

December 21, 2012

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-9980-P: Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation

Dear Secretary Sebelius:

Dialysis Patient Citizens (DPC) appreciates the opportunity to comment on the proposed rule *Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation*.

As America's largest patient-led dialysis organization, DPC represents more than 24,000 dialysis and pre-dialysis patients and their families. DPC's mission is to improve the quality of life of dialysis patients by engaging policy makers, providers and the public. Through patient education, empowerment and advocacy, we work to increase awareness about kidney disease and promote favorable public policy.

We would like to thank the Department of Health and Human Services (HHS) for issuing this Proposed Rule related to Essential Health Benefits (EHB). The EHB packages put forward by each state will form the basis of health coverage for millions of Americans with kidney disease and will provide critical health insurance benefits and peace of mind for beneficiaries. While states are now tasked with creating their individual benefit packages, the federal government still has an important role to play in the process, and upon reviewing CMS-9980-P, there are several key areas we would like to highlight for your consideration when preparing the final rule on this critical issue.

I. ESRD Services as Essential Benefits

First and foremost, we urge HHS to ensure that coverage for end stage renal disease (ESRD), which includes dialysis and transplant services, is considered an essential health benefit in each and every state-based benefit package.

Each year in the United States, more than 100,000 Americans are diagnosed with ESRD, an irreversible condition which is fatal without a kidney transplant or lifesaving dialysis treatments. Currently, more than 485,000 Americans suffer from ESRD and 340,000 are on dialysis, a number that is expected to

double over the next decade. This dramatic rise is attributable to the increased prevalence of diabetes and hypertension, two skyrocketing chronic diseases and the leading risk factors for ESRD.

When defining essential benefits for health plans, we find it difficult to imagine the exclusion of dialysis and transplantation, as both are absolutely essential to the survival of an ESRD patient. In fact, these life-preserving treatments allow hundreds of thousands of Americans to live high quality and fulfilling lives. Mandating coverage of ESRD as an essential benefit will enable thousands of Americans to take advantage of new coverage opportunities created by the exchanges. We understand that Medicare is committed to ensuring treatment for ESRD patients regardless of their age, but we believe this should not lead to the exclusion of these services in private plans. Medicare ESRD coverage does not begin immediately upon diagnosis and many patients do not realize their kidneys are failing until it is too late. This means many Americans still rely on private coverage for dialysis and transplant services and we hope that HHS will work with the states to ensure this critical coverage.

Upon review of state benchmark plans, many do not list dialysis services even though it is a routinely covered benefit by these plans. We recommend HHS specify in the final rule that these plans must cover benefits regularly covered by the benchmark plan, regardless of whether those benefits are listed in the data collection template used by the states to report to HHS on their base-benchmark plan, to ensure coverage of critical services and consistency with common practice.

In addition, the proposed rule restates that these state benchmark centered EHB packages will be in place for 2014 and 2015. We are hopeful that during this initial period, the federal government will thoughtfully analyze each state package and determine a comprehensive national EHB package to put in place after 2015. We believe the original intent of the ACA was to have a national benefit package to ensure that Americans do not receive disparate health coverage dependent on their state of residence. We hope that if and when this national package is determined, coverage of ESRD services will be included.

II. Need for More Category Definition

We also have serious concerns about the lack of category definition provided in the proposed rule. The Affordable Care Act (ACA) spelled out 10 broad coverage categories that will form the basis of EHB packages, and therefore the basis of all health insurance plans sold in this country. While we are encouraged to see that “preventive and wellness services and chronic disease management” is included as a category, we are wary that no further direction has been provided to the states to help better define what services should be included in that category. As representatives of chronic kidney disease (CKD) patients, many of whom suffer from multiple chronic conditions, we are worried that this lack of specificity will lead to very different benefit packages across the states and the potential for discriminatory practices.

For instance, must benefit packages include both “preventive and wellness services” and “chronic disease management” benefits, or will fulfilling one aspect of the category be sufficient? In terms of treatment for chronic conditions, will states fulfill their statutory obligation by simply covering diabetes or arthritis, or do benefit packages need to include a more robust set of chronic disease management services? Answers to these questions, and many more like them, are vital to designing these benefit packages and ensuring the quantity and quality of coverage that the ACA intended. This concern extends beyond the specific category mentioned above, to all 10 categories laid out by the ACA and we urge HHS

to provide more robust information to help the states adequately define and fulfill the EHB component of health reform.

III. Concern for Permitting Substitution of Benefits

We are also leery about the proposal to allow substitution of benefits within categories. We appreciate the move away from permitting substitution of benefits across categories, but we are still concerned that allowing benefit substitution within a category could lead to discrimination against certain disease groups. DPC represents many of the most expensive chronic disease patients in the country and we have reservations that this flexibility will allow insurance companies to remove coverage of CKD and ESRD services, even if it is included in the original benchmark plan of a state. We urge HHS to reconsider this provision and ensure that benefit packages in all health plans sold inside and outside of the exchanges have consistent EHB packages.

IV. Improvement in Prescription Drug Coverage Still Needed

We are greatly encouraged by HHS' move away from the restrictive prescription drug coverage guidelines outlined in the December 16, 2011 Essential Health Benefits Bulletin released by the Center for Consumer Information and Insurance Oversight (CCIIO). The modifications laid out in CMS-9980-P are substantially better than the Bulletin; however, there is still significant room for improvement.

The proposal to ensure that every plan cover the greatest of: 1) the same number of drugs in each category and class as the EHB benchmark plan; or 2) one drug in every category or class will provide more robust prescription drug benefits than the original proposal of simply one drug in every category or class. This shift will ensure that drug coverage in the EHB packages will be more consistent with coverage in the market today and will increase access to critical medications. However, we are still troubled by the assertion that the benchmark package needs only to cover one prescription drug in a category where it currently has no coverage. This threatens to undermine care for all those suffering from chronic conditions.

Typical dialysis patients take more than a dozen medications each day to manage their kidney failure, its effects on other organs and to manage other common comorbidities. Additionally, kidney transplant recipients are reliant on immunosuppressive medications to ensure the viability of the transplanted organ. If the standard is to require only one drug per category or class, medically necessary medications will not be covered for many patients. This will have a serious impact on the quality of care patients receive and the quality of life they are able to enjoy.

We urge HHS to consider Medicare Part D rules that set aside six therapeutic categories –antidepressants, antipsychotics, anticonvulsants, antineoplastics, immunosuppressants and antiretrovirals– and require plans to include “all or substantially all” of these drugs on their formularies. We recommend HHS include the Medicare Part D requirement to cover “all or substantially all” of the drugs in six protected classes of drugs in the final rules. This inclusion will ensure patients have access to a full range of critical medicines, including new therapies. We also encourage HHS to review the proposal to base drug classification categories on the United States Pharmacopoeia to ensure that this will not lead to decreased access for certain compounded and pediatric medications.

It would be a disservice to patients for HHS to develop new coverage rules that diminish patient choice and reduce access to life saving medicines. Prescription medication is a critical tool in the management

of chronic diseases, the prevention of disease progression and costly complications, and we encourage HHS to consider redesigning the standard to provide more comprehensive prescription drug coverage through the exchanges.

V. Protect Patients from Discrimination

Finally, we would like to address the issue of discriminatory benefit design. We appreciate the ACA's stated commitment to ensuring that health plans no longer include discriminatory benefit designs aimed at reducing access to care for specific disease groups, ages, genders, etc. and we welcome HHS' assertion that it will prohibit these policies in EHB packages.

To that end, we urge HHS to specify in the final rule that plans will be prohibited from designing benefits that place arbitrary visit/treatment or dollar limits on specific services; place more burdensome participant cost-sharing on specific beneficiaries; design benefits in ways to exclude coverage for services based on age, health status and other population characteristics; or include restrictive provider networks. These critical patient protections will ensure that insurance companies cannot use benefit design or cost-sharing as a means to discriminate against kidney disease and other vulnerable patient populations.

VI. Conclusion

With more than 31 million Americans currently suffering from chronic kidney disease, it is vital for patients to have access to kidney treatments, especially dialysis and transplants, in the new health insurance exchanges. It is critical that HHS take the necessary steps now to ensure that some of the most vulnerable patients are able to take full advantage of the reforms laid out in the ACA. We thank you for your consideration and welcome the opportunity to work with you on this and other important issues in the future.

Sincerely,

A handwritten signature in black ink, appearing to read "Hrant Jamgochian". The signature is fluid and cursive, with the first name "Hrant" being more prominent and the last name "Jamgochian" following in a similar style.

Hrant Jamgochian, J.D., LL.M
Executive Director