



September 22, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-6074-NC: "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans"

Dear Acting Administrator Slavitt:

On behalf of Kidney Care Partners (KCP), I appreciate the opportunity to provide comments on the Request for Information entitled "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans" (RFI). As you know, KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both CKD and irreversible kidney failure, known as ESRD.¹

We reiterate our continued disappointment that CMS has not protected dialysis patients who wish to remain in their Exchange plans and must rely upon charitable assistance to do so. These patients have the same rights as those who can afford such coverage directly. The number of patients with kidney failure relying on charitable assistance in Exchange plans is extremely small. According to the American Kidney Fund (AKF), which operates under an Advisory Opinion from the Office of the Inspector General (OIG), there were only 6,400 patients in 2015 with kidney failure who receive AKF assistance to meet their Exchange plan coinsurance obligations. This number constitutes 0.05 percent of the 12.7 million Americans currently enrolled in Exchange plans. As we describe in detail in the letter, these patients' rights to remain in the plan of their choice should not be limited merely because they need charitable assistance.

At the outset, we also wish to echo the concerns outlined in the RFI stating that it is not appropriate to steer individuals toward or away from certain health insurance plans. KCP and our members do not condone any activity that seeks to direct patients to health insurance plans that may not be appropriate for them. As we have noted in previous letters, KCP strongly supports efforts to ensure that

¹ A list of KCP members is provided in Appendix A.

dialysis patients receive accurate and complete information about their plan options so that they can select the plan that best meets their needs, as well as the needs of their families. In light of our ongoing concerns, we are troubled that the RFI fails to seek information about behaviors that health plan issuers have undertaken to steer dialysis patients away from private insurance options. Because it is equally important that issuers, as well as providers, empower individuals to allow them to select their own plans, we also provide updated information about documented issuer behaviors that discriminate against patients with kidney failure and make specific recommendations as to how CMS can stop the inappropriate steering in which some issuers are engaging.

In sum, we ask that CMS protect the right of all patients, as promised them by the President, to select the health plan that best meets their needs. This means that not only providers, but also issuers, who are found to have inappropriately steered patients toward or away from certain plans for the provider's or issuer's benefit should be prohibited from doing so.

I. CMS should distinguish between educating individuals about insurance options from “steering” individuals toward or away from certain plans.

A. CMS should not confuse educational and charitable practices with steering.

While KCP condemns practices by any entity – including issuers – meant to steer individuals toward or away from certain plans, it is important to distinguish legitimate educational and charitable practices from steering.

Under the Conditions for Coverage, dialysis facilities are required to convene interdisciplinary teams. This team “is responsible for providing each dialysis patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient’s treatment plan and expectations for care.” It includes not only health care providers, but also social workers.² The social worker is responsible evaluating a patient’s psychosocial needs, as well as his/her family and other support systems.³ In the preamble to the 2008 Final Rule updating the Conditions for Coverage, CMS acknowledges in the preamble that social workers, or other members of the interdisciplinary team, may perform a variety of tasks, including assisting with insurance coverage.⁴ When working with patients, this assistance includes providing educational information about a patient’s health insurance options so that the patient can make an informed decision about what insurance plan is right to

²42 C.F.R. § 494.80.

³*Id.*

⁴73 *Fed. Reg.* 20370, 20424 (Apr 15, 2008).

meet his/her needs and, when appropriate, the needs of his/her family members. The obligation is echoed in the CMS Patient Rights documents also emphasize that patients must be told about any financial assistance available to them.⁵ Despite accusations from some issuers, providing this information in a balanced and accurate manner is not steering and should not be considered as such. Also, informing an individual that he/she has access to charitable or other types of financial assistance should not be conflated with the concept of steering.

In addition, it is not steering when an individual seeks to obtain charitable assistance so that he/she may retain existing private insurance. As CMS has noted in various regulatory contexts, eligibility for Medicare coverage due to a diagnosis of ESRD does not require enrollment in Medicare. There is no question that individuals who can afford to pay their coinsurance obligations are allowed to maintain their existing coverage, or even to change their insurance policies by remaining in the group or individual market. Patients who may not have the same financial resources but with assistance from a not-for-profit, 501(c)(3) charitable organization operated, consistent with federal law could make a similar choice, should be allowed to do so.

Conversely, it is steering when issuers undertake specific actions that require or incentivize individuals with ESRD to drop their private coverage or place it as secondary to Medicare and/or Medicaid before these individuals are required to do so. KCP members have documented the following activities undertaken by specific Exchange plan issuers with the intent of dropping individuals from coverage based on their health status:

- **Misleading patients:** Some plans mislead enrollees by suggesting that federal law requires individuals with ESRD to enroll in Medicare four months after having been diagnosed with ESRD.
- **Incentivizing patients to shift to Medicare:** Some plans will pay the Medicare coinsurance amounts or other cost-sharing obligations on behalf of the individuals if they shift their coverage to Medicare.
- **Increasing patients' coinsurance obligations:** Some plans increase individuals' coinsurance obligations by dropping the plans' payments to providers to rates at or slightly above the Medicare rates, placing individuals in the position of being responsible for paying the remainder of the rates plans negotiated with providers.

These behaviors are discriminatory and seek to push these patients into Medicare and, thus, should be prohibited.

⁵CMS, "Dialysis Facility Patient Rights," available at <https://www.medicare.gov/dialysisfacilitycompare/#resources/patients-rights>.

B. Individuals with kidney failure have the same right to select a plan that best meets their needs – even if it is not a Medicare or Medicaid plan.

While the kidney care community remains supportive of the unique status of patients with kidney failure in that most have the ability to enroll in Medicare prior to turning 65 years old, this unique status does not under current law eliminate their right to exercise the same choice that other Americans under 65 years old have to select a health care plan that best suits their needs and those of their families. These patients are not necessarily “more vulnerable” to steering because of their disease status, but some could inappropriately view these patients as not needing the same choices as other individuals because they have Medicare and/or Medicaid as a default option for coverage. Such a conclusion is false because while Medicare and/or Medicaid can be beneficial to many patients with kidney failure, it does not meet every patient’s needs—especially when considering the complex health issues that most kidney failure patients face, it is particularly important that they be afforded the same choice as other Americans in selecting an appropriate health plan.

As the Congress has repeatedly recognized by extending the Medicare Secondary Payer (MSP) provisions that apply to all group health plans,⁶ Medicare is not necessarily the best fit for all patients. For example, patients with other family members who require coverage may wish to retain their private coverage rather than duplicate cost sharing requirements across two different plans. Other patients may wish to enroll in plans with better chronic care management benefits, which Medicare patients under 65 years old cannot access. Currently, Medicare patients who enroll based on their diagnosis of ESRD are prohibited from selecting Medicare Advantage. In about half of the States, patients who qualify for Medicare because of a diagnosis of ESRD may not be able to access Medigap plans and, therefore, wish to rely upon private insurance, which may have more favorable cost-sharing obligations or expanded coverage. Whatever the reason, patients with kidney failure have the same right as all Americans to select the health plan that works best for them and their families. It should not be assumed that Medicare is always the right choice for every such patient.

Similarly, there are a small number of Medicaid eligible individuals who may wish to retain their Exchange coverage or retain Medicaid as secondary coverage. Current law does not prohibit such individuals from retaining their Exchange coverage, but it does prohibit them from receiving a subsidy or tax credit if doing so. There are also valid reasons an individual may seek to retain private insurance rather than enroll in Medicaid. For example, it can be difficult for individuals to find

⁶42 U.S.C. § 1395y.

health care providers who will accept Medicaid enrollees.⁷ Similar to Medicare, Medicaid coverage in many states is limited to an individual, leaving their family members to have to find another option for insurance. Perhaps most importantly, individuals who rely upon Medicaid have a *de facto* barrier to being able to travel. Many Medicaid program will not cover treatments provided in noncontiguous States. Such restrictions can be particularly difficult for individuals with family members in other States. Additionally, 30 State Medicaid programs also provide assistance to certain Medicaid eligible, but not enrolled, individuals to allow them to obtain private insurance.⁸ As long as these individuals are able to legitimately meet their coinsurance obligations, they should be permitted to do so. In fact, some States have established programs approved by CMS through its waiver process to encourage some Medicaid eligible individuals to retain their private coverage. Patients with kidney failure should not be prohibited from participating in these waiver programs simply because of their medical condition.

We agree that CMS should ensure that there is not duplicative coverage; however, the solution is not to allow the issuer to decide that the patient must enroll in a government program, but rather to allow the patient to make that choice and have CMS provide the information necessary to issuers, providers, and others about each patient's enrollment status.

C. AKF's HIPP program does not increase the risk of steering.

As we have written in many previous letters and discussed with your staff, patients with kidney failure have come to rely upon AKF to assist them as they battle kidney failure. AKF plays a critical role in helping the nation's dialysis patients maintain their access to health insurance coverage. Established in 1971 by patients for patients, the AKF seeks to help patients retain their autonomy to select the health plan of their choice and now provides direct assistance to patients in all 50 states, the District of Columbia and every U.S. territory. As the Department of Health and Human Services (HHS) OIG concluded: "AKF is a bona fide, independent, publicly-funded, 501(c)(3) charitable organization whose charitable purposes include aiding ESRD patients and their families."⁹

⁷For example, the Kaiser Family Foundation has reported that only 44 percent of primary care providers accept new Medicaid patients. Kaiser Family Foundation, "Issue Brief: Primary Care Physicians Accepting Medicaid, A Snapshot" available at <http://kff.org/medicare/issue-brief/primary-care-physicians-accepting-medicare-a-snapshot/> (Oct. 2015).

⁸For example, Arkansas is one State that provides such assistance in this way through a CMS-approved waiver. Other States providing such programs include Colorado, Iowa, and Missouri, as well as many others. Illinois specifically provides assistance to patients with certain chronic conditions, including cancer, HIV/AIDS, and kidney disease. See <http://www.dhs.state.il.us/page.aspx?Item=19229>.

⁹ OIG, Advisory Opinion 97-1, at 6.

AKF's HIPP program began serving patients with kidney failure in 1997, many years before the enactment of the Affordable Care Act (ACA). When the ACA came online, AKF offered assistance for ACA plans in the same way it historically offered assistance for the full spectrum of insurance products.

Patients who are in the Exchanges and receive assistance make up less than 10 percent of all of the patients the AKF assists. Of these 6,400 Exchange patients, one-quarter relies upon the assistance because they live in States that prohibit them from purchasing Medigap policies. The vast majority of the patients who receive this assistance are minority patients, particularly African Americans. To qualify for this assistance, they must meet strict low-income requirements.

The AKF process for awarding patients with year-long assistance grants is completely separate from any of the entities who provide donations, as the OIG has recognized in writing. This process relies upon the financial information provided by the patient. As with most charities, AKF does not have the resources to confirm each applicant's insurance status.

Given the long and positive history of the AKF in administering funds to support patients with kidney failures in all types of health insurance – not only Exchange plans – KCP continues to be perplexed that CMS has not clarified that a program such as AKF with the guardrails placed upon it by the OIG should be permitted to provide assistance to patients seeking to exercise the choice guaranteed them in the ACA. This assistance allows those who are otherwise marginalized – particularly minority patients – to exercise their choice. Issuers should not be permitted to discriminate against these patients merely because they rely upon a 501(c)(3) charity for assistance rather than an employer, family member, or other individual who can support them. It is also disappointing that patients with kidney failure have been singled out for such treatment, when patients with cancer or HIV/AIDS are allowed to rely upon such third party assistance to remain in the health insurance plan of their choosing.

D. The Congress and Administration have concluded that eligibility does not mean enrollment for purposes of selecting a health plan.

KCP also is concerned that the RFI contains language that suggests that the decisions by the Congress (through the MSP provision), the Internal Revenue Services (IRS, through the tax credit and subsidies regulations), and even CMS (through previous Notice of Benefit and Payment Parameter regulations) should now not apply for purposes of Exchange plan coverage. In each of these contexts, federal policy-makers have concluded that the unique status of patients diagnosed with ESRD being eligible for Medicare does not eliminate their right to retain existing private coverage or even obtain new private coverage. While issuers may wish to eliminate their responsibility for these patients, patients have been very

clear over the years that they support policies that promote patient choice in selecting their coverage options.

Eliminating this right to select their coverage would have an immediate negative impact on individuals with kidney failure. As noted earlier in the letter, Medicare and/or Medicaid are not always the right option for individuals and their families. Forcing them into a Medicare- or Medicaid-only option could increase their financial burden, reduce their access to providers of their choice (especially for their family members), cause disruption in their care management (especially for other chronic diseases they may be managing), and even reduce their chance for a transplant.

The RFI particularly raises a question about the potential impact on patients receiving transplant. As noted previously, selecting the right coverage is a highly personal decision even when transplant is involved. For example, a recent study found that particularly for minority patients with kidney failure, private insurance increased their chances of receiving a kidney transplant. Researchers looked at the relationship between transplant status (both deceased donors and living kidney transplantation (LKT)) and the recipients' health insurance status. They found that "a higher proportion of patients with private insurance, relative to those without private insurance, received LKT." African American patients were 11 times more likely to receive a transplant if they had private insurance than if they were enrolled in Medicaid. The researchers concluded that "[r]ecipient insurance status is associated with LKT, positively with private insurance and negatively with Medicaid."¹⁰ Given these findings, CMS should not assume that Medicare, and especially Medicaid, will always be the best choice for every patient with kidney failure.

Medicare may also not be the best option for transplant patients because once a patient receives a transplant, he/she can no longer remain in Part A and retain Part B only for purposes of receiving their immunosuppressive medications. In light of concerns about care coordination and maintaining provider relationships, there are clearly reasons why some patients with kidney failure would want to try to retain their private coverage for purposes of receiving a transplant and the follow-up care.

Additionally, patients with kidney failure are equally unique in that they are not subject to late enrollment penalties during the MSP 30-month period. Given the MSP statutory requirements, as well as the IRS and CMS decisions that clearly state that eligibility does not require enrollment, they are in a different place with regard to enrollment timing. In addition, the individual patient should have the ability based on accurate and complete information to decide whether he/she prefers

¹⁰AM Reeves-Daniel, AC Farnety, *et al.*, "Ethnicity, medical insurance, and living kidney donation," 27 *Clin Transplant*. E498-503 (2013).

Exchange coverage versus Medicare, even if the penalty were to apply. Issuers and the government should not paternalistically make that decision for the patient.

E. CMS should be clear that actions that discriminate against individuals with kidney failure, as well as the act of providing inaccurate or incomplete information to steer individuals toward or away from particular plans, are prohibited.

In previous letters, KCP has strongly supported the antidiscrimination provisions in the MSP statute, as well as the Section 1557 requirements more recently implemented by the Office of Civil Rights (OCR) and the Department of Labor requirements related to employer plans. Patient organizations have filed complaints with both OCR and the Department of Labor seeking to enforce the existing laws and to stop issuers from discriminating against individuals with kidney failure. We encourage CMS to work with these patient organizations to identify and stop discriminatory practices that steer individuals with kidney failure away from Exchanges plans.

We also recognize that some providers could also engage in behaviors that are not appropriate. To that end, we could support policies that would require all entities discussing insurance options with beneficiaries to provide accurate and complete information about plan design, coinsurance obligations, any potential penalties for late enrollment in Medicare, and the right for Medicare eligible individuals with kidney failure to postpone enrollment into these programs. Issuers should be required to accept third party payer assistance from organizations, such as the AKF, which meet specific guardrails that we have identified in previous letters. In previous letters and discussions, KCP has recommended the following guidelines:

- Provides assistance for at least one full plan or calendar year (and not merely to secure temporary coverage for short-term or one-time procedures or conditions);
- Has procedures that protect patient choice and prohibit any direction that the patient use only certain insurers or providers and provide assistance for a full range of insurance products including but not limited to: Medicare Part B, Medigap, QHP and other commercial, Medicaid, EHGP, and COBRA plans;
- Is a bona fide, publicly or privately funded, 501(c)(3) charitable organization run by independent Board of Directors;
- Has uniform procedures that include an application process, independent determination of financial need by the charity's employees, and geographic diversity;

- Has uniform procedures that sever any nexus between insurer or provider donations to the charity and the beneficiary's receipt of grant assistance, including procedures prohibiting providers from limiting use of their donations to certain patients other than for financial need, and procedures prohibiting providers or insurers from having any input in the assessment or approval of patient applications;
- Meets the requirement CMS finalized in NBPP (*e.g.*, notice requirements 45 CFR § 156.1250(b));
- Complies with other applicable federal, state, and local laws.

In addition, CMS could give providers with easy to search information to allow them to assist in preventing patients already enrolled in Medicare and who are not eligible for other coverage from mistakenly enrolling in an Exchange or another plan. Similarly, providers could assist with identifying patients who are not eligible for tax credits or subsidies from seeking those as well. Given the existing obligations on providers to assist patients with a variety of issues, including insurance coverage, providers would be well positioned to help address any problems that may arise.

These recommendations would protect patient rights, while also establishing a framework to protect against steering.

II. CMS should address issuers concerns about covering individuals with kidney failure by addressing the risk adjusters rather than allowing issuers to discriminate against such individuals.

Dialysis treatments were among the original essential health benefits contemplated when the ACA was implemented. As such, the cost of individuals relying on these treatments was incorporated into the actuarial valuation of the plans. Thus, it is no surprise that patients requiring dialysis have enrolled in Exchange plans. More importantly, the valuation incorporated these individuals into the planning and issuers should have taken that into account when developing their plan products.

Even so, KCP understands that issuers need effective tools and mechanisms to address the needs of complex patients with chronic diseases. To that end, we continue to recommend that CMS address the needs of issuers through appropriate risk adjustment policies rather than allowing issuers to avoid having to cover individuals with kidney failure. While we continue to review the recently released Notice of Benefit and Payment Parameters (NBPP) proposed rule, we believe that adding ESRD-specific risk adjusters and providing options for identifying higher-

cost patients that improves the transfer of resources are important first steps to addressing the very real problems issuers have had in managing the Exchange population. CMS should work closely with providers and issuers to make sure the risk adjustment policies are appropriate and avoid placing patients with kidney failure in the losing position of not being able to fully exercise their choice when selecting a health plan. It is also important that CMS work with insurers to promote enrollment by health individuals to help balance the risk pool.

Eliminating charitable assistance will not solve the issuers' problems. As noted, in 2015 there were only 6,400 patients with kidney failure who receive charitable assistance to remain in Exchange plans. They constitute only 0.05 percent of all Exchange enrollees. Therefore, KCP strongly opposes any policies that would prohibit issuers from accepting charitable assistance to individuals with kidney failure when the appropriate guardrails are in place.

In fact, to prohibit discrimination and treat patients with kidney disease in the same manner as patients with HIV/AIDS, CMS should require issuers to accept such payments.

III. CMS, not issuers, should enforce statutory and regulatory requirements.

Finally, KCP once again urges CMS to enforce the statutory antidiscrimination requirements through its existing authority and Section 1557 to protect individuals with kidney failure from being steered away from Exchange plans by issuers. We also ask that CMS work with providers to establish clear and accurate guidelines for providing information to patients, consistent with the ESRD Conditions for Coverage requirements, to ensure that patients receive the information they need to make appropriate decisions about the health insurance plan that best meets their needs. We oppose allowing issuers or any other nongovernmental entity implementing penalties or seeking payment adjustments from providers, just as we would oppose allowing providers to retroactively bill claims that issuers inappropriately failed to pay because they steered individuals away from Exchange plans and into Medicare and/or Medicaid.

Similarly, we oppose allowing issuers to apply Medicare rates or rates similar to Medicare rates when the patients involved are patients with kidney failure. As KCP has noted in comment letters since 2010, the current Medicare methodology for determining the ESRD prospective payment system rates is flawed in terms of the methodology used to establish the case-mix adjusters. MedPAC has raised similar concerns even in its most recent letter on the system. These concerns suggest that it would not be appropriate to apply these rates outside of the Medicare program. However, even if the methodology were corrected, the rates do not cover the cost of providing dialysis services. The Moran Company has documented year

after year that ESRD Medicare margins are negative. Most recently, it predicted that by 2018, 77 percent of all dialysis facilities would have negative Medicare margins. Given the inadequacy of this rate, it would be inappropriate to apply it to other insurance categories. Perhaps most importantly, issuers are extremely sophisticated organizations that negotiate rates with all types and sizes of providers on a regular basis. They have enormous market power. The marketplace should be allowed to work in terms of establishing rates.

IV. Conclusion

KCP appreciates the opportunity to provide a response to the RFI. As noted, we would welcome the opportunity to develop real-world, practical solutions to stop bad actors – both providers and issuers – from discriminating against individuals with kidney failure in a way that prevents them from exercising their right to select the health plan that best meets their needs. Please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com with any questions that may arise.

Sincerely,

A handwritten signature in black ink that reads "Frank Maddux M.D." with a stylized flourish at the end.

Frank Maddux, M.D.
Chairman
Kidney Care Partners

Appendix A: KCP Members

AbbVie
Akebia Therapeutics, Inc
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
AstraZeneca
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners Inc.
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medicare Care Renal Therapies Group
Greenfield Health Systems
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical, Inc.
Renal Physicians Association
Rogosi Institute
Sanofi
Satellite Health Care
U.S. Renal Care