
August 19, 2021

Hon. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Calendar Year (CY) 2022
Proposed Rule (CMS-1749-P)

Dear Administrator Brooks-LaSure:

Dialysis Patient Citizens (DPC) writes to offer its comments on the above referenced proposed rule.

DPC's membership, currently over 30,000, is restricted to kidney disease patients and their family members. DPC is a patient-led organization. Our by-laws require that the President, Vice President and at least 51% of the Board be current dialysis patients. The non-dialysis patients serving on our Board are former dialysis patients with kidney transplants. Our volunteer board members have represented their peers on CMS technical expert panels and/or advisory committees of other health care organizations such as the National Quality Forum and Patient-Centered Outcomes Research Institute. DPC also conducts an Annual Membership Survey to ascertain patients' experiences with their care and views on health policy issues. DPC is committed to promoting access to high-quality dialysis care for individuals with ESRD; to prevention of, delayed onset of, and safe transition to ESRD among individuals with chronic kidney disease; and access to kidney transplantation as well as to other alternatives to dialysis that may emerge.

We appreciate the intention stated in the rule to begin addressing health equity problems that have festered for far too long. For the first time the Agency is accounting for disadvantage in performance metrics—albeit only in a limited capacity—nevertheless this is a step forward in the ESRD program. But we fear that the Agency is pursuing a policy of health equity on-the-cheap that offers inadequate resources to truly reduce disparities. The events of the past year and a half, and resulting realizations about the effects of racial discrimination on health, have opened a window for policymaking to address disparities. It would be a waste to adopt only half-measures during the all-too-brief period this window is likely to remain open. We endorse an alternative approach.

I. Quality Incentive Program Issues

In this proposed rule CMS is modifying the scoring and payment methodologies to provide that no facility would receive a payment reduction for PY 2022. It will also suppress the use of certain ESRD QIP measures (for example, the Standardized Hospitalization Ratio) for scoring and payment adjustment purposes in the PY 2022 ESRD QIP, because CMS has determined that circumstances caused by the COVID-19 Public Health Emergency (PHE) have “significantly affected the validity and reliability of the measure and resulting performance scores.” We agree with and appreciate the Agency taking this action. As a reduction-only program for a particularly vulnerable population, the QIP must be implemented with special care.

The proposed rule requests information on the possible stratification of QIP measures based upon dual-eligibility status.

There have now been three different studies demonstrating how the QIP transforms racial and socio-economic disparities into payment reductions for clinics serving the most disadvantaged patients. First, the initial Report to Congress on Social Risk Factors¹ demonstrated that QIP scores are affected by socio-economic factors. The report found that dialysis clinics serving patients who are eligible for Medicaid as well as Medicare (“dual eligibles”) have lower scores on anemia management, fistula use, and catheter use. The report also found racial disparities in dialysis adequacy and fistula use measures. The study determined that clinics serving poorer patients are more likely to get the full 2% QIP penalty.

Next, a 2019 study by the Institute for Public Health at Washington University found that “facilities located in low-income ZIP codes and with high proportions of Black or dually enrolled Medicare and Medicaid patients had lower performance scores and higher penalties under Medicare’s ESRD QIP.”² The authors concluded that the ESRD QIP “could cause facilities to avoid caring for high risk patients that are perceived to be likely to have negative outcomes measured under the program. Penalties imposed on dialysis facilities in low-income ZIP codes could worsen facility quality by taking away valuable resources.”

The authors also suggested that “ESRD QIP penalties could also spur facilities to improve quality, which could reduce disparities.” However, a third study dispels this possibility.

Sheetz et al (2021) used publicly available Medicare data to evaluate whether penalization was associated with improvement in dialysis center quality from 2015 through 2018 and whether the effect of penalization on quality varied at dialysis centers with different underlying characteristics. The study found that penalized centers were located in ZIP codes with a higher average proportion of non-White residents (36.4% vs. 31.2%) and residents with lower median income (\$49,290 vs. \$51,686). The study concluded that penalization for performance in 2015 was not associated with improvement in total performance scores in 2017, and that this was consistent across dialysis centers with different characteristics.³

The authors commented that their

“findings highlight several potential issues with the design of the ESRD QIP. First, the program uses a broad list of measures that reflect a range of quality priorities. Thus, they may not permit centers to focus sufficient efforts to address each measure independently. This aligns with concerns that annual penalties are based on a growing number of measures that change frequently. Second, because the measures do change frequently, it is possible for centers to receive penalties in a given year for their performance on measures no longer incentivized by the

¹ Assistant Secretary for Planning and Evaluation, Report to Congress on Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Programs <https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs>

² <https://publichealth.wustl.edu/wp-content/uploads/2019/08/8-23-19-ESRD-QIP-Policy-Brief-Final.pdf>

³ Kyle H. Sheetz, Laura Gerhardinger, Andrew M. Ryan, et al. Changes in Dialysis Center Quality Associated With the End-Stage Renal Disease Quality Incentive Program: An Observational Study With a Regression Discontinuity Design. *Ann Intern Med.* [Epub ahead of print 1 June 2021]. doi:10.7326/M20-6662

program. We found that a greater proportion of nonpenalized centers happened to be chain-affiliated. This observation may suggest that larger chains with greater infrastructure are better equipped to manage the frequent changes in quality benchmarks and data reporting. If this is true, penalization may be more closely associated with the structural capabilities of the center rather than clinical quality. Third, the program issues annual penalties. This further assumes that centers can implement effective changes on a yearly timescale... Finally, the ESRD QIP may levy a disproportionate share of penalties on certain types of centers. Because many of these centers care for poor and otherwise underserved communities, they may exacerbate existing health care disparities.”

We agree with all these critiques. With regard to the first three points, we urge the Agency to convene kidney stakeholders to reach consensus on a more targeted and longer-range set of high-priority QIP measures.

With regard to the final point, we believe that a social-risk stratification of the QIP is merited, as we have stated for at least five years. However, over the course of the five years that the Agency has declined to act on the ASPE findings, leading health policy analysts have moved toward advocating a new approach to addressing social risk.

In a *Health Affairs Blog* post this past April, Jonathan Jaffery and Dana Gelb Safran wrote that, inasmuch as “differential resources... may be required to achieve a given level of outcomes in a socioeconomically vulnerable population... rather than adjusting the performance scores to account for a more at-risk population, we propose to adjust payment.” Their approach contemplates both “upfront supplemental payments to providers who care for disproportionately higher-risk populations” and applying a “multiplier” to pay-for-performance (P4P) adjustments “such that organizations serving a population with greater social risk would receive larger rewards for an equivalent level of outcome, compared to providers caring for lower-risk populations.”⁴

This call was echoed six weeks later by one from Phillips, Ostrovsky and Bazemore to create a “social-needs payment adjustment ... to increase resources to clinics based on the social risk of their patient population, and to align this mechanism with processes that enables clinics to identify at-risk patients who can benefit from those resources.”⁵

DPC proposes creation of a Social-Needs Payment Supplement (SNPS) to augment the ESRD PPS. This concept builds on those advocated by health policy thought leaders in the area of social determinants of health as a way of addressing health disparities without adjusting quality measures. It has the twin benefits of keeping a single, high standard for P4P programs and public reporting, while funneling money to providers who care for the neediest patients and offsetting P4P penalties that are most likely attributable to patients’ social needs.

As we envision the SNPS for dialysis, it would largely function as a credit against payment reductions under the QIP. This is because academic studies have found that QIP payment reductions are most frequently levied against facilities serving disadvantaged populations. However, under our proposal, facilities serving disadvantaged patients and providing high-quality care which are not penalized under

⁴ <https://www.healthaffairs.org/doi/10.1377/hblog20210414.379479/full/>

⁵ <https://www.healthaffairs.org/doi/10.1377/hblog20210526.933567/full/>

the QIP would be eligible for bonus payments that would be funded by unspent outlier pool dollars and money previously withheld for adjusters that went unclaimed.

Our SNPS proposal would apply to a subset of clinics serving patients subject to high levels of deprivation. For instance, one method of designating this subset of clinics might be to take the upper quintile of clinics serving dual eligibles.

To incentivize the highest possible performance, the SNPS would be graduated based on distribution of QIP Total Performance Scores within the Deprivation Subset. One option might be a 2% credit for the highest performing quartile; 1.5% for the second tier; 1% for the third tier; and .5% for the lowest tier. This would create competition within the peer group.

We suggest a pilot project in which clinics in the Deprivation Subset are invited to enroll in an SNPS program through which they agree to provide specified extra assistance to their patients. The pilot could be evaluated over the period it is funded by ESRD dollars unspent in prior years. If outcomes are improved, the Agency and stakeholders could petition Congress to permanently authorize funding.

Other Requests for Information

Health Equity Score for facilities. The Agency proposes to develop a score comparing outcomes for disadvantaged versus non-disadvantaged patients within each facility and across facilities. We support such an effort.

COVID Vaccine measures. The Agency proposes to develop a QIP measure on the percentage of facility personnel who received the COVID vaccine. We favor such an effort. The Agency also proposes a QIP measure on the percentage of facility patients who received the COVID vaccine. We do not support this concept. We know that even prior to COVID there was a well-defined geographic pattern of uptake to voluntary vaccinations, corresponding to regional subcultures. We also know that this pattern largely holds for COVID vaccinations, although now the pattern is influenced by political leanings as well. We see no point to collecting data that mostly reflects patient demographics, not clinical quality. We hope that, over time, we will find that clinicians leverage the trust they gain among patients to persuade the hesitant to accept the vaccine. If this can be accomplished in a way that negates regional patterns, it may make sense to add a measure. However, given the incredibly high COVID mortality rate for dialysis patients, we feel that that providers are highly motivated to secure vaccinations for their patients, and the need for a government or payer nudge in this area is low.

II. Proposed Changes to ESRD Treatment Choices (ETC) Model

The proposed changes to the ESRD Treatment Choices (ETC) Model are intended to incentivize dialysis providers to decrease disparities in rates of home dialysis and kidney transplants among ESRD patients with lower socioeconomic status. It will now give extra points for placement of lower income beneficiaries. The Agency trumpets this change as making the model “the first CMS Innovation Center project to address health equity.” However, the agency is providing no additional resources to nephrologists and dialysis clinics to give extra assistance to disadvantaged patients.

We would note at the outset that the ETC model’s design offers a poor vehicle for addressing health disparities. Its randomly selected intervention regions are disproportionately white and affluent.

The proposed rule notes at page 192 that “Beneficiaries with limited resources may require more assistance from ESRD facilities and Managing Clinicians to use alternative renal replacement

modalities.” We agree. However, this change continues the unrealistic thinking about resources and scarcity that has pervaded the ETC program.

Each facility begins with a finite supply of units of staff time available to devote to education and support for moving patient candidates to preferred modalities. This supply was not increased by the ETC demonstration. Research commissioned by Kidney Care Partners indicates that dually eligible/LIS beneficiaries are half as likely as non-low-income beneficiaries to be placed on home dialysis; we can infer from this that the additional staff time required for switching is substantial. If the units of assistance available are held constant but units expended per candidate are increased, the expected outcome would be fewer switches.

By the same token, what if the new formula provides insufficient incentives for providers to try switching the disadvantaged patient? With no new dedicated pot of money, we presume providers would stick to whatever gaming techniques or resource redeployments they decided upon last year.

In our view, a “health equity” initiative that is unfunded presents too much risk of a zero-sum or negative-value outcome if it works to modify incentives, and of inaction if it does not sufficiently modify incentives. We hope that the program staff and Actuary have seen data on actual resource use requirements to complete modality switches and determined that our fears are unwarranted. But we simply do not see how an unfunded approach can increase both equity and efficiency, the latter being a statutory requirement for CMMI models. Increasing transplants and home dialysis among the disadvantaged should lower Medicare expenditures and is a worthy goal towards which CMMI should invest funding.

President Biden is known for having said, “Don’t tell me what you value, show me your budget.” The proposed rule’s dime-store approach to disparities tries to “tell” us it values health equity, but in failing to meaningfully budget for it, the rule shows us otherwise. This seems uniquely inappropriate for a Biden Administration initiative. We continue to believe that Medicare coverage of medically necessary dental care for transplant candidates, and compensation of the full costs to living organ donors of the valuable gift they bestow not only on the kidney patient but also the Medicare program, are two initiatives that would promote both equity and efficiency. We also believe that a demonstration of staff-assisted home dialysis could improve uptake among disadvantaged patients. Further, supplemental payments to clinics serving disadvantaged patients, as we proposed in Section I above, would better ensure that resources are brought to bear on switching those patients to home modalities.

Request for Information on placement of PD catheters.

The Rule also seeks feedback on barriers to increased placement of PD catheters, options to promote placement of PD catheters in a more timely manner, and whether barriers to PD catheter placement can be addressed as part of the ETC Model.

We are pleased that the Agency now recognizes that the ETC’s single-minded focus on dialysis clinics and nephrologists was ill-advised. But we remain concerned that the Agency continues to address barriers to home dialysis one provider-type at a time rather than holistically as an extended series of barriers and decision points that face patients beginning when they are in earlier stages of kidney disease. The “playbook” on home dialysis published by Kaiser-Permanente illustrates the relevant continuum of care and opportunities to influence modality choice within an integrated system—a system that must somehow be replicated within the fragmented fee-for-service environment of Original Medicare.

A basic problem is that the resource-based relative value unit system in the Physician Fee Schedule inadequately accounts for the cost to surgeons in developing PD catheter placement as a niche practice area, but more importantly, it does not account for the increased value accruing to patients and to Medicare when these catheters are timely placed. Obviously, this is not a situation that can be addressed within the ETC's bonus-and-penalty payment adjustments to facilities and nephrologists.

We believe CMMI has authority to supplement, beyond the PFS, payments to surgeons that increase access to and availability of procedures that are "gateways" to improved chronic care and likely to reduce Medicare expenditures downstream. Placement of PD catheters is surely such a gateway procedure. We think supplemental payments should be offered to surgeons on a pilot basis. If CMMI can identify localities in which unavailability of PD placement is a potential cause of less-than-expected home dialysis use, such localities might be especially appropriate for testing this intervention.

III. ESRD Prospective Payment System Issues

Historically, DPC has been supportive of the ESRD payment bundle, while also recognizing its possible pitfalls for patients, including potential for stinting and disincentives for innovation. A particular concern is the treatment of new products that must go into the bundle. What patients want most of all are innovations that will improve their quality of life, even more so than those adding longevity. Some of these products might also reduce complications and save on hospital expenses downstream. But CMS has said it won't pay more for improved quality of life or for avoided complications. We hope the new administration will review the policy in this area and reverse those pronouncements.

Recently, we informed the Agency of indications that there has been a precipitous drop—about 2/3—in sales of Parsabiv since the TDAPA add-on payment ended and the drug was placed in the ESRD bundle. We recognize that usage during the TDAPA period is not necessarily an appropriate baseline from which to judge a drop in utilization, and that it may not be within the competency of the Medicare program to determine an appropriate level of usage for Parsabiv, but we do think CMS needs to consider how Medicare's own payment incentives may contribute to stinting on care within a bundled payment environment.

Particularly worrisome is data on parathyroid hormone (PTH) levels reported by Amgen. Lab value data for a sample of patients treated by dialysis providers whose protocols changed when TDAPA ended indicate that between December 2020 and April 2021, 40.8% fewer patients had PTH levels below 600.

Several unusual aspects underlie this situation. First, Parsabiv is a particularly expensive drug to be rolled into a bundle, and one that is required by a relatively small proportion of patients. The large amount of money that providers can keep if they withhold it from an appropriate patient creates an outsized temptation for bean-counters to promote stinting strategies.

Second, the condition that Parsabiv treats is asymptomatic, so we fear that patients who need the drug and are denied it might not have the knowledge and motivation to raise the issue with their providers.

Third, Parsabiv is far more commonly indicated for Black patients. This raises the possibility that healthcare disparities could be aggravated, in terms of poorer outcomes for Black patients, and lower costs of treating White patients, creating an economic incentive to avoid accepting Black patients. Further exacerbating the potential of access problems is the disproportionate need for calcimimetics among dual eligibles, for whom states often pay less than Medicare rates.

In sum, it is hard to imagine a bundled payment scenario posing more risk of negative consequences for patients than this one. As such, we have concluded that the safest course for patients would be for CMS to create a clinical adjuster to target the calcimimetic dollars added to the bundle last year to the patients most likely to use these drugs. We urge designation of an adjuster triggered by the billing of the drug HCPCS code. This would ensure perfect alignment between patient use of calcimimetics and a paid adjuster.

Finally, we are concerned that there is a gap in protections for patients denied treatment with a bundled product or service. Medicare beneficiaries have clearly delineated appeal rights for denials of Part A or B coverage by a MAC and for denials of Part C or D coverage by an insurer. Beneficiaries can also file grievances over quality of care. But there is no clear avenue for contesting the denial of services under the ESRD bundle as it involves a provider, not a MAC or insurance plan. We urge the Agency to designate a process for adjudicating disputes, and educate beneficiaries on how to access it.

All of the foregoing further reduces the already deficient incentives for venture capital to invest in drugs and technologies covered by the bundle, so we would here reiterate our request that this issue be briefed to and reviewed by new political appointees.

Thank you 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 Vice President of Public Policy Jackson Williams (at 202-768-4506 or jwilliams@dialysispatients.org).

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Hrant Jamgochian".

Hrant Jamgochian, J.D., LL.M.
Chief Executive Officer