



December 20, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9980-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Dear Acting Administrator Tavenner:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments and recommendations on the “Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation.”¹ Specifically, we encourage the Agency to specify coverage of End Stage Renal Disease (ESRD) as an essential health benefit. While we appreciate the strong desire to allow States to maintain flexibility, expressly defining essential health benefits to include ESRD-related services would ensure that there is no ambiguity in coverage now or in the future that could jeopardize enrollees who develop kidney failure and need life-sustaining treatments. Additionally, we urge the Agency to fulfill its statutory obligation to prevent discrimination based on health status by providing more clarity as to the types of activities or policies that would constitute discrimination.

KCP is an alliance of members² 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 ESRD.

I. CMS Should Ensure Coverage for ESRD by Including Existing Life-Sustaining Services in the Definition of Essential Health Benefits

Coverage for ESRD-related services holds a unique position in the U.S. health care delivery system. It is the only disease-specific condition covered by Medicare, but that coverage does not begin immediately upon diagnosis. Many individuals who are under age 65 develop kidney failure as a result of hypertension, diabetes, or other precursor conditions. Once diagnosed with kidney failure, an individual has only two treatment options – transplantation or dialysis. Often, even those individuals who obtain a transplant may require dialysis for some period prior to the transplant actually occurring. These are important, life-saving and life-sustaining treatment options to which all Americans who need them should have access.

Typically, Medicare coverage begins on the fourth month after diagnosis, unless an individual seeks to maintain his/her group health coverage.³ Once diagnosed, individuals enrolled in exchange

¹77 Fed. Reg. 70644 (Nov. 26, 2012).

²See Appendix A for list of members.

³See 42 U.S.C. § 1395y.

plans should be able to obtain ESRD-related services without having to address potential ambiguities in their plan coverage options.

Given the lag that could result if ambiguities in terms of coverage exist, KCP urges CMS to expressly state that ESRD-related services are an essential health benefit. Americans who participate in health benefit exchange plans should have a clear indication that if they develop kidney failure, there will be no gap in their coverage now or in the future.

Gaps in coverage pose a serious risk to individuals living with kidney disease. Individuals need access to critical pre-ESRD services to prepare for transplant and/or dialysis, as well as the services related to these treatments once they begin. Coverage that provides access to these comprehensive services will lead to improved patient outcomes and quality of life.

We understand that most of the benchmark plans cover ESRD-related services and over time as benchmark plans change or adopt different coverage policies, they should not be able offer less than adequate coverage and treatment options to their enrollees based upon a diagnosis of kidney disease. Given the federal government's commitment to cover beneficiaries after an initial waiting period, there should be no opportunity for insurance plans to drop coverage or steer individuals away from seeking the care they need based upon their disease status. This is especially true in the context of ESRD for which transplant or dialysis are the only options for sustaining a patient's life. Therefore, we ask that the Final Rule avoid any ambiguity and specify coverage for the existing life-sustaining services the federal government already made a commitment to cover through the Medicare ESRD program.

Providing for explicit coverage for in-center and home dialysis modalities and transplantation does not interfere with the flexibility the Agency seeks to provide to the States.⁴ Instead, it would affirm the unique place that coverage for ESRD-related services has in the health care system and ensure that no ambiguity occurs if benchmark plans were to change their coverage over time. This clarification is also consistent with the Administration's goal that chronic patients will have access to adequate coverage and not be discriminated against. It is essential that participating payors have explicit guidelines to adequately cover dialysis and transplant services. Establishing ESRD-related services directly as an essential health benefit would eliminate any confusion that could lead to gaps in obtaining these life-sustaining treatments.

II. Specifying Coverage for ESRD Would Also Strengthen Efforts To Protect Patients with Kidney Failure from Discrimination

In addition to resolving any potential for ambiguity, specifying ESRD-related services as an essential health benefit would also ensure that anti-discrimination provisions protect individuals living with kidney failure. In the Proposed Rule, CMS states its intent to give full force to the Affordable Care Act's prohibition on discrimination on the basis of disability or health status.⁵ KCP appreciates the inclusion of such language. Our members have experienced first hand how "plan design" options can be used as a means of discouraging individuals from maintaining their private coverage to access life-sustaining ESRD-related services. Given these experiences, we also encourage the Agency to be more specific in terms of the types of activities that are prohibited.

⁴ 77 *Fed. Reg.* at 70648-51.

⁵ *Id.* at 70652-53.

Specifically, we encourage the Agency to specify that plans shall:

- Ensure that there are safe guards related to “actuarial equivalency” so that coverage policies provide for adequate treatment of chronic conditions;
- Ensure that there are safe guards that require payors to construct adequate provider networks so that patients with chronic diseases can be treated in local areas and are not forced to drive long distances or change physician relationships;
- Not restrict the duration or number of dialysis sessions for patients, such as based on a fixed number of treatments per week, to less than the number for which payment may be made pursuant to statute;
- Not require assignment of benefits for such services;
- Ensure that out-of-pocket payments for such services are counted towards meeting any out-of-pocket maximum applied under a Medicare Advantage plan and not treated as routine for purposes of calculating beneficiary copayments;
- Accept premium payments made by third parties and not deny or limit coverage for patients for such services if premiums, copayments, or other payments are made by third parties on their behalf; and
- Meet minimum network adequacy standards specified by the Secretary with respect to such services.

These important patient protections would ensure that issuers do not use benefit design or cost-sharing structure to discriminate against ESRD patients on the basis of their health care needs, consistent with the goals of the Administration to “make it illegal for insurance companies to discriminate against people with pre-existing conditions.”⁶

V. Conclusion

KCP appreciates the opportunity to provide comments to CMS in response to the Proposed Rule. We would welcome the opportunity to provide you and your team with additional information if that would be helpful. Please feel free to contact Kathy Lester at (202) 457-6562 or klester@pattonboggs.com.

Sincerely,



Ronald Kuerbitz
Chairman
Kidney Care Partners

⁶Department of Health and Human Services, “News Release: Obama administration moves forward to implement health care law, ban discrimination against people with pre-existing condition” (Nov. 20, 2012).



Appendix A

Abbott Laboratories
Affymax
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita, Inc.
Dialysis Patient Citizens
DCI, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Kidney Care Council
Mitsubishi Tanabe Pharma America
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
Sanofi
Satellite Healthcare
Takeda Pharmaceuticals U.S.A (TPUSA)
U.S. Renal Care
Watson Pharma, Inc.