KIDNEY CARE PARTNERS

November 27, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-9930-P – Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019

Dear Administrator Verma,

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 [PPACA]; HHS Notice of Benefit and Payment Parameters for 2019" (Proposed Rule). 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 appreciates the Agency's desire to provide more flexibility to States under PPACA in particular. However, we also want to make sure that there are adequate safeguards in place to prevent discrimination 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 while providing States with greater flexibility.

I. Essential Health Benefits

The Proposed Rule would allow the States to select new benchmark plans on an annual basis and provide states with more options when selecting a benchmark plan. As CMS finalizes this policy, KCP ask that the Agency take appropriate steps to make sure that dialysis treatments remain a benefit under any state benchmark plan, given that it is an essential health service and has been included in every benchmark plan to date.

The Congress has established unique coverage rights for individuals with ESRD. Not only did the Congress grant individuals diagnosed with ESRD with eligibility to enroll in Medicare three months after their diagnosis of having the

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

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 attestation of the diagnosis of ESRD by a physician.[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.

In addition, these provisions prohibit insurers from differentiating benefits they provide ESRD patients on the basis of their having the disease.[6] By extension, these protections have also applied to individual coverage available through the Exchanges because these plans have been required to include the same benefits as the State's three largest small group, state employee, Federal Employee Health Benefit Plans, or the State's leading Health Maintenance Organization. All of these plans provide coverage for dialysis for individuals with ESRD.

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 <u>eligible</u> for enrollment does not mean he/she is considered to have <u>enrolled</u> in Medicare. Thus, when interpreting PPACA, 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.[7] 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.[8]

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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] 42 U.S.C. § 1395y(b)(1)(C).
[7] IRS, "Eligibility for Minimum Essential Coverage for Purposes of the Premium Tax Credit" Notice 2013-41.
[8] *Id.* at 4-5.

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.[9] Unlike the MSP statute which expressly requires group health plans to provide 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.

Protecting choice remains paramount. Each American 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.

KCP believes that the Congress also meant to protect this choice when it used the wording the "typical" employer plan at Section 1302(a) of PPACA. It is important to recognize that typical employer plans cover dialysis treatments and have done so pre-dating the passage of PPACA. We are concerned that changing the definition to allow States to use the least costly plans in any of the 50 States as a benchmark would not meet the definition of "typical" and would jeopardize access to essential, life-saving dialysis treatments. It would also mean that individuals living with a chronic disease would face substantially higher out-of-pocket costs, which is contrary to the Administration's overall health care goals.

Similarly, we are concerned that without clear guidance to protect patients with chronic diseases, such as kidney failure, the proposal to allow States to substitute benefits within and between EHB categories could also result in dialysis treatments being excluded from coverage. There really is no substitute coverage for dialysis.

The purpose of PPACA's EHBs is to make sure that all Americans have access to benefits that are critical to maintaining their health. For Americans who are living with kidney failure and cannot access a kidney transplant, dialysis treatments are their only option for staying alive. This is why typical employer plans have always covered it. While State flexibility is important, it is also important to make sure that plans in the Exchanges continue to provide such essential treatment options.

As noted above, the Congress has also indicated that individuals requiring dialysis have the right to maintain private, non-governmental coverage for at least 30 months after their diagnosis with the disease. In addition, the antidiscrimination

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[9] CMS, *Medicare and the Marketplace: The Relationship between Medicare and the Health Insurance Marketplace*, April 2016, available at: https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Overview1.html.

provisions of that same statutory provision should continue to apply to the Exchanges as well. We ask the final rule re-affirm these rights.

Providing States with flexibility when establishing benchmark plans should not change the unique status of individuals with ESRD. They should be able to maintain their right to select a health plan of their choice, just like other Americans can. Dialysis is life-saving treatment that is essential to the individuals are living with kidney failure and cannot access a transplant. Therefore, KCP asks that CMS clarify in the final rule that life-saving dialysis treatments are a necessary part of any benchmark plan. Additionally, we ask that CMS protect the current balance and patient choice by not finalizing the proposed modifications to section 156.111(a)(3) and 156.115(b)(1)(ii).

II. Qualified Health Plan (QHP) Certification Standards

The Proposed Rule would expand the role of states in the QHP certification process for federally-facilitated exchanges (FFEs) by relying on States for accreditation requirements, compliance plans, quality improvement strategy reporting, and service area. It would also provide States with more flexibility in terms of allowing them to establish network adequacy standards and eliminate the meaningful differences requirements.

KCP again appreciates the need for States to be able to establish and enforce standards that meet the unique needs of their citizens, especially those citizens with chronic diseases who need life-saving and life-sustaining treatments like dialysis. As it has done in other instances, the federal government can establish a framework that makes sure that individuals who are likely to experience discrimination are protected, while allowing States more flexibility and establishing greater transparency.

KCP agrees that it is important to reduce burdensome regulations and red tape that cost the health care system – including providers and patients – millions of dollars every year. We believe there is a common sense way to achieve an appropriate balance between patient protections and increased flexibility that are aligned with the Administration's overarching goals.

First, while States should have flexibility to establish and enforce standards that meet their unique needs, we ask that in the final rule CMS clarify that coverage for dialysis treatments must be sufficiently robust to ensure that individuals living with ESRD have access to the providers, items, and services they need to receive life-sustaining dialysis treatments as prescribed.

Over the years, KCP and our members have worked closely with various States' Department of Insurance. During the vast majority of these conversations,

we are told that the States would like to have additional direction from the federal government. Based on these conversations, we believe that in the areas of establishing adequate coverage and network standards, there is a shared role in which CMS can provide a framework to help States exercise their flexibility as effectively and efficiently as possible.

Thus, we ask that CMS clarify in the final rule and guidance that coverage for dialysis services must be consistent with the coverage offered to other patients, especially those with chronic diseases. We believe States could particularly benefit from guidance about protecting dialysis patients from discriminatory activity, such as a loss of benefits after the first three months on dialysis, increased cost-sharing obligations (including a clear statement about the need to protect low-income patients who rely upon charitable assistance), and other practices that a few plans have sought to implement to discriminate against dialysis patients. For example, as noted in Section I, we ask that CMS reaffirm that plans must provide at least 30 months of primary coverage for ESRD patients, consistent with the intent of the Congress. Providing a framework for protecting these patients could also help States ensure that they are exercising their flexibility in a manner that also protects consumer choice.

Second, we also encourage CMS to work with States to make sure that plans provide easy to read and understandable statements about what is and is not covered under their insurance product offerings. Transparency is critically important to patients and consumers. Statements that are written in legalese or buried in hundred page documents do not promote transparency or consumer choice. PPACA mandates such disclosures already, but this Administration through providing greater State flexibility has the opportunity to ensure that consumers are in fact receiving the information they need to make decisions about coverage that best meet their needs.

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
Baxter
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
Northwest Kidney Centers
Nephrology Nursing Certification Commission
NxStage Medical, Inc.
Renal Physicians Association
Renal Support Network
Rogosin Institute
Sanofi
Satellite Health Care
U.S. Renal Care