



September 10, 2018

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 1691-P Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendment to Correct Existing Regulations Related to the CBP for Certain DMEPOS

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) 2019 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.

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 2015 (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

¹ United States Renal Data System (USRDS), 2017 Annual Data Report: Epidemiology of Kidney Disease in the United States.

dialysis,”² and “make home dialysis economically feasible and available to the ESRD patient 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 2015 was 82% higher than at its nadir in 2007.⁵ The Alliance is encouraged by the growth in PD which has resulted from the bundled payment and wishes to see it continue. HHD 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 is still only a fraction of what kidney professionals have said is clinically appropriate. For Calendar Year 2019, the agency did not propose any policy changes explicitly intended to increase access to home dialysis. Nonetheless, the Alliance believes that there is work still to be done to assure that all patients, regardless of age, race/ethnicity or geographic location, 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) 2019 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

1. The Alliance commends CMS for recognizing the importance of education in addressing disparities in access to all modality options and urges the agency to consider ways to increase the uptake of Kidney Disease Education laid out in this section.

The Alliance was encouraged by CMS’s focus on reducing disparities in access to all dialysis modalities and is eager to support CMS’s efforts to do so.

To help illustrate this problem in greater detail, we would like to share some new data from the Moran Company on racial disparities in access to home dialysis. Across the country, Black dialysis patients are 29.1% less likely than average to be receiving PD and Hispanic patients are 8% less likely than average to be receiving PD. For home hemodialysis (HHD), Hispanic patients are likewise 8% less like than average to receive HHD and black patients are 18.7% less likely than average to receive HHD.⁷

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

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), 2017 Annual Data Report: Epidemiology of Kidney Disease in the United States, available at https://www.usrds.org/2017/download/v2_c01_IncPrev_17.pdf

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

⁷ *Distribution of Dialysis Patients Utilizing Home Modalities in 2015 by State*, the Moran Company.

One important strategy to reduce these disparities in modality access and uptake is through education, as CMS notes in the proposed rule. Research shows that patients who receive modality education before beginning dialysis are more likely to choose home therapy. According to the International Society for Peritoneal Dialysis, education is paramount: “Of the approximately 382,000 dialysis patients in the United States, very few dialyze at home and 75% of those starting in-center hemodialysis (HD) therapy report not being aware of the option to dialyze at home. If informed of such a choice, 40% select home dialysis...”⁸

The Alliance is making four recommendations to ensure that providers and practitioners are informing patients of their treatment options, and providing equal access to dialysis modalities.

A) The Alliance recommends that CMS focus State Surveyors on assuring that providers are adhering to the existing ESRD Conditions for Coverage requirement for a facility attestation in each in-center patient’s care plan as to why home is not an appropriate modality for that patient.

While facilities currently maintain some degree of documentation that indicates a patient was informed of treatment options, the full care team often does not have access to information to the facts and circumstances behind the patient’s decision making regarding treatment modality. The Alliance recommends that CMS focus State Surveyors on a review of the facility adherence to include additional information in the patient care plan on his or her decision to receive in-center dialysis, as such information will help identify potential barriers to home dialysis as the patient progresses and a plan of action to overcome those barriers. Such information will also help to facilitate substantive and comprehensive patient education over time as the patient’s clinical and psychosocial needs evolve.

B) The Alliance recommends that CMS expand the Kidney Disease Education benefit.

The Kidney Disease Education (KDE) benefit is an important tool for patients and providers. Medicare covers up to six sessions of kidney disease education services for patients with Stage IV chronic kidney disease. Doctors, physician assistants, nurse practitioners, and clinical nurse specialists can offer these services.

However, current uptake of the KDE benefit has been historically low and continues to fall. According to the United States Renal Data System (USRDS), in 2011 and 2012, less than 2% of eligible Medicare beneficiaries used the KDE benefit. And MedPAC concluded that in the same years, Medicare only paid for KDE for approximately 4,200 patients; in 2013 that number fell to 3,600.

The Government Accountability Office (GAO) recommended that “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 [KDE] benefit,”⁹ reflecting a deep understanding of the positive impact of KDE on modality choice.

The Alliance urges CMS to follow GAO’s recommendation and look for ways to increase uptake of the KDE benefit. Implementation of the following recommendations would increase uptake of KDE:

⁸ Thomas A Golper et al., *Systematic Barriers to the Effective Delivery of Home Dialysis in the United States: A Report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis*, 58 AM. J. KIDNEY DIS. 879–885 (2011), <https://www.ncbi.nlm.nih.gov/pubmed/21903316> (last visited Jun 11, 2018). Emphasis added.

⁹ <https://www.gao.gov/assets/680/673140.pdf>.

i. CMS should consider waiving the coinsurance requirement associated with KDE.

Currently, Medicare beneficiaries are responsible for the 20 percent coinsurance requirement associated with KDE as a Part B benefit. In general, Medicare pays 80 percent of the approved amount for a Part B covered service in excess of the annual deductible, and the beneficiary is liable for the remaining 20 percent.¹⁰ For some beneficiaries, the 20 percent coinsurance is prohibitive to accessing the services. The Alliance recommends that CMS waive the coinsurance requirement that would otherwise be applicable under section 1833(a)(1) of the Social Security Act with respect to KDE services for beneficiaries. Doing so would allow more beneficiaries to access KDE services.

ii. CMS should designate KDE as a preventive service.

As stated above, Alliance members, particularly our physician members, are concerned that the co-pay associated with KDE disincentivizes both providers and patients from taking advantage of these services. Providers are reluctant to bill patients for a service that was provided for free in the past, and patients may not have the financial means to pay the coinsurance fee.

However, CMS has the authority to add full coverage of preventive services in Medicare through the National Coverage Determination process if the new service meets certain required criteria.¹¹ The Alliance believes that KDE meets these criteria and encourages CMS to support inclusion of KDE as a preventive service.

C) The Alliance recommends that CMS encourage the utilization of certain patient tools to encourage ESRD patients to participate in shared modality 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, including modality choice, 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.

¹⁰ Section 1833(a)(1) of the Social Security Act.

¹¹ <https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html>.

D) The Alliance recommends that CMS support the development of process metrics to measure and track adherence to modality education requirements.

We believe there is a need for further measurement and accountability in the facility setting for meeting modality education requirements. We believe CMS should support the development of two process metrics with respect to modality education. The first metric would evaluate the proportion of patients who receive modality education within 90 days of starting dialysis. The second would evaluate the proportion of patients who receive modality education annually thereafter. These two metrics would encourage facilities to provide modality education to patients, and in the context of any changes that they may experience during their time on dialysis.

2. The Alliance recommends clarifying any outstanding issues caused by language in the 2017 ESRD PPS Rule relating to additional dialysis sessions by encouraging all Medicare Administrative Contractors (MACs) to follow CMS's Medicare Program Integrity Manual and the intent of Congress to assure that the maximum number of patients are utilizing home dialysis and transplantation.

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 or lack of 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. We believe that the draft LCDs proposed by every MAC are inconsistent with clinical evidence and the care of complex renal patients.

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

3. The Alliance recommends that CMS clarify that ESRD facilities can report remote patient monitoring costs as administrative costs on cost reports.

For CY 2019, CMS is proposing to use ESRD facility Medicare cost reports (form CMS-265-11) for CY 2016 to "rebase" the ESRD market basket and reflect the 2016 cost structure of ESRD facilities.¹² As part of these efforts, we recommend CMS also clarify that ESRD facilities can report remote patient monitoring (RPM) costs as administrative costs on their cost reports to reflect these costs in any future rate setting under the ESRD PPS. We believe this clarification is appropriate given recent payment policy changes relating to telehealth that may have created confusion regarding how to appropriately account for RPM

¹² 83 Fed. Reg. 34304, 34319 (July 19, 2018).

costs. CMS proposed a similar clarification in the CY 2019 Home Health Prospective Payment System Proposed Rule.¹³

Clarifying how to treat costs associated with RPM is important because of recent changes regarding Medicare payment for telehealth services. Section 4012 of the 21st Century Cures Act directed CMS to provide information on the current use of and/or barriers to telehealth services. Although “telehealth” is reimbursable by Medicare under certain conditions, RPM is not considered a Medicare telehealth service as defined under section 1834(m) of the Social Security Act because it does not involve an “interactive” telecommunications system that is capable of two-way, real-time interactive communication between the patient and distant site physician.¹⁴ Rather, RPM utilizes telecommunications technology to enable the patient to collect or transmit his or her own clinical data, such as weight, blood pressure, and heart rate for monitoring and analysis by a physician remotely, without the two-way interactivity required for telehealth as defined by section 1834(m).

RPM is increasingly becoming an important tool that providers use to augment the care that they provide to home dialysis patients. RPM leverages digital technology to collect vital dialysis and health related data from patients in their home (for example, from the dialysis device) and electronically transmit that data to the dialysis care team in a different location. Based on their review and interpretation of that data, the dialysis care team can more quickly adjust one or more of the dialysis parameters to better manage the patient’s renal condition. In some cases, adjustments can be made remotely.

Therefore, we believe it is important to clarify that ESRD facilities may report the costs of RPM on their cost reports as administrative costs.

II. Calendar Year (CY) 2019 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 11.6 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.”¹⁵ 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.

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

¹³ 83 Fed. Reg. 32340, 32425 (July 12, 2018) (“[W]e believe the expenses of remote patient monitoring, if used by the HHA to augment the care planning process, must be reported on the cost report as allowable administrative costs [] that are factored into the costs per visit.”).

¹⁴ See 42 CFR § 410.78.

¹⁵ 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.

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 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 urges CMS to develop an alternative QIP measure weighting scheme for facilities that treat predominantly or exclusively patients dialyzing at home.

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.¹⁶ However, The Alliance has become aware that small sample size remains a problem when measuring small facility or home-only performance.

In addition, home-only facilities are ineligible for the ICH-CAHPS, SIR, and NHSN dialysis event measures—and many are also ineligible for the Vascular Access Type measure due to small sample size (not meeting the 11 patient requirement). The Alliance is concerned that applying these limitations to the weighting schema presented in the proposed rule implies that 82% of the TPS for these facilities would be based on just 3 QIP measures: SHR and SRR (23% each), and STrR (36%). Heavy weighting of these 3 measures will clearly distort the Total Performance Score (TPS) for home-only facilities, leading to inaccurate patient perceptions about facility quality and performance.

Therefore, the Alliance urges CMS to establish an alternative QIP measure weighting scheme for facilities that predominantly or exclusively treat patients dialyzing at home. 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.

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The Alliance appreciates the opportunity to provide comments to the ESRD PPS and QIP proposed rule for CY 2019. We are eager to continue to serve as a resource for CMS as you work to increase access to

¹⁶ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/ESRDQIPFrequentlyAskedQuestions.pdf>

all dialysis modalities. Please do not hesitate to reach out to Alliance members or staff to discuss how we can work together. Please contact Michelle Seger at michelle@homedialysisalliance.org or 202-466-8700 if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Stephanie Silverman". The signature is written in black ink and includes a long horizontal flourish at the end.

Stephanie Silverman
Executive Director



Alliance for Home Dialysis Endorsing Members

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American Kidney Fund
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