

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.

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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.

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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

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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 day⁵—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.

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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

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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.

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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).

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- 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.

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- 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.*

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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).

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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 disproportionately 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

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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>.

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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.

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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

²⁴42 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](https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace%20Master%20FAQ%208-28-14%20v2.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-](https://www.medicare.gov/sign-up-change-plans/get-parts-a-and-b/special-conditions)

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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).

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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.

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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

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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-medicare-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).

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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.

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- 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.

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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").

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- 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.”).

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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.

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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>.

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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;

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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 law⁵⁵ 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

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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-ethnicity/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.

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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).

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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 HIPPA;
- 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