



August 23, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1628-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CMS-1615-P—Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program

Dear Acting Administrator Slavitt:

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) 2017 and to the ESRD Quality Incentive Program (QIP) for payment year (PY) 2020.

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. Currently, 10.2 percent of incident dialysis patients and 11.5 percent of prevalent dialysis patients receive 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 population.”³ In the years since, data indicates that the ESRD PPS—which pays for home peritoneal

¹ United States Renal Data System (USRDS), 2015 Annual Data Report: Epidemiology of Kidney Disease in the United States.

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

³ *Id.* at 49,060.

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 According to the Medicare Payment Advisory Commission’s (MedPAC) 2015 Report to Congress on Medicare Payment Policy, “there is increased use (from 8 percent of beneficiaries to 10 percent) of home dialysis, which is associated with improved patient satisfaction and quality of life.”⁵ 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 2013 was 52% higher than a decade prior, and 71% higher than at its nadir in 2007.⁶ The Alliance is encouraged by the growth in PD as a result of the bundle 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.

Since our comments to the Proposed Rule for ESRD PPS in CY16, two important analyses have been published regarding barriers to home dialysis. In November 2015, the Government Accountability Office (GAO) released its report entitled “END-STAGE RENAL DISEASE: *Medicare Payment Refinements Could Promote Increased Use of Home Dialysis.*” In March 2016, the economist Alex Brill, former chief economist to the House Ways & Means Committee, published “Economic Benefits of Increased Home Dialysis Utilization and Innovation.” Brill and the GAO recognized many of the same barriers to home dialysis utilization, including Medicare payment policies that contribute to reduced access to and use of home dialysis. The Alliance appreciates that the Agency’s responsiveness to the GAO findings in elements of the proposed rule.

Overall, the Alliance believes that payment parity for PD in the ESRD bundled payment has had, and will continue to have, a demonstrable effect on the growth of home dialysis. The Alliance shares CMS’ commitment to ensuring the highest quality of care and access to life-sustaining dialysis treatments for all ESRD patients. The Alliance is pleased to offer the following specific comments related to this year’s Proposed Rule.

I. Calendar Year (CY) 2016 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

1. The Alliance commends CMS for its proposal to increase the training add-on payment adjustment.

The Alliance strongly supports CMS’ proposal to increase reimbursement for the training for home dialysis patients by increasing the training add-on from 1.5 to 2.66 hours of registered nurse (RN) labor as a move in the right direction. Providing training for patients and care partners is a critical element of facilitating and maintaining a home treatment regimen for the highest number of appropriate patients. As CMS works to improve their own data related to costs, this is an appropriate interim step.

While we appreciate that CMS does not intend to use the training add-on payment adjustment to reimburse a facility for all of its costs associated with home dialysis treatments, it is our understanding that CMS does intend to reimburse for the full cost of the incremental labor necessary to deliver home training treatments. Therefore, we request that CMS apply a “fully loaded” labor rate. As OMB Circular

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 Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, March 2016, Chapter 6, available at [http://www.medpac.gov/documents/reports/chapter-6-outpatient-dialysis-services-\(march-2015-report\).pdf?sfvrsn=0](http://www.medpac.gov/documents/reports/chapter-6-outpatient-dialysis-services-(march-2015-report).pdf?sfvrsn=0).

⁶ United States Renal Data System (USRDS), 2015 Annual Data Report: Epidemiology of Kidney Disease in the United States, available at https://www.usrds.org/2015/view/v2_01.aspx.

76-A states, in calculating direct labor, agencies should not only include salaries and wages, but also other “entitlements” such as fringe benefits.⁷ CMS uses the fringe benefits assumptions from OMB Circular 76-A in calculations in other sections of the proposed rule, but neglected to apply it in the calculation of the training adjustment. The factor defined in OMB 76-A for civilians is 36.25%, so we recommend that the reference wage rate be increased from the proposed \$35.93⁸/hour to \$48.95/hour (\$35.93 x 1.3625), and the resultant training add-on payment adjustment should be \$130.21.

While we support efforts to ensure the sufficiency of the home dialysis training adjustment, we do have concerns with CMS’ approach to making the adjustment budget neutral. The Alliance believes that CMS has the authority to increase the training add-on without applying budget neutrality. First, the statute does not mention having home dialysis training add-on in the ESRD PPS, and therefore attaches no requirement for a budget neutrality calculation.⁹ Second, as CMS has recognized in the past, the budget neutrality language set forth in 42 U.S.C. § 1395rr(b)(14)(A) applied only to the first year of the ESRD PPS.

Furthermore, while CMS currently implements payment adjustments, such as the case-mix adjusters and outlier payments, in a budget neutral way, the training add-on is categorically different. The purpose of case-mix adjusters is to adjust the base rate in order to account for those patients who require more care, while maintaining a constant level of overall resources being provided across the program. The result is a slightly higher rate for some facilities treating those more complex patients, which is then accounted for elsewhere in the program. In contrast, the training rate is an “add-on,” not an “adjuster.”¹⁰ The training add-on is not redistributing existing resources according to patient need. Rather, it is meant to reimburse facilities for additional costs that otherwise would not be necessary for the typical in-center patient. These costs are outside of the base rate and, as such, does not require budget neutrality.

We strongly support CMS’ multi-pronged effort to improve the data around cost of home dialysis training treatment. In our own analysis of resources necessary to deliver home training, we have found similar data variances, especially between those programs with a higher volume of home patients and those who were training only a few individuals. We believe that the analysis and audits proposed will result in greater understanding of common errors, and lead to agency clarification and guidance around the reporting elements that will greatly improve data quality.

Given the lack of data, we appreciate CMS’ transparency in describing the proxy methodology used to calculate the proposed increase. As independent reports have estimated that the total staff time spent training home patients for both PD and HHD exceeds 2.66 hours per session, we look forward to revised methodologies made possible by improved cost report data.

2. The Alliance supports CMS’ reaffirmation of its longstanding policy to pay for additional HD sessions with medical justification, but recommends addressing certain confusing and/or inaccurate language in the Proposed Rule relating to additional dialysis sessions.

⁷ www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_corrections

⁸ <https://www.gpo.gov/fdsys/pkg/FR-2016-06-30/pdf/2016-15188.pdf> Federal Register / Vol. 81, No. 126 / Thursday, June 30, 2016 / Proposed Rules 42815

⁹ See generally, 42 U.S.C. § 1395rr(b)(14).

¹⁰ Display Copy 51.

The Alliance appreciates CMS' acknowledgement of the growing use of more frequent hemodialysis treatments, and the reiteration of their longstanding policy for payment of medically justified treatments. CMS' policy supports clinical decision-making for management of acute and chronic conditions in ESRD patients. In the development of the ESRD PPS, the per-treatment unit of payment for HD was designed to enable individualization of care both in-center and at home. This payment structure, along with long-standing medical justification payment policies, has generally worked well and there is no evidence of overuse of additional treatments.

Recognizing the clinical benefits of more frequent treatment to manage the needs of their patients, physicians are prescribing more frequent dialysis to patients for whom it is clinically beneficial, supported by the long-standing CMS policy supporting payment for extra sessions where medically justified. Many Medicare Administrative Contractors (MACs) have applied this payment policy to include the medical justification derived from treating patients' chronic conditions, including cardiovascular issues, poor blood pressure control, poor phosphorus control, poor tolerability of the dialysis treatment, low sleep quality and depressive symptoms. Accordingly, more frequent dialysis has been shown to improve clinical outcomes in these instances, including reduced cardiovascular death and hospitalization^{11, 12} lower blood pressure¹³, reduced use of antihypertensive agents¹⁴, and reduced serum phosphorus¹⁵. Studies have also shown that patients have better mental health outcomes, including social function, which is vitally important for overall well-being¹⁶. The sum of the profound clinical benefits results in improved health-related quality of life, which correlates directly with morbidity and mortality.

With regard to CMS' proposed language relating to "Payment for Hemodialysis When More Than 3 Treatments are Furnished per Week," the Alliance strongly supports the autonomy of MACs in making medical justification decisions on a local level, either case by case or through a Local Coverage Determination. However, we are concerned that certain language in the proposed rule is inaccurate, and other language, intended only as example, may be interpreted as restrictive guidance by MACs. This could result in restricted access to vitally important treatments, and scale back the progress that has been made in the health of patients with ESRD.

The Alliance is particularly concerned with language in the Proposed Rule suggesting that additional sessions are prescribed for patient "preference," or due to limitations of "evolving technology." Physician and patient groups, some who are part of the Alliance, would not support the prescription of non-medically necessary dialysis sessions. Every dialysis session involves some risk¹⁷, and the benefit of any additional session must exceed the risk in the view of the prescribing physician in consultation with the patient. Needless to say, exposing patients to non-justified risk is not consistent with any aspect of current medical practice or standards of care.

¹¹ Weinhandl ED, Liu J, Gilbertson DT, Arneson TJ, Collins AJ: Survival in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. *J. Am. Soc. Nephrol JASN* 23: 895-904, 2012

¹² Weindhandl ED, Nieman KM, Gilbertston DT, Collins AJ: Hospitalization in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. *Am. J. Kidney Dis. Office. J, Natl Kidney Found.* 65: 98-108, 2015.

¹³ Kotanko P, Garg AX, Depner T, et al. Effects of frequent hemodialysis on blood pressure: Results from the randomized frequent hemodialysis network trials. *Hemodial Int. Int. Symp. Home Hemodial.* 19: 386-401, 2015.

¹⁴ Jaber BL, Collins AJ, Finkelstein FO, Glickman JD, Hull AR, Kraus MA, McCarthy J, Miller BW, Spry LA.; FREEDOM Study Group: Daily hemodialysis (DHD) reduces the need for anti-hypertensive medications [Abstract] *J Am Soc Nephrol* 20: SA-PO2461, 2009.

¹⁵ FHN Trial Group, et al: In-center hemodialysis six times per week versus three times per week. *N. Engl J Med*, 363: 2287-2300, 2010.

¹⁶ Finkelstein FO, Schiller B, Daoui R et al: At-home short daily hemodialysis improves the long-term health-related quality of life. *Kidney Int.* 82: 561-569, 2012.

¹⁷ The Agency acknowledges these risks when it states that while additional treatments could lead to "potential quality of life and physiological benefits there is also risk of a possible increase in vascular access procedures and the potential for hypotension during dialysis."

In addition, all currently available hemodialysis technology has been cleared to perform a broad range of therapies, including three times a week treatment. The clinical practice and benefits of more frequent hemodialysis have been described and published long before the availability of the current technology¹⁸, and is practiced routinely in other parts of the world, which does not have consistent access to the current technology available in the US. Practice has evolved to establish that baseline at three times per week, with the typical interval between treatments being one day (with one two-day interval between treatments per week). Evolving clinical literature has, however, shown that certain patient conditions (for example, fluid gains or phosphate levels) require a shorter interval between treatments to be more appropriately clinically addressed. It is this fact that defines medical necessity, not the degree of toxin clearance that can happen in one (or three) sessions.

Therefore, to avoid potential confusion and prevent the risk of misinformation, we recommend that the following statements be eliminated from the Proposed Rule:

- “When a beneficiary’s plan of care requires more than 3 weekly dialysis treatments, whether HD or daily PD, we apply payment edits to ensure that Medicare payment on the monthly claim is consistent with the 3-times weekly dialysis treatment payment limit.”
- “The option to furnish more than 3 HD treatments per week is the result of evolving technology. We believe that use of this treatment option provides a level of toxin clearance on a weekly basis similar to that achieved through 3-times weekly convention in-center HD. However, HD treatments exceeding three times per week are generally shorter and afford patients greater flexibility in managing their ESRD and other activities.”
- “Rather, the intent of this proposal is to provide a mechanism for payment for evolving technologies that provide for a different schedule of treatments that accommodate a patient’s preference and thereby improve that patient’s quality of life.”

We also note our concern with the references to congestive heart failure and pregnancy in the Proposed Rule. Although it is true that patients with these conditions have been shown to benefit from additional hemodialysis sessions, the Agency has been careful to stress in previous rulemakings that there is no “national policy for medical justification for additional dialysis treatments, and [that the Agency relies] upon either a MAC’s local coverage determination (LCD) policy or medical review by a physician working under the direction of the MAC’s medical director.”¹⁹ As CMS expressly reaffirms in the Proposed Rule, “[t]his proposal does not affect our policy to pay the full ESRD PPS base rate for medically justified treatments beyond 3 treatments per week,” we ask that the Agency reiterate again in final rulemaking that there is no national coverage decision for additional hemodialysis sessions. Further, we ask for clarification that the determination of medical justification for both acute and chronic prescriptions involving more than three sessions per week is left entirely to the discretion of the MACs. Finally, we ask that the agency reiterate its policies that a MAC, if it wishes to restrict coverage to any certain conditions or require any unique documentation, must execute a formal LCD process with public comment.

¹⁸ For example, in Suri et al. Daily Hemodialysis: a Systematic Review. CJASN, January 2006, Vol. 1, No. 1, pp 33-42, Suri et al reported that daily hemodialysis was an internationally (including in the United States) recognized dialytic prescription in both in-center and home settings long before the advent of currently leading home hemodialysis technology in the United States. The recognition of the value of additional treatment sessions, and the evolution of this prescription, was not the result of evolving technology. It was the result of evolving clinical evidence and practice.

¹⁹ 79 Fed. Reg. 66146.

3. CMS should rescind its proposal for more frequent hemodialysis, and take alternative steps to resolve treatment session reporting issues.

Although we understand and support the Agency’s desire to encourage centers to accurately report the number of treatments being furnished, we feel strongly that the Agency’s proposal for a new equivalency payment methodology should be rescinded.

The rule states that the proposal for creation of an equivalency payment construct is in response to inconsistencies in reporting all treatments delivered, and that ESRD facilities have expressed concern that the current payment policy results in an inability to report all dialysis treatments on their monthly claim. However, Alliance members currently use Medicare’s existing process for reporting all treatments through the UB-04 claim form, in keeping with CMS guidance. As recently as 2014, CMS instructed providers in the ESRD final rule to include all treatments on the claim form. Treatments without medical justification (either due to a lack of documentation, or to be compliant with a formal local coverage decision) would be reported, but indicated as not expecting payment through use of an appropriate line-item modifier (i.e., “GZ”). In order to improve the accuracy of reporting, the Alliance recommends reiteration of the instructions accompanying the UB-04 claim form, as well as increasing technical assistance around the importance of reporting all treatments on claims.

II. Comprehensive End-Stage Renal Disease Care Model and Future Payment Models

Since its inception in 2012, the Alliance for Home Dialysis has been focused on improving our understanding of the barriers to home dialysis and the strategies for increasing access. In a paper published earlier this year, noted economist Alex Brill confirmed that barriers to home dialysis exist on multiple levels, including those related to patients, providers, facilities, and reimbursement.²⁰ The Alliance appreciates the opportunity to offer input on innovative approaches to care delivery and financing for ESRD beneficiaries, and would like to offer our organization as a resource to CMS on these issues at any time.

In the proposed rule, CMS specifically asks, “Are there specific innovations that are most appropriate for evaluating patients for suitability for home dialysis and promoting its use in appropriate populations?” The Method to Assess Treatment Choices for Home Dialysis (MATCH-D) has been designed specifically for this purpose – 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>. We would also suggest examination of “My Life, My Dialysis Choice,” a decision tool for patients, which helps patients to conceptualize the medical treatment as a choice to be integrated within their existing lifestyle.

III. 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 11 percent of ESRD patients who dialyze at home be assessed and included as appropriate in the QIP. The inclusion of this

²⁰ Brill, A. “Economic Benefits of Increased Home Dialysis Utilization and Innovation.” March 2016. Available online, <http://static1.1.sqspcdn.com/static/f/460582/26886975/1456781059513/MGA+home+dialysis+paper+for+release.pdf?token=cfXmbqMBaTCw1q22XlaXoPbNICI%3D>

population in the QIP ensures 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, experiences of home patients are not currently considered in 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.”²¹ 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.

The Alliance appreciates that the current ICH-CAHPS may not be appropriate for assessing the care of home patients. Metrics designed for in-center conventional dialysis may not capture 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. Therefore, moving forward, the Alliance urges CMS to invest in the development and adoption of a patient experience instrument validated for assessing the home dialysis population. In developing this tool, the Alliance encourages collaboration with stakeholders, particularly home dialysis patients and facilities with large home programs, to ensure that the survey instrument is designed to capture the experience of home dialysis patients in all settings in a manner that is not overly burdensome for patients and providers. Also, in the development of these measures, CMS should recognize that PD and HHD are distinct from each other and from in-center dialysis. Thus, quality measures in the QIP should reflect the unique nature of each modality and should be developed based on data specific to that modality.

The Alliance appreciates the opportunity to provide comments on the ESRD PPS for CY 2017 and the ESRD QIP for PY 2020. We look forward to working with CMS in the future to advance policies that support appropriate utilization of home dialysis. Please contact Elizabeth Lee at elee@homedialysisalliance.org or 202-466-8700 if you have any questions.

Sincerely,



Stephanie Silverman
Executive Director

²¹ 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.



Submitting Members

**American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Baxter
Cleveland Clinic
DaVita
DEKA
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Greenfield Health Systems
Home Dialyzors United
Medical Education Institute
International Society for Peritoneal Dialysis - North American Chapter
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
NxStage Medical
Outset Medical, LLC
Renal Physicians Association
Satellite Healthcare
Southwest Kidney Institute
The Rogosin Institute
TNT Moborg International Ltd.**