DPC
DIALYSIS PATIENT CITIZENS

Improving Life Through Empowerment

August 30, 2013

Hon. Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1526-P: End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Dear Administrator Tavenner:

Dialysis Patient Citizens (DPC) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the proposed payment rule for the Medicare End Stage Renal Disease (ESRD) program. As America's largest patient-led organization representing dialysis patients, DPC's membership consists of more than 26,000 dialysis and pre-dialysis patients and their families. We seek to ensure the patient point of view is considered by policy makers.

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. However, improving quality of life for patients can only go so far without improving the quality of care patients receive. DPC knows that a diagnosis of ERSD does not mean the end of life. Dialysis patients can lead long and productive lives because Congress and CMS have shown commitment to ensuring patients have access to quality kidney care. It is for these reasons that we respectfully submit comments on the NPRM.

I. Payment Issues

A. The Proposed 9.4 Percent Cut Would Jeopardize Patient Access to Care

We have serious concerns about the proposed cut to dialysis reimbursement in the NPRM. As the Medicare Payment Advisory Committee (MedPAC) has indicated, the average margin of a dialysis facility is between 3 and 4 percent. A cut of 9.4 percent would move the current margin

into the negative for most facilities. While we understand that Congress required CMS to recalculate payment rates to account, as best as it can, for the reduction in the use of erythropoietin stimulating agents (ESAs), we do not believe that requirement relieved CMS of its ongoing statutory duty to ensure that dialysis payments cover dialysis costs. We therefore urge CMS to determine an appropriate payment amount that guarantees access to high-quality dialysis care for beneficiaries, true to the spirit in which the Medicare ESRD benefit was created.

The need for dialysis payments to adequately cover the costs of treatment has a unique importance due to the circumstances under which Congress enacted ESRD coverage.[1] The ESRD benefit was created in response to national revulsion over unequal access to life-saving dialysis care. Prior to 1972, a "patchwork" system of dialysis was in place, with funding coming from Public Health Service demonstration grants, research and educational institutions, private charitable efforts and state programs. A patient's ability to obtain dialysis could depend on whether there was capacity in his or her vicinity (which might be a function of such serendipities as whether a nearby academic medical center had a nephrology program or a local VA hospital had excess capacity to dialyze non-veterans), whether the patient had financial means to afford dialysis, or worst of all, whether a patient was deemed "worthy" of the treatment.

In the late 60s and early 70s, Congress considered two options: (1) amending the Public Health Service Act to reinforce the piecemeal system with additional grants or subsidies for individual facilities, and (2) amending the Social Security Act to create a nationwide kidney care infrastructure through Medicare coverage. Congress rejected option one and chose option two. In creating the ESRD entitlement Congress expressed its judgment that access to dialysis must not be dependent on the vagaries of where it was being offered for random reasons, or on the patient's economic circumstances.

Also of note was the emphasis by sponsors of the bill on the need for sufficient dialysis infrastructure to allow kidney failure patients to be able to return to work (at that time, nearly all of those considered potential dialysis patients were under 65). In sum, Congress' intent was that there be nationwide availability of dialysis services, with sufficient access that patients could travel to dialysis, dialyze, and go to work full time. This implies intent that payment be sufficient to guarantee a concomitant level of geographic and hourly availability.

In the NPRM, CMS said the proposed cut is a "significant reduction" that could "potentially impact beneficiaries' access to care." We agree that any reasonable person would conclude that a cut to reimbursement by a percentage that is substantially in excess of the average facility margin has a strong potential for negatively impacting access to care. We also believe that when the agency is confronted with such circumstances, it has a legal obligation to go beyond simply estimating a reduction in input costs for ESAs; it must also determine the costs of providing care to patients as a whole, and set a payment amount adequate to assure nationwide availability of dialysis services.

[1] The following discussion draws upon these references: Richard A. Rettig, Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972 in *Biomedical Politics* (1991); Norman G. Levinsky, Lessons from the Medicare End Stage Renal Disease Program, *New England Journal of Medicine* 329:1395-1399 (1993); and George E. Schreiner, How End Stage Renal Disease – Medicare Developed, *American Journal of Kidney Disease* 35:S37-S44 (2000).

Cutting nearly $1 billion per year in support to the U.S. kidney care infrastructure will result in retrenchments that reduce access to dialysis services. Of particular concern to us is the analysis of Medicare cost reports conducted by the Moran Company for the Kidney Care Council indicating that a substantial number of providers—approximately 35 percent—already have a negative gross margin. Those facilities are surely at risk for closure or reduced hours of service.

Our suspicion is that facilities in areas with lower population density may be particularly vulnerable. Our most recent survey of DPC members and non-DPC member dialysis patients found that, with regard to travel times, 8 percent of patients travel for more than 30 minutes to their facilities. Probably not coincidentally, about 8 percent of facilities are located in regions classified as rural. Another 12 percent drive 21-30 minutes, seemingly corresponding to the 11% of patients in rural micropolitan areas (i.e., small cities not adjacent to urban areas). A particular fear would be seeing patients currently in the 21-30 minute category migrating to the 30+ minute category in the future.

The Institute of Medicine has highlighted the importance of reasonable travel times for dialysis:

> "The distance between a patient's residence or place of work and the site of treatment, the available means of transportation, the average travel time, and the financial resources to meet the travel and patient time costs are important issues to patients. Rural patients, for example, may have more difficulty in reaching a treatment facility than their urban counterparts, and poor, urban patients may have fewer transportation resources than do suburban patients. Little is known, however, about access limits imposed by the costs and availability of transportation.
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> For a dialysis patient needing treatment three times a week, having to travel long distances can be very troublesome. Among the St. Louis focus-group participants were individuals who traveled almost 100 miles from rural areas into the city for care. Alternatives for rural patients may include home dialysis or moving closer to caregivers. These options may be economically infeasible or medically inappropriate."[2]

B. CMS Must Consider the Cost of Providing Care in Setting Payments

Section 1881(b)(2)(B) of the Social Security act provides that "The Secretary shall prescribe in regulations any methods and procedures to (i) determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals determined to have end stage renal disease, and (ii) determine, on a cost-related basis or other economical and equitable basis… the amounts of payments to be made."

This provision was enacted in 1978, when Congress authorized a prospective reimbursement rate for dialysis providers.[3] We can find no case law interpreting the meaning of this provision. However, a strikingly similar provision was enacted authorizing prospective payment for

[2] Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program, *Kidney Failure and the Federal Government* (1991) at 154.
[3] Id. At 195.

Medicaid providers at about the same time. The Boren Amendment became law in 1980 under the same circumstances: a movement from "reasonable cost" basis to an "economically operating" basis for payment. The Boren Amendment (later repealed) required that hospital rates be "reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with applicable State and Federal laws, regulations, and quality and safety standards and to assure that individuals eligible for medical assistance have reasonable access (taking into account geographic location and reasonable travel time) to inpatient hospital services of adequate quality."[4]

Note that although the purpose of these prospective payment statutes was to grant agency officials greater flexibility, both retained the premise that officials were required to ascertain the costs of providing care. The Medicaid provision gave rise to a large body of litigation between providers and state Medicaid agencies over adequacy of rates. Providers' resort to the federal courts to obtain more generous reimbursement was controversial, and Congress repealed the Boren Amendment in 1997. We do not mean to suggest that Section 1881(b)(2)(B) gives patients or providers rights that can be asserted in the courts. But we do believe that courts' interpretations of the analogous language in Boren offers guidance to the agency in understanding the core principles of payment embodied in Section 1881(b)(2)(B).

Our comments will focus on the Tenth Circuit Court of Appeals' decision in *AMISUB (PSL), Inc. v. Colorado Dept. of Social Services*, 879 F.2d 789 (1989). *AMISUB* was a suit by three hospitals challenging the State of Colorado Medicaid agency's system for reimbursement of inpatient hospital services.

Beginning in 1988, the Colorado Medicaid Agency implemented a new provider reimbursement formula that used the payment amounts for Medicare's diagnostically related groupings (DRGs) as its starting point. Different base rates were determined for special "peer groups" of hospitals such as urban and rural, with hospitals in each group presumed to have similar costs. But in calculating the Medicaid base rates, the Medicare amount was first reduced by multiplying it by .88 (i.e., presuming that Medicaid patients, in general, incur only 88% of the medical costs of Medicare patients); and then by multiplying the .88 reduced payment by .54, for a total reduction of provider reimbursement from the Medicare amount of 46%. The .54 reduction was known as the budget adjustment factor (BAF), and was based solely on keeping the Medicaid program within its historical budget. The court found that the BAF "ha[d] no relation to the actual costs of hospital services."

To be sure, the circumstances in the *AMISUB* case were different from those confronting dialysis providers today because, the court found, *no* Colorado hospital could recover its actual costs. Based on the Moran analysis, currently, about 65 percent of dialysis facilities recovered their costs prior to the sequester. Under the proposed rule, about 22 percent of facilities would recover their costs. While this is better than zero, Colorado could at least try to justify its negative-margin payment by pointing to those hospitals' ability to obtain higher payments from other

[4] See Edward Alan Miller, Federal Administrative and Judicial Oversight of Medicaid: Policy Legacies and Tandem Institutions under the Boren Amendment, *Publius* 38:315-342 (2007).

sources. Obviously, given the predominance of Medicare as the principal payer for ESRD, cross-subsidization is not a meaningful factor here.

At first blush, the facts of *AMISUB* seem inapplicable to the NPRM; after all, Section 632 required CMS to actually calculate putative reductions in input costs in order to meet budget considerations, so CMS' efforts to reduce payments hardly appear to be as arbitrary as the Colorado .54 "budget adjustment." But upon closer inspection, the 12 percent reduction in the NPRM is indeed arbitrary. At any given time, some element or elements of input costs will be declining. For instance cost per hour worked in health care and social assistance industry occupations declined between 2008 and 2009; natural gas prices dropped by nearly two thirds between 2005 and 2011; real estate prices dropped between 2006 and 2009; and interest rates dropped between 2009 and 2012. If CMS calculated actual reductions for any such input costs during their periods of decline in the same manner as it did for ESA utilization under Section 632, without keeping in mind the bigger picture as we believe Section 1881(b)(2)(B) requires, the resulting payment would surely not cover the costs of any facility. We do not believe Congress would ever intend such absurd results, letting "snapshots" supersede a statute that has been in force for 35 years.

We note that while Section 632 required CMS to calculate putative cost reductions attributable to reductions in utilization, it did not mandate that CMS reduce payment by the amount of its estimate but rather that it adjust the payment to "reflect" lower utilization. It is somewhat ironic that CMS so rigidly applied the estimate to the payment amount, given that CMS often criticizes the superficiality of savings estimates contained in GAO and OIG audit reports. We do not believe it was Congress' intent that the agency rigidly apply the estimate to the payment amount in the absence of other cost-related considerations. We would also note that CBO projected only $200 million in savings, almost five times less than CMS' proposed reduction.

The *AMISUB* opinion proceeds to discuss how an administered pricing system should take costs into account in an "economical" manner. The court reviewed how the costs of individual facilities can be placed on a distribution, with the administered price set at a given percentile of facilities to pressure more costly facilities to find efficiencies. It cites expert testimony from a former HCFA official on how, in the Medicaid sphere, the cut-off might be set as low as the 50th percentile but no lower.

As noted earlier, the NPRM would essentially set the cut-off for payments to dialysis facilities at the 22nd percentile. This would be an unfair result for Medicaid payments to hospitals; and it is all the more absurd for dialysis facilities that enjoy none of the cross-subsidization opportunities available to hospitals.

C. Incentives for Innovation

We would like to reiterate our concern that a static payment policy may dampen incentives to develop innovations in ESRD treatment. With the implementation of the bundled payment system for the ESRD program, there are limited mechanisms for introducing new therapies. Ensuring high-quality care and protecting the integrity of the bundle includes providing incentives for the development of new technologies and DPC strongly encourages CMS to

consider new mechanisms for treatment innovation and implementation of new programs to reward advances in the care for ESRD patients.

DPC strongly supports the KCP position that calls on CMS to establish a new technology adjustor that would allow for additional payments in a non-budget neutral manner. Instituting this adjustor would add the new money needed to create incentives for innovation in an area that has seen few historic changes in care.

Without some mechanism to incentivize changes and innovations in dialysis care, kidney disease patients run the risk of being left behind while other areas of care advance. New technologies have the potential to lead to better diagnoses, better treatment and better outcomes for patients, which in turn means lower costs and higher patient satisfaction. Operating under the current structure of the ESRD PPS, there is little motivation to move forward on new technologies to improve care for this vulnerable population. An adjustor would provide a mechanism to reward innovative ideas and would increase incentives for new therapies to treat kidney failure.

Thank you again for your consideration of our comments and concerns. If you have any questions or would like additional information, please do not hesitate to contact me or our Government Affairs Director Jackson Williams (at 202-789-6931 or jwillaims@dialysispatients.org).

Sincerely,

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