October 6, 2016

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

RE: CMS-9934-P: "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018"

Dear Acting Administrator Slavitt:

On behalf of Kidney Care Partners (KCP), I want to express my appreciation for the opportunity to provide comments on the proposed rule entitled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018" (Proposed Rule). 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]

KCP remains concerned about efforts by certain health insurers to discriminate against individuals with ESRD. Therefore, we ask that as it finalizes the Proposed Rule, CMS ensure that it protects the right of these individuals to select the health plan that best meets their needs and to create appropriate risk mitigation policies to support plans in covering these individuals. We specifically recommend that CMS:

- Not interpret the guaranteed renewability statute and the anti-duplication provision at SSA § 1882(d)(3) to prohibit renewal of an individual with ESRD who is eligible for, and in some instances enrolled in, Medicare; and

- Finalize the proposed payment adjustments related to individuals with ESRD.

I. The Congress and the Administration Have Established Unique Coverage Rights for Individuals with ESRD and These Rights Should Not Be Denied.

As CMS indicates in the preamble to the Proposed Rule, the Congress has established unique coverage rights for individuals with ESRD. Not only did the

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

Congress grant individuals diagnosed with ESRD with eligibility to enroll in Medicare three months after their diagnosis of having the disease,[2] but the Congress also carved out specific Medicare Secondary Payer (MSP) requirements to provide these individuals with choice of coverage.[3] Under the ESRD MSP provisions, individuals with ESRD who are eligible for Medicare may enroll in the federal program, but maintain their group health plan as primary coverage for up to 30 months beyond the initial three-month waiting period after diagnosis of ESRD.[4] The Congress has frequently extended the right of these individuals to maintain their group health policies as primary multiple times.[5] The Congressional actions demonstrate the ongoing belief by federal policy-makers that individuals with ESRD should not be forced to accept Medicare as their primary insurer.

Similarly, the Administration has further clarified the unique place of individuals with ESRD in federal health care coverage by affirming that simply because an individual with ESRD is eligible for enrollment does not mean he/she is considered to have enrolled in Medicare. Thus, when interpreting the Affordable Care Act (ACA), the Internal Revenue Service (IRS) has indicated that individuals with ESRD who do not affirmatively enroll in Medicare are eligible for coverage in a qualified health plan subsidized by the premium tax credit.[6] The IRS noted a clear rationale why some individuals might wish to remain in a subsidized qualified health plan:

> Some of these programs, such as Medicare part A coverage requiring payment of premiums, receive a lower or no government subsidy, disadvantaging individuals who could enroll in the coverage only at high cost and would be forced to forgo subsidized qualified health plan coverage.[7]

CMS has echoed this policy in its own regulations as well. CMS guidance clearly states that the anti-duplication statute does not apply to individuals with ESRD.[8] Unlike the MSP statute which expressly requires group health plans to provide

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[2] 42 U.S.C. § 426-1.
[3] 42 U.S.C. § 1395y(b)(1)(C).
[4] *Id.*
[5] The Congress has extended the MSP twice since its initial enactment. In the Omnibus Budget Reconciliation Act (OBRA) of 1981, the Congress established the MSP period as up to 12 months. It extended the period from the initial 12 months to 18 months in OBRA 1990 and then again in the Balanced Budget Act (BBA) 1997 from 18 months to 30 months. Congress has considered extending the provision to 36 months in subsequent legislation as well.
[6] IRS, "Eligibility for Minimum Essential Coverage for Purposes of the Premium Tax Credit" Notice 2013-41.
[7] *Id.* at 4-5.
[8] CMS, *Frequently Asked Questions Regarding Medicare and the Marketplace*, August 1, 2014, available at: *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare- Marketplace_Master_FAQ_8-28-14_v2.pdf*.

primary coverage during the first 30 months an individual is enrolled in Medicare based upon his/her diagnosis with ESRD, these rules are not limited to group health plans, but rather apply to all qualified health plans under the ACA.

KCP is deeply troubled that the lack of clarity in the Proposed Rule seems to ignore the unique position of individuals with ESRD when it comes to selecting coverage. Current law specific to ESRD patients clearly indicates that unless an individual with ESRD affirmatively enrolls in Medicare, he/she may maintain a qualified health plan and even access tax credits and subsidies to offset its costs. Therefore, we take issue with the statement:

> Since Medicare Secondary Payer rules do not apply to health coverage in the individual health insurance market, Medicare always pays primary to individual health insurance coverage. Some issuers have a provision in their individual health insurance policies indicating that the coverage will pay secondary to Medicare not only for individuals who are currently covered by Medicare but also for those who could obtain Medicare coverage (such as those individuals who must pay for Part A coverage) but who are not currently covered.[9]

As noted above, the IRS has affirmed that an individual with ESRD – regardless of the MSP provisions – is not required to enroll in Medicare and may select and receive tax credits and subsidies to assist in purchasing and maintaining any qualified health plan, including an individual health insurance policy. CMS has also noted that the anti-duplication requirements do not apply to individuals with ESRD. We ask that CMS in the final rule reaffirm that individuals with ESRD who select individual qualified health plans are entitled to retain such coverage as primary.

We continue to maintain that the structure of the ACA extends the ESRD-related MSP requirements on group health plans to individual plans in the Exchanges. Specifically, the ACA requires the Secretary to make sure that the scope of the essential health benefits "is equal to the scope of benefits provided under a typical employer plan."[10] Regulations also require that coverage in the small group and individual market be "substantially equal" to the essential health benefit benchmark plan.[11] Substantially equal applies to coverage of benefit amount, duration, and scope."[12] Because the benchmark plans are subject to the MSP requirements related to individuals with ESRD, they also apply to the individual plans as well.

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[9] Proposed Rule, Display Copy at 41.
[10] ACA § 1302(b)(2)(A).
[11] 42 C.F.R. § 156.115.
[12] *Id.*

As KCP has communicated in previous letters to CMS and the Administration, it is critically important that CMS protect individuals with ESRD from discriminatory practices or attempts to prevent them from exercising their rights under the ACA. As the IRS has even noted, individuals may seek to remain in individual plans rather than enroll in a federal health program, like Medicare, because enrolling in the government plan could lead to higher premiums and out-of-pocket costs. There may also be differences in coverage and care coordination that lead to an individual with ESRD preferring private insurance. Each individual should be allowed to examine all the insurance options and select the plan that best meets his/her medical and financial needs. While Medicare may be the option that works for a majority of individuals with ESRD, it is not the right fit for everyone. It would be inappropriately paternalistic of the federal government to suggest now – after having previously affirmed the right to choose – that these individuals must always enroll in Medicare because some insurance companies do not want to provide them with the coverage they have a right to receive.

While KCP supports, as noted in Section II, improvements in the risk pool, it is important for CMS to remember that dialysis treatments are defined as an essential health benefit. Therefore, the costs of these treatments are included in the valuation of the plans. Thus, any financial concerns that some insurers have raised about covering these patients should be examined very closely to understand fully whether the actual payments they have made exceed the actuarial valuation and are not addressed by the proposed improvements in the risk pool.

Legally, this Administration has already clearly indicated that individuals with ESRD are not viewed as having duplicative coverage if they decided not to enroll in Medicare upon their diagnosis with ESRD. These requirements, taken together with the Congressional mandate that group health plans remain primary for the first 30 months after enrollment in Medicare – again denoting in statutory language that private coverage for individuals with ESRD is not duplicative of federal coverage – demonstrate that individuals with ESRD should maintain their unique status when it comes to coordination of benefits. Because these laws are more specific than the general provisions at SSA § 1882 and 42 C.F.R. § 147.106, they are to be applied in lieu of the more general laws.[13]

In sum, the guaranteed renewability statute and the anti-duplication provision at SSA § 1882(d)(3) should <u>not</u> be interpreted to prohibit renewal of an individual with ESRD who is eligible for, and in some instances enrolled in, Medicare. The individual should also not be forced by the insurer into a different plan or allowed to apply policies that discriminate against individuals with ESRD to coerce them into enrolling in Medicare.

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[13] *See Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 524-26 (1989); *Crawford Fitting Co. v. J. T. Gibbons, Inc.*, 482 U.S. 437, 444-45 (1987).

II. The Proposed Risk Adjusters Are a Positive Step toward Addressing the Need to Improve the Risk Adjusters for Enrollees with ESRD.

While KCP understands the need to minimize risk pool impacts, it is important to distinguish policies that inappropriately discriminate against individuals with ESRD from policies related to establishing policies that appropriately mitigate an insurer's risk. In the past, we have encouraged CMS to work with insurers to establish appropriate risk policies. Thus, we are pleased that CMS has proposed two policies that would establish an ESRD-specific risk adjuster, as well as a more general policy that would also address the risk associated with ESRD and other similarly situated patients.

KCP supports the proposed RXC-HCC pair, which relates to ESRD phosphate binders. We believe this policy would help align payment with those ESRD patients who incur costs beyond those already included in the actuarial valuation of these patients.

Similarly, KCP supports CMS's proposal to better reflect the high-cost enrollees by altering the risk adjustment methodology to better account for these enrollees. We believe that this proposal should address insurers' concerns about the cost of providing for the care of individuals with ESRD.

We ask CMS to finalize these proposals because it is extremely important to protect the rights of all Americans – including those individuals with ESRD – to select the health plan that best meets their needs, as President Obama promised when he signed the ACA into law.

III. Conclusion

KCP appreciates the opportunity to provide comments on the Proposed Rule. Please do not hesitate to contact Kathy Lester at 202-903-6627 or klester@lesterhealthlaw.com if you have any questions or would like to discuss our comments 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 Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners Inc.
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medicare Care Renal Therapies Group
Greenfield Health Systems
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical, Inc.
Renal Physicians Association
Rogosin Institute
Sanofi
Satellite Health Care
U.S. Renal Care