December 21, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Acting Administrator Slavitt,

On behalf of Kidney Care Partners (KCP), I want to thank you for providing us with the opportunity to comment on the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017" Proposed Rule (Proposed Rule). KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with both chronic kidney disease (CKD) and End-Stage Renal Disease (ESRD).[1]

Earlier this fall, Secretary Sylvia Burwell described how the Affordable Care Act (ACA) is "working to deliver access, affordability, and quality coverage" in an address at the Howard University College of Medicine.[2] She cited an analysis prepared by the Assistant Secretary for Planning and Evaluation (ASPE) noting that approximately 17.6 million uninsured people have obtained coverage since the law took effect.[3] Yet, despite this success, the ACA is not working for another group of individuals who have relied on President Obama's promise that:

> [i]f you like your health care plan, you keep your health care plan. Nobody is going to force you to leave your health care plan. If you like your doctor, you keep seeing your doctor. I don't want government bureaucrats meddling in your health care. But the point is, I don't want insurance company bureaucrats meddling in your health care either.[4]

---

[1]*See* Appendix A for a list of the members.
[2]HHS Press Office, "Secretary Burwell Previews Third Open Enrollment" (Sept. 22, 2015).
[3]*See also*, ASPE, "Data Point: Health Insurance Coverage and the Affordable Care Act" (Sept. 22, 2015).
[4]President Barak Obama statement at a town hall event in Grand Junction, Colorado (August 15, 2009) (cited in Lori Robertson, "Keep Your Health Insurance? Not Everyone," *FactCheck.org* (Aug. 18, 2009) (http://www.factcheck.org/2009/08/keep-your-insurance-not-everyone/)).

During the past few years, however, Marketplace issuers have sometimes subtly and at other times not so subtly adopted policies that discriminate against enrollees with kidney disease when it progresses and the enrollees require dialysis. While the ACA was meant to strengthen protections for Americans with health insurance,[5] those requiring dialysis treatments find themselves subjected to rules that discourage staying with their plans or force them into Medicare, even if they want to retain private insurance. Nowhere is this problem more apparent than in the case of plans refusing to accept third party payments from the not-for-profit public charity, the American Kidney Fund (AKF), and in the design of plan networks that dis-incentivize or otherwise make it difficult for enrollees to obtain the lifesaving treatments they require.

While we are sympathetic to the concerns issuers have expressed about the risk pool, it is not a valid reason for discriminating against individuals requiring dialysis treatments. CMS should work with issuers and address the risk pool problems through the risk adjustment, reinsurance, and risk corridors policies. These are distinct issues and should be addressed as such.

The ACA promised to end pre-existing condition discrimination, limitations on care, and coverage cancellations. The White House characterized these practices as ways "insurance companies could take advantage of you" and stated that "[t]he Affordable Care Act creates a new Patient's Bill of Rights that protects you from these and other abusive practices."[6] It also promised a "marketplace" – "a one-stop shop where consumers can choose a private health insurance plan that fits their health needs."[7]

Secretary Burwell has reiterated this commitment to protecting enrollees from discrimination and promoting patient choice as part of the Agency's goal of promoting "a better, smarter and healthier health care system with engaged, educated and empowered people at the center of it."[8] Part of being an engaged and empowered consumer is have the opportunity to "pick[] the right coverage."[9] Being engaged and empowered is particularly important for dialysis patients.

KCP applauds the Administration for the strides it has made in reducing the number of un- and under-insured Americans. However, the ACA can only be

---

[5]HHS Press Office, "Statement by HHS Secretary Sylvia M. Burwell on the Affordable Care Act" (June 25, 2015).
[6]White House, "HealthCare.gov Is Open for Business" (*available at* https://www.whitehouse.gov/healthreform/healthcare-overview and last accessed Dec. 7, 2015).
[7]*Id.*
[8]Sylvia Mathews Burwell and Valerie Jarrett, "Invest In Your 'Healthy Self' (and Post a #HealthySelfie While You're At It!)," *HHS Blog* (June 11, 2015) (*available at* https://www.whitehouse.gov/blog/2015/06/11/invest-your-healthy-self-and-post-healthyselfie-while-you-re-it and last accessed Dec. 7, 2015).
[9]*Id.*

effective if it lives up to the promises made by the President and provides all Americans regardless of their health condition with the ability to choose the health plan that is right for them. Prohibiting issuers from discriminating against enrollees who require dialysis treatments would likely increase their efforts to try to prevent or at least to slow the progression of kidney disease. Therefore, KCP urges CMS to:

(1) Require issuers to accept payments from not-for-profit charitable organizations that existed prior to the enactment of the ACA, have been reviewed favorably by the Office of Inspector General, provide at least one year of assistance to individual enrollees, and offer assistance for the purchase of any coverage option; and

(2) Provide federal oversight of issuers to ensure the adequacy of networks, instead of relying upon States, including establishing time and distance standards and minimum provider-covered person ratios, as well as ensuring continuity of care and reducing wait times.

I. CMS should require issuers to accept payments from not-for-profit charitable organizations that (1) existed prior to the enactment of the ACA; (2) have been reviewed favorably by the Office of Inspector General; (3) provide assistance for at least one year; and (4) offer assistance for the purchase of any coverage option.

KCP is pleased that CMS is considering "expand[ing] the list of entities for whom issuers are required to accept payments to include not-for-profit charitable organizations."[10] While we understand the need to minimize risk pool impacts, it is important to distinguish policies that support long-standing charitable organizations from policies related to establishing appropriate risk corridors. We encourage CMS to work with issuers to establish appropriate risk corridors, which we understand is beyond the scope of this particular rulemaking. Most importantly, we strongly urge CMS to require that issuers accept payments from not-for-profit charitable organizations that meet the following requirements.

(1) The not-for-profit organization existed prior to the enactment of the ACA;

(2) The Office of the Inspector General (OIG) has reviewed the arrangement and determined that it presents no concerns through an Advisory Opinion;

[10] 80 *Fed. Reg.* 75488, 75558 (Dec. 2, 2015).

(3) The organization provides at least one year of assistance to enrollees; and

(4) The organization offers assistance for the purchase of any coverage option (*e.g.,* qualified health plans, other private coverage, Medicare, Medicaid).

It is also important to note that even if a dialysis patient enrolls in a Marketplace plan, at the end of 33 months, he/she is automatically enrolled in Medicare under the Medicare Secondary Payer law.[11]

We understand that if an individual enrolls in Medicare, then he/she relinquishes access to Marketplace plans; however, KCP vehemently opposes denying individuals access to Marketplace plans simply because they have the option of enrolling in Medicare because by virtue of their health condition they have become eligible for Medicare. Consistent with rulings by the IRS, these individuals should not be forced to enroll in a government program, but rather permitted to select the coverage that best meets their needs like every other American.

A. AKF charitable support provides dialysis patients with critically important assistance.

AKF is a qualified public charity, founded in 1971, whose mission is to help people fight kidney disease and live healthier lives. One of AKF's core mission components is to help low-income dialysis patients in the United States access health care. It accomplishes this mission through its grant programs, including the Health Insurance Premium Program (HIPP), which was established in 1997. In reviewing this program, the OIG has concluded that AKF is a "bona fide 501(c)(3) charitable and educational organization."[12] The OIG also indicated that AKF reviews patient applications for HIPP assistance based upon "assessment of need and eligibility criteria." HIPP assistance is available to all individuals with kidney failure who rely on dialysis for survival. AKF's HIPP is not a "healthcare provider or commercial entity"[13] seeking to skew the risk pool, but rather like the Ryan White HIV/AIDS Program, "a core medical service for eligible low-income people"[14] living with a chronic disease.

In the 18 years since AKF launched the HIPP program, AKF has provided premium support and cost-sharing assistance to Medicare beneficiaries so that they can maintain their Medigap policies, as well as their Medicare Part B, COBRA, and other commercial insurance. During these nearly two decades, there have been no

---

[11] Social Security Act (SSA) § 1862.
[12] OIG, Advisory Opinion 97-1.
[13] *See* 79 Fed. Reg. 15240, 15241 (March 19, 2014).
[14] *See Id.* at 15242.

questions or concerns raised about this assistance skewing the risk pool for these plans.

People living with kidney failure have come to rely upon AKF's HIPP. In 2014, AKF provided direct assistance to patients in all 50 states, the District of Columbia and every U.S. territory. As the OIG summarized in its Advisory Opinion: "AKF is a bona fide, independent, publicly-funded, 501(c)(3) charitable organization whose charitable purposes include aiding ESRD patients and their families."[15]

The story of Eric Dolby demonstrates the critical role AKF plays in patients' lives. Mr. Dolby was working as a nurse when he was diagnosed with hypertension in 2000. Six year later, his kidneys failed and he began dialysis. He was unable to continue to work as a traveling nurse. During this time, his financial resources were depleted. He found himself homeless and living at a truck stop in Houston, TX. After fighting with his pride, he let his social worker know that he was homeless. She referred him to AKF. Once the AKF received his application, they provided him with the financial resources that he needed to pay for healthcare costs. AKF was able to help him get the care that he needed by paying his health insurance premium. Once he had his health insurance covered, he was able to focus on getting back on his feet. Mr. Dolby's experience shows the important role that charitable assistance for dialysis patients plays in helping individuals overcome the hardships they experience.

B. Requiring issuers to accept payments from the AKF poses little to no risk of impacting the risk pool.

There is no evidence to support the conclusion that allowing AKF to continue to provide premium support and cost-sharing assistance to those enrolled in Marketplace plans, as it does today with other types of insurance programs, would inappropriately skew the risk pool. There are approximately 468,386 Americans who have been diagnosed with kidney failure receiving dialysis.[16] While the vast majority of these Americans rely upon dialysis, approximately 76 percent seek to enroll in Medicare when initially diagnosed with kidney failure.[17] Approximately 23.6 percent of individuals with kidney failure retain their employer-based group health insurance when they are initially diagnosed.[18] As patients remain on dialysis, this percentage is reduced. Dialysis facilities report that approximately 10 percent of prevalent patients access commercial insurance. Thus, if these historic trends remain steady a small percentage of this very small population would likely seek to remain in a Marketplace plan. Even if all of the individuals who do not seek Medicare enrollment were to seek coverage in the Marketplaces, they are dwarfed

---

[15] OIG, *supra* note 12, at 6.
[16] United States Renal Data System, 2015 Annual Data Report (Vol. 2, Reference Table D.1).
[17] *Id.* (Vol 2, Reference Table C.3).
[18] *Id.*

by the 17.6 million Americans[19] who have gained coverage through the ACA. Given these numbers, it is difficult to understand how such a small number of individuals could impact risk pools that are made up of thousands of individuals.

C. Guardrails should protect access and individual choice.

KCP understands the concerns that some issuers have expressed about the impact third party payments may have on their risk pools. For example, we agree that allowing individuals to obtain coverage before a major procedure only to have them drop coverage after the procedure is complete presents problems for issuers. But, these concerns should not lead to policies that are counter to the intent of the ACA, as articulated by the President, as well as the Secretary, to provide access and choice to affordable plans.

Thus, in addition to calling on CMS to require that issuers accept payments from not-for-profit charitable organizations, we support including guardrails that still provide dialysis patients with meaningful access and choice to private plans. Specifically, we recommend that CMS adopt the following guardrails.

(1) The not-for-profit organization existed prior to the enactment of the ACA. This criterion would guard against new entities that might try to establish themselves as non-profit foundations to avoid ACA requirements. The AKF has been providing assistance to dialysis patients since 1971, well before the enactment of the ACA.

(2) The Office of the Inspector General (OIG) has reviewed the arrangement and determined that it presents no concerns through an Advisory Opinion. As you are aware, the OIG reviews arrangements to determine if they "constitute grounds for the imposition of a civil monetary penalty under Section 231(h) of the Health Insurance Portability and Accountability Act of 1996." This additional layer of review protects against inappropriate inducements to select a particular provider, practitioner, or supplier. The OIG in Advisory Opinion No. 97-1 reviewed the AKF arrangement and found that it "would not constitute grounds for the imposition of civil monetary penalties under Section 231(h) of HIPAA."

(3) The organization provides at least one year of assistance to enrollees. As noted above, we understand that some individuals enroll only to receive a particular procedure or service that is particularly expensive and then end their coverage. First, dialysis patients require regular, predictable treatments so this behavior is unlikely to occur. More importantly, the AKF

[19]*See supra* note 2.

provides a year of funding from the date of the initial grant for those individuals who meet its criteria.

(4) The organization offers assistance for the purchase of any coverage option (*e.g.,* qualified health plans, other private coverage, Medicare, Medicaid). Requiring the organization to provide payment assistant regardless of the type of plans (*e.g.,* qualified health plan, private coverage, Medicare, Medicaid) ensures that enrollees are not incentivized to use only one type of coverage. There will be an even playing field that allows enrollees to select or maintain the coverage that best meets their needs and does not unnecessarily burden the Marketplaces in relation to other types of health plans.

KCP does not support limiting access to third party assistance to only those who are not <u>eligible</u> for other minimum essential coverage because such a limitation discriminates against individuals who require dialysis. Current Medicare law extends eligibility to individuals three months after their diagnosis with kidney failure.[20] These individuals, however, are not forced to accept this coverage and federal law protects their right to remain in employer group health plans.[21] Federal law also already recognizes that "[a]n individual is eligible for minimum essential coverage under the [Medicare program] for purposes of the premium tax credit only if the individual is enrolled in the coverage."[22] CMS policy regarding third party payers should be consistent with the IRS guidance and allow individuals who are <u>eligible</u> by virtue of kidney failure, but have not taken the step of <u>enrolling</u> in Medicare, to have the choice of remaining in Marketplace plans.

There are many reasons enrollees who need dialysis might prefer to remain in a private insurance plan offered through the Exchanges; they should have the same rights as other Americans to keep their insurance if they like it. Dialysis Patient Citizens (DPC) conducted a survey of patients using questions from the Consumer Assessment of Health Plan Survey (CAHPS) to gauge relative satisfaction with their coverage. DPC found that 77 percent of patients rate their private health insurance as the "best health insurance plan possible," compared to 71 percent for Medicare. They also found that Medicare beneficiaries have more difficulty getting the health care that they want or need than those enrolled in private plans. One reason for the difference in satisfaction is that Medicare requires higher cost sharing for chronically ill patients than some private insurance plans and Medigap policies are not available to those individuals who are under 65 years old in half of the United States. In addition, these under 65 years old patients may have families and enrolling in Medicare could negatively impact their family's insurance situation.

---

[20] SSA § 226A.
[21] *Id.* at § 1862.
[22] IRS, Notice 2013-41 "Eligibility for Minimum Essential Coverage for Purposes of the Premium Tax Credit."

Dialysis patients are not unlike those individuals living with HIV/AIDS for whom CMS has required issuers to accept payments. Both patient populations have high medical needs. While the Ryan White Program was established by the Congress to assist HIV/AIDS patients to afford their insurance, AKF has been reviewed by the OIG and determined an appropriate model to do the same for dialysis patients. Given these parallels, CMS should treat AKF as it does Ryan White.

All Americans should have the right to access the coverage that best meets their needs. This right should not vanish because they are diagnosed with kidney failure and require dialysis treatments. The right also should not be reserved for those Americans who can afford their premiums/coinsurance or have wealthy family or friends who can help them. Those individuals who rely upon *bona fide* public not-for-profit charities should have these same choices. Therefore, we urge CMS to require issuers to accept payments from not-for-profit charitable organizations that (1) existed prior to the enactment of the ACA; (2) have been reviewed favorably by the Office of Inspector General; (3) provide assistance for a year; and (4) offer assistance for the purchase of any coverage option.

II. CMS should provide federal oversight of issuers to ensure the adequacy of networks, instead of relying primarily upon the States, including establishing time and distance standards and minimum provider-covered person ratios, as well as ensuring continuity of care and reducing wait times.

KCP is also pleased that CMS proposes various ways to ensure the adequacy of Marketplace plan networks. Dialysis patients have experienced various forms of discrimination by health plans over the years and it is critically important that CMS and other federal agencies provide clear standards to ensure appropriate access to quality care. Therefore, we ask that CMS provide <u>federal</u>, rather than rely primarily on the States, oversight of issuers. We also support establishing time and distance standards, as well as minimum provider-covered person ratios. In addition, we agree that CMS should enact policies to ensure the continuity of care and reduce patient wait times.

A. The federal government, not States, is in the best position to assess network adequacy.

KCP strongly supports active monitoring of network adequacy. While having States engage in such monitoring is important, we reiterate the recommendation that we made to the Office for Civil Rights when commenting on the "Nondiscrimination in Health Programs and Activities" proposed rule. It is critically important that the federal government take a more proactive role in ensuring that

Marketplaces do not discriminate against these individuals, which includes maintaining adequate networks.

Unfortunately, enrollees who develop kidney failure and require dialysis are already experiencing problems with network adequacy and other forms of discrimination meant to push them toward enrollment in Medicare. In at least 20 States,[23] the benchmark plans indicate that if an individual is eligible for Medicare, he/she cannot enroll in a Marketplace plan, which is contrary to federal law. In 22 States,[24] the fact that an individual is eligible for Medicare results in a plans reducing coverage to the amount that it would pay if the individual were enrolled in Medicare, even if the individual has chosen not to enroll in Medicare. CMS has been very clear that issuers may not exclude dialysis patients from coverage, but much stronger federal enforcement of this requirement is needed.

If an individual enrolls in a plan, his/her problems frequently continue. One practice we have identified is limiting access to providers located significant distances from patients. An essential life-saving treatment, dialysis requires patients to be at a facility, unless they can rely upon home dialysis modalities, three times a week for three to four hours each treatment. Adding an hour or longer drive to this schedule is an unnecessary hardship when there are facilities closer to the enrollee's home. We have also seen plans limit nephrologists or other specialists who are essential to providing care to dialysis patients. Another problem has been that enrollees who are referred for transplant often find that there is no transplant hospital in the network, forcing them to incur additional costs.

These practices – instituting long drive times and restricting access to necessary specialists and transplant hospitals, along with increasing the cost burden for enrollees requiring dialysis – discriminate against dialysis patients in violation of the intent of the ACA and other anti-discrimination laws. While we understand that ACA issuers may be struggling with risk, CMS should address these concerns through appropriate risk adjustment, reinsurance, and risk corridor policies rather than allowing discriminatory practices to stand.

Given that States too have an interest in maintaining their Exchanges, we believe it is critically important for the federal government to engage in active oversight to ensure network adequacy and prohibit discrimination against dialysis patients in particular.

---

[23]These States are: Arizona, Connecticut, Delaware, Florida, Georgia, Illinois, Kentucky, Maine, Michigan, Missouri, North Carolina, Nevada, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, Washington, and West Virginia.
[24]These States are: Alabama, Arizona, California, Colorado, Connecticut, Florida, Georgia, Indiana, Louisiana, Maryland, Maine, Michigan, Minnesota, Missouri, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and Wisconsin.

KCP also support the metrics for evaluating network adequacy identified in the Proposed Rule:

- Prospective time and distance standards at least as stringent as the FFE standard; and

- Prospective minimum provider-covered person ratios for the specialties with the highest utilization rate for its State.

As noted already, time and distance standards are important given the current practice of some issuers to use narrow networks to encourage enrollees requiring dialysis to leave their plans and enroll in Medicare. We agree that using the standards established in the Medicare Advantage program would be appropriate. Dialysis patients have also had difficulty accessing nephrologists and other specialists in network, so establishing minimum ratios would be helpful. When establishing these minimums, CMS should ensure access to dialysis facilities and nephrologists. Given the evolving nature of plans, we also encourage CMS to update the metrics as new practices that discourage enrollment of, or discriminate against, certain populations are identified.

B. CMS should require issuers, when a provider is terminated without cause, to ensure continuity of care.

KCP strongly supports the proposal to require an issuer, in cases where a provider is terminated without cause, to allow an enrollee in active treatment to continue treatment until the treatment is complete or for 90 days. Continuity of care is a critical issue for dialysis patients. Being able to maintain access to their care team would allow for a smooth transition to other network providers, in the event their providers are terminated. Because these patients require monthly visits with their physicians, as well as dialysis three times a week, it is not easy for them to immediately change providers. A 90-day transition period would allow a dialysis patient time to consider his/her options and seek treatment from other providers if necessary.

C. CMS should add a wait time standard.

KCP supports adding a wait time standard across qualified health plans in the federal facilitated exchanges, as well as for State exchanges. Access to specialists is critically important to all chronically ill patients, especially those requiring dialysis. To provide adequate coverage for dialysis, which is an essential health benefit, plans must not only include the specialists necessary to care for such patients, but also a sufficient number of them in the network to ensure patients can schedule appointments with them in a timely manner. We urge CMS to tailor these standards to ensure that issuers are addressing the specific needs of the populations they are

serving and cannot use long wait times as a tool encourage individuals to disenroll from their plans.

III. Conclusion

KCP appreciates the opportunity to provide comments on the Proposed Rule. We urge CMS to promulgate policies that align with the intent of the ACA to provide access to affordable and high quality coverage. To meet these goals, practices that discriminate against certain types of enrollees, including dialysis patients, should be abolished. To this end, KCP urges CMS to: (1) Require issuers to accept payments from not-for-profit charitable organizations that existed prior to the enactment of the ACA, have been reviewed favorably by the Office of Inspector General, provide at least one year of assistance to individual enrollees, and offer assistance for the purchase of any coverage option; and (2) Provide federal oversight of issuers to ensure the adequacy of networks, instead of relying upon states, including establishing time and distance standards and minimum provider-covered person ratios, as well as ensuring continuity of care and reducing wait times. We understand the concerns that issuers have about the risk pool, but discrimination should not be allowed to continue for that reason. Instead, we support efforts to appropriately address risk adjustment, reinsurance, and risk corridors. These are distinct issues and should be addressed as such.

We look forward to working with you on these issues. Please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com if you have any questions.

Sincerely,

Edward R. Jones, 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
Amgen
AstraZeneca
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Fresenius RTG
Greenfield Health Systems
Hospira
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Rogosin Institute
Sanofi
Satellite Healthcare
U.S. Renal Care