure available to them at the center. In addition, FMCNA social workers are involved in educating patients about their disease and providing supportive and goal directed counseling to patients in connection with their treatment plan, treatment goals, building a support network, and identifying community resources for those patients who are seeking transplants.

27. In collaboration with the social workers, financial coordinators assist patients with the financial components of their care, which includes educating patients on their insurance

choices and helping them interact with insurers and potential insurers and apply for Medicare or Medicaid as the interpretive guidance to the Conditions for Coverage require.

28. There are benefits and drawbacks associated with all forms of coverage, each with its own scope of coverage, out-of-pocket costs, network of providers, and rules for eligibility, enrollment, and coordination with other benefits. No single form of coverage is best for all ESRD patients, because each patient has unique health, financial, and personal circumstances. I understand that ESRD patients, who are chronically disabled, also may need to switch to a new form of coverage from time to time as their individual circumstances change. Financial coordinators and social workers provide patients with comprehensive and accurate information so that they can make an informed choice about the insurance option that best meets their individualized needs.

29. FMCNA supports a patient's right to choose the insurance that best meets his or her individualized needs and, therefore, consistent with its requirements under the Conditions for Coverage, FMCNA does not direct patients towards any particular insurance option or plan.

30. In my role with the Company, I am aware that patients treated at FMCNA dialysis facilities have expressed a variety of reasons for choosing individual coverage, either inside or outside the Marketplace, over governmental coverage options, including but not limited to:

a. The patient may not be eligible for Medicare or Medicaid. For example, the patient may not have earned the required number of work credits, or may not satisfy the citizenship requirement. For a patient who is completely ineligible for government programs, the individual plan is the only insurance available to him/her;

b. The patient's estimated out-of-pocket costs are lower under an individual plan than under other available coverage, including Medicare. This may occur because unlike Medicare, Marketplace coverage has a cap on out-of-pocket spending. Individual coverage also may be preferred in the many states in which Medigap supplemental plans are unavailable to ESRD patients under age 65.

c. The patient has family members covered under existing coverage such that, if coverage is dropped in favor of Medicare coverage for ESRD, their family members would not have coverage unless they then access the Marketplaces as individuals, in which case total out-of-pocket costs may be higher;

d. The individual plan offers better benefits than other options.

   i. For instance, an individual plan may offer a travel/housing benefit for a transplant donor as well as for the patient, and the patient may want to keep individual market coverage until he/she rules out that a potential family member would need to travel a long distance to take part in a transplant;

   ii. The individual plan may also offer better prescription drug benefits than government insurance. Most Medicare drug plans have a coverage gap, and require beneficiaries to pay a large percentage of the cost of prescription drugs. This situation, colloquially called a "donut hole", has led patients to ration their medications, resulting in unnecessary hospitalizations and increased costs for the entire health care system. For an ESRD patient who takes multiple prescriptions, which is common for patients with this diagnosis, an individual plan may offer better drug coverage at a lower cost. Dialysis patients take an average of 11-12 medications with 17-25 doses per day; and

   iii. The patient may want to continue to benefit from case management programs in his/her individual plan that are not available with Medicare or Medicaid;

e. Individual plans may be preferred to Medicaid because they typically have a larger network of providers, which improves access to the many specialists ESRD patients often require.

31. If forced to switch from an individual plan to another form of coverage, it is my understanding that patients could be locked into less desirable coverage for a period of time, or even permanently. Some individuals forced to enroll in Medicare, for example, would face significant penalties if they later sought to re-enroll in an individual plan, as disenrollment from Medicare may require repayment of all costs covered by Medicare, payment of any outstanding Medicare balances, and repayment of retiree benefits received from Social Security or Railroad

Retirement. And enrollment periods for individual plans are limited, meaning that an individual could not reapply for a Marketplace plan after January 31, 2017 until November 1, 2017, and coverage would not begin until January 1, 2018.

32. Those patients who are not eligible for Medicare or Medicaid because they are in the three-month waiting period, lack sufficient work credits to qualify, or fail to satisfy citizenship requirements, are in an even worse position. Absent access to an individual market plan, it is my understanding that these individuals would be uninsured and left with the option to forego life-saving treatment or face incurring total financial liability for their treatment.

F. FMCNA'S CHARITABLE SUPPORT OF THE AMERICAN KIDNEY FUND

33. It is my understanding that many ESRD patients find themselves unable to pay for insurance premiums on their own due to their financial situation. In an effort to assist such patients and ensure that they have access to the medical services they need and one less thing to worry about, charitable organizations such as the American Kidney Fund ("AKF") have developed charitable programs to provide premium support.

34. Specifically, the AKF's Health Insurance Premium Program ("HIPP"), which began decades ago, provides assistance to financially-needy ESRD patients to cover the costs for health insurance premiums under Medicaid (where states require premiums), Medicare Part B, Medigap, individual plans, employer group plans, and COBRA. I understand that the AKF's policies require that assistance is provided on a first-come, first-served basis, based on financial need, regardless of the patient's selection of provider or type of health insurance coverage.

35. In 1997, AKF along with a number of unnamed providers sought guidance from the Office of Inspector General ("OIG") with respect to the structure and operation of HIPP. In response, OIG issued Advisory Opinion 97-1 ("AO 97-1"), which lays out the requirements for

ensuring compliance with a federal law prohibiting improper remuneration to patients. A true and accurate copy of AO 97-1 is attached hereto as Exhibit 1.

36. FMCNA carefully adheres to the parameters delineated in AO 97-1.

37. Since that time, FMCNA has made charitable contributions to AKF. In accordance with AO 97-1, FMCNA does not participate in the AKF's decisions to award patient grants. The donations that FMCNA has provided to the AKF were provided without any restriction or conditions on how the AKF awards grants. The insurance coverage that is purchased with AKF's premium assistance covers all of the patient's medical services not just dialysis services. As I state herein, industry research shows that the vast majority of dialysis patients suffer from co-morbid conditions, many of which require the patient to be treated by medical specialist. As a result, the majority of the insurance benefits purchased with premium assistance are used to pay for services other than dialysis.

38. Approximately 75% of FMCNA patients receiving premium support from HIPP use their grants to pay for government-program related health insurance coverage (including Medicare, Medigap, and Medicare Advantage).

G. THE INTERIM FINAL RULE AND RELATED CMS POLICY

39. CMS first addressed "[t]hird [p]arty [p]ayments of [p]remiums for [q]ualified [h]ealth [p]lans in the Marketplace" by "hospitals, other healthcare providers, and other commercial entities" in a half page "Q&A" document posted to its website on November 4, 2013 (the "November 2013 Q&A"). In issuing the November 2013 Q&A, the only harm CMS identified was that such third-party assistance "could skew the insurance risk pool and create an unlevel field in the Marketplaces."

40. Shortly thereafter, on February 7, 2014, CMS released a second Q&A on its website

(the "February 2014 Q&A"), indicating that its November 2013 Q&A did "not apply" to certain forms of premium assistance, including payments made "from private, not-for-profit foundations . . . (b) if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status. In situation (b), CMS would expect that premium and any cost sharing payments cover the entire policy year."

41. Over two years later, on August 23, 2016, CMS issued a Request for Information (the "RFI") seeking "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." The RFI did not identify any specific policies that CMS was considering at the time; rather, it asked for comments on a series of questions, and outlined broad authorities that CMS might have to regulate in this area.

42. On the same date as the RFI, FMCNA received a letter from CMS describing the RFI and stating, "We believe this RFI would be of particular interest to you," without any explanation of why the dialysis industry and its vulnerable patients were being targeted. A true and accurate copy of this letter is attached hereto as Exhibit 2.

43. FMCNA submitted a thirty page response to the RFI, a true and accurate copy of which is attached hereto as Exhibit 3.

44. Without issuing a Notice of Proposed Rulemaking, on December 12, 2016, three days prior to the end of open enrollment in the Marketplace for coverage effective January 1, 2017, CMS issued an interim final rule published in the Federal Register on December 14, 2016 (the "IFR"), which addresses premium assistance only with respect to dialysis facilities. The IFR adds requirements to the Conditions for Coverage for ESRD facilities.

45. Based upon my reading of the IFR, dialysis facilities supporting premium assistance for "individual market health plans," whether directly or through a third party—including any bona fide, independent charitable organization like the AKF— are required to (1) provide patients with a wide range of information related to "all available coverage options;" and (2) disclose premium assistance to the applicable issuer for "each policy" and obtain assurances that the issuer will accept the payments for the duration of the plan year.

46. It is my understanding that the IFR is a CMS regulation that will govern the dialysis facilities that FMCNA owns, operates, or for which it provides administrative services.

47. CMS issued the IFR with an effective date 30 days from the date of publication in the Federal Register, or January 13, 2017, seven days prior to the change in administrations.

48. On December 16, 2016, CMS issued a Notice of the IFR to State Survey Agency Directors (the "CMS Letter to State Survey Agency Directors") with an immediate effective date, instructing that the answer "No" to any of a series of questions about disclosures to patients and insurers related to coverage and premium assistance "would indicate non-compliance" with the Conditions of Coverage. A true and accurate copy of that letter is attached hereto as Exhibit 4.

H. THE IFR WILL RESULT IN IRREPARABLE HARM TO FMCNA AND ITS PATIENTS

49. In addition to each of the statements above, I am familiar with the harms that FMCNA and the dialysis patients that its dialysis facilities treat will suffer as a result of the IFR.

i. FMCNA Will Suffer Irreparable Harm As A Result Of The IFR

a. Significant Challenge and Cost Of Compliance

50. In accordance with existing requirements under the Conditions for Coverage discussed above, FMCNA counsels patients as to the financial and insurance aspects of their care.

51. From my reading of the IFR, FMCNA would be required to compile and make available to both new and existing patients a substantial volume of coverage information beyond the information currently required under the Conditions for Coverage. This may include:

a. Current information about all available health coverage options, including but not limited to Medicare, Medicaid, Children's Health Insurance Coverage, and individual market plans, with annual updates;

b. Current and anticipated costs associated with each health plan option including covered services, care providers, drug coverage, co-pays co-insurance, deductibles, and enrollment periods;

c. Transplant-related coverage limitations;

d. Risk for loss of coverage and possible penalties; and

e. Current information about financial assistance offered by the facility (or its parent) directly or indirectly to support enrollment in an individual market health plan, including overall contributions to date.

This level of detailed disclosure is unprecedented. To my knowledge, no other provider type is required to disclose information of this sort to patients. The staffing resources required to provide the expanded and detailed information to patients will increase substantially. We will expend significant resources compiling and updating this information, and it is doubtful that we will be able to assemble complete information from insurers who will be reluctant or uncooperative in answering questions. Providing the above listed information will require designated staff members at each facility to review this information with each patient and answer questions or concerns of the patient in the context of the patient's individualized plan of care. This activity alone will take a significant number of additional manpower hours to complete, in addition to the significant number of hours needed by our employees to analyze and understand the information and complete training on the process. Moreover, it is unclear at this time whether it will result in facilities having to hire additional employees, perhaps some with greater insurance expertise, in order to meet this requirement.

52. In my experience, gathering and analyzing this type of information is an incredibly time-intensive process. Each coverage option and coverage type has its own complex rules for benefits, coverage, enrollment, and termination. Coverage options vary widely from state to state and even from locality to locality. Taking Medicaid as an example, each state's Medicaid program is unique, as federal rules were designed to give states significant flexibility to tailor Medicaid to their particular needs. The eligibility categories through which ESRD patients may qualify for Medicaid are different in each state. Patients may be required to enroll in Medicaid managed care in some states, or in some localities, while in others patients are enrolled in traditional fee-for-service Medicaid. And there are multiple legal authorities in each state that must be reviewed to accurately assess Medicaid coverage options, which may include Medicaid State Plans, Medicaid waivers, state regulations, and state informal guidelines. In some instances, accessing sources needed to confirm Medicaid coverage information will be difficult.

53. Adding to the complexity of gathering the required information, and thus the time involved in doing so, some states maintain their State Plans online while others do not. The CMS website does not contain full copies of State Plans, only amendments to individual sections of the State Plans.

54. Medicaid is one of only many coverage options that FMCNA must assess. The terms of coverage for each individual plan are dictated by the issuers' contract for that plan, requiring an individualized assessment of each plan. Issuers themselves are better positioned to provide the level of detail that CMS is now asking dialysis providers to disclose to patients, given that out-of-pocket costs are not fully known until claims have been adjudicated, a lengthy and complex process.

55. For FMCNA, with facilities in 48 states, the District of Columbia and Puerto Rico, 30 days to conduct a state-by-state, much less locality-specific, survey of these coverage options is wholly inadequate.

56. From my understanding, the coverage information that must be disclosed to patients under the IFR is not limited to the treatment of ESRD. It also appears to include information related to patients' other medical conditions. Many if not most ESRD patients experience medical conditions in addition to renal disease. For example, 50% of patients beginning dialysis have diabetes and up to 75% have peripheral vascular disease; left ventricular hypertrophy is present in 75-80% of ESRD patients. Cardiovascular disease accounts for almost 50% of deaths among the ESRD patient population. As a dialysis provider, FMCNA facilities do not have ready access to cost and other data related to medical conditions other than ESRD. For instance, Medicaid managed care rates are dictated by the terms of insurers' contracts with individual providers and are not publicly available. FMCNA facilities do not have access to Medicaid managed care rates other than those in their own contracts.

57. This is a significant amount of information that our employees will need to digest and understand. As such, we will likely need to provide them with training, which may well require several sessions. The 30 days for compliance makes it unreasonable and impossible to complete this task as the training cannot occur until the gathering and analysis of the information has been completed.

58. In order to compile all of the information required by the IFR in the short time provided, FMCNA has engaged the assistance of an outside law firm because it did not believe it could meet the demand with the use of current employees alone, especially when the bulk of the time occurred during the holiday season.

59. As a result, FMCNA is already incurring compliance costs, and they will only increase when the IFR becomes effective. I understand that FMCNA will likely be unable to recover these costs even if it prevails in this litigation, and I am aware of no other way that FMCNA can be reimbursed for these expenses.

b. The IFR's Lack of Clarity

60. In addition to the significant costs associated with compliance, the IFR's vague language also poses significant challenges to compliance. Since publication of the IFR, FMCNA has taken immediate steps in its best efforts to implement the new Conditions for Coverage in the unusually compressed 30-day timeframe required.

61. The IFR indicates that it "implements new requirements for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans." However, nowhere in the IFR is the key term around which the regulation revolves, "individual market health plans", defined. CMS's past issuances on premium assistance, including the November 2013 Q&A and the February 2014 Q&A have been limited to the Marketplace and QHPs. But already, FMCNA is aware of one insurer that is interpreting the term "individual market health plans" more broadly. FMCNA received a letter from Blue Cross Blue Shield of Minnesota ("BCBSMN") indicating that BCBSMN's policy, which BCBSMN deems "consistent with the IFR" prevents third party premium assistance for "fully-insured commercial lines of business, including individual/family plans and group plans". A true and accurate copy of BCBSMN's December 27, 2016 letter is attached hereto as Exhibit 5.

62. In light of CMS's failure to define "individual market health plan," I expect there will be disagreement among patients, providers and insurers as to which plans fall under this definition, and there are likely to be disputes between various parties as insurers seek to make the definition as expansive as possible.

c. Noncompliance Will Likely Result In Enforcement Actions and Termination Of Medicare Coverage

63. Since publication of the IFR, FMCNA has been making best efforts to try to ensure it is poised to comply with the IFR upon its effective date of January 13, 2014.

64. However, given all that I understand needs be done in such a short period of time, FMCNA cannot be sure that its facilities can comply with all of the requirements of the IFR by January 13, 2017. As a result, if the IFR becomes effective and FMCNA's facilities are found to be in violation of it, FMCNA and its facilities face significant consequences, including, as discussed below, possible termination because the IFR's requirements are a Condition for Coverage.

65. In addition, even absent the tremendous time constraints, the IFR's significant deficiencies, vague language and confusing nature as described herein, render compliance with the IFR exceedingly difficult, if not impossible. FMCNA is undertaking its best efforts to understand and implement the IFR to the best of its abilities, but given that the surveyors charged with ensuring compliance will be relying upon their own interpretation of a vague and confusing rule, there is a high likelihood that in some instances facilities will be found to be non-compliant.

66. My concern of termination of Medicare coverage is real. On December 16, 2016, CMS issued the CMS Letter to State Survey Agency Directors (attached hereto as Exhibit 4) stating that, effective immediately, as part of their surveys, the state surveyors much check for compliance with the IFR.

67. It is my understanding that the letter demonstrates that CMS intends to begin enforcement actions against dialysis providers once the IFR takes effect on January 13, 2017. In fact, on January 3, 2017, a FMCNA facility received an inquiry from the Michigan Department of

Health and Human Services regarding compliance with the IFR, which is not yet even effective, with respect to a survey that was already underway at that facility.

68. Non-compliance as a means to challenge the IFR – and the resulting risk of termination – is not a valid option for FMCNA's dialysis facilities. Doing so would put FMCNA's dialysis facilities at risk because noncompliance with the Conditions for Coverage can lead to termination of Medicare certification.

69. Most of FMCNA's patients have Medicare as their primary form of health care coverage. If FMCNA's facilities were terminated from the Medicare program, those facilities would lose a significant amount of their revenue. It is not hard to imagine that such a loss would result in, at minimum, FMCNA having to close facilities and potentially lay off employees. Some of FMCNA's facilities already operate at a break-even or even less than break-even state. If these facilities lost their revenue from Medicare, it would be exceedingly difficult to continue to operate them.

d. Certain IFR Requirements Directly Conflict with AO 97-1

70. Based on my reading of the IFR, compliance with the IFR subjects FMCNA's dialysis facilities to other enforcement penalties.

71. If insurers do not provide the requisite assurances, the IFR states that the dialysis provider shall "take reasonable steps" to ensure that its contributions are not used by AKF to support premium assistance for patients whose insurers in the individual market have denied assurances.

72. It is my understanding, however, that under AO 97-1 FMCNA is prohibited from interfering with AKF's decisions to award patient grants. As a result, it is my understanding that FMCNA would risk substantial civil monetary penalties under AO 97-1 if it chooses to so interfere.

73. It is also my understanding that the IFR directly conflicts with AO 97-1 in another respect. The IFR requires providers to disclose to patients "current information about the facility's . . . contributions to patients or third parties that subsidize the individual's enrollment in individual market health plans." Yet, under my reading of AO 97-1, FMCNA must "not disclose directly or indirectly to individual patients they refer [to AKF] that such [providers] have contributed to AKF to fund [premium assistance] grants." (emphasis added).

74. Yet again, FMCNA is left with an untenable choice—violate the IFR and risk termination of its facilities from the Medicare program or deviate from AO 97-1 and risk civil monetary penalties.

ii. FMCNA'S Patients Will Lose Access To Life-Sustaining Dialysis Care As A Result Of The IFR

75. In addition to the harm that will be caused to FMCNA, I expect that the IFR's requirements will cause harm to dialysis patients because of the IFR's requirement that dialysis providers obtain assurance from insurers that they will accept premium payments for patients whose premiums are paid by a charity.

76. My reading of the IFR is that FMCNA will now need to collect assurances from, several, if not all of, the insurers in each of the 48 states and territories where it owns, operates, or provides administrative services for facilities, which is not only an arduous process, but a process in which FMCNA has no control over its ability to obtain a response from the insurer in a timely manner.

77. If the insurance company declines the request for an assurance, or even fails to reply or replies after the window for the patient to secure the insurance of their choice closes, premium assistance could be prohibited for some patients, resulting in the patient's termination from an individual market plan.

78. A patient's termination may, in certain instances, result in patients having no insurance coverage whatsoever because they do not qualify for Medicare or Medicaid. And for other patients, who choose to switch to Medicare, even though they would have preferred to retain individual coverage, their ability to switch back if the IFR is held invalid has been lost because enrollment periods have closed or there are steep financial penalties. For patients without coverage, their only option for care is to seek care in the emergency room of local hospitals when their situation becomes critical, often commencing a cycle of admissions and discharges that produces poor patient outcomes and strains local hospital resources.

79. Because the IFR's effective date is only 11 business days prior to the close of open enrollment for individual plans, it likely will be impossible as a practical matter for FMCNA to seek and obtain the insurer assurances the IFR requires in time for patients to obtain a premium grant and secure individual coverage.

80. Furthermore, while the IFR requires FMCNA to obtain the assurance, it does not place any requirement on the insurance company to respond to such request. Indeed, there is no incentive for insurers to provide assurances to providers. Additionally, the IFR provides the insurers with protection to deny premium assistance, which will enable them to discriminate in ways the ACA was intended to foreclose.

81. The harm that patients will suffer if they are forced to switch insurance and/or are left with no insurance at all cannot be quantified. As described above, dialysis is a life-saving treatment. If a patient has to go without dialysis for a period of time, even several days to a week, it can result in death.

82. In addition, patients may also suffer irreparable harm in that their access to care may be impacted if the IFR goes into effect. FMCNA reviews the financial viability of each facility

on a facility by facility basis. Due to the fact that the reimbursement rate paid by Medicare or Medicaid typically does not actually cover the cost of the dialysis treatment that patients receive, it is necessary for a facility to have some patients who are covered by commercial insurance. Indeed, it is often the case that just 1 or 2 commercial patients can help keep a facility financially viable. However, if a facility is not performing in a manner that makes it financially viable, it is placed into FMCNA's mitigation program, which works to bring the facility back into financial viability or in some cases results in the facility being closed.

83. Several of the facilities that are owned by FMCNA in the Eastern District of Texas are economically fragile and at particular risk as a result of the IFR. We anticipate that at least two of those facilities, which currently treat approximately 170 patients, are likely to be put into FMCNA's mitigation program. If these facilities were to close, the patients treating at these facilities would be forced to travel between 50-60 miles round trip to obtain their dialysis treatment three times per week. The personal and negative impact to the patients' access to care will be significant. In addition, the IFR will reduce our ability to open new facilities where current access is limited since the capital budgeting process will be impacted negatively by issuer refusals to accept premium assistance. I am also aware that patients without convenient access to care may become less compliant with their treatment plans and suffer sub-optimal clinical outcomes as a result. Logistical difficulties in arranging for transit lead to missed treatments. Missed treatments negatively impact patients' health and can result in increased hospitalizations and emergency room use, which tax local hospital resources and impose costs on the healthcare system due to preventable medical intervention.

84. While FMCNA is committed to continuing to provide services to all of its patients, it is possible that because the IFR will enable insurers to reject premium support for many (or a

significant portion) of our patients with individual marketplace coverage, FMCNA may be forced to consider closing facilities. This will negatively impact patients' access to care and may require many patients to have to travel greater distances to receive their dialysis treatments.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on January 6, 2017.

William J. Valle

EXHIBIT 1

[Names and addresses of Requestors have been redacted]

Re: Advisory Opinion No. 97-1

Dear [Names have been redacted]:

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

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

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

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

I. FACTUAL BACKGROUND

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

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

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

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

B. Parties to the Proposed Arrangement

1. The Companies

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

2. American Kidney Fund

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

---

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

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

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

C. Health Insurance Premium Program

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

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

---

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

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

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

D. The Proposed Arrangement

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

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

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

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

II. LEGAL ANALYSIS

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

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

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

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

A. Donations By The Companies Do Not Constitute

---

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

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

Remuneration To An Eligible Beneficiary

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

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

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

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

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

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

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

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

III. LIMITATIONS

The limitations applicable to this opinion include the following:

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

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

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

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

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

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

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

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

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

Sincerely,

/S/

D. McCarty Thornton
Chief Counsel to the Inspector General

EXHIBIT 2

DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS for MEDICARE & MEDICAID SERVICES
7500 Security Boulevard, Mail Stop AR-18-50
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR PROGRAM INTEGRITY

Center for Program Integrity

DATE

Dear [Medicare-enrolled dialysis facility]:

Today, CMS released a Request for Information (RFI) on inappropriate steering of people eligible for or receiving Medicare and/or Medicaid benefits into an individual market plan. In this RFI, CMS expressed serious concerns about reports of healthcare providers and provider-affiliated organizations steering people eligible for Medicare or Medicaid benefits to an individual market plan for the purpose of obtaining higher payment rates. CMS noted that arrangements driven by providers and provider-affiliated organizations that move people eligible for Medicare and/or Medicaid benefits may harm the individual, may harm the individual market single risk pool, may harm other enrollees in the individual market single risk pool, and potentially raise overall health care costs.

As we explained in the RFI, we believe there is potential for harm when a healthcare provider or provider-affiliated organization steers people eligible for Medicare and/or Medicaid benefits to enroll in an individual market plan for the healthcare provider's financial gain through higher payment rates without taking into account the needs of these individuals. People who are steered away from Medicare and/or Medicaid and to an individual market plan may experience a disruption in the coordination of their care, changes in prescription drug benefits, loss of dental care for certain Medicaid beneficiaries, and changes in the network of providers. Enrollment decisions should be made, without influence, by the consumer and based on their individual circumstances and health and financial needs. Moreover, in the case of an individual actually receiving Medicare and/or Medicaid benefits, as opposed to potentially eligible for such benefits, section 1882(d)(3)(i)(II) of the Social Security prohibits selling such a person insurance coverage knowing that it duplicates such Medicare and/or Medicaid benefits. Under section 1882(d)(3)(A)(ii), this act is punishable by imprisonment of up to five years and/or civil money penalties.

Further, CMS laid out in the RFI a number of options that we are considering with respect to these harms. We are considering revisions to Medicare and Medicaid provider enrollment rules, imposition of civil monetary penalties for individuals that failed to provide correct information to the Exchange when enrolling consumers into individual market plans, and potential regulatory changes that would allow individual market plans to limit their payment to healthcare providers to Medicare-based amounts for particular services and items of care. There may also be ways to use our existing authorities to impose civil monetary penalties on health care providers who induce Medicare eligible individuals to delay/forgo Medicare enrollment if the Medicare eligible individual is later penalized for delayed enrollment. CMS is further exploring the nexus between Medicare and Medicaid statutes and state law tortious interference claims made by individual market plans against providers engaged in this behavior.

CMS is committed to ensuring that the interests of the consumers are put first. We expect our providers to do the same. Individuals should receive health care services from the appropriate program or plan, and individual market risk pools should not be interfered with by inappropriate steering of consumers who otherwise should be receiving care through the Medicare and/or Medicaid programs. We believe this RFI would be of particular interest to you and it may be viewed directly at http://www.archives.gov/federal-register/public-inspection/. For your convenience, we note that comments are due September 22, 2016.

Sincerely,

Shantanu Agrawal, MD
Deputy Administrator for Program Integrity

EXHIBIT 3

September 22, 2016

BY ELECTRONIC SUBMISSION

Attn: Andrew M. Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201
http://www.regulations.gov

Re: U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans, RIN 0938-ZB31 (File Code: CMS-6074-NC) (referred to herein as the RFI)

Dear Mr. Slavitt:

Fresenius Medical Care North America (FMCNA) appreciates the opportunity to respond to CMS' Request for Information (RFI). Our patient populations include 187,000 end-stage renal disease (ESRD) patients, who comprise ~.06% of the general population and ~.33% of the Medicare population. Patients with ESRD are a vulnerable patient population that needs the protections of the Affordable Care Act (ACA) and access to the individual market exchanges (Marketplaces). With the enactment of the ACA, formerly underinsured and uninsured patients like ours are now provided a choice of health insurance coverage options for the first time in history. In 2013, CMS and Internal Revenue Service (IRS) determined that dialysis patients would have the option to enroll in Marketplace plans even if eligible for Medicare or Medicaid coverage. Approximately 1,600 (fewer than 1%) of our patients have opted for Marketplace coverage. We explain below our understanding of the reasons why patients make this choice. For instance, for chronically ill patients who have co-morbidities and a high utilization of healthcare services, they may be able to reduce their personal, annual out-of-pocket costs of care by $8,000 or more by selecting Marketplace coverage rather than Medicare. The reason for this differential is that Marketplace plans offer out-of-pocket caps on deductibles and co-pays, while Medicare coverage does not. Choice of coverage requires complex and individualized analysis, and it simply is not the case that Medicare coverage is always the best choice for the patient.

FMCNA does not engage in steering. Our role is to educate the patient so that the patient can choose coverage options. Our education aims to identify choices that are in the patient's best interest. Under the Conditions for Coverage under which we operate, we are required to provide counseling to patients by (a) "providing information and helping patients apply for Medicare, Medicaid and other insurance

benefits to assure payment for care,"[1] and (b) evaluating "financial capabilities and resources; access to available community resources; and eligibility for federal, state, or local resources".[2] FMCNA discharges these obligations by providing such counseling and education in a manner that is consistent with the best interests of the patients.[3] FMCNA does not steer patients to any particular type of coverage choice. Instead, we help optimize patients' ability to make informed choices through education and counseling.

FMCNA has worked with the American Kidney Fund (AKF) for twenty years to provide our patients with access to the AKF's Health Insurance Premium Program ("HIPP").[4] The AKF is an independent charitable organization that enables dialysis patients to afford the coverage of their choice, based solely on financial need. The AKF provides premium support on a first-come, first-served basis without regard to the patient's selection of provider or type of health insurance coverage, and it funds premium payments according to the patient's choice of coverage, including Medicare Part B, Medigap, Medicare Advantage, employer group health plans, and Marketplace plans. Over 75% of our patients who receive AKF premium grants use those grants to pay for government-program related health insurance coverage (including Medicare, Medigap, and Medicare Advantage). As noted, less than 1% of our patients are on Marketplace plans. Fewer still, approximately 700, or four-tenths of one percent (0.4%) of our patient population, receive AKF premium assistance for their Marketplace plan premiums.

While we do not steer patients to particular health insurance plans, we are aware of insurers who do. We are concerned that insurers are increasingly deploying inappropriate tactics to steer patients away from Marketplaces with the effect of restricting consumer choice and access to care, discriminating against patients in violation of the ADA and other statutes, and creating a backdoor means to impose pre-existing condition exclusions contrary to the goals of the ACA and the Marketplaces. CMS is correct to focus on inappropriate steering, but the steering issue needs to be evaluated from *both* the provider and insurer perspectives.

We would like to work cooperatively with CMS and all industry participants to restore balance and stability throughout the healthcare system by assuring that

---

[1] ESRD Surveyor Training, Interpretive Guidance Final Version I.1 (Oct. 2008), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-certification/guidanceforlawsandregulations/dailysis.html (hereinafter "Interpretive Guidance") (interpreting 42 C.F.R. §494.140(d)).

[2] Interpretive Guidance (interpreting 42 C.F.R. § 494.80(a)(7)).

[3] Under the Conditions for Coverage, dialysis providers are required to recognize the individualized and personal needs, wishes and goals of the patient and to honor the patient's right to be informed about and participate in all aspects of care. *See* 42 C.F.R. § 494.70 and § 494.80 and the interpretive guidance issued thereunder.

[4] The Office of Inspector General reviewed and approved the HIPP program and its safeguards against fraud and abuse in 1997, in OIG Advisory Opinion 97-1.

there are adequate means to address any unscrupulous steering practices and by adopting clear guardrails to allow charities like the AKF to continue to pursue the charitable mission of assuring patient choice and access through premium grants.

I. Dialysis patients face challenging clinical and socioeconomic conditions, and they need and deserve the ability to choose the health insurance options that suits their individual circumstances.

A. Dialysis patients are predominantly disabled, low-income and poorly educated.

An ESRD patient must navigate multiple issues including health coverage, co-payments and co-insurance, interaction with multiple physician specialists, management of multiple co-morbidities and multiple medications,[5] and balancing medical appointments and dialysis treatments with the normal affairs of life. Due to their disability and chronic illness, dialysis patients face serious challenges in balancing these competing needs. Adding to these challenges, this predominately disabled patient population is disproportionately concentrated in disadvantaged communities associated with low-incomes[6] and reduced educational opportunities.[7]

---

[5] The typical patient with ESRD typically takes 7 – 10 medications per month. Jai Radhakrishnan, "The burden of prescription coverage of kidney failure patients in the United States," Kidney International (2006) 69, 1099 – 1100.

[6] The relationship between an individual's socioeconomic characteristics and ESRD diagnosis is well documented. Multiple studies show that low-income status is strongly correlated with a patient's heightened risk of developing ESRD. In one study, low-income individuals, defined as persons earning less than $15,000, were associated with a 50% increased risk of ESRD. *See* Lipworth L., Mumma M.T., Cavanaugh K.L., et al: Incidence and predictors of end-stage renal disease among low-income blacks and whites. PLoS One 2012; 7: pp. e48407. In another, researchers found that "neighborhood poverty was strongly associated with ESRD incidence in both blacks and whites." Volkova, Nataliya et al. "Neighborhood Poverty and Racial Differences in ESRD Incidence." *Journal of the American Society of Nephrology : JASN* 19.2 (2008): 356–364. *PMC*. Web. 6 Sept. 2016.

[7] Research has shown that dialysis patients are widely lacking in "health literacy," which is defined as the "ability to obtain, process, and understand basic health information to make appropriate health decisions about one's health and medical care." *See* Nielsen-Bohlman LT, Panzer AM, Hamlin B, Kindig DA, editors. (Eds.): Health Literacy: A Prescription to End Confusion, Washington DC, Committee on Health Literacy, Board on Neuroscience and Behavioral Health, National Academies Press, 2004. One study concluded that limited health literacy among dialysis patients is associated with a higher risk of death. *See* Cavanaugh, Kerri L. et al. "Low Health Literacy Associates with Increased Mortality in ESRD." *Journal of the American Society of Nephrology : JASN*21.11 (2010): 1979–1985. *PMC*. Web. 13 Sept. 2016. The researchers noted that although print materials are commonly used to educate dialysis patients on their condition, these materials are often written at high reading levels and therefore are potentially ineffective at achieving their purpose. *See id.*

B. The Conditions for Coverage require dialysis providers to assist patients with understanding the financial and insurance aspects of their care.

The Conditions for Coverage[8] applicable to dialysis providers set forth an array of requirements for dialysis facilities, including substantial obligations to provide holistic counseling services designed to treat the whole patient, and not merely the patient's ESRD. For example, dialysis providers must convene an "interdisciplinary team" to undertake "comprehensive assessment" of patient needs, including "psychosocial needs," "evaluation of the patient's abilities, interests, preferences, and goals," and "evaluation of family and other support systems."[9] This assessment informs an "individualized comprehensive plan of care that specifies the services necessary to address the patient's needs," including monitoring "psychosocial status" and providing "necessary monitoring and social work interventions to assist the patient in achieving and sustaining an appropriate psychosocial status."[10] In Appendix H of the State Operations Manual, CMS notes that one obligation of this assessment is for the dialysis facility to "identify community social agencies and other resources and assisting patients and families to utilize them."[11] As discussed more fully below, the American Kidney Fund is one such option.

The interpretive guidance for the Conditions for Coverage further elaborates that dialysis providers must "provide services such as . . . providing information and helping patients apply for Medicare, Medicaid and other insurance benefits to assure payment for care".[12] They must also evaluate "financial capabilities and resources; access to available community resources; and eligibility for federal, state, or local resources[13]," and "make good faith efforts to help the patient resolve nonpayment issues" prior to discharge or transfer for nonpayment of fees[14]. The guiding principle in providing these services is that the provider should act in the best interest of the patient.[15]

Because many dialysis patients do not have strong networks of social, financial and other supports when undertaking treatment, providers like FMCNA

---

[8] 42 C.F.R. § 494 et seq. *See also* 73 Fed. Reg. 20370, Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities, Centers for Medicare and Medicaid Services, April 15, 2008.

[9] 42 C.F.R. § 494.80(a).

[10] 42 C.F.R. § 494.90(a)(6).

[11] State Operations Manual Appendix H, Tags V-447 and 493.

[12] Interpretive Guidance (interpreting 42 C.F.R. §494.140(d)).

[13] Interpretive Guidance (interpreting 42 C.F.R. § 494.80(a)(7)).

[14] Interpretive Guidance (interpreting 42 C.F.R. 494.180(f)(1)).

[15] *See e.g.,* 42 C.F.R. § 494.80.

play a comprehensive role under the Conditions for Coverage requirements in patients' care, including informing patients as to the financial and insurance aspects of that care. FMCNA takes these obligations seriously, and is guided by its core value of putting patients' interests first.

C. Because of the ACA and prior legislative enactments, individuals with ESRD have multiple health coverage options, including both government-sponsored and commercial coverage.

1. Individuals with ESRD who qualify for Medicare have the option to enroll in Medicare or in Marketplace plans, and they may also qualify for premium tax credits under the Marketplace plans.

Although most dialysis patients are eligible for Medicare, dialysis patients are not required to choose Medicare as their only health insurance option.[16] FMCNA strongly supports this position because it enhances patient choice.

Very early in the implementation of the ACA, policymakers considered whether individuals with ESRD could qualify for a Marketplace premium tax credit to purchase a plan on a Marketplace. While individuals generally cannot qualify for premium tax credits for a qualified health plan purchased on a Marketplace if they are "eligible for minimum essential coverage"[17] (such under Medicare),[18] both the Internal Revenue Service and CMS concluded in guidance issued before the ACA took effect that dialysis patients could enroll in Marketplace plans and be eligible for premium tax credits despite their Medicare eligibility. Noting the statutory requirement that individuals with ESRD must "file an application" to be entitled to Medicare and the need to determine the patient's ESRD diagnosis, the IRS concluded in IRS Notice 2013-41 that an individual was only eligible for minimum essential coverage (and therefore ineligible for premium tax credits) when the "responsible agency" had made a determination that the individual has a disability or a particular illness.[19] Because no such determination is made until the individual files an application for Medicare, individuals who might be entitled to Medicare had they applied may opt instead to enroll in a Marketplace plan and claim premium tax credits.

---

[16] *See* 42 U.S.C. §§ 18031(d)(2)(a), 18032(a)(1); 42 U.S.C. § 18032(f); 45 C.F.R. § 147.104; CMS, "Frequently Asked Questions Regarding Medicare and the Marketplace," Questions A.3, B.1 and B.2 (Aug. 1, 2014, last updated April 28, 2016).

[17] Internal Revenue Code § 36B(c)(2)(B)(i).

[18] *Id.* at § 5000A(f)(1)(A)(i).

[19] Internal Revenue Bulletin 2013-29, Notice 2013-41, C-2 (July 15, 2013), *available at* https://www.irs.gov/pub/irs-irbs/irb13-29.pdf.

CMS concurred with the IRS's interpretation. In a series of Frequently Asked Questions, CMS clarified that individuals with ESRD are not required to enroll in Medicare, that individuals with ESRD who do not have Medicare may enroll in a Marketplace plan, and that individuals with ESRD who do not have Medicare may qualify for a Marketplace premium tax credit.[20] Any final CMS policy on this issue that results from this RFI should, therefore, reaffirm that a dialysis patient who is eligible for, but not yet enrolled in, Medicare and who has made an informed choice to enroll in a Marketplace plan should be able to retain the coverage of his/her choice and not be forced into Medicare.

2. Individuals with ESRD who qualify for Medicaid have the option to enroll in Medicaid and/or Marketplace plans, and they may also qualify for premium tax credits under the Marketplace plans.

Similarly, those dialysis patients who are eligible for Medicaid are not required to enroll in Medicaid, and instead, may purchase Marketplace plan coverage.[21] Those who do purchase Marketplace plan coverage may or may not qualify for premium tax credits. In our patient population, very few dialysis patients choose Marketplace plan coverage over Medicaid – primarily, we think, because the total personal cost of care for most patients would be higher with Marketplace plan coverage.

The ACA created a new Medicaid eligibility category based solely on income.[22] Thirty-one states and the District of Columbia have adopted this category. In the remaining nineteen states, our dialysis patients must satisfy a low income test and also must demonstrate a categorical basis for Medicaid eligibility (e.g.,

---

[20] CMS, "Frequently Asked Questions Regarding Medicare and the Marketplace," Questions B-1, B-2 and B-3 (Aug. 1, 2014, last updated August 28, 2014), *available at* https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf.

[21] *See* 42 U.S.C. §§ 18031(d)(2)(a), 18032(a)(1) (requiring Marketplaces to make qualified health plans available to "qualified individuals," and providing that "[a] qualified individual may enroll in any qualified health plan available to such individual and for which such individual is eligible"; 42 U.S.C. § 18032(f) (defining "qualified individuals" without regard to eligibility for other health insurance coverage); 45 C.F.R. § 147.104 (guaranteeing the availability of Marketplace coverage); 45 C.F.R. § 155.310 (giving individuals applying for Marketplace coverage the right to decline an eligibility determination for Medicaid); CMS, State Health Official/State Medicaid Director Letter Re: Minimum Essential Coverage, SHO No. 14-002 (Nov. 7, 2014) (indicating that individuals eligible for certain forms of Medicaid coverage that qualify as minimum essential coverage are ineligible for premium tax credits but not suggesting that those individuals are barred from enrolling in Marketplace plans altogether), *available at* https://www.medicaid.gov/federal-policy-guidance/downloads/sho-14-002.pdf.

[22] *See* § U.S.C. 1902(a)(10)(A)(i)(VIII) (creating new category). *See also* NFIB v. Sebelius, 567 U.S. ___, 132 S. Ct. 2566 (2012) (holding that Medicaid expansion was optional for the states).

disability).[23] This difference plays out under the Marketplace rules in this manner: a dialysis patient who qualifies for Medicaid eligibility solely on the basis of income is considered eligible for minimum essential coverage, and as such, is ineligible for premium tax credits. To this patient, Marketplace coverage would likely be unattractive because the personal out-of-pocket costs to the patient would be much higher under the Marketplace plan.

By contrast, a dialysis patient who qualifies for Medicaid eligibility on the basis of meeting the low income test and the categorical test for disability ***is*** eligible for premium tax credits under the Marketplaces unless and until the patient applies for Medicaid coverage and is determined by the Medicaid program as meeting the categorical requirement.[24] Thus, many Medicaid eligible individuals (those that qualify through a disability category) remain eligible to enroll in Marketplace plans and receive federal Marketplace premium tax credits so long as they have not applied for Medicaid coverage.

Adding further complication for potential Medicaid enrollees, the IRS and CMS do not treat some forms of Medicaid coverage as minimum essential coverage even if an individual is actually enrolled in Medicaid. Relevant for ESRD patients, CMS has determined that coverage under the optional "medically needy" eligibility group is not sufficiently comprehensive in some states to qualify as minimum essential coverage, and that coverage in all states with this optional category is not minimum essential coverage for individuals who must "spend down" to be eligible.[25] Thus, premium tax credits are available for many patients in this optional eligibility group even if they actually enroll in Medicaid. Indeed, CMS has made clear that these individuals may enroll in both a qualified health plan and Medicaid, and has acknowledged that it may be in the best interest of the individual *not* to enroll solely in Medicaid, as doing so may violate the ACA's individual mandate and lead to penalties unless the individual is eligible for a hardship exemption.[26]

While a Medicaid-eligible patient may choose Medicaid as the best option, education about available coverage options is particularly critical for Medicaid eligible patients to be able to make an informed choice based on their individual circumstances. We strongly urge that any final CMS policy on this issue that results recognize the complexity in Medicaid coverage options and that there is not a "one

---

[23] *See* 42 U.S.C. § 1902(a)(10)(A)(i)(II)(bb).

[24] Internal Revenue Bulletin 2013-29, Notice 2013-41, C-2 (July 15, 2013). *See also* CMS, State Health Official/State Medicaid Director Letter RE: Minimum Essential Coverage, SHO NO. 14-002 (Nov. 7, 2014).

[25] CMS, Medicaid Secretary-Approved Minimum Essential Coverage (Feb. 16, 2016), *available at* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/downloads/state-mec-designations.pdf. *See also* CMS, State Health Official/State Medicaid Director Letter Re: Minimum Essential Coverage, SHO No. 14-002 (Nov. 7, 2014).

[26] *Id.*

size fits all" approach to health coverage. As a result, such guidance or regulations should not only unequivocally reinforce our obligation to educate patients about their coverage options, but also provide the flexibility so that each ESRD patient have same rights as other Americans to select the health coverage that makes the most sense for him or her.

II. The American Kidney Fund has a 19-year history of assisting dialysis patients with premium payments under guidance issued in 1997 by the Office of Inspector General.

A. The AKF's Health Insurance Premium Program advances patient choice and patient access.

Through HIPP, the AKF assists dialysis patients in paying health insurance premiums for Medicare, Medigap, Medicare Advantage, Marketplace and other commercial plan coverage. Less than one-half of one percent of our patients receive grant assistance from the AKF to fund Marketplace plan coverage.

The AKF's HIPP was designed based on guidance provided to the AKF by the Office of Inspector General (OIG) in "Advisory Opinion 97-1" (AO 97-1). Under this guidance, eligibility for HIPP assistance is available to *any* financially needy ESRD patient regardless of the patient's choice of dialysis provider and regardless of whether that provider supports the AKF through donations. While we and other dialysis providers make charitable contributions to AKF, we do not participate in their decisions to award patient grants in accordance with AO 97-1.

The OIG noted with approval HIPP's built-in safeguards to protect against inappropriate influence exerted by donors to HIPP. Donors contribute to HIPP on a voluntary basis and are not permitted to disclose to each other or other dialysis providers the amounts they contribute to AKF. Providers are prohibited from advertising the availability of possible financial assistance to the public. The OIG also noted that donors make their contributions unconditionally and without any guarantee or promise that "patients referred to AKF for possible financial assistance with their insurance premiums will receive such assistance."[27] Premium grants are awarded on a first-come, first-served basis regardless of the identity of the patient's dialysis provider to ensure that no provider may influence the selection of grantees.

The safeguards detailed in OIG's AO 97-1 for AKF's operation of HIPP have provided a structure that has enhanced patient choice for nearly two decades. The OIG's determination that HIPP was "not likely to influence patients to order or receive services from particular providers" was based on the program's robust internal firewalls to prevent fraud and abuse.[28] More importantly, HIPP supports

---

[27] Office of Inspector General, "Advisory Opinion No. 97-1," *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf.

[28] Furthermore, in a FAQ dated February 7, 2014, CMS expressly encouraged insurers to accept third-party payments from private, not-for-profit foundations made on behalf of QHP

patients' freedom to choose the health coverage that best suits their needs and does not in any way influence patients in making that choice.[29] As the OIG accurately observed in 1997, "AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice."[30] In ensuring that patients have health insurance options, the AKF's HIPP is aligned with the fundamental principles underlying the ACA.

B. FMCNA provides counseling to patients about potential premium assistance in accordance with OIG guidance and does not steer patients.

In discharging our obligations under the Conditions for Coverage, we offer our patients the assistance of a "financial coordinator" who is charged with assisting patients with the financial components of their care, including identifying all available sources of assistance for which they qualify. This may include assistance from HIPP. For patients who wish to apply for an AKF grant, the financial coordinator will assist the patient in completing the application after acquiring the necessary documentation, including a signed and dated consent form from the patient. The financial coordinator then submits the application for the patient utilizing the AKF Grant Management System. Providing this assistance is consistent with the conditions of participation imposed on dialysis providers by the CMS Conditions for Coverage.

In assisting patients who wish to apply for premium support, FMCNA has carefully adhered to the parameters delineated in AO 97-1 and complied with its obligations under the Conditions for Coverage. We prohibit advertising to the public about the availability of potential assistance through HIPP, prohibit disclosing directly or indirectly to patients our contributions to HIPP, and do not state or suggest that patients applying for HIPP will be guaranteed premium assistance or other financial support. In the interest of transparency, FMCNA publicly acknowledges that we make periodic donations to the AKF in support of HIPP. We also clearly state that our Corporate Finance Committee, which approves donations, does not track the amount of premium support that HIPP provides on behalf of patients dialyzing in our units for the purpose of determining the amount of FMCNA donations.

---

enrollees who satisfied defined criteria based on financial status without consideration to the enrollee's health; HIPP meets this criteria. *See* "Third Party Payments of Premiums for Qualified Health Plans in the Marketplace," Feb. 7, 2014, *available at* https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf.

[29] *See* "HIPP Guidelines August 2016," American Kidney Fund, *available at* http://www.kidneyfund.org/assets/pdf/financial-assistance/hipp-guidelines.pdf.

[30] Advisory Opinion No. 97-1.

III. FMCNA supports further analysis and safeguards against steering by both providers and insurers.

A. FMCNA has seen evidence of steering by insurers who are targeting dialysis patients in an effort to cancel their Marketplace plan or other commercial coverage.

FMCNA has growing concerns about steering by insurers as they deploy measures aimed at removing dialysis patients from their commercial plans without legal basis. These practices have created an effective "end run" around the prohibition on pre-existing condition exclusions enacted as part of the ACA[31] and threaten to undermine the consumer choice principles of the law.

Insurers in several states have informed patients with ESRD that they cannot use AKF grant funds to pay the premiums on their Marketplace plans. Many plans are requiring patients to sign attestations "under penalties of perjury" regarding the source of patient funds to pay premiums. They are holding premium payment checks written by the AKF until only a few days before policies may be cancelled for nonpayment of premium, and then notifying patients only days before cancellation that they will not accept AKF checks. By singling out a patient class with a particular diagnosis and telling those patients that they must use their own funds to purchase a health insurance plan they have chosen but cannot afford without help, insurers are effectively denying coverage to a patient based on a pre-existing medical condition – in direct contravention of the ACA. [32]

Insurers have also engaged in the practice of designing plan benefits to limit coverage for dialysis treatment in an effort to deprive dialysis patients of the value of their health insurance and to prompt them to drop commercial coverage. By way of example, numerous group health plans attempt to escape their responsibilities under the Medicare Secondary Payer statute, by designing plans that effectively exclude coverage for dialysis long before the end of the mandated coordination of benefits period.[33] Despite the fact that group health plans are required to provide

---

[31] 42 U.S.C. § 300gg-3(a). See also, *See* Remarks on the Patient Protection and Affordable Care Act, DAILY COMPILATION OF PRESIDENTIAL DOCUMENTS, (quoting President Obama: "uninsured Americans with a pre-existing condition ... will finally be able to purchase the coverage they need") (March 23, 2010), *available at* http://www.presidency.ucsb.edu/ws/index.php?pid=87658&st=&st1=.

[32] The ACA prohibits a health plan in the group or individual market from imposing "any pre-existing condition exclusion with respect to" the plan or coverage. A pre-existing condition exclusion, under the statute, is "a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage." *Id.* at § 2704(b)(1)(A). By refusing to accept the only means that a patient with ESRD has to afford their health insurance coverage, the plan has effectively denied coverage to the patient based on a condition that existed before the patient enrolled in coverage.

[33] Social Security Act § 1862(b)(1)(B)(ii); (b)(1)(C).

coverage under those plans to individuals who have ESRD for 30 months, health plans provide incentives to individuals with ESRD to switch their employer-based coverage to Medicare, and there are instances where group health plans change the benefit design of their plans as soon as an enrollee is diagnosed with ESRD, both in direct contravention of CMS regulations on these very issues.[34] Similarly, we are aware of Marketplace plans that reduce benefits to a percentage of Medicare after a specified number of treatments (usually 42 treatments) that get the patient through the three-month waiting period for Medicare coverage. The effect of these benefit designs is to move patients to Medicare and eliminate the Marketplace option. These practices are unfair and have a serious adverse impact on dialysis patients.

Although CMS has partially addressed third-party premium payments,[35] it has not clearly addressed the situation where a charitable organization makes a grant to a dialysis patient to assist that patient in paying for health insurance expenses. We urge the agency, in its final guidance on this issue, to state clearly that a grant payment made to an individual with ESRD that is consistent with the stringent guidelines set forth in OIG Advisory Opinion 97-1 may be used for payment of premiums and cost sharing on a Marketplace plan, and *must* be accepted by the insurer of that plan.

B. Insurer actions have the effect of deterring racial minorities and disabled individuals from enrolling into individual Marketplace plans in violation of the ACA's nondiscrimination provision.

The practices in which insurers are engaging violate the nondiscrimination provision outlined in Section 1557 of the ACA and the implementing regulations promulgated by the Office of Civil Rights (OCR).[36] Through their policy of rejecting

---

[34] *See* 42 C.F.R. § 411.108(a) (listing prohibited actions); *see also id.* at § 411.102.

[35] *See* 45 C.F.R. § 156.1250 (requiring that insurers accept payments from federal government programs such as Ryan White). CMS has indicated that grants from charitable organizations to Marketplace enrollees do not present the same concerns as grants directly from providers. *See* CMS, Frequently Asked Question Regarding Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces (Feb. 7, 2014), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf.

[36] 42 U.S.C. § 18116 (2016); 81 Fed. Reg. 31376 (May 18, 2016). Section 1557 applies to "any health program or activity" which receives federal financial assistance. The provision incorporates four different anti-discrimination statutes: title VI of the Civil Rights Act of 1964, which prohibits discrimination based on race, color, and national origin; title IX which prohibits discrimination based on sex; the Age and Discrimination Act which prohibits discrimination based on age; and section 504 of the Rehabilitation Act of 1973, which prohibits discrimination based on disability. Section 1557 also explicitly states that "the enforcement mechanisms provided for and available under [the four different statutes] shall apply for purposes of violations of this subsection." In the OCR final rule, the agency confirmed the broad reach of section 1557. Although OCR declined to extend section 1557's applicability to discrimination based on "health status, claims experience, medical history," OCR expressly recognized that depending on the facts, discrimination based on these characteristics can effectively constitute discrimination on a basis prohibited by section 1557. OCR also clarified that it is well established that *deterrence* from participation in a health program or

premium payments from third-party payers, insurer actions have the effect of steering dialysis patients away from individual Marketplace plans, and are compelling them to enroll in Medicare/Medicaid rather than exercise their legal right to choose their preferred insurance coverage without fear that they would be rejected for pre-existing conditions. Some insurers have also pressured dialysis patients to enroll in Medicare by altering their benefit plan designs to cover only three months of dialysis.

As described further below, these policies constitute intentional discrimination under Section 1557 because they discriminate against an individual based upon an ESRD diagnosis, a diagnosis which has been legally recognized as a "disability" and therefore constitutes a protected class under Section 1557. In addition, because dialysis patients are disproportionately from racial and ethnic minority groups, this policy likely violates Section 1557 because it disproportionately targets individuals based on their race, a protected class, by utilizing their ESRD diagnosis as a proxy through which to effectuate discrimination.

Insurers who engage in these practices effectively deny enrollment to an individual based on a pre-existing condition which, if the insurer had done so directly, would have been a clear violation of the insurance reform provisions of Title I of the ACA.[37] As a consequence, the insurers are able to exclude these patients from their risk pools, even though dialysis patients have as much of a statutory right to enroll in the plan of their choosing as everyone else does – as CMS and the IRS have expressly clarified.

---

activity on the basis of a prohibited criterion is itself a form of discrimination. For example, arbitrary coverage limitations that disproportionately affect a protected class without any basis for the normal operation of a health program can constitute discrimination. Importantly, OCR also explicitly adopted the position that a violation of section 1557 can be asserted both under disparate treatment or disparate impact theory irrespective of the underlying protected class. See 42 U.S.C. § 18116 (2016); 81 Fed. Reg. 31376 at 31440 (May 18, 2016). ("OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation."). In other words, a facially neutral policy could violate section 1557 so long as its application disproportionately and adversely affects members of any protected class, even without evidence of intentional discrimination. The OCR's interpretation regarding the causes of action available to plaintiffs under section 1557 is significant. Because the various anti-discrimination statutes incorporated by section 1557 had different causes of action, such as requiring the showing of intentional discrimination (disparate treatment) while others inferred discrimination based on a policy's disproportional effects (disparate impact), it was unclear whether a uniform right of action was available to plaintiffs under section 1557, or whether the right of action changed depending on the basis of plaintiff's protected class. In concurring with prior legal precedent that interpreted section 1557 to create a uniform cause of action, OCR effectively asserted that enforcement of section 1557 will not be avoided through subtle discriminatory tactics and facially neutral policies. *See id.* (citing *Rumble v. Fairview Health Servs*, No. 14-cv-2037, 2015 U.S. Dist. LEXIS 31591, at *29-31). Therefore OCR's implementing regulations confirmed that section 1557 was intended to be a comprehensive nondiscrimination provision.

[37] 42 U.S.C. § 300gg-3(a).

Most remarkable is the fact that these reverse steering practices are conspicuously targeting individuals because of their disability, a protected class under section 1557.[38] In the final rule implementing section 1557, OCR clarified that the definition of "disability" for the purposes of section 1557 would incorporate the definition of disability set forth in the Americans with Disabilities Act (ADA).[39] More critically, ESRD has been recognized as a disability under the ADA because it substantially limits an individual's major life activity of eliminating waste and cleansing blood from their body.[40] Therefore when insurers engage in activities that steer patients with ESRD away from the individual markets by compelling them to enroll in a federal program against their statutorily protected freedom of choice, there is a strong basis for the OCR to find that insurers are intentionally deterring individuals from participating in a "health program" because of their disability. Indeed, were it not for their ESRD disability, insurers would not be singling patients out for enrollment in Medicare.

Alternatively, because dialysis patients are predominately African-American or Hispanic,[41] these insurers are discriminating against racial minorities by using a patient's ESRD diagnosis as a surrogate through which to effectuate discrimination. The OCR has explicitly stated that it will not turn a blind eye to discrimination being performed under the guise of a seemingly legitimate attribute, such as health status, if the facts demonstrate that it is actually producing a discriminatory impact on a protected class.[42] Considering together the evidence that dialysis patients are being deterred from participating in individual Marketplace plans, and the overwhelming evidence that dialysis patients are significantly more likely to be racial and ethnic minorities, the OCR could find that insurers' steering activities are in violation of section 1557 because they produce a disparate impact based on race.[43] Put differently, the policies adopted by insurers can be interpreted as discriminating based on health status, i.e. ESRD, which serves as a proxy for disproportionately deterring racial minorities from enrolling in Marketplace plans.

---

[38] 42 U.S.C. § 18116(a) (incorporating 29 U.S.C. § 794(a)).

[39] 81 Fed. Reg. 31376, at 31407.

[40] *See Fiscus v. Wal-Mart Stores, Inc.*, 385 F.3d 378, 384 (3d Cir. 2004).

[41] *See supra* Part II.A.

[42] *See* 81 Fed. Reg., 31736, at 31405.

[43] *See Raytheon Co. v. Hernandez*, 540 U.S. 44, 52 (2003) (asserting that a *prima facie* disparate-impact theory of discrimination involves a facially neutral policy which, in practice, "falls more harshly on one group than another....").

IV. Responses to CMS Questions

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

Dialysis providers have regulatory obligations under the Conditions for Coverage to provide education to patients about their coverage options.[44] We provide patients with information so that patients may make informed choices from the health coverage options available to them. While an unscrupulous provider could seek to unduly influence a patient to select coverage options that are to the provider's advantage and not in the patient's best interest, we do not engage in such practices. Our numbers are inconsistent with any such scheme. As noted, only a small number of our patients opt for coverage under a Marketplace plan. Among our 187,000 patients nationwide, only about 1,600, constituting less than 1 percent of our patients, have elected to obtain Marketplace coverage. Of those, only approximately 700, representing *fewer than four-tenths of one percent* of our patients, receive AKF assistance to help fund their Marketplace plan premiums. These numbers are consistent with individual patient choice, and are not indicative of a program to steer patients to Marketplace plans.

Further, we do not believe that the AKF is involved in steering patients to any particular type of coverage, or that it is in a position to do so. As a preliminary matter, the AKF is not a provider affiliated organization. The AKF is an independent charitable organization. It is not affiliated with or subject to the control of providers. FMCNA, and other dialysis organizations, make charitable contributions to the AKF, but there is no link between our donations and the AKF's grant-making activities, and there are numerous safeguards in place to prevent any influence over grant awards. As AO 97-1 makes clear, when an organization – like the AKF - makes an independent determination of financial need, and receipt of assistance does not depend upon the patient's use of a particular provider or coverage option, such assistance is lawful and, in our experience, an important tool in promoting patients' ability to choose the health insurance coverage options that suit their circumstances.

Due to the nature of its grant-making process, we do not believe the AKF has any opportunity to steer. The AKF awards premium grants based solely on two factors: the patient's confirmation of ESRD status and financial need. AKF grants are made on a first-come, first-served basis, without regard to the patient's choice of insurance coverage (whether government or commercial) and without regard to the patient's choice of provider. Our patients use AKF premium grants to defray the costs of all types of coverage. In fact, among our patients who receive some level of AKF premium support, the vast majority (over 75%) use AKF grants to fund premiums for Medicare Part B, Medicare Supplemental Insurance (Medigap), and

[44] See discussion, infra pp. 1-2.

other government-program related products (such as Medicare Advantage) and not for premiums for stand-alone commercial insurance (such as employer-sponsored group health plans and individual plans on or off the Marketplace).

To the extent that other providers are inappropriately steering patients by unduly influencing their choice of insurance coverage or provider, FMCNA supports CMS' efforts to address those situations. In doing so, however, CMS should also take care not to dismantle or impede the important and lawful charitable work of independent charitable programs like the AKF HIPP, which has benefited chronically ill and financially needy patients since long before the enactment of the ACA.

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

The impact to the Marketplace risk pool when Medicare eligible consumers elect Marketplace coverage in lieu of governmental programs depends on the demographics of those who make that election. Obviously, if those consumers are healthy, the impact would be positive for the risk pool, and if those consumers are very sick (or seeking coverage for a select period of time during which utilization of medical services is unusually high), the impact would be negative. In the case of our patients, the impact to the risk pool would likely be negative since these patients are chronically ill and suffer from co-morbidities. As noted, however, the ESRD patient population is small. These patients represent a mere .006% of the total 11.1 million effectuated enrollment in ACA Marketplace plans (or about one in every 16,000 Marketplace plan enrollees).[45]

Patients should be able to make an informed choice from among all available health insurance options, free from undue influence. Accordingly, if there are providers who are inappropriately steering patients to Marketplace plans, or, conversely, if there are insurers who are inappropriately steering patients away from Marketplace plans, those activities should be addressed. The solution, however, should not penalize consumers by reducing their coverage options. The fundamental purpose of the ACA and the Marketplace program was to give vulnerable patient populations – like the ESRD patient population – a choice of coverage options. For many of our patients, Medicare/Medicaid coverage is among those options, and for many it is the right one, but it is not the only one. CMS and the IRS have rightly concluded that ESRD patients have the option to choose commercial coverage. They are not forced to choose the government-sponsored

[45] March 31, 2016 Effectuated Enrollment Snapshot (June 30, 2016), *available at* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fect-sheets-items/2016-06-30.html (stating that "[o]n March 31, 2016, about 11.1 million consumers had effectuated Health Insurance Marketplace coverage").

option, but have the right to choose the coverage that best suits their individual circumstances.

While we do not have a means to determine whether insurers have accurately anticipated composition of the risk pool for the Marketplaces, we do note that there are many reasons why insurers should have anticipated that formerly underinsured and uninsured ESRD patients would elect Marketplace coverage. For example:

- Federal law makes Marketplace coverage an option for dialysis patients who are eligible for Medicare or Medicaid coverage. The federal subsidies that are available to a large portion of the dialysis population created a financial incentive for these patients to consider and potentially select Marketplace coverage. Insurers should have anticipated that some consumers would elect Marketplace coverage.
- ESRD patients are often unemployed since their disease is debilitating and they have to spend considerable hours receiving treatment during normal work hours. It follows that many patients do not have access to employer-sponsored health plans. The Marketplaces give these patients a commercial coverage option, and insurers should have anticipated that some patients would elect that option.
- With the elimination of the pre-existing condition limit for Marketplace plans, the ACA provided commercial insurance options to ESRD patients for the first time in history, and insurers should have anticipated that some patients would elect that option.
- ESRD patients do not generally qualify for Medicare coverage during the first three months after the onset of ESRD (except for those for whom home therapy is an option). As such, insurers should have anticipated that ESRD patients would seek Marketplace coverage at least during this three-month waiting period, and that some would opt to continue coverage beyond the initial three-month period, for reasons including continuity of care.
- With regard to Medicaid eligibility, we understand that eligibility status can change throughout the year as patients experience changes in job status and income. For these patients, rather than risk moving in and out of Medicaid coverage, Marketplace coverage may provide more stable coverage and may avoid the obligation to satisfy multiple deductibles in a plan year as coverage switches multiple times from Medicaid to a Marketplace plan.

3. *Are there examples of steering practices that specifically target people eligible for or receiving Medicare and/or Medicaid benefits to enroll in individual market plans? In what ways are people eligible for or receiving Medicare and/or Medicaid 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?*

We are aware of steering practices by insurers that specifically target people eligible for or receiving Medicare and/or Medicaid benefits and that are aimed at pushing them off the Marketplace plans or other coverage options of their choice. Insurers have sent intimidating, incomplete and misleading information to our patients and have invoked fear of losing coverage for critical, life-saving care. For instance:

- An insurer held a patient's premium check written by the AKF for thirty (30) days (and did not deposit it). It then sent notices to the patient stating that they would not accept AKF checks, and as such, the patient's insurance would lapse in a matter of days. The patient had little time to challenge the insurer's practices or to develop a plan for paying the premium to avoid a lapse in coverage.
- Another insurer issued a Bulletin to its patients stating that it "may" decline to accept premium payments made directly or indirectly by any third party "in accordance with law." The insurer did not explain the parameters of any such "law," and importantly, did not explain that state regulators were then considering whether and how insurers may be allowed to reject premium payments. Instead, the insurer stated to patients "You are required to immediately notify [us] of any change in information provided with respect to any third party payment" and "Any person or entity that violates these restrictions and/or makes any ineligible third party payment described above will be held responsible . . . ".[46]
- Some insurers have demanded, without legal basis or justification, that patients sign affidavits or attestations swearing under the penalties of perjury as to the source of the funds used to pay their premiums.[47]
- Patients have had to delay or reschedule treatment due to an insurer's rejection (sometimes without notice to the patient) of a third-party payment.

---

[46] *See* Provider Bulletin issued by BlueCross BlueShield of Minnesota on August 22, 2016, attached as Exhibit 1.

[47] *See* letter dated June 9, 2016, from United Healthcare to a patient, attached as Exhibit 2.

Demanding that members of a patient population that is typically low income and poorly educated sign legal documents under "penalties of perjury" and threatening vague legal consequences for using premium support, all without stating any legal basis for doing so, is unfair, deceptive, and discriminatory. The use of such aggressive tactics and the rejection of premium payments aimed at terminating commercial coverage for a chronically ill, largely economically disadvantaged, and disproportionately minority patient population constitute a particularly insidious type of "steering."

These steering tactics are directly at odds with the principle of patient choice embodied in the ACA and threaten the ability of ESRD patients to make coverage decisions that best suit their needs by maximizing continuity of coverage and minimizing out-of-pocket costs. Insurer steering also violates the ACA's prohibition on discrimination in the offering of health care coverage on the basis of disability, race or national origin. It is well-established that African Americans are more at risk for kidney failure than any other race, comprising more than a third of kidney failure patients in the United States.[48] Hispanic, Asian, and Native Americans, similarly, are far more likely to experience the conditions that lead to ESRD - such as high blood pressure and diabetes - than are Caucasians.[49] Insurers should not be permitted to use the receipt of third party premium support as a proxy for prohibited discrimination on a pre-existing condition, particularly where such discrimination has a disparate impact on racial and ethnic minorities, and on a patient population that is disabled.

In some states, Departments of Insurance have intervened to address these heavy-handed and discriminatory practices, but insurers continue to innovate to adopt new strategies aimed at keeping ESRD patients off the Marketplaces and other commercial plans. We therefore urge CMS to give all states clear guidance that these insurer "steering" practices are impermissible under the law.

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

---

[48] Choi, Andy I. et al. "White/Black Racial Differences in Risk of End-Stage Renal Disease and Death." *The American Journal of Medicine* 122.7 (2009): 672–678.*PMC*. Web. 6 Sept. 2016.

[49] Nicholas S.B., Kalantar-Zadeh K., and Norris K.C.: Racial disparities in kidney disease outcomes. Semin Nephrol 2013; 33: pp. 409-415.

Since FMCNA does not pay premiums and does not steer individuals to Marketplace plans, we are unfamiliar with methods that may lead to inappropriate steering. As noted above, with less than 1% of our patients enrolling in Marketplace plans and only 0.4% receiving AKF premium support for Marketplace plan premiums, the facts fully support our position that we do not steer. With regard to the AKF, while it does pay premiums, its grants are awarded on a first-come, first-served basis, once the patient establishes an ESRD diagnosis and financial need. Grants are awarded without regard to the patient's choice of insurance coverage, whether governmental or commercial. Thus, the AKF process does not provide the AKF any opportunity to steer patients into Marketplace plans.

With regard to transparency, FMCNA supports a HIPP program that is transparent. The payment procedure that is most effective for our patients is one in which the AKF sends premium checks directly to insurers and thereby, gives insurers transparency on the source of funds. Due to insurer efforts to steer patients away from commercial coverage by refusing to accept AKF checks, the AKF has implemented different procedures in some states, but again, we favor a program that is entirely transparent.

5. *How are enrollees impacted by the practice of a health care provider or provider-affiliated organizations enrolling an individual into a Marketplace 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.*

For those patients who elect to enroll in commercial coverage, we advise them of any programs available to them to help pay those premiums consistent with our obligations under the Conditions for Coverage. We strive to offer the highest level of service possible, while taking all aspects of our patients' health and well-being into account. When we discharge our responsibilities properly, the impact is that our patients have the choices that the ACA and the Marketplaces were designed to provide as well as the information needed to choose the coverage that best suits their individual circumstances.

While many patients choose to enroll in Medicare or Medicaid when eligible, other patients report to our financial counselors a wide variety of reasons why they want to delay enrollment in Medicare or Medicaid or choose a Marketplace plan or other commercial coverage. For example:

- A patient has family members covered under existing coverage such that, if coverage is dropped in favor of Medicare coverage for ESRD, their family

members would not have coverage unless they, too, access the Marketplaces, in which case total out-of-pocket costs may be higher.

- A Marketplace plan offers a travel/housing benefit for the transplant donor as well as the patient, and the patient wants to keep individual market coverage until he/she rules out that a potential family member would need to travel a long distance to take part in a transplant.
- A Marketplace plan offers a more advantageous prescription drug benefit.
- A patient cannot afford Medicare Part D.
- A Marketplace plan offers an out-of-pocket maximum that is financially advantageous. By comparison, there is no limit to a patient's responsibility for the deductibles and co-pays payable under Medicare.
- A patient lives in a state without Medigap coverage, and as such, cannot adequately insure exposure for deductibles and co-pays. Note that Medigap coverage is available in only 27 states for ESRD patients under age 65.
- A patient may have better continuity of care and may be able to avoid resetting deductibles and out-of-pocket cost limits by remaining on a Marketplace plan instead of moving on and off of Medicaid due to income fluctuations.
- A patient may want to continue coverage that provides access to particular physicians who may not participate in Medicare or Medicaid.
- A patient simply exercises the choice that the law allows.

Many patients are focused on minimizing their out-of-pocket costs for care, and as such, these financial considerations play a big role in their decision making. To appropriately determine the total financial implications to an individual, we simulated the movement of individuals who are representative of the population for a target market, Manhattan, to a Marketplace Bronze and Silver plan. For ESRD patients, who have patterns of high utilization compared to the general population, there are substantial savings in out-of-pocket spend realized by switching to a Marketplace plan (or Medicare Advantage) from a Medicare fee-for service (FFS) plan without Medigap coverage. (See **Figure 1** and **Figure 2** below). The main driver behind this savings is the benefit of an out-of-pocket maximum that is not provided by Medicare FFS. Given that the financial implications for individuals are dependent upon their personal situations, any steps taken to address inappropriate steering should take these considerations into account. Our simulation leads us to believe that retaining the option to enroll in Marketplace coverage when it best suits an individual's personal situation (regardless of whether or not eligible for Medicare and/or Medicaid) is integral to the overall wellbeing of our patients.

Figure 1 - Individual Financial Obligation (Out-of-pocket Spend Only, Excludes Premiums) Comparison across Payer Types – Manhattan Market

Financial Impact on Individuals in 25th Percentile: Manhattan Market
Annual Individual Financial Expenditures (Excluding Premiums) ($)

Condition	Medicare FFS[2]	Medicare Advantage	Silver Exchange Plan	Bronze Exchange Plan
(1) Diabetic	$2,956	$1,671	$4,739	$6,728
(2) ESRD	$17,114	$3,923	$6,850	$6,850
(3) CHF	$4,689	$2,004	$6,238	$6,850
(4) Cancer	$4,058	$1,875	$5,474	$6,850
(5) Healthy / Limited HCCs	$928	$1,804	$2,968	$2,968

Financial Impact on Individuals in 75th Percentile: Manhattan Market[1]
Annual Individual Financial Expenditures (Excluding Premiums) ($)

Health Conditions	Medicare FFS[2]	Medicare Advantage	Silver Exchange Plan	Bronze Exchange Plan
(1) Diabetic	$3,960	$5,729	$6,850	$6,850
(2) ESRD	$24,022	$7,392	$6,850	$6,850
(3) CHF	$7,040	$7,737	$6,850	$6,850
(4) Cancer	$6,465	$6,170	$6,850	$6,850
(5) Healthy / Limited HCCs	$2,305	$5,078	$4,831	$6,850

1. Financial analysis excludes premium payments; Assumes $4,900 and $6,850 OOP maximum for MA and ACA plans, respectively; Assumes Commercial/ACA average allowed unit costs 30% higher than Medicare FFS 2. Assumes Medicare Supplementary coverage is not purchased

Source: Analysis of 2014 MarketScan, 2014 Medicare 5% claims and Public Use files

Figure 2 - Individual Financial Obligation (Out-of-pocket Spend and Premiums) Comparison across Payer Types – Manhattan Market

Financial Impact on Individuals in 25th Percentile: Manhattan Market[1]
Annual Individual Financial Expenditures ($)

Condition	Medicare FFS[2]	Medicare w/ Plan F	Medicare Advantage	Silver Exchange Plan	Bronze Exchange Plan
(1) Diabetic	$4,612	$7,035	$1,671	$17,915	$18,356
(2) ESRD	$18,770	$9,614	$3,923	$17,292[3]	$16,066[3]
(3) CHF	$6,346	$8,148	$2,004	$19,414	$18,478
(4) Cancer	$5,714	$7,864	$1,875	$18,650	$18,478
(5) Healthy / Limited HCCs	$2,584	$5,406	$1,804	$16,144	$14,596

Financial Impact on Individuals in 75th Percentile: Manhattan Market[1]
Annual Individual Financial Expenditures ($)

Health Conditions	Medicare FFS[2]	Medicare w/ Plan F	Medicare Advantage	Silver Exchange Plan	Bronze Exchange Plan
(1) Diabetic	$5,617	$7,035	$5,729	$20,026	$18,478
(2) ESRD	$25,679	$9,614	$7,392	$17,292[3]	$16,066[3]
(3) CHF	$8,697	$8,148	$7,737	$20,026	$18,478
(4) Cancer	$8,122	$7,864	$6,170	$20,026	$18,478
(5) Healthy / Limited HCCs	$3,961	$5,406	$5,078	$18,007	$16,170

1. Financial analysis includes premium payments for individuals and drug costs; Assumes $4,900 and $6,850 OOP maximum for MA and ACA plans, respectively; Assumes Commercial/ACA average allowed unit costs 30% higher than Medicare FFS 2. Assumes Medicare Supplementary coverage is not purchased 3. ESRD premiums may be lower on exchange compared to other Medicare populations due to prevalence of ESRD individuals under 65 and ACA premium rate setting based on age
Source: Analysis of 2014 MarketScan, 2014 Medicare 5% claims and Public Use files

The total financial obligation differential for our ESRD patients is of particular interest. As seen in **Figure 1** and **Figure 2**, out-of-pocket expenditures for individuals in Medicare FFS can be high, especially for those individuals under 65 who cannot purchase supplemental plans. In particular, the simulation in **Figure 2** shows that if a high-utilizing Medicare FFS member with ESRD does not have supplemental coverage, this individual can save ~$8,000 dollars a year in healthcare expenditures by enrolling in a Marketplace plan. As indicated, there are savings realized whether or not the individual is paying the premiums or has premium support, though the savings to the individual are obviously greater in cases where the individual also has access to premium assistance. Given that currently only 27 states offer Medigap plans to ESRD patients under the age of 65, we believe this analysis highlights the importance of avoiding a "one size fits all" approach to health coverage and ensuring that each individual, regardless of health status, retain the right and ability to select the type of coverage that makes the most sense for him or her.

For a Medicaid-only eligible individual, in almost all cases, our expectation is that Medicaid coverage would be superior to a Marketplace plan from a pure cost perspective. This is true, in part, because federal law limits states' ability to charge

premiums, co-payments and other forms of cost sharing.[50] Thus, Medicaid beneficiaries may get their coverage at little or no out-of-pocket expense to them. In addition, access to outpatient prescription drugs in Medicaid is usually generous. A Marketplace plan, by contrast, may not be as generous. We counsel our patients in accordance with this understanding, and while patients are always free to make their own choices, the result is that we have very few Medicaid-only eligible patients who elect Marketplace coverage.

Setting aside the positive financial impact of choosing a Marketplace plan over Medicare for select, high utilizing, portions of the population (such as our ESRD patients), and the cost factors that may lead patients to choose Medicaid if eligible for it, we believe that respecting individual choice of health insurance options is a vitally important aim in itself. Individuals need to have the ability to independently evaluate all of the attributes that make up the value proposition of a healthcare product (both financial and non-financial) to ensure they select an option that meets their personal situation. FMCNA is clearly not alone in this view. Indeed, the ACA, and healthcare.gov, were designed to promote consumer choice and informed decision making.

6. *How are enrollees impacted by the practice of a health care provider enrolling an individual into a Marketplace 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 co-payments 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 co-payments and deductibles where the enrollee's chosen provider is out-of-network to the individual market plan.*

Because we do not enroll patients in health insurance plans or pay premiums, we have limited insight into the issues raised by this question. As illustrated in greater detail in our response to question 5 above, it is inaccurate to assume that Medicare and/or Medicaid coverage is always the best option for patients, financially or otherwise. Patient choices regarding coverage can be quite complex and should take into account a number of factors that are unique to the patient and that are then weighed against the availability of other coverage options,

[50] *See generally* Social Security Act § 1916(a)(3) (providing that cost sharing under a plan must be "nominal in amount"). *But see id.* at § 1916A (providing states with limited flexibility to charge greater cost sharing for Medicaid beneficiaries with incomes above 100% of the federal poverty level).

both government and commercial. In the end, it should be up to the patient to make that choice.

Currently, ~56 million people are enrolled in Medicare and ~73 million people are enrolled in Medicaid. Current take-up rates (i.e. the proportion of eligible individuals who choose to enroll in government programs) of ~99% for Medicare and ~68% for Medicaid indicate that while most individuals enroll for Medicare if eligible, a large portion of individuals eligible for Medicaid are not enrolled in the program.[51] Approximately 32 million people are eligible for but not enrolled in Medicaid. While secondary research did not yield employer sponsored coverage rates for Medicaid eligible populations, if we assume that 55% of these individuals have access to health insurance coverage through their employer (based on the average employer-sponsored coverage rates for the non-elderly), that leaves ~18 million individuals who are Medicaid eligible but not enrolled.[52] These uninsured individuals would experience both financial and non-financial changes from enrolling in any health plan, including a health plan offered on a Marketplace.

Exactly which health plan would most benefit a non-insured individual, however, is highly dependent upon personal factors, which is why patient choice and education are critical. As noted in our response to Question 5, while many ESRD patients decide that Medicare or Medicaid coverage makes the most financial sense for them, some can realize savings by enrolling in Marketplace plans with out-of-pocket maximums.[53] Still other individuals have other reasons to want to obtain Marketplace coverage, such as continuity of care or family coverage. The Conditions for Coverage obligate us to educate patients on these factors and provide the information needed for them to make a decision that best suits their individual circumstances.

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

AO 97-1 was issued by the OIG in response to the requestor's (including the AKF's) questions about compliance with the Civil Monetary Penalties Law in relation to HIPP. We believe that CMS should consider the attributes of a well-run HIPP as

[51] Kaiser Family Foundation. "Total Number of Medicare Beneficiaries". 2015; Kaiser Family Foundation. "Total Monthly Medicaid and CHIP enrollment" (June 2016); The Milbank Quarterly. "Health Insurance Coverage and Take-Up: Lessons from Behavioral Economics". March 2012; Assistant Secretary for Planning and Evaluation. "Understanding Participation Rates in Medicaid: Implications for the Affordable Care Act" (March 2012).

[52] Kaiser Family Foundation. "Employer-Sponsored Coverage Rates for the Nonelderly by Age" (2014).

[53] *See, e.g.*, Figure 1 and Figure 2 above.

expressed in AO 97-1 and should consider memorializing the guidance therein in regulations applicable to charities that fund premiums for government-sponsored programs, including the Marketplaces (which receive government support in the form of premium tax credits and reinsurance and risk corridor protections). In addition, we would suggest some additional safeguards to protect the transparency and integrity of programs run by charitable originations, like HIPP. Such guardrails should include:

- The organization must operate in accordance with the legal requirements of AO 97-1;
- The organization must award grants on a first-come, first-served basis to applicants who establish financial need based on the organization's objective financial need criteria to ensure that no preferential treatment is given to applicants who receive treatment for particular providers;
- The organization must establish an appropriate separation between fund-raising activities and grant-making activities, thereby assuring the independence of grant-making decisions;
- Premium grants must be portable so that a patient can switch providers during the grant year;
- The organization awards grants in a manner that allows patients freely to choose their provider and their coverage option, such as grant awards that cover an entire policy year.
- The charitable organization must require periodic certifications from providers who assist patients in applying for grants to the effect that such providers are not providing any assurances or guarantees to patients that they will receive grant assistance, since the grant-making decision rests entirely with the charitable organization.

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

Our financial coordinators do screen for Medicare and Medicaid eligibility as part of their counseling process since the patient needs to evaluate all options to make a coverage decision. That said, at times, we lack complete information about a patient's Medicaid eligibility and/or enrollment, and would appreciate any efforts by CMS to work with states to provide more accurate information for us to inform patient choice.

The task of educating patients on the advantages and disadvantages of various coverage options -- including the impact of signing up for a Marketplace plan – is most effectively assigned to providers. Dialysis providers, in particular, are already charged with this responsibility under the Conditions for Coverage. These patients are in our clinics at least three times weekly and have a relationship of trust and confidence with our social workers and financial coordinators. Our financial coordinators receive in-depth training on the requirements for eligibility for commercial insurance programs, plans available through the Marketplace, as well Medicare and Medicaid. Additionally, they are trained to discuss health insurance options with patients, based on what is best for the patient's care and financial situation. Charitable organizations like the AKF do not have these patient relationships and do not have the physical proximity with the patient or the technical know-how to undertake this role. Requiring them to perform this function would increase their overhead, unnecessarily divert funds from their charitable mission, and duplicate services that dialysis providers, in particular, are required to provide under the Conditions for Coverage.

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

While we do not offer or provide any assurance of premium assistance to our patients, we do provide education on coverage options to our patients as required by the Conditions for Coverage. Our approach is individualized for each patient since each patient may consider different factors and weight the multiple factors differently. Since most patients need to consider how to pay for their care, we do assist patients in assessing eligibility for various coverage options, evaluating the costs to the patient of each coverage option and gathering information about a patient's financial resources, such as assets, income and expenses. When a patient has determined that commercial insurance may be a better fit for his or her personal needs, we will offer information to the patient about available financial assistance and how to apply for such assistance. We do not guarantee to any patient that he or she will receive such financial assistance, since decisions are made by the charities that provide the assistance, not by FMCNA. Donations to such charities by FMCNA are not linked to or conditioned upon the receipt of assistance by any particular patient, and the receipt of grant assistance by a patient does not hinge upon the use of a particular provider or coverage option.

If a patient receives a premium grant, the most efficient process is for the charitable organization to send a check directly to the insurer. We understand that AKF uses that process, when possible. As insurers have increasingly deployed methods to deter patients from enrolling in commercial coverage by refusing to accept payments made directly to the insurers by such charities, the AKF has modified its procedures in some instances. For instance, under a modified

procedure, AKF would send checks payable to the patient to the patient's dialysis center, and the checks would be held for patient until the next treatment. At the next treatment, one of our counselors would open the check with the patient as part of a dialogue about the patient's coverage choices. For those patients choosing commercial insurance coverage, the patient would then endorse the check to the insurer. We understand that checks are not sent directly to patients' homes because of concerns about theft or about patients' ability to manage their financial affairs in a manner to assure timely premium payment.

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

FMCNA does not offer or provide assurances regarding premium assistance to Marketplace patients (or any patients), and as such, we do not object to any such prohibitions on providers' making such offers or assurances.

With regard to cost-sharing waivers, we do have an indigent waiver program that is consistent with the waiver exception and safe harbor under the anti-kickback statute. Our indigent waiver program applies equally to patients with federal health program and commercial coverage. Our expectation is that all providers provide cost-sharing waivers on this basis.

We do not believe that Medicare Part A eligibility should prohibit a provider from making a patient aware of the potential for third party assistance for Marketplace or other commercial coverage. Both CMS and the IRS have expressly determined that Medicare and Medicaid-eligible individuals have the option to seek coverage from Marketplace plans under the ACA, and a small segment of our patients currently make this choice because the Marketplace plan better suits their personal needs.

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

Under the Conditions for Coverage, dialysis providers are already required to recognize the individualized and personal needs, wishes and goals of the patient and to honor the patient's right to be informed about and participate in all aspects of care. As such, and as FMCNA recognizes, the decision on coverage options lies with

the patient, it is incumbent upon the provider to provide neutral, practical advice regarding the potential costs and benefits of various options to help inform a patient's decision. That being said, we support and would like to contribute to an effort to develop further guidance about how to ensure that patients are fully informed of their insurance options and provided all available choices.

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

We support CMS' efforts to implement measures that address any tactics used by providers or insurers to unduly influence patients in a manner that steers them into or away from any type of coverage, including Marketplace plans. FMCNA commits to collaborate with CMS and others to devise means to identify and eliminate any such abusive practices and to support reporting and other data sharing activities that produce demonstrable results in enhancing patient access and choice without undue influence by providers or insurers.

In this regard, it is possible that additional reporting and data sharing regarding the correlation between patient assistance programs and cost-sharing waivers in certain scenarios may assist in this effort. For example, if a provider is out-of-network and does not have a contract with the insurer for a negotiated reimbursement rate for dialysis treatment and that provider's data shows a high correlation between patients who receive premium assistance and patients who receive cost-sharing waivers, this data may raise concerns regarding steering.

Our numbers regarding Marketplace coverage enrollment by our patients and AKF support of those patients show that we are not engaged in steering.[54] We support initiatives to create transparency to CMS regarding these numbers.

In addition, the counseling that we provide patients would be better informed if CMS would share more data with us about patient eligibility for premium tax subsidies and coverage eligibility. In particular, when providing coverage options to our patients, we often lack clear and accurate information about the patient's eligibility and /or enrollment in Medicaid. Any gaps in our information diminish our ability to advise patients of their coverage choices. If CMS could work with state Medicaid programs to provide us better information about patient Medicaid status, our patients would be better informed about their coverage options.

---

[54] We have over 187,000 patients nationwide, and only about 1,600, constituting less than 1% of our patient population, have elected to obtain Marketplace coverage. Of these, only approximately 700, representing only 0.4% of our patients, receive AKF assistance to help fund their Marketplace plan premiums. Our Marketplace plan patients represent only about 1 in every 7,000 Marketplace plan subscribers. Those with AKF support represent only about 1 in every 16,000 Marketplace plan enrollees.

We also urge CMS to consider requiring insurers to report information that would enable CMS to better understand and respond to any instances of insurer steering.

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

FMCNA generally negotiates provider contracts with payors throughout the country to establish mutually agreeable rates for the services provided. Our experience is that insurers consider a number of factors when negotiating these rates, as do we. These negotiations are private matters, and the parties on each side are sufficiently sophisticated to protect their own interests.

Based on some of the press articles that we have seen on this topic, it appears that some providers may be adopting a comprehensive out-of-network strategy in which they refuse generally to contract with payors with the aim of receiving per-treatment dialysis reimbursement in excess of the negotiated rates payable to contracted providers. Insurers already have ample means to protect themselves in these situations by limiting benefits for out-of-network providers. But patients may not have a means to protect themselves if the out-of-network provider does not adequately disclose to the patient that the provider is out-of-network; in this instance, unless the provider is routinely waiving the patient cost-sharing obligation (a practice which may raise other concerns), the patient will be subject to higher co-pays and deductibles.

We recommend that CMS consider requiring out-of-network providers to disclose to patients the extent of their cost-sharing obligations under a Marketplace plan and that CMS seek data to determine whether these same patients receive both premium assistance and cost-sharing waivers from these out-of-network providers. In addition, we suggest that CMS consider applying some of the network adequacy and out-of-network reimbursement rules that are applicable to Medicare Advantage plans for application to Marketplace plans. Medicare Advantage plans have network adequacy requirements that ensure an appropriate level of provider contracting, and in addition, Medicare Advantage plans impose Medicare-based rates on out-of-network providers. Applying similar rules in the Marketplace context would address steering concerns.

14. *We seek comment on policies that would allow individual market plans to make retroactive payment adjustments to providers, when health care providers are*

found to have steered Medicare or Medicaid beneficiaries to enroll in a Marketplace plan for the provider's financial gain.

Insurers have sufficient legal recourse under existing law to challenge providers who purportedly steer Medicare or Medicaid beneficiaries to enroll in a Marketplace plan for the provider's financial gain. Insurers have access to the courts to address these private commercial issues, including any claimed retroactive payment adjustment. Indeed, United Healthcare's recent complaint against American Renal Associates is a good example of the type of recourse available. As such, additional remedies, need not, and should not, come from CMS.

We support CMS' providing clear standards for determining standards for appropriate education of patients and for third party premium support.

Conclusion

FMCNA welcomes the opportunity to collaborate with CMS and industry participants to address concerns about patient steering while preserving the premium assistance support that many of our patients have relied on for almost two decades. Without that premium assistance, many of our patients lack the resources to access the coverage options offered by the Marketplaces, as well as coverage options offered by Medicare, Medigap, Medicare Advantage and other commercial coverage. Their insurance options become illusory without the support of organizations like AKF.

We support measures to assure that premium assistance programs are properly run and that neither providers nor insurers are steering or improperly influencing patient choice. We think that greater expanded data reporting and data access might be an effective tool to highlight and then eliminate inappropriate steering practices. Greater transparency would be an effective regulatory means to address inappropriate provider or insurer behavior.

Thank you for your attention to this matter. We look forward to a continuing dialog and to working with CMS to advance the interests of our patients.

Very truly yours,

Ronald J. Kuerbitz
Chief Executive Officer

Exhibit 1

PROVIDER BULLETIN
PROVIDER INFORMATION

BlueCross BlueShield Minnesota

August 22, 2016

Updated: Third Party Payments of Premium and/or Cost-Sharing

The information in this Bulletin replaces Provider Bulletin P50-15, which was published on December 7, 2015.

As required by law and applicable regulatory guidance, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) will accept premium and cost-sharing payments made on behalf of enrollees by the following persons/entities:

(1) the Ryan White HIV/AIDS Program;
(2) other Federal and State government programs (or grantees) that provide premium and cost-sharing support for specific individuals;
(3) Indian tribes, tribal organizations, and urban Indian organizations;
(4) family (related legally or by blood) and individual friends of the enrollee; and
(5) religious institutions and other not-for-profit organizations, but only **when each of the following criteria has been demonstrated** (as such criteria may be modified in accordance with applicable law or regulatory guidance): (a) the assistance is provided on the basis of the enrollee's financial need; (b) the institution or organization is not a healthcare provider; and (c) the institution or organization is financially disinterested, e.g., the institution/organization does not receive funding from entities with a pecuniary interest in the payment of health insurance claims.

Blue Cross may, in its sole discretion and in accordance with applicable law and regulatory guidance, **decline to accept** premium and cost-sharing payments made directly or indirectly* by any third-party that is not listed above, and any other person or entity from which Blue Cross is not required by law to accept third-party premium and/or cost-sharing payments. "Payments" include those made by any means, for example: cash, check, money order, credit card payment, electronic fund transfer, etc. Third parties not listed above are referred to as "ineligible third parties." For purposes of clarity, but not limitation, commercial (or for-profit) entities, hospitals, and other healthcare providers (including, without limitation, suppliers) are ineligible third parties. Religious institutions and other not-for-profit organizations that do not meet the criteria set forth above are also ineligible third parties.

Any cost-sharing paid by ineligible third parties will not be counted toward an enrollee's deductible or out-of-pocket maximum. "Cost-sharing" includes payments such as deductibles, copayments and coinsurance. Blue Cross may make retroactive adjustments to account for any payments made by ineligible third parties.

You are required to immediately notify Blue Cross of any change in information provided with respect to any third-party payment.

Any person or entity that violates these restrictions and/or makes any ineligible third party payment described above will be held responsible for and will be required to reimburse Blue Cross for all costs associated with the relevant plan or policy related to the violation or ineligible payment.

Payments of premiums and/or cost-sharing by ineligible third parties have the potential to create conflicts of interest, skew the health coverage risk pool and increase the risk of adverse selection. This is detrimental to the long-term viability of the health coverage market overall and can result in increased rates for the entire market.

Continued on back

Bulletin P43-16
Distribution: All participating providers. http://www.bluecrossmn.com/healthy-public-personal/home-providers/forms-and-publications

Blue Cross maintains sole discretion with respect to its acceptance of third-party payments. Blue Cross may make changes to its administration of same at any time and as otherwise needed to support compliance with law and/or applicable regulatory guidance.

If you have questions about this third-party payment policy or whether Blue Cross will accept premium and/or cost-sharing payments made by a specific person or entity, please contact provider services at **(651) 662-5200** or **1-800-262-0820**.

*Indirect payments include, for example, an ineligible third-party making a check out to or otherwise paying the enrollee to permit the enrollee to pay amounts due to Blue Cross.

Exhibit 2

UnitedHealthcare

June 9, 2016

via overnight delivery

Member:
Carrier Name: UnitedHealthcare of North Carolina, Inc.
Policy #:

Dear

Thank you for your payment in the amount of $ on June 3, 2016, for the above medical policy.

Our records show that the American Kidney Fund may have improperly paid your premiums in the past. Your medical policy does not allow a party like the American Kidney Fund to pay your medical premium.

We need to make sure that you paid your premium with your own money. We also need to make sure you do not expect to be reimbursed for this payment from a party like the American Kidney Fund.

What do I need to do?

We want to ensure that you get the help you need. Please sign the attached document and send it back in the envelope we have provided by **June 20, 2016.**

What happens if I don't send back the document?

If you don't sign and return the document, we will not be able to accept your payment. We will return any payment received and you will not have coverage.

What happens if I did receive money from American Kidney Fund to pay my premium?

Please call us right away. You will need to make your payment from your own money.

Do I have any other options?

- You may be eligible to enroll in Medicare if you have End-Stage Renal Disease. We have nurses available to talk to you about this option and other aspects of managing your care. Please call us toll-free at 866-561-7518, TTY 711. We will help you understand all of your options.

- You may be eligible to enroll in North Carolina Medicaid coverage. Please contact the North Carolina Division of Medical Assistance to discuss whether you can access the care you need through their program. Call toll-free **1-800-662-7030**, TTY 1-877-452-2514.

DECLARATION

Under penalty of perjury, I, hereby state that the following information is true and correct to the best of my knowledge and belief, as of the date that I signed this document.

1. I am over the age of majority, suffer from no legal disabilities, and have personal knowledge of the information contained in this Declaration.

2. I am the policyholder listed on Policy Number issued by UnitedHealthcare of North Carolina, Inc. (the "Policy").

3. I applied for the Policy of my own free will after considering available options.

4. I am aware that the Policy states that I must pay my own premium unless payment is made by one of the following parties:

    a. Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act;
    b. Indian tribes, tribal organizations or urban Indian organizations; or
    c. State and Federal Government programs.

5. I hereby certify that the funds used to make the payment on June 3, 2016, in the amount of were not supplied to me (and will not be reimbursed to me) by any third party entity other than one listed in 4 above. Further, I will not pay any future premium for the Policy with funds received from (or reimbursed by) a prohibited third party entity.

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

Executed _____, 2016, at _____, _____.
DATE CITY STATE

_____
SIGNATURE

EXHIBIT 4

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-16-ESRD

DATE: **December 16, 2016**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Notice of Interim Final Rule (IFR) Third Party Payment and Information on Implementation Plan

Memorandum Summary

- **Publication:** The Centers for Medicare & Medicaid Services (CMS) has published an IFR on third party payment requirements in the Federal Register on December 14, 2016. This rule implements new requirements for Medicare-certified dialysis facilities that make financial contributions to patients in order to support enrollment in individual market health plans either directly or indirectly through a parent organization or third party.
- **The IFR establishes new standards under the End Stage Renal Disease (ESRD)** Conditions for Coverage (CfC) *42 CFR 494.70 Patient Rights (c) Standard: Right to be informed of health insurance options* and *42 CFR 494.180 Governance (k) Standard: Disclosure of financial assistance to insurers.*
- The requirements of the IFR apply to any dialysis facility offering financial contributions in the form of premium assistance to support enrollment in individual market health plans. The requirements will be effective 30 days from the date of publication with the exception of one portion of 42 CFR 494.180(k) which may be delayed to July 1, 2017 if there is a potential for a coverage gap for the beneficiary.
- A survey tool has been developed to assess compliance with the new standards pending completion of Interpretive Guidance.

Background

On December 14, 2016, the IFR concerning Third Party Payment requirements for dialysis facilities was published in the Federal Register (see https://www.gpo.gov/fdsys/pkg/FR-2016-12-14/pdf/2016-30016.pdf). This rule affects ESRD suppliers offering financial contributions to Medicare and/or Medicaid eligible patients supporting enrollment in individual market health plans. The rule implements new requirements for dialysis facilities that make financial contributions in the form of premium assistance to support enrollment in individual market health plans whether directly, indirectly, or through a third party. These requirements are intended to ensure insurance coverage decisions are made openly and transparently with full,

accurate information, and the information provided is not affected by the financial interest of the dialysis facility. The new standards apply to any dialysis facility offering financial contributions for payment of individual market plan premiums directly or by contributing to an organization that supports payment of individual market premiums. Dialysis facilities that do not offer financial assistance supporting individual market enrollment and do not make financial contributions to other entities that provide financial assistance *are not subject to the new requirements*. Dialysis facilities determined to be out of compliance with the new standards must follow standard procedures for correction of deficiencies.

Discussion

The IFR establishes two new standards under the ESRD CfC: 42 CFR 494.70 Patient Rights and 494.180 Governance:

42 CFR 494.70 (c) Standard: Right to be informed of health insurance options, requires facilities to inform ESRD patients of all health coverage options available including Medicare, Medicaid and locally available individual market plans on admission and annually. The information provided to all patients will also include the following: current and anticipated costs associated with each health plan option including covered services; care providers; prescription drug coverage; co-pays; co-insurance; deductibles; coverage limitations associated with transplant; risks for loss of coverage; penalties and enrollment periods for Medicare and the individual market. Furthermore, the dialysis facility will provide all patients with current information about financial assistance offered by the facility to support enrollment in an individual market plan including the risks associated with assistance. The facility will also be required to disclose current information regarding overall financial contributions to date that support enrollment in an individual market plan.

42 CFR 494.180 Governance (k) Standard: Disclosure of financial assistance to insurers requires applicable dialysis facilities to disclose to the health insurance issuer that premium assistance will be provided to the purchaser of the policy and must obtain the issuer's written agreement that payments will be accepted throughout the duration of the plan year to avoid interruptions in the patient's health insurance coverage.

A surveyor tool is provided to assist surveyors in assessing compliance with the new standards. This tool should be utilized pending the issuance of Interpretive Guidance. Surveyors are expected to incorporate the surveyor tool into the survey process upon the effective implementation date of the regulation.

Following the entrance conference, the surveyor should conduct an interview with the facility administrator or designated personnel using the surveyor tool and document their responses to each question. The surveyor tool consists of a total of seven questions. Question one determines whether the requirements are applicable to the facility. If the answer to question one is "no" the surveyor will not proceed to the additional questions. A "no" response to questions two through six would indicate a deficiency at *42 CFR 494.70 Patient Rights (c) Standard: Right to be informed of health insurance options* and a "no" response to question seven would indicate deficient practice at *42 CFR 494.180 Governance (k) Standard: Disclosure of financial assistance to insurers*.

Contact: Please email any questions to the ESRD mailbox at ESRDQuestions@cms.hhs.gov.

Effective Date: Immediately. This policy should be shared immediately with all survey and certification staff, their managers and the State/Regional Office training coordinators.

/s/
David R. Wright

Attachment- Evaluation of Third Party Payment Worksheet

cc: Survey and Certification Regional Office Management

Evaluation of Third Party Payment Requirements Worksheet

Facility: _____ **Date/Time:** _____

Interviewee: _____ **Surveyor:** _____

Interview a designated facility staff member during the entrance conference by answering the questions below. If the interviewee answers "No" to question 1 **do not** proceed further. The answer "No" for questions 2 -6 would indicate non-compliance at 494.70 Patient Rights and a "No" to question 7 would indicate non-compliance at 494.180 Governance

Questions	Response	Deficiency
Does the facility provide financial contributions to ESRD patients in the form of premium assistance to support enrollment in individual market plans directly, through a parent organization or another entity? **If No do not proceed with additional questions**	Y/N	
Does the facility provide all patients with current information about financial assistance offered by the facility, parent organization or third party to support enrollment in an individual market health plan including limitations and risks associated with assistance?	Y/N	Y/N
Does the facility provide all patients with current information regarding the facility's or parent organization's overall contributions to date made to patient's or third parties supporting enrollment in individual market health plans?	Y/N	Y/N
Does the facility provide all patients current information about available health plan options including but not limited to Medicare, Medicaid and individual market plans available to the patient on admission and annually?	Y/N	Y/N
Does the information provided to all patients include at least the following? • Current and anticipated costs associated with each health plan option including covered services,	Y/N	Y/N

Evaluation of Third Party Payment Requirements Worksheet

Questions	Response	Deficiency
care providers, prescription drug coverage, co-pays, co-insurance, deductibles and enrollment periods for Medicare and the individual market • Coverage limitations associated with transplant including patient costs for pre and post-transplant care of patient and living donor • Risk for loss of coverage and possible penalties		
Does the Social Worker or a designated staff member review all the above information with each patient and answers questions or concerns identified by the patient regarding health insurance options in the context of the patient's individualized plan of care?	Y/N	Y/N
Does the facility have policies and procedures for • Communication with individual market health insurance issuers to disclose the facility's intent to offer financial assistance to patients supporting enrollment in an individual market plan • Obtaining the issuer's agreement to accept payments for duration of plan year	Y/N	Y/N

EXHIBIT 5

Blue Cross and Blue Shield of Minnesota
and Blue Plus
P.O. Box 64560
St. Paul, MN 55164-0560
651 662-8000
800 382-2000

VIA EMAIL AND OVERNIGHT DELIVERY

December 27, 2016

Karen A. Gledhill
Senior Vice President and General Counsel
Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451-1457

Dear Ms. Gledhill,

I am writing in response to your letter of December 20, 2016. In your letter, you requested that Blue Cross and Blue Shield of Minnesota and Blue Plus (collectively referred to in this letter as "Blue Cross") take certain actions to clarify their acceptance of premium assistance funded by the American Kidney Fund (AKF) for coverage obtained outside of the individual market plan segment that was addressed in the Interim Final Rule (IFR) recently released by the Centers for Medicare and Medicaid Services (CMS).

In a letter dated November 4, 2016, we notified your organization that, for coverage that takes effect on or after January 1, 2017, Blue Cross will no longer accept direct or indirect premium or cost-sharing payments (in whole or in part) from the American Kidney Fund (AKF). On December 12, 2016, a follow-up communication was sent to your organization to clarify the scope of the policy articulated in the November 4th letter. That follow-up communication indicated that:

"The policy applies to fully-insured commercial lines of business including individual/family coverage and group coverage. It does not currently apply to government program plans, including Medicare Advantage or Cost plans, Medicare supplement plans and Medicaid plans (PMAP and MNCare). If a member has more than one plan, for instance, an individual commercial plan and a Medicare Cost plan, this third party payment policy currently only applies to their commercial plan." Similarly, the policy does not currently apply to Medicare Part D plans.

The follow-up communication to your organization further indicated that members in fully-insured commercial individual/family and group coverage are bound by these third party payment limitations under the terms of their policy/plan contract.

In your December 20th letter, you also requested that: (i) Blue Cross update the Provider Bulletin P43R1-16, dated November 1, 2016; and (ii) Blue Cross send a follow up communication to the individual market plan members that received notice in November of 2016 that Blue Cross will no longer accept AKF payment in connection with individual market plans in 2017. Updates to

Bulletin P43R1-16 are already in process – the content of those updates is determined at Blue Cross' discretion. Regarding the member letters, those letters were sent to members in individual market plans that we had identified as supported by AKF payment, and the payment policy articulated therein applies with respect to individual market plans.

The website page you enclosed with your letter is linked from the "Individual and Family Plans" page of the Blue Cross website, and is provided for those shopping for individual/family plans available in the commercial market. However, Medicare Plans (including Medicare Supplement plans) and Minnesota Health Care Programs (including Medicaid) are addressed in separate areas of the Blue Cross website – the website page you enclosed with your letter does not appear in those areas of the website, because the third party payment policy does not currently apply to plans in those government program market segments.

The current scope of Blue Cross' third party payment policy, which is consistent with the IFR, is further articulated in Blue Cross' Third Party Payer Guidelines, available on the website, which specifically state:

> These requirements govern Blue Cross and Blue Shield of Minnesota's and Blue Plus' (Blue Cross') acceptance of certain payments by third party payers. This policy applies to fully-insured commercial lines of business, including individual/family plans and group plans. It does not currently apply to government program plans, including Medicare Advantage or Cost plans, Medicare supplement plans and Medicaid plans (PMAP and MNCare). If a member has more than one plan, for instance, an individual commercial plan and a Medicare Cost plan, this third party payment policy currently only applies to their commercial plan. For plans effective on or after January 1, 2017, members are bound by third party payment limitations under the terms of the policy/plan contract. Blue Cross has the discretion to reject payments from third party payers in accordance with applicable law. Payments of premiums and/or cost-sharing by ineligible third parties have the potential to create conflicts of interest, skew the health coverage risk pool, and increase the risk of adverse selection. This is detrimental to the long-term viability of the health coverage market overall and can result in increased rates for the entire market.
>
> For members in individual/family plans, an exception to this policy may be made, at Blue Cross' discretion, for certain individuals who are newly enrolling in Medicare Part A and/or Part B during the 2017 Original Medicare General Enrollment Period (which occurs from January 1 to March 31, 2017), and who are not eligible for a Medicare special enrollment period.

We appreciate your inquiry and the opportunity to clarify where our guidelines clearly delineate between those covered in the commercial segment and the government programs segment (where the third party payments in question currently continue to be accepted).

Sincerely,

Joel A. Mintzer

Deputy General Counsel

EXHIBIT F

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No._____
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al*.,	)	
	)	
Defendants.	)	

DECLARATION OF J. CHRISTOPHER BRENGARD IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

1. I am the Chief Executive Officer of U.S. Renal Care, Inc. ("USRC" or the "Company"), a plaintiff in the above-captioned case, and I am submitting this declaration in support of the plaintiffs' motion for a temporary restraining order and preliminary injunction prohibiting the enforcement of the Interim Final Rule (the "Rule") issued by the Centers for Medicare and Medicaid Services ("CMS"), Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment, 81 Fed. Reg. 90,211 (Dec. 14, 2016) (to be codified at 42 C.F.R. §§ 494.70, .180). I have personal knowledge of the facts set forth in this declaration or believe them to be true based on my experience in the dialysis industry. If asked to do so, I would testify truthfully about the facts set forth in this declaration.

I. BACKGROUND

A. USRC's Business

2. I founded USRC in 2000 with the goal of growing the Company into the highest-quality dialysis provider available to patients with chronic and acute renal disease. I have served as CEO of USRC since its inception and am familiar with all aspects of the Company's business.

3. USRC is headquartered in Plano, Texas. It owns, co-owns, and manages hundreds of dialysis facilities across the United States, each of which is enrolled in the Medicare program or (for newer facilities) in the process of becoming enrolled in the Medicare program.

The Company's dialysis facilities provide both in-center and in-home dialysis services for end-stage renal disease ("ESRD") patients. The Company also manages several acute-setting dialysis programs in conjunction with local hospitals.

4. USRC serves more than 23,000 patients across 31 states and the Territory of Guam, making it the third-largest dialysis-provider chain in the United States by number of patients. The Company has a significant rural presence, with 43 dialysis facilities more than 10 miles from the nearest alternative and 20 facilities more than 20 miles from the nearest alternative.

B. CMS's Regulation of Dialysis Facilities

5. As a participant in the Medicare and Medicaid programs, USRC is subject to rules and regulations promulgated by the Department of Health and Human Services ("HHS"). Dialysis providers, such as USRC, must comply with these rules and regulations in order to receive Medicare funds. Within HHS, CMS has been charged with Medicare-related rulemaking.

6. CMS conducts regulation and enforcement activities to ensure that Medicare dialysis facilities comply with federal standards for patient health and safety and quality of care. It also administers a survey and certification program. This program is a joint effort of the federal and state governments. At the federal level, CMS establishes standards and regulations for the safe and effective operations of dialysis facilities, develops guidelines and procedures for the operation of dialysis facilities, provides training for conducting surveys, and coordinates the survey activities of individual states. State survey agencies investigate complaints lodged against dialysis providers.

C. ESRD And Coverage Options For Dialysis Treatment

7. Nearly all patients served by USRC's dialysis facilities suffer from ESRD, an irreversible medical condition in which a person's kidneys cease functioning. Persons who suffer from ESRD require a regular course of long-term dialysis—multiple times per week—in order to survive. Dialysis is a medical procedure that removes toxins from the blood, as well as

harmful waste, extra salt, and fluids that build up in the body due to kidney failure. A person suffering from ESRD will die within a short period of time without dialysis or a kidney transplant. ESRD patients are often afflicted with multiple pre-existing co-morbidities as well, such as diabetes, hypertension, and congestive heart failure.

8. ESRD patients have a variety of insurance options available to them—from private insurance offered by an employer or purchased individually, to whole or partial public coverage through Medicare, Medicaid, or similar programs. The specific options available to a given patient depend on a number of factors, including, but not limited to, state of residence, age, and financial status. The majority of USRC's patients are insured by Medicare or Medicaid.

9. CMS requires dialysis facilities to provide their patients with information about health care coverage options. *See* CMS, *ESRD Surveyor Training, Interpretive Guidance* 271 (2008), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/downloads/esrdpgmguidance.pdf (stating that the services dialysis facilities should offer include "providing information and helping patients apply for Medicare, Medicaid and other insurance benefits to assure payment for care").

10. In accordance with that obligation, USRC educates its patients on their choices, providing comprehensive, accurate information consistent with Medicare requirements. It does not direct patients towards any particular insurance option or plan. Whenever possible, the USRC team includes a patient's family members in the education process. Patients are also referred to external sources of information, such as CMS educational materials.

11. USRC employs an interdisciplinary team that includes social workers, insurance counselors, and members of each patient's medical care team. The team regularly assesses a patient's psychological well-being, financial capabilities and resources, and insurance options, and communicates with the patient on these issues.

12. USRC's social workers generally have a master's degree in social work and are licensed, if necessary, in the states in which they work. They work closely with patients on a number of different focus areas, including emotional support, disease education, family and other

support systems, and goal setting. They help patients find community resources for transportation, home health services, and nutrition. They help traveling patients arrange for dialysis treatments in a visiting center. They help patients understand their rights and responsibilities, as well as the Code of Conduct and grievance procedures within their centers. They help patients select the type of coverage needed and, if necessary, apply for premium financial assistance. By presenting a full picture of the patients' needs to the dialysis team, social workers help ensure the best decisions will be made regarding the patients' overall health and well-being.

13. USRC's insurance counselors are trained to assist patients review, manage, and maintain private insurance options, including COBRA plans, employer-sponsored plans, and other commercial plans. They work closely with patients to assess current insurance status, risks to maintenance of that status, and healthcare coverage needs (e.g., individual and dependent insurance needs, need for coverage while traveling). They help the patient to understand insurance options available to them, coordinate additional insurance education resources for the patient if requested, and help the patient to enroll in a new insurance plan or maintain existing coverage. By working to understand the breadth of the patient's insurance needs, USRC's insurance counselors help patients to obtain the best coverage available based on the patient's individual situation.

14. USRC's counseling is not limited to the initial stages of patients' treatment. USRC social workers and insurance counselors educate patients about insurance options throughout the time they receive treatment, including up to transplantation. Patients who request assistance are not left to navigate the process on their own.

15. Consistent with CMS's patient-oriented approach, USRC educates patients on not only Medicare and Medicaid insurance options, but private insurance options as well. Thus, if a patient has multiple insurance options, USRC, through social workers and insurance counselors, provides balanced, comprehensive information on each option, including short- and long-term implications. USRC seeks to ensure that its social workers and insurance counselors engage in

unbiased dialogue with each patient.

16. Although USRC provides information about all of the choices available to patients, it is aware that many patients conclude that private insurance affords a better healthcare option for them and their families—and in some cases the only option available to ensure those patients receive the life-sustaining treatments that ESRD patients require.

1. Many ESRD Patients With Commercial Insurance Are Not Eligible To Enroll In Public Insurance Or Cannot Afford Medicare Coverage

17. Most critically, approximately 310 USRC patients are ineligible to enroll in either Medicare or Medicaid. They are either too young to qualify for Medicare, or they cannot meet the citizenship requirement. The only insurance available to most of these patients is through the private market, and many of them are currently receiving charitable premium assistance to support their enrollment in qualified health plans ("QHPs"), plans that are certified by the Health Insurance Marketplace established by the Affordable Care Act. Without access to charitable assistance, these patients will incur significant financial expense, with many becoming uninsured due to limited financial means to pay premiums. Those who become uninsured may lose access to the dialysis treatments they need to survive.

18. Even if a patient is eligible for public insurance, there are many reasons that a patient would prefer commercial insurance. A patient is potentially exposed to higher out-of-pocket costs on Medicare than on a QHP. For example, Medicare Part B beneficiaries must make coinsurance payments of 20% of the cost of physician and outpatient services, with no out-of-pocket limit. Coinsurance costs can be significant for ESRD patients, because not only must they receive regular dialysis treatments, they must also commonly receive treatment for ESRD co-morbidities such as diabetes, anemia, and hypertension. On the other hand, their out-of-pocket expenses are subject to an annual cap under a QHP; that cap varies by plan, but the maximum cap in 2017 is $7,150. This difference can amount to thousands of dollars in extra expenses for Medicare beneficiaries.

19. While a commercial "Medigap" plan can cover these out-of-pocket expenses,

Medigap is not available to ESRD patients under 65 in 23 states. Therefore, patients in these states face uncapped out-of-pocket expenses on Medicare. Approximately 228 USRC patients are currently receiving charitable assistance for QHP plans in states that do not give ESRD patients access to Medigap.

2. Patients With Commercial Health Plans Have Access To More Providers And Achieve Better Outcomes Than Patients Enrolled in Public Health Insurance Options

20. Commercial insurance generally provides broader access to primary care physicians and specialists than Medicare. It is important for ESRD patients to retain access to the primary-care providers and specialists that they have built relationships with, and to have access to the full spectrum of preventative care and medication that their private plan provides. That may not be possible if the patient switches from commercial insurance to public insurance.

21. QHPs may also offer better prescription drug benefits than government insurance. Most Medicare drug plans, for example, have a coverage gap, referred to as a "donut hole." In 2016, Medicare beneficiaries in that gap were responsible for paying 45% of the plan's cost of brand-name prescription drugs, and 58% of the cost of generic drugs. For ESRD patients, many of whom must take more than ten prescriptions per day, a QHP often offers better drug coverage at a lower cost.

22. There are also a number of treatment-related reasons why QHPs might be preferable to Medicaid.[1] Most significantly, many physicians and other healthcare providers do not accept any Medicaid patients. This means that QHPs generally provide broader access to specialists and transplant providers than Medicaid. For instance, an ESRD patient enrolled in

[1] In fact, a number of states explicitly encourage their Medicaid beneficiaries to obtain primary commercial insurance, maintaining Medicaid as secondary coverage. This encouragement is not limited to ESRD patients. These programs especially target beneficiaries with chronic conditions, because QHPs grant these beneficiaries access to services not covered by Medicaid and they allow beneficiaries to more easily cover family members.

Medicaid who has epilepsy and who cannot safely travel will not be able to receive neurological treatment if no neurologists in the area accept Medicaid. If the patient lives in a large state, that patient may have to travel great distances to find a neurologist who does accept Medicaid. Because specialists more commonly accept commercial insurance, the patient is much more likely to receive needed local epilepsy treatment if that patient can obtain a commercial plan.

23. In addition, Medicaid covers only a single individual, while QHPs provide the opportunity for family coverage. For many patients, choosing a plan that covers all members of their family is essential, as well as a financial and administrative benefit.

24. Furthermore, in many cases, QHPs provide access to medications not covered by state Medicaid plans or the Medicaid program generally.

25. QHPs also provide more geographic flexibility, allowing patients to travel out of state. Most Medicaid programs will not provide coverage for services obtained out of state, because each state has its own Medicaid plan.

3. Patients with QHPs Are More Likely To Receive A Kidney Transplant Than Medicare Or Medicaid Patients

26. A patient with private insurance coverage, including with a QHP, may be more likely to receive a kidney transplant than a patient on either Medicare or Medicaid.

27. Certain transplant centers will not accept Medicare or Medicaid, and some Medicaid plans will not pay for live transplant surgery, the type of surgery with the highest success rate. In Texas, for instance, there is only one transplant center that accepts Medicaid.

28. As mentioned above, QHPs also provide much broader access to specialists that may be necessary for a patient to be eligible for the transplant list. For example, dental infections are a leading obstacle to kidney transplant eligibility. Many QHPs provide access to oral specialists, while many Medicare and Medicaid plans do not.

4. Many ESRD Patients Enrolled in QHPs Would Be Harmed If They Lost That Coverage

29. Given all these reasons, the majority of ESRD patients would not benefit from moving from a QHP to public health insurance. Instead, that would expose more than 750

USRC patients—those receiving premium assistance to remain enrolled in QHPs—to significant, and likely unaffordable, out-of-pocket expense increases. Some of those patients would be ineligible for any health insurance at all if they lost QHP coverage.

30. Harm to patients will manifest by impacting access to, and quality of, care. For example, Medicare-eligible patients who are also eligible for Medicaid in a state whose Medicaid program provides minimum essential coverage would potentially lose access to specialists because of Medicare's reduced network. Similarly, Medicare-eligible patients in states that provide Medigap coverage for ESRD patients would potentially lose only access to specialists and the out-of-pocket costs of Medigap premiums.

31. Medicare-eligible patients who are ineligible for Medicaid and who reside in states that do not make Medigap coverage available to ESRD patients, on the other hand, face significant financial costs. As stated above, unlike QHP plans, Medicare has no cap on out-of-pocket expenses. These patients will be required to pay Medicare's 20% coinsurance for treatment until they have exhausted their life savings and potentially become eligible for Medicaid.

32. For patients who are ineligible for Medicare—which includes young ESRD patients who do not meet the years-worked requirement, and non-citizens—the situation is even more dire. Some may be eligible for Medicaid in a state whose Medicaid program provides minimum essential coverage, although that coverage will be limited and they will lose access to important ancillary treatment, such as chemotherapy. The loss of this access may deprive them of the opportunity to secure a kidney transplant. The rest would be left with something less than the minimum essential coverage, and many would be left with no coverage at all. For these patients, all non-emergency health care costs would have to be paid out of pocket.

33. In addition, approximately 905 USRC patients have already elected a QHP for 2017. If their insurers begin rejecting third-party premium payments, those receiving charitable assistance will be forced to cover their own costs until they can enroll in Medicare, or until they reduce their savings sufficiently to qualify for Medicaid. Patients receiving charitable assistance

typically choose a plan with a higher premium and lower deductible and out-of-pocket costs, because charitable assistance covers the premium but not the other costs. These patients will now be obligated to pay higher premiums than the premiums they would have selected had they known they could be deprived of their charitable premium assistance.

D. USRC's Charitable Contributions

34. USRC contributes to the American Kidney Fund ("AKF"), a nonprofit dedicated to helping people fight kidney disease and lead healthier lives. AKF operates independently of USRC and other dialysis providers. When USRC and other providers donate to AKF, they do so without any conditions or restrictions whatsoever.

35. AKF provides a range of services, including educational resources, prevention activities, and financial assistance to people with kidney disease. The need for that financial assistance is great; I understand from information provided by AKF that 70% of people with ESRD have to stop working because of their ESRD or other health problems, and 60% of the patients AKF assists have annual incomes under $20,000. *See Charitable premium assistance: Patients*, American Kidney Fund, http://www.kidneyfund.org/advocacy/third-party/patients/ (last visited Jan. 5, 2017). AKF's financial-assistance programs include assistance with health care coverage costs, grants for children with ESRD, grants for disaster relief, and assistance with transportation costs, prescription medications, and other expenses related to ESRD.

36. AKF provides assistance with the costs of many forms of health care coverage, including Medicare Part B, Medicaid, Medigap, QHPs, employer group health insurance, and COBRA coverage. AKF provides that assistance based on financial need, regardless of the beneficiary's choice of dialysis provider or form of health care coverage. AKF does not help ESRD patients choose between forms of health care coverage.

II. OPERATION OF THE RULE

37. I have read and analyzed the Rule's provisions and am familiar with how the Rule would affect USRC and its dialysis facilities.

38. I understand that the Rule would apply to USRC's dialysis facilities because

USRC contributes to AKF, which provides premium assistance for some QHPs.

39. The Rule would require USRC's dialysis facilities to disclose to health insurance issuers each health insurance plan for which AKF will furnish premium assistance using funds provided by USRC. Under the Rule, USRC's facilities must attempt to obtain each issuer's assurances that it will accept premium assistance for the duration of the plan year. If the issuer does not provide those assurances, then (1) neither USRC nor its facilities may make donations to AKF that will be used for premium assistance for the plan at issue and (2) USRC's facilities must take "reasonable steps" to ensure that AKF does not furnish premium assistance for that plan using funds previously provided by USRC. The Rule does not define "reasonable steps."

40. Because I understand that health insurance issuers have a financial disincentive to accept patients with renal disease, I have no doubt that the Rule would prevent many patients from obtaining the coverage they consider best for themselves and their families.

41. Separately, the Rule would require USRC's dialysis facilities to provide a variety of information to patients. Under the Rule, USRC's facilities must inform patients about the advantages and disadvantages of every health care coverage option available to each patient, potentially including Medicare, Medicaid, the Children's Health Insurance Program, and all QHPs.

42. For each coverage option, USRC's facilities must provide details about the costs of ESRD care, kidney transplantation, and treatment for each patient's other medical conditions. The facilities must also inform patients about the availability and limitations of premium assistance for QHPs. In addition, the facilities must disclose both USRC's donations to AKF and the reimbursements USRC receives from the plans for which premium assistance is provided.

43. The Rule is to become effective on January 13, 2017. USRC's dialysis facilities will be terminated as Medicare suppliers if they do not comply by that date.

III. THE RULE'S IMPACT ON USRC

A. USRC's Dialysis Facilities May Be Unable to Comply with the Rule by the Deadline

44. I have serious doubts about whether USRC's dialysis facilities can comply with the Rule by the deadline. There are two main obstacles.

45. First, it may be impossible for USRC's facilities to comply with both the Rule and HHS Office of Inspector General ("OIG") guidance regarding dialysis providers' contributions to AKF, HHS OIG, *Advisory Opinion No. 97-1* (1997), https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf. That guidance outlines how providers can contribute to AKF without violating federal laws prohibiting improper remuneration to patients.

46. As relevant here, the guidance states that dialysis providers' donations to AKF may not be earmarked for particular beneficiaries or groups of beneficiaries. But the Rule would require USRC to do exactly that. Under the Rule, if a health insurance issuer does not provide assurance that it will accept premium assistance for the duration of the plan year—and issuers are very unlikely to do so, given that they are financially disincentivized to accept patients with renal disease—then USRC must take two steps that would run afoul of the OIG guidance. First, the Rule would require USRC to stop making donations to AKF that would be used for premium assistance for the particular plan at issue or any patients selecting that plan. In so doing, USRC would be forced to channel its funds to other plans and other patients in direct violation of the OIG guidance. Second, the Rule would require USRC's dialysis facilities to take "reasonable steps" to ensure that AKF does not furnish premium assistance for particular plans using funds previously provided by USRC. Any such steps are almost certain to require a degree of earmarking that violates the OIG guidance.

47. USRC could not necessarily avoid this issue by discontinuing its contributions to AKF. The Rule applies to USRC's dialysis facilities so long as USRC contributes to AKF, and the Company last donated on December 2, 2016. It is unclear whether the Rule would cease to apply to USRC's facilities immediately after USRC stopped contributing, or if USRC instead must not have made contributions for a longer period of time.

48. The OIG Advisory Opinion also prohibits providers from "disclos[ing] directly or indirectly to individual patients they refer [to AKF] that such members have contributed to AKF to fund the grants."

49. In direct conflict with that prohibition, the patient disclosure provisions of the Rule require USRC to disclose to patients that it makes charitable contributions to AKF.

50. Moreover, it would be devastating to ESRD patients if USRC and other dialysis providers stopped donating. As discussed, many ESRD patients experience great financial difficulty, and AKF provides assistance with the costs of many forms of health care coverage, not just QHPs. Without AKF assistance, many patients would struggle to afford coverage even if they switched from QHPs to another form of coverage.

51. Second, by promulgating the Rule without any notice or opportunity for comment, CMS left USRC's dialysis facilities with insufficient time to request the required assurances from issuers and to take the necessary steps based on the issuers' responses. CMS promulgated the Rule on December 14, 2016 and provided only 30 days for compliance. During that time period, USRC's facilities must contact approximately 50 issuers for whom patients would receive premium assistance payments from AKF, obtain responses from each, and for the issuers that decline to provide the required assurances, take "reasonable steps" to ensure that AKF does not furnish premium assistance for the plan at issue using funds previously provided by USRC. Quite simply, it is not feasible for USRC's facilities to do all that the Rule requires by January 13.

52. If CMS terminated USRC's dialysis facilities from the Medicare program based on noncompliance with the Rule, the results would be devastating for USRC. Most of USRC's patients have Medicare as their primary form of health care coverage, and USRC would lose over half of its revenue without Medicare payments. That would require the Company to close many of its dialysis facilities and lay off a significant number of its employees.

53. Even if USRC were able to keep some dialysis facilities open initially, it would probably be forced out of business eventually. The Company would lose the economies of scale

associated with its current nationwide presence, would have difficulty attracting new employees following layoffs, and would struggle to maintain its reputation as a leading dialysis provider. USRC could not continue to compete under those conditions. In all likelihood, the termination of USRC's dialysis facilities from the Medicare program would ultimately result in the Company's bankruptcy.

B. USRC Would Incur Substantial Costs To Comply With The Rule

54. Even if every single one of USRC's dialysis facilities could comply with the Rule, doing so would be very burdensome because USRC serves large numbers of patients across numerous states. If permitted to take effect, the Rule would require each of USRC's dialysis facilities to provide information about every health care coverage option available to every existing patient and each new one. With the exception of Medicare, those options differ—often significantly—among the 32 states and territories in which USRC operates. The details of Medicaid and the Children's Health Insurance Program themselves vary significantly based on which state administers them, and the Rule would require USRC to identify and prepare responsive guidance with respect to those nuances on an expedited timeline. QHPs, meanwhile, often differ substantially between states, requiring USRC to collect information about each plan separately and prepare responsive guidance to patients.

55. Those difficulties are compounded by the fact that the Rule would require USRC to provide information not only about the cost of ESRD care and kidney transplantation but also about the cost of treatment for each patient's other medical conditions. The Company serves more than 23,000 patients, and many if not most of those patients have other medical conditions in addition to renal disease.

56. To comply with the Rule, USRC would need multiple full-time employees at its headquarters to compile information about the coverage options available in 32 states and territories, as well as the cost of treatment for each patient's other medical conditions. Even if USRC could assign that task to existing employees at some facilities, it would be able to accept fewer new patients because of decreased staff availability, or it would incur large overtime

expenses and place significant burdens on its existing employees. In any event, the result would be increased expenses and decreased revenue.

57. USRC is already incurring costs to review, comply with, and respond to the Rule, and these compliance costs would only increase when the Rule becomes effective. I understand that USRC may be unable to recover these costs even if it prevails in this litigation, and I am aware of no other way that the Company can be reimbursed for these expenses.

C. The Rule Would Render Many of USRC's Dialysis Facilities Financially Unviable

58. The Rule would—and is manifestly intended to—shift ESRD patients away from QHPs and toward Medicare and other public health care coverage. Under the Rule, a health insurance issuer can greatly limit premium assistance for its plans by declining to provide assurances that it will accept premium assistance for the duration of the plan year. Without those assurances, dialysis providers may not make charitable contributions that will be used for premium assistance for that issuer's plans, and they must take "reasonable steps" to prevent previously donated funds from being used for that purpose. Few if any issuers will provide the required assurances, because patients with end-stage renal disease require costly ongoing treatment. The result will be a large reduction in the availability of premium assistance for QHPs.

59. Most ESRD patients are unable to work, and many have limited financial means and depend on premium assistance. Without that assistance, many of those patients would be unable to afford QHPs, even if that type of coverage is best for them and their families.

60. That shift would cause significant financial losses to USRC. Only about 3,000 of USRC's more than 23,000 patients have private health insurance, but USRC receives significantly higher reimbursement for dialysis treatments for those patients than it does for patients with public health care coverage. USRC actually loses a small amount of money on each treatment for a patient with public health care coverage, so patients with private health insurance effectively enable the treatment of patients with public health care coverage.

61. If the Rule went into effect, USRC would lose many of its patients with private health insurance, approximately half of whom depend on premium assistance. USRC would suffer financial losses and would be forced to scale back its operations in response. It would have to close some of its dialysis facilities, and the patients at those facilities would have to travel to less convenient dialysis facilities or switch providers altogether. The closure of dialysis facilities would be particularly burdensome for patients in rural areas, where USRC often operates the only nearby dialysis facility.

62. This injury would begin as soon as the Rule took effect because patients will enroll in public health care coverage if they currently depend on premium assistance for QHPs but are unsure whether that assistance will remain available. Even if those patients ultimately returned to QHPs, USRC would suffer financial losses in the meantime. As with the costs of compliance with the Rule, I understand that USRC may be unable to recover these losses even if it prevails in this litigation, and I am aware of no other way that the Company can be reimbursed for these damages.

D. The Rule Would Damage USRC's Reputation

63. USRC has an excellent reputation for honesty and trustworthiness among its patients and business partners, and it depends on that reputation to conduct is business successfully. Physicians in the communities USRC serves refer ESRD patients to the Company's facilities because they know that patients can expect outstanding care and fair business practices. The patients themselves select USRC for the same reasons, based on information they receive from their physicians, existing USRC patients, and others in the community.

64. The Rule's becoming effective would damage that reputation in at least two ways. First, CMS has alleged that dialysis providers such as USRC are engaged in improper conduct, and some physicians would view the Rule's taking effect as a ratification of those claims. I understand that CMS issued the Rule in part because it contends that dialysis facilities are inappropriately influencing patients to choose QHPs over Medicare and other public options

based on the facilities' financial interest in higher reimbursements from private insurers, rather than the patients' preferences for more coordinated care or additional benefits that may be available through QHPs. That claim harms USRC's reputation by suggesting that the Company is prioritizing its financial self-interest over patients' health and well-being and that it is concealing its true reasons for providing health insurance information to patients.

65. Physicians who specialize in the treatment of patients with renal disease are generally familiar with the regulatory requirements for Medicare coverage of dialysis and are likely to learn about the Rule as it takes effect. I believe that many physicians would view USRC, its dialysis facilities, and its employed social workers as partly responsible for the conduct that purportedly triggered the rule.

66. Even a small loss of trust by physicians would seriously damage USRC's business, making it more difficult for USRC to operate its dialysis facilities, which are central to the Company's business strategy and its ability to provide services to patients. In addition, patients and treating physicians would be less likely to use USRC's dialysis facilities because the negative implications of the Rule would erode the Company's longstanding goodwill and trust established with those individuals.

67. This reputational harm would begin immediately after the Rule became effective because physicians are likely to learn about the Rule as it takes effect. Once the injury occurred, it would be impossible for USRC to reestablish its good reputation in the near future because the invalidation of the Rule would not undo the damage caused by CMS's allegations.

68. Second, the requirement that USRC disclose to patients information about its contributions to AKF and its reimbursements from QHPs will harm USRC's relationship with its patients. Many patients are likely to conclude (erroneously) as a result of the required disclosure that the Company is receiving a quid pro quo for its donations. When patients learn that USRC contributes to a nonprofit that provides premium assistance to low-income patients, they are likely to assume that the disclosure is mandated because of a conflict of interest. The required disclosure sets a tone of distrust for USRC's relationships with its patients. Even if USRC also

provided information showing that the AKF operates independently of the Company, patients would likely view that information skeptically in light of the mandated disclosure. This distrust could disadvantage USRC relative to competitors that do not contribute to nonprofits providing premium assistance, because patients who are suspicious of USRC may choose another provider.

69. In addition, patients would lose trust in USRC due to the Rule's obligation that USRC disclose sensitive financial information to the patients' insurers. The fact that a patient cannot afford insurance premiums, and thus must receive charitable assistance, is information that patients trust USRC to keep private. USRC would breach that trust by disclosing the information to insurers. That breach of trust would not only violate patients' expectations of confidentiality and privacy, but also would cause a number of patients to lose vital private coverage that is in many ways much more beneficial than government coverage, from both a financial and health-outcome perspective. Patients would likely blame USRC for that loss of coverage, harming USRC's goodwill with its patients.

70. This potential loss of coverage from the Rule's disclosure obligation would further incentivize patients with QHP coverage to choose providers that do not contribute to nonprofits providing premium assistance. If a provider does not donate to AKF or another organization providing assistance, it need not disclose to insurers that its patients receive such assistance. A substantial portion of charitable premium assistance goes to patients of providers who do not donate, and under the OIG's Advisory Opinion, charities must make premium assistance available to patients regardless of whether their providers contribute. When the Rule is implemented, these noncontributing providers will have no obligation to seek assurance that insurers will accept third-party QHP premium payments, and their patients may be able to continue to receive this assistance for QHP coverage. Because QHP plans have significant advantages—both financial and in terms of health outcomes—over public insurance, many patients are therefore likely to leave USRC for another provider if doing so allows them keep their QHP coverage.

71. These reputational harms would likely begin on the day the Rule took effect,

when USRC had to start making the required disclosures to patients and insurers. And the harms would only increase in the following weeks as more and more patients received the disclosure to patients and learned of USRC's disclosures to insurers. Once the injury occurred, it would be impossible for the Company to reestablish its good reputation because the invalidation of the Rule would not reverse the negative effects of the disclosures.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on January 5, 2017.

J. Christopher Brengard

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 4:17-cv-16
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	

[PROPOSED] ORDER GRANTING PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Pending before the Court is Plaintiffs' Emergency Motion for Temporary Restraining Order and Preliminary Injunction. Having considered the Motion and the supporting affidavits, the Court grants the requested injunction and preliminarily enjoins implementation of the Interim Final Rule, published at 81 Fed. Reg. 90,211 (Dec. 14, 2016), titled *Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment*. Due to the expedited nature of these proceedings, this Order will stay the effective date of the Interim Final Rule until a final adjudication of Plaintiffs' claims, with a more detailed written decision explaining the Court's reasoning to follow.

Plaintiffs have satisfied each of the four prerequisites for a temporary restraining order and preliminary injunction, and the balance of equities favors granting such relief. *See Byrum v. Landreth*, 566 F.3d 442, 445 (5th Cir. 2009). *First*, Plaintiffs have demonstrated a substantial likelihood of success on the merits. HHS promulgated the Rule without notice-and-comment procedures as required by the Administrative Procedure Act, 5 U.S.C. § 553, and the Medicare Act, 42 U.S.C. § 1395hh(b)(2). And HHS's reasons for invoking the good-cause exception to

notice-and-comment rulemaking, *see* 5 U.S.C. § 553(b)(B); 42 U.S.C. § 1395hh(b)(2)(C), do not withstand legal or factual scrutiny, as Plaintiffs have convincingly demonstrated. "Good cause" is only rarely satisfied, and the justifications offered by HHS here do not satisfy that high standard. In fact, Plaintiffs have demonstrated that the Rule likely will cause the disruptions to patient health-insurance coverage it is purportedly designed to address.

Plaintiffs have also established a substantial likelihood that the Rule is arbitrary and capricious. For example, HHS failed to consider at all the negative effects on ESRD patients from forcing them to transition from private insurance coverage to public coverage, and therefore overlooked an "important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2016) ("reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions"). The Rule also facilitates unlawful discrimination by insurers, in violation of the Affordable Care Act's anti-discrimination provisions and its requirement that insurers accept every individual that applies for coverage. *See* 42 U.S.C. § 18116; *id.* § 300gg-4(a). Finally, the Rule unreasonably departs from HHS's prior guidance, as established in its 1997 Office of the Inspector General opinion, without acknowledging that it was doing so. *See FCC v. Fox Television Stations*, 556 U.S. 502, 516 (2009).

Second, absent an injunction staying the effective date, the Court finds that Plaintiffs will suffer immediate, irreparable harm in the form of coverage disruption for individual End Stage Renal Disease ("ESRD") patients (whose interests are represented in this litigation by Dialysis Patient Citizens) and substantial, irrecoverable economic losses for Provider Plaintiffs, which would result from, among other things, possible Medicare program termination, facility closures,

the loss of business and patient relationships, and the costs to comply with the Rule's inconsistent and vague standards.

Third, the balance of equities favors preliminary relief because Defendants will not be harmed by a preliminary injunction that preserves the status quo while the Court addresses the merits of Plaintiffs' legal challenges to the Rule.

Fourth, the public interest lies in maintaining ESRD patients' access to insurance coverage options of their choice, and in ensuring that government agencies comply with the law, including the notice-and-comment requirements of the APA and the Medicare Act.

Finally, this Court has authority to enjoin the Interim Final Rule's implementation on a nationwide basis, and it finds that it is appropriate to do so in this case. *See Texas v. United States*, 809 F.3d 134, 188 (5th Cir. 2015).

THEREFORE, HHS's Interim Final Rule published at 81 Fed. Reg. 90,211 is hereby enjoined. Specifically, Defendants (and their agents) are enjoined from implementing and enforcing the following regulations as amended by 81 Fed. Reg. 90,211: 42 C.F.R. §§ 494.70 and 494.180, pending further order of this Court.

IT IS SO ORDERED