
September 4, 2020

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1732-P
7500 Security Boulevard
Baltimore, Maryland 21244

**Re: CMS 1732-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program**

Dear Administrator Verma:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the Proposed Rule that updates and revises the End Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2021 and to the ESRD Quality Incentive Program (QIP).

The Alliance is a coalition of kidney dialysis stakeholders representing patients, clinicians, providers, and industry. We have come together to promote activities and policies to facilitate treatment choice in dialysis care, while addressing systemic barriers that limit access for patients and their families to the many benefits of home dialysis.

We appreciate that CMS has long recognized home dialysis—peritoneal dialysis (PD) and home hemodialysis (HHD)—as an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health[1] . In the final rule implementing the new ESRD PPS on January 1, 2011, the agency indicated that the new bundled payment would "encourage patient access to home dialysis,"[2] and "make home dialysis economically feasible and available to the ESRD patient population."[3] The most recently available data show that in 2017, 11.9 percent of prevalent dialysis patients received treatment at home. [4] We acknowledge that all patients must have good access to the treatment option that best meets their clinical needs, whether

[2] 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010).
[3] *Id*. at 49,060.
[4] [4] United States Renal Data System (USRDS), 2019 Annual Data Report: Epidemiology of Kidney Disease in the United States.

that is PD, HHD, or in-center dialysis, but specifically thank CMS for its support of home modalities and urge continued growth in this area.

We are pleased to offer the following specific comments related to this year's Proposed Rule.

**Calendar Year (CY) 2020 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)**

1. **The Alliance thanks CMS for its expansion of the TPNIES to include capital-related assets that are home dialysis machines, and offers the following comments:**

The Alliance strongly supports CMS' creation of the TPNIES program as an important means for encouraging innovative dialysis technologies and supports the inclusion of capital-related assets. Still, the current ESRD bundled payment lacks incentives for facilities to adopt new supplies and equipment, which has limited innovation and the uptake of new dialysis products, including products for home dialysis. We were encouraged when CMS finalized this add-on payment in last year's rulemaking and expanded it to include home dialysis machines in this year's rulemaking. We urge CMS to finalize this policy, and also to consider expanding TPNIES coverage to all capital-related assets that impact or are related to the care of home dialysis patients, to ensure that care for these patients continues without interruption while also incentivizing innovation.

This proposal also builds on President Trump's Executive Order on Advancing American Kidney Health, thus recognizing that as demand for home dialysis increases, more options for care are needed. The add-on payment would help cover the implementation costs of new home dialysis innovations, making them more widely available to growing numbers of patients who need them.

In addition, we request that CMS consider the following additional recommendations to ensure the above- described intent of the policy is achieved:

a. CMS must ensure that the ESRD PPS includes adequate reimbursement for new equipment and supplies upon TPNIES' expiration.

The Alliance respectfully raises concerns that CMS does not plan to incorporate additional dollars into the ESRD PPS base rate for new equipment and supplies upon TPNIES' expiration. The availability of a short-term add-on payment is one important factor an innovator will consider when making decisions to invest in developing a new technology. However, we are concerned that without the assurance of sustained and adequate reimbursement outside of the TPNIES period, an opportunity to ensure that optimal clinical gains for patients and better value for the Medicare program could be missed. As a threshold matter, we strongly urge CMS to reconsider its decision not to update the ESRD base rate upon TPNIES' expiration.

b. The Alliance urges CMS to consider quality of life and patient-reported outcomes when determining what is "new and innovative" under the substantial clinical improvement standard.

While we support utilization of the substantial clinical improvement standard, we want to emphasize the importance of quality of life metrics and patient-reported outcomes related to equipment and technology for dialysis care, especially home dialysis. We urge CMS to consider the totality of the circumstances and a broader body of relevant evidence, in addition to randomized clinical trials (RCTs), under TPNIES.

While we understand that RCTs are considered the "gold standard" of evidence, we urge CMS to consider that such trials are not always feasible, especially in the ESRD population, which has traditionally experienced difficult recruitment and high study drop-out rates, which is only exacerbated by COVID-19. Further, other factors which are not always measured in RCTs, such as ease of use or improved quality of life, are often essential to patients when determining what dialysis modality to choose and they deeply affect whether a patient is compliant with therapy over time. If the Administration truly wants to increase the number of patients dialyzing at home, it is essential that all available evidence be considered when determining whether a product or technology is new and innovative under the program.

c. CMS should make certain adjustments to the TPNIES payment.

We are pleased that CMS has finalized the TPNIES proposal and proposes expanding it to include capital equipment of home dialysis machines, as it will help to incentivize new advancements in dialysis care. However, adjustments can be made to the TPNIES payment paradigm that will further incentivize development Specifically, we urge CMS to consider business arrangements other than outright purchase of home dialysis machines and equipment. Many facilities maintain subscriptions with manufacturers or lease equipment, and we believe that these arrangements should be accounted for under TPNIES.

d. CMS should instruct MACs to provide public, timely, and consistent Payment Determinations.

We recommend that CMS modify the proposed rule language on Medicare Administrative Contractors (MACs) invoice pricing determinations to exclude language that gives MACs flexibility to determine pricing based on "charges and payment amounts for other equipment and supplies that may be comparable or otherwise relevant." This line undermines CMS approvals for applicants of TPNIES as, by definition, approved products have achieved a substantial clinical improvement over existing products.

Presently, the ESRD PPS Final Rule for 2020 and this proposed rule confer discretion to the MACs to establish TPNIES payment rates based upon invoices received. Without more defined payment parameters and public transparency, there could be significant variation in regional payments and the program as a whole could be undermined. To resolve these ambiguities and increase patient access, we recommend that CMS more clearly define the payment parameters and instruct the MACs to publish an online database that provides a discrete TPNIES payment amount, no later than March 31 of the first year of TPNIES eligibility.

e. CMS should establish a two-way process for the review of evidence for TPNIES that allows for rapid patient access to new and innovative products.

We recommend that CMS provide reasonable and clearer parameters at the start of discussions with applicants regarding the types of evidence and studies that technical expert panel reviewers want to see. This is similar to the process that FDA takes when considering approval of new products and would provide an opportunity for CMS and applicants to discuss an evidentiary standard that balances robust evidence of substantial clinical improvement with the need for patients to access these technologies as soon as possible. Accordingly, while we appreciate that CMS will allow companies a three-year window to apply for TPNIES after receiving a new marketing authorization, we encourage the TPNIES Work

Group reviewers to not use the three-year window as a reason to require multi-year studies when TPNIES applicants have otherwise demonstrated the technology represents a substantial clinical improvement over existing dialysis equipment and supplies. Such an approach is aligned with the very nature of the TPNIES incentive to spur adoption of new, innovative technologies and ensure patients have access to these options faster.

f. CMS should extend TPNIES eligibility to at least three years.

We recommend that CMS extend the TPNIES adjustment period from two years to at least three years. CMS has expressly stated that the basis for the TPNIES payment adjustment is to enable and support the adoption of new technologies in the ESRD continuum of care, and we wholeheartedly agree. In its current form, the ESRD PPS Final Rule requires providers to cover the incremental cost of using new technologies under the existing ESRD PPS bundled rate at the conclusion of the two-year TPNIES period. However, two years is an inadequate amount of time after taking into account the scale of resources and time necessary to build a responsible support and distribution infrastructure nationwide. This is especially true for companies in their earlier stages. Furthermore, a three-year adjustment period will provide companies with more time to collect data on a technology's safety and efficacy, and allow for greater cooperation between CMS, manufacturers and other third parties in standing up potential data infrastructure. Therefore, we urge CMS to extend eligibility to at least 3 years, if not permanently.

g. We urge CMS to articulate a process for appealing adverse determinations.

We recommend that CMS establish a formal appeal process for manufacturers whose applications for TPNIES were denied. We are concerned that, without an opportunity to review CMS' initial determination, situations may arise in which new technologies fail to obtain a favorable TPNIES determination due to technical errors or insufficient information in the initial application. A formal appeals process would ensure that applicants have an opportunity to seek additional, independent review as necessary. The standard process for seeking review of Medicare Part A/B claims may not apply here.[5] However, we are mindful that CMS has in the past – and has authority to do going forward – set forth a framework for conducting administrative appeals within the Office of Medicare Hearings and Appeals (i.e., a hearing before the Departmental Appeals Board). We encourage CMS to apply the same reasoning here.

**2. The Alliance supports inclusion of calcimimetics in the ESRD PPS base rate, but believes that only 2019 utilization data should be utilized.**

The Alliance supports CMS' proposal to include calcimimetics in the ESRD PPS base rate and agrees with the majority of the underlying methodology. However, while we understand the rationale behind wanting to utilize 2 years of data, we are concerned that utilizing 2018 data may be problematic. In particular, we are concerned that relying on 2018 data could impact the stability of such figures because generic calcimimetics only entered the market in late 2018. Looking at 2019 data only, our members report that utilization has been stable over the course of the year and should be stable going forward. The entrance of generics into the market in late 2018 may cause instability that does not reflect current reality. We urge CMS to consider utilizing only 2019 data in order to achieve consistency.

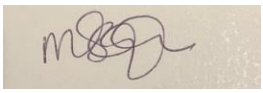
[5] *See generally* 42 C.F.R Part 405, Subpart I.

3. **We support CMS' proposal to hold facilities harmless related to the low-volume payment adjustment during the COVID-19 pandemic.**

The Alliance supports CMS' proposal to hold harmless ESRD facilities if an increase in treatment counts for 2020 is related to COVID-19 and would prevent them from qualifying for the low-volume payment adjustment. We agree with CMS that the shifting of patients, due to the need to distance patients throughout multiple clinics in order to avoid COVID-19 exposure, could cause some low-volume clinics to temporarily dialyze patients who would not be there during normal times. For many of these clinics, the low-volume payment adjustment is a very important tool, and we commend CMS for holding them harmless as they attempted to help patients appropriately social distance.

The Alliance appreciates the opportunity to provide comments to the ESRD PPS and QIP proposed rule for CY 2021. We are eager to continue to serve as a resource for CMS as you work to increase access to all dialysis modalities. Please do not hesitate to reach out to Alliance members or staff to discuss how we can work together. Please contact me at michelle@homedialysisalliance.org or 202-733-7326 if you have any questions.

Sincerely,



Michelle Seger
Managing Director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