January 10, 2017

Ms. Sylvia Burwell
Secretary
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244-1850

Re: CMS-3337-IFC: Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities--Third Party Payment

Dear Secretary Burwell and Acting Administrator Slavitt:

On behalf of Kidney Care Partners (KCP), I am writing to provide comments on the recently released Interim Final Rule with Comment (IFC) entitled “Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment.” As described in detail below, KCP is deeply concerned about the process used to issue the changes to the End-Stage Renal Disease (ESRD) Conditions for Coverage (CfC). While we support the effort to promote transparency and encourage more patient education, we are concerned that the proposed modifications seek to protect insurance companies from covering high-cost patients rather than protect the right of individuals with kidney failure who require dialysis treatments to select the health plan that best meets their needs.

Therefore, we ask that the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS or the Department) rescind the IFC immediately or at least delay its implementation until a full notice-and-comment period with adequate time for the thoughtful review of all comments has occurred. We also ask that CMS and HHS require issuers to accept third party premium payments from legitimate charitable organizations, such as the American Kidney Fund (AKF). Leaving it to the discretion of issuers will most likely result in no issuer accepting such payments. There is no reason patients with kidney failure requiring dialysis require less protection than patients living with HIV/AIDS. This policy also contradicts CMS’s ongoing efforts to make sure that commercial payers do not avoid their obligations to pay during the coordination period.
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. KCP was founded in May of 2003. Our goal is to bring together patient advocates, dialysis care professionals, providers and manufacturers. Our mission, individually and collectively, is to ensure:

- Chronic kidney disease patients receive optimal care;
- Chronic kidney disease patients are able to live quality lives;
- Dialysis care is readily accessible to all those in need; and
- Research and development lead to enhanced therapies and innovative products.

I. The proposed modifications should have been made through regular notice-and-comment rulemaking.

KCP strongly disagrees with the Department’s conclusion that it has good cause to waive the ordinary rulemaking process because of “risks” supposedly identified by commenters. First, the “risks” identified are concerns raised by the self-interested health plan issuers who have been working to eliminate their obligations to provide coverage to any patient with kidney failure who requires dialysis. Second, the “risks” described are not consistent with the facts as detailed in KCP’s response to the Department’s Request for Information (RFI) or the responses of many others in the kidney care community that the IFC preamble ignores. Given the facts that the preamble has not identified, let alone addressed, KCP does not believe that the criterion of good cause required to waive the rulemaking requirements has been met.

The Administrative Procedures Act (APA) requires the Department to publish a substantive rule no less than 30 days before its effective date and to go through notice-and-comment rulemaking, unless one of three exceptions waiving these requirements applies.1 The Department claims that it has “good cause” to waive the rulemaking process because in its view patients are at risk of three harms.2 The preamble describes the harms as:

- Negatively impacting their determination of readiness for a kidney transplant;
- Potentially exposing patients to additional costs for health care services; and

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1See, 5 U.S.C. § 553.
2See, Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities--Third Party Payment, Interim Final Rule with Comment, Display Copy at pg. 11-12.
• Putting them at significant risk of a mid-year disruption in health care coverage.

While it is clear that the Department and CMS reviewed carefully the substantive comments made by health plan issuers, it is equally clear from the lack of reference to the comments made by patients, patient advocates, and the kidney community more generally, that it has ignored comments showing that these supposed risks have not resulted in any harm during the last 20 years that the AKF’s Health Insurance Premium Program (HIPP) has been in place. We are also troubled by the fact that the Department dismissed the patient comments as “form letters.” While there were a substantial number of comments that were form letters, these came from patients with other diseases or conditions. They were not from dialysis patients to whom these regulations will apply. We urge the Department to more closely review the dialysis-specific comments before it implements the IFC.

Charitable assistance has not resulted in a lack of readiness for a kidney transplant. The preamble describes the concern that if patients retain commercial coverage four months or longer after being diagnosed with kidney failure they will be less likely to receive a kidney transplant. That statement has no factual support.

We recognize that some transplant centers want to ensure that individuals seeking a transplant can pay for transplant services. Proving that a patient will maintain future coverage can be a requirement for some transplant centers before they agree to transplant a patient. However, this criterion is required by the transplant center and not limited to commercial insurance. For example, in some centers in California and Virginia we understand that patients with only Medicare coverage may not be considered for transplant. In Texas, only one transplant center will accept patients who have Medicaid as their payer. The problem is not fixed by limiting charitable assistance.

First, AKF does provide assistance to patients with kidney failure who are receiving dialysis and preparing for transplant and continues through the end of the quarter in which the transplantation occurs.

Second, once a patient receives a transplant, there are other assistance programs especially in relation to immunosuppressive drugs to which a patient in need of further assistance could apply. Most patients have insurance through the end of the calendar year or for at least one quarter post-transplant. During this period, patients work with their financial counselors and social workers to coordinate this also they can enroll in Medicare up until the month of transplant, receiving Part B benefits for 36 months. Some may also have access to Medicaid. Perhaps most importantly, many transplant patients return to work and can access new commercial coverage options as well.
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, commercial 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.” Given these findings, CMS should not assume that Medicare, and especially Medicaid, will always be the best choice for every patient with kidney failure.

In addition, Medicare itself does not provide ongoing coverage for transplant patients, which the preamble seems to ignore. Once a patient receives a transplant, he/she can no longer remain in Part A after 36 months and retains Part B for the same period of time. 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 Exchange coverage versus Medicare, even if the penalty were to apply. Issuers and the government should not paternalistically make that decision for the patient.

Unfortunately, the IFC ignores these comments, which were offered as part of the KCP response to the RFI. Yet, these comments show that the assertion that charitable premium assistance will make it less likely patients in need of a transplant will be considered for one is an unsubstantiated assumption. The choice should be left to the individual patient and not dictated by an insurance issuer or the federal government.

**Charitable assistance does not financially disadvantage patients with ESRD if they remain in commercial insurance.** Understanding the financial impact of any insurance product on an enrollee is a highly fact-specific endeavor and there

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is no one answer that fits each and every person. Thus, the preamble’s concern that enrollment in the Marketplace can be financially disadvantageous for some individuals with kidney failure may be true, but only partially. As KCP and others in the kidney care community, including several patients and patient advocates, commented in response to the RFI, there are also several examples of how enrollment in Medicare can financially disadvantage individuals with kidney failure when compared to what their financial obligations would be under commercial insurance.

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. 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 financially the right choice for every patient.

Similarly, Medicare coverage – especially without an appropriate wraparound product such as Medigap – does not always provide the full coverage an individual with kidney failure needs. For example, Medicare does not provide dental coverage, which can be extremely important to patients who wish to obtain a transplant. Oral infections or other problems that are not quickly addressed can result in a patient being removed from the transplant list. In addition, drug coverage and cost sharing options may be more advantageous under commercial insurance.

Additionally, not all individuals with dialysis qualify for Medicare because they may not have enough work quarters. They may also not qualify for Medicaid and so their only option for coverage are the Exchange plans.

Each patient should have the right to review the plans and select the coverage that best meets his/her needs. The federal government should not promote the misstatements of issuers to try to justify policies that support insurers’ financial interests over those of the patients. The Department should protect individuals from discrimination that results in disparate access to needed services and coverage.

*Charitable assistance does not necessarily lead to mid-year suspension of policies.* Finally, the preamble notes that issuers have suspended coverage for individuals with kidney failure when the issuers have learned that AKF has provided
financial assistance directly to the patient and the patient has used the funds to pay his/her health insurance premiums. This problem is not one created by the acceptance of charitable assistance, rather it is a problem created by the health plan issuers, some of whom are now trying to dictate to enrollees what sources of income they may use to pay their premiums. This practice is simply outrageous. Patients are allowed to receive assistance from family and friends and use the money to pay their premiums. They could also receive assistance from religious organizations or other charitable entities. However, issuers have targeted individuals who had previously had their premiums paid directly by AKF. They require these individuals to sign a statement saying that the individual did not receive any money from AKF. If the patient refused, the issuer suspended the coverage. This mid-year suspension is a creation of the issuers, not the charitable assistance.

By contrast, when AKF agrees to provide assistance to individuals with kidney failure they make a year-long commitment to do so. There is no mid-year interruption in coverage, unless the issuer of the plan intervenes and suspends the coverage. This example provides support for KCP’s recommendation that CMS and the Department require plans to accept third party premium assistance from legitimate charitable organizations.

II. The Department's concerns about steering by dialysis facilities are misplaced.

KCP condemns practices by any entity meant to steer individuals toward or away from certain plans, but reiterates that it is important to distinguish legitimate educational and charitable practices from steering. Individuals with kidney failure have relied on AKF for assistance since 1971 generally and with regard to the HIPP program specifically since 1997, long before the Affordable Care Act. Given the long and positive history of the AKF in administering funds to support individuals with kidney failure in all types of health insurance – including government sponsored, Exchange, and other commercial 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 individuals with kidney failure.

Until this past year when issuers threatened to leave the Marketplaces while also experiencing the extremely high profit margins, the federal government expressed no concern about this assistance or the practice of steering.

Yet, during the last few years, KCP and others in the kidney care community have identified specific written policies created and implemented by issuers that discriminate against these patients either because they rely upon a 501(c)(3) charity for assistance rather than an employer, family member, or other individual who can support them or because they have the pre-existing condition of kidney disease. The following activities have been 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.

The federal government has issued no rulemaking, guidance, or other documentation seeking to stop issuers from steering such individuals into Medicare. Once again, the preamble ignores these concerns, which were raised in the comment letter KCP submitted on the RFI. We ask that CMS and the Department focus on protecting patients and not issuers. In doing so, it should prohibit the discriminatory behaviors and practices identified above. Similarly, we would welcome the opportunity to work with CMS and the Department to ensure that the education provided to patients under the CfcS is complete, accurate, and transparent.

### III. While KCP supports transparency, the proposed changes do not provide sufficient protections to patients and instead seek to protect insurance companies.

#### A. Proposed Requirements

**Disclosure to Consumers.** KCP supports efforts to ensure that patients receive accurate and appropriate information to make balanced decisions about all aspects of their care, including health insurance. In concept, we agree that patients need information about their plan options and how the different coverage and cost of these plans affect their health care services. Facilities do not always have the level of detailed information outlined in the proposed CfcS, however. Issuers do. Therefore, we ask that before CMS finalizes the “Disclosure to Consumer Requirements” (42 C.F.R. § 494.70(c)), it refine the requirement and extend it to issuers, as well as Medicare. To this end, we recommend that all plan issuers, including Medicare, Medicaid, and Medigap plans, provide the information required in a standardized format so that it is easy to compare the coverage and costs of each
plan. CMS, not the dialysis facilities, should provide the educational materials supporting this information as well. In this way, the patients will receive the information in an accurate and consistent manner. Dialysis facilities can then provide this material directly to the patients, as they do today, and allow them to make the choice that best meets their needs.

We do not understand the value of requiring patients to receive information on reimbursement for certain insurers. This requirement would violate confidentially agreements that are part of the contracts between facilities and insurers and would potentially violate other laws. In addition, these amounts can change from month-to-month. While we agree that information about coverage options and cost is important, reimbursement amounts do not empower patients and are likely to create confusion.

Finally, the assumption about the cost of this provision does not represent the true cost. Assuming that social workers would spend only 45 minutes with each patient talking about their options and signing the disclosure form ignores the fact that education requires repetition over multiple visits. Thus, the cost is grossly underestimated.

**Disclosures to Issuers.** KCP does not support the suggested “Disclosures to Issuers” (42 C.F.R. § 494.180(k)) because we do not believe that an issuer should be permitted to reject premium assistance from entities that meet the guardrails we have recommended in previous letters. If these guardrails do not achieve the balance the Department or CMS seeks, we would welcome the opportunity to refine or revise them in a way that would find such a balance. It remains disappointing that issuers are allowed to reject charitable assistance for patients with kidney failure, especially since dialysis was included in all of the benchmark plans as a required service.

**B. Responses to IFC’s specific questions**

The preamble to the IFC also requests comments on three specific areas:

- Whether patients would be better off if premium payments in this context were more strictly limited;
- Alternative options where payments would be prohibited absent a showing that a third party payment was in the individual’s best interest; and
- What such a showing would require and how it could prevent mid-year disruptions in coverage.

We answer these in turn below.
Patients would not be better off if premium payments in this context were more strictly limited. As noted previously, KCP continues to be dismayed by the fact that individuals living with HIV/AIDS continue to have a right to receive charitable assistance to pay their premiums, but individuals living with kidney failure do not. We describe again in this letter how some individuals with kidney failure have legitimate reasons, including financial and coverage-related, for wanting to stay out of the Medicare program. The Congress has always allowed them to have that option, as the preamble to the IFC recognizes. However, the Department is limiting this right by refusing to require issuers to accept charitable assistance from AKF on behalf of individuals with kidney failure. We understand that issuers would be better off if premium payments were not only more strictly limited but also eliminated altogether; however, patients would not be. We once again urge the Department to look at all the facts, not just those offered by the insurance industry comments, and focus on protecting each and every individual’s right to choose, regardless of their financial status.

It would be inappropriately paternalistic for the federal government to identify “alternative options where payments would be prohibited absent a showing that a third party payment was in the individual’s best interest.” One of the hallmarks of the American health care system has been to find more ways to empower individuals to make informed decisions. This Administration has repeatedly emphasized the importance of empowering patient decision-making as well. However, when it comes to third party premium payments, the failure to act to allow individuals with kidney failure to exercise their own choice when they need charitable third party assistance stands at odds with this fundamental principle. Those entities that want the federal government to require all such patients to enroll in Medicare may argue that individuals who cannot afford the premiums on their own should not have the right to obtain charitable assistance to do so. These same entities then attack those individuals who can afford the premiums in the other ways described in this letter that also push them into Medicare. Their goal is to eliminate the individual’s choice entirely. That is simply inappropriate and the federal government should not be complicit in such activity. Identifying specific circumstances under which someone other than the individual would have to show the individual’s choice to receive a third party payment was appropriate would only further this erosion of individual decision-making and empowerment.

Given that it is the issuers’ refusal to accept third party payments that results in mid-year coverage disruptions, the most appropriate solution is to require issuers to accept third party payments directly from legitimate charitable entities to prevent mid-year disruptions in coverage. As KCP has noted in previous letters, the problem of mid-year disruption does not occur because of the fact of third party payments. In fact, the AKF policy clearly provides assistance for dialysis patients through an entire plan year and always has. The disruption occurs only when an issuer decides not to accept a third party payment
directly and then prohibits the individual who is enrolled in the plan to use funds provided to him/her and deposited in his/her own bank account to pay the premium amount. Thus, the best solution to this problem is to require the issuers to accept the payments directly.

IV. The Department and CMS should not be involved in a dispute over negotiated rates between providers and issuers.

We believe it is important that the true reason for the continued push by issuers to require individuals with kidney failure who need dialysis to enroll in Medicare be stated. While the IFC repeatedly asserts that the purpose of the new requirements is to protect patients, the real issue seems to be that issuers believe they are reimbursing dialysis facilities too much for the services being provided. The IFC states that: “All commenters who addressed the issue made clear that enrolling a patient in commercial coverage (including coverage in the individual market) rather than public coverage like Medicare and/or Medicaid is of significant financial benefit to dialysis facilities.”4 The preamble describes comments that suggested facilities can receive $100,000 or more from commercial insurers than they do from the Medicare program. It also cites numbers that United Healthcare used in a recent court filing. No evidence is provided supporting that these comments by issuers are in fact correct. However, it appears that the real problem is that issuers simply do not want to pay the cost of covering individuals with kidney failure who require dialysis.

This issue is a private contracting matter between the issuers and the dialysis facilities. The federal government has no role to play in setting these rates and should not be promoting policies that allow issuers to reject covering such individuals because they do not like the rates they negotiated.

V. Conclusion

On behalf of KCP, I thank you for the opportunity to provide comments on the IFC. As described in detail, we remain deeply troubled that the Administration has focused on protecting health plan issuers over the rights and interests of patients with kidney failure who require dialysis. We are sincere in our request to work with you to find appropriate guardrails to ensure the provision of charitable third party payments. However, leaving the decision of whether or not to accept such payments to issuers who want to shift the responsibility for these patients to the federal government even if the patient wishes to retain private coverage creates a de facto rule that such payments are not permissible. Patients deserve better.

4See, supra note, Display Copy 12.
Therefore, we ask that you rescind the IFC and work with the kidney care community to build off of the proposed disclosure requirements while also requiring issuers to accept third party premium assistance from legitimate charitable organizations, such as the AKF. Please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com if you would like to set up a time to discuss our recommendations for addressing these concerns in more detail.

Sincerely,

Frank Maddux, M.D.
Chairman
Kidney Care Partners
Appendix A: KCP Members

AbbVie
Akebia Therapeutics, Inc
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
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 Renal Administrators Association
Nephrology Nursing Certification Commission
NxStage Medical, Inc.
Renal Physicians Association
Rogosin Institute
Sanofi
Satellite Health Care
U.S. Renal Care