



August 28, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1674-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CMS 1674-P - CMS Proposed Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (CMS 1674-P)

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 makes revisions to the End Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2018 and to the ESRD Quality Incentive Program (QIP). We also appreciate the opportunity to respond to the Request for Information (RFI) on Medicare flexibility and efficiencies, particularly relating to the facilitation of individual preferences in care delivery.

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.

Home dialysis—peritoneal dialysis (PD) and home hemodialysis (HHD)—is an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health. In 2014 (the most recent year for which data is available), 11.6 percent of prevalent dialysis patients received treatment at home.¹ CMS has long recognized home dialysis as an important treatment option. 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

¹ United States Renal Data System (USRDS), 2016 Annual Data Report: Epidemiology of Kidney Disease in the United States.

² 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010).

population.”³ In the years since, data indicates that the ESRD PPS—which pays for home peritoneal dialysis at the same rate as dialysis provided in the facility—has led to an increase in the utilization of home dialysis, particularly PD.⁴ The percentage of dialysis patients on home therapies has been growing in recent years, largely attributed to the growth in PD. Home dialysis use overall in 2014 was 73% higher than at its nadir in 2007.⁵ The Alliance is encouraged by the growth in PD as a result of the bundle and wishes to see it continue. HDD has not had the same type of growth, but it is another important treatment option for patients that should be fully supported within the bundled payment environment.⁶

The 2015 GAO report entitled *END-STAGE RENAL DISEASE: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis* identified specific barriers to home dialysis. We appreciate that CMS made changes to the payment for the home dialysis training add-on in 2017, but utilization of home dialysis remains only a fraction of what kidney professionals have said is clinically appropriate. While CMS hasn’t included any provisions in this proposed rule that would increase access to home dialysis, the Alliance believes that there is work still to be done to assure that all patients, regardless of age or demographics, retain the right to choose and access the dialytic modality and setting that they and their physicians feel is best to meet their individual needs. We encourage CMS to continue to identify and remove barriers to home dialysis.

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

I. Calendar Year (CY) 2018 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

1. The Alliance recommends clarifying any outstanding issues from the 2017 ESRD PPS Rule relating to additional dialysis sessions by encouraging all MACs to follow CMS’s Medicare Program Integrity Manual.

We respectfully ask that CMS ensure that all MACs are abiding by the requirements included in the Medicare Program Integrity Manual in implementing their policies regarding payment for more frequent dialysis. Inconsistent reimbursement for medically justified treatments undermines the physician-patient relationship, undercuts physicians’ ability to design clinically appropriate treatment regimens for their patients, and threatens patient choice in treatment modality that is protected under statute.

In addition, we respectfully request that CMS review CG modifier usage differences across MACs to ensure that the data provides meaningful insight into clinical practice regarding more frequent dialysis. Designation of medical necessity for billing purposes differs by MAC and providers will be required to use the CG modifier to comply with each MAC’s billing rules. Use of the CG modifier thus should not be interpreted solely as a clinical determination of medical necessity. Rather, use of the CG modifier will

³ *Id.* at 49,060.

⁴ Allan J. Collins, MD, FACP, “ESRD Payment Policy Changes: The New ‘Bundled’ Dialysis Prospective Payment System (PPS) in the United States”, National Kidney Foundation Spring Clinical Meeting Presentation (Mar. 2012), available at http://www.usrds.org/2012/pres/USDialysisBundle_impact_NKFCM2012.pdf.

⁵ United States Renal Data System (USRDS), 2016 Annual Data Report: Epidemiology of Kidney Disease in the United States, available at https://www.usrds.org/2016/view/v2_01.aspx.

⁶ [Intensive Hemodialysis: Time to Give the Therapy Greater Consideration](#), 11/2016, American Journal of Kidney Diseases, by Allan Collins and Christopher Chan; [Every other day nocturnal home hemodialysis: an alternative approach to reduce burden](#), 8/31/16, Nephrology News, by: Brigitte Schiller

represent a combination of clinical decision making on the part of the provider and compliance with MAC billing rules.

2. The Alliance requests that CMS provide dialysis facilities adequate time and detailed instructions to be used for the implementation of the shift of oral cinacalcet from a separately billable Medicare Part D drug to a Part B drug billable under the ESRD Program Bundle.

The Alliance understands that with the approval of Parsabiv, an IV formulation of etelcalcetide, which is the same class as the oral drug Sensipar (cinacalcet), both of these drugs will be newly covered under Medicare Part B. With the coverage of Sensipar moving from Medicare Part D, dialysis facilities and providers take on a new responsibility for managing the provision of this drug within the ESRD bundle. Dialysis facilities will have to begin working with physicians to ensure patients have access to the oral form (e.g. Sensipar) when it is medically appropriate.

The Alliance appreciates that CMS recently released guidance on the implementation of transitional drug add-on payments. However, facilities and dialysis organizations also need adequate time to prepare for this change. Some smaller dialysis organizations do not have ready access to pharmacies if they decide to use oral cinacalcet (Sensipar) as their calcimimetic of choice. There are additional challenges if the organization chooses etelcalcetide (Parsabiv). Rates of hypocalcemia are high, and monitoring may be needed with implementation, such as baseline and follow-up electrocardiograms in the clinic, depending on concern for cardiovascular side effects, which may be greater with the IV form.

Peritoneal dialysis patients will require use of the oral formulation (cinacalcet), and acquisition of the calcimimetic and assurance of patient compliance will be challenging. Note that Medicare beneficiaries will have a 20% co-pay as this medication is moved from Part D to part B, if they do not have supplemental insurance.

The Alliance is committed to supporting value-based care in order to improve patient care and outcomes, and wants to mitigate any challenges posed to facilities that serve home dialysis patients. We encourage CMS to give facilities adequate time to make the change, as well as explicit instructions for how the change is to be made. In the near term, Alliance asks that CMS engage with facilities in a transparent process as this change is implemented, specifically regarding timing and new requirements.

II. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

The Alliance believes that the ESRD QIP offers tremendous opportunities to drive improvements in the quality, safety, and efficacy of dialysis care. That is why it is critical that the experiences, both quality of life and clinical, of the approximately 11 percent of ESRD patients who dialyze at home be appropriately measured as part of QIP. This will help ensure that quality improvements extend to all modalities, not just in-center care. Home dialysis patients have historically experienced unique and important quality of life benefits, including more autonomy and flexibility over when they dialyze and greater ability to maintain employment. Unfortunately, the experiences of home patients are not currently considered in the ICH-CAHPS survey, an important component of the ESRD QIP. The Alliance believes such exclusion is contrary to the intent of Congress, which required CMS to adopt “to the extent feasible, such measure

(or measures) of patient satisfaction.”⁷ This also significantly limits the ability to assess and improve the quality of care provided to home patients, and to compare care across modalities and settings.

Additionally, industry data show that home patients, in particular PD patients, benefit from, on average, significant clinical advantages such as longer residual renal function, less frequent hospitalizations, higher likelihood to receive a transplant, and survival advantage in early years. These differential outcomes are not fully reflected in the current QIP methodology scoring.

1. CMS should continue efforts to develop quality of care measures relevant to the home population.

In the final CY17 rule (CMS-1615-P: *Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program*), CMS stated that the agency is considering developing an additional ICH-CAHPS survey for home patients. The Alliance strongly encourages CMS to support the development of such a survey.

Metrics designed for in-center conventional dialysis do not apply to all of the clinical and/or quality-of-life benefits of home dialysis, and may impose additional burdens on facilities without enhancing the home dialysis patient’s experience of care. Further, PD and HHD are distinct from each other and from in-center dialysis; quality measures should reflect the unique nature of each modality and should be developed based on data specific to that modality. As the agency is aware, there are private sector efforts to develop a survey tool to measure home dialysis patient experience. We encourage CMS to work closely with these efforts, and actively support the psychometric testing and validation necessary to ensure that it is a valid and reliable instrument that can be utilized broadly across providers in assessing the experience of home dialysis patients.

2. The Alliance suggests that CMS reset the QIP PD adequacy target to a level more appropriate to the modality.

The Alliance believes that quality measures should reflect the unique nature of each modality and should be developed based on data specific to that modality. Significantly, The Alliance believes that there is an opportunity to improve PD adequacy scoring within the current QIP methodology. PD therapy is inherently different from methods of hemodialysis and outcomes should be measured accordingly. For example, many PD patients experience residual renal function, which is not captured by QIP. This is a particularly significant scoring limitation with the pediatric PD population.

The Alliance suggests that the current target for PD adequacy is set too high, given industry experience, and leads to a disconnect between PD QIP ratings and the positive differential clinical outcomes actually experienced by patients on PD compared to traditional hemodialysis. Revising the targets downward would more accurately capture and reflect the actual experiences of PD patients.

3. The Alliance requests that CMS consider the impact of current QIP weighting on small facilities, especially home-only facilities.

⁷ See Section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275), adding new Section 1881(h) of the Social Security Act.

The Alliance is concerned that the current makeup of the QIP score could be a barrier to home dialysis uptake at small dialysis facilities or so-called stand-alone “home only” programs. The Alliance appreciates CMS’s commitment to fairness in the QIP, and its understanding that, sometimes, a small sample size can put a facility at risk for a QIP payment reduction because one or two low scores on one measure can dramatically alter its score results overall.⁸ However, The Alliance has become aware that small sample size remains a problem when measuring small facility or home only performance.

The clinical section of the QIP, comprising 75 percent of the total score, includes only two measures for most home only programs: a Kt/V score and a score for hypercalcemia. Therefore, as opposed to larger programs, which are scored on many more clinical data points, home only programs have 75% of their score dependent on only two measures. The Alliance is concerned that this uneven weighting will cause these small clinics to stop providing a home dialysis modality because they do not want to risk a poor QIP score based only on two factors. The Alliance urges CMS to closely look into this issue, perhaps utilizing the newly formed Kidney Affinity Group to do so.

Specifically, CMS could apply the current low volume scoring adjustment, which is typically applied facility-wide if a facility has only 11-25 eligible cases for a given clinical measure, separately to only the home dialysis patients at each facility, should the home program meet the rest of the criteria. This change would alleviate the problems that come along with small sample size for these small, but important, providers.

III. Request for Information on Medicare Flexibilities and Efficiencies

The Alliance appreciates the opportunity to offer input on innovative approaches on how to make Medicare more flexible and efficient, and would like to offer our organization as a resource to CMS on these issues as relates to home dialysis at any time. However, the Alliance has been pleased to offer opportunities and ideas about “specific innovations that are most appropriate for evaluating patients for suitability for home dialysis and promoting its use in appropriate populations,” including in the context of our comments to last year’s ESRD PPS rulemaking. The Alliance would appreciate feedback on those recommendations, and if possible, an update on whether any of the recommendations from that rulemaking have been implemented.

1. CMS should review the 2015 Government Accountability Office (GAO) report, “Medicare Payment Refinements Could Promote Increased Use of Home Dialysis,” and implement GAO’s recommendations on the Kidney Disease Education benefit.

In November 2015, the Government Accountability Office (GAO) released a report entitled “END-STAGE RENAL DISEASE: *Medicare Payment Refinements Could Promote Increased Use of Home Dialysis*,”⁹

Specifically, the Alliance urges CMS to implement GAO’s recommendation on Kidney Disease Education: “the Administrator of CMS should examine the Kidney Disease Education benefit and, if appropriate, seek legislation to revise the categories of providers and patients eligible for the benefit.”¹⁰ In addition, we support access to KDE for patients with Stage 3 and 5 Chronic Kidney Disease, in addition to the

⁸ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/ESRDQIPFrequentlyAskedQuestions.pdf>

⁹ <https://www.gao.gov/products/GAO-16-125>

¹⁰ <https://www.gao.gov/assets/680/673140.pdf>

current eligibility at Stage 4. The Alliance understands that changes to KDE policy are not within the purview of this specific rulemaking, however we encourage stakeholders across CMS to contribute to this vital effort whenever possible.

Currently, Medicare covers up to 6 sessions of KDE services provided by doctors, nurses, physician assistants and clinical nurse specialists for individuals with stage IV chronic kidney disease that require dialysis. However, this benefit is extremely underutilized as less than 2% of eligible patients used the KDE benefit. According to GAO, the expanded utilization of the KDE benefit could lead to increased uptake of home dialysis therapies, therefore the Alliance urges CMS to follow GAO's recommendation to look at the benefit and determination if eligible provider categories should be expanded.

2. The Alliance recommends that CMS utilize certain patient tools to encourage ESRD patients to participate in shared decision-making with clinicians.

Increased use of technology and new and innovative tools can often help encourage patients to take on a more active role in their healthcare decisions, alongside their care provider. The Alliance is supportive of two specific tools that do exactly that:

- The “Method to Assess Treatment Choices for Home Dialysis” (MATCH-D) has been designed specifically to help nephrologists and dialysis staff identify and assess candidates for home dialysis therapies (PD and HHD). Beyond assessing individual cases, the tool also works to sensitize clinicians to key issues about who can use home dialysis. The tool is available free for download at <http://homedialysis.org/match-d>. The Alliance appreciates CMS's support of this tool in guidance.
- “My Life, My Dialysis Choice” is a decision tool for patients, which helps patients to conceptualize the medical treatment as a choice to be integrated within their existing lifestyle. This tool is available for free at <https://mydialysischoice.org/>.

The Alliance encourages CMS to support utilization of these two tools through public education efforts focused on both providers and patients.

The Alliance appreciates the opportunity to provide comments on the ESRD PPS and QIP rules and looks forward to working with CMS in the future to advance policies that support appropriate utilization of home dialysis. Please contact Michelle Seger at michelle@homedialysisalliance.org or 202-466-8700 if you have any questions.

Sincerely,



Stephanie Silverman
Executive Director



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