

Ms. Charlene Frizella, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1418-P
P.O. Box 8010, Baltimore, MD 21244-8010

Re: CMS-1418-P; ESRD Bundled PPS Proposed Rule

The Home Hemodialysis Work Group, a coalition made up of patients, patient organizations, providers, physicians, and renal organizations appreciates the opportunity to provide these comments regarding CMS 1418-P (The Proposed Rule). Our coalition was founded based on a shared interest in maintaining patient access to home dialysis therapies

We applaud CMS's articulated support for home dialysis within the proposed rule and concur with CMS on the importance of protecting and expanding beneficiary access to home dialysis options. Although utilization of all home modalities trail what most believe is **ideally** appropriate based on patient outcomes, quality-of-life, and total cost of care measures, we believe that current home hemodialysis access is particularly restricted. Only 15% of dialysis clinics offer home hemodialysis training services and only 1% of patients currently are treated with the modality. Payment policy change through the expanded bundle can clearly remove current barriers to access, and help the Agency and the kidney care community to achieve its stated goals.

Certain elements of the proposed rule clearly support home dialysis modalities. Specifically, a single bundled payment that is independent of location will facilitate all home home therapies and will remove some of the historical disincentives related to separately billable injectibles. Moreover, we believe the per treatment unit of payment and the retention of the current policy allowing providers to bill for all medically justified treatments delivered are essential elements of a supportive bundle.

Implementation of the expanded bundle is clearly an enormous challenge, and unintended consequences are possible. It is critical that negative consequences are minimized for the patients' sake. We urge CMS to ensure that a) all operational and economic issues are considered and b) implementation of such changes that are essential to achieving the stated goals of MIPPA. We also support "early warning" metrics to help guide early intervention to prevent negative outcomes from anticipated care delivery changes once the implementation of the bundled PPS begins. Home dialysis is beginning to expand and offers tremendous promise to improve clinical outcomes. Still, with only 15% of facilities offering this therapy option to beneficiaries, monitoring for unanticipated reductions in access to this therapy due to regulatory changes must be a priority.

Our coalition has three specific comments on the proposed bundle to improve its ability to achieve the Agency's stated goals. First, CMS should recognize that home training is not a routine service and create a unique payment to compensate for the significant incremental costs of this prerequisite service to allow patients to go home. Second, CMS should delay applying the QIP penalty for adequacy in home dialysis until a robust adequacy measure that is consistent with the broad range of therapy frequency and/or durations that are offered in the home is validated. Finally, since many home patients use their nephrologist as their primary care physician, we urge CMS to review the policy on inclusion of labs and limit the labs to a discrete list of ESRD-related labs only.

Home Patient Training Payment

Home dialysis training is a resource-intensive, readily identifiable episode of clinical care performed prior to initiation of home dialysis and repeated as needed as the beneficiaries' medical needs evolve. It is not a general or administrative service, as the proposed rule implies.

Effective home therapy training is a prerequisite to sending patients home safely on dialysis. The clinical intensity of the training is recognized in the recently updated ESRD Conditions for Coverage which require that home hemodialysis training be overseen by a registered nurse. The training consists of a number of discrete education requirements including the nature and management of ESRD; the full range of techniques associated with home hemodialysis (e.g., the effective use of dialysis supplies and equipment and delivering the physician's prescription of urea clearance and effective administration of erythropoiesis-stimulating agents, if prescribed, to achieve and maintain a target level of hemoglobin or hematocrit); how to detect, report, and manage potential dialysis complications, including water treatment problems, availability of support resources and how to access and use resources; how to self-monitor health status and record and report health status information; how to handle medical and non-medical emergencies; infection control precautions; and proper waste storage and disposal procedures (42 C.F.R. §494.100.)

Based on the Conditions for Coverage, and to meet the needs of the patients, home hemodialysis training is most often administered on a 1 nurse to 1 patient ratio. The training is typically delivered over 18 sessions of 5 hours each (over 3 to 4 weeks) in addition to a home qualification visit, representing nearly 100 hours of direct nursing time per trained patient. Per current regulations, up to 25 initial training sessions are allowed and retraining is permitted when medically justified. Through the course of training, patients are transformed from medical novices to experts in their own care. Dialysis is a complex medical procedure. CMS has recognized that this service is not only clinically complex, but also is costly for providers. In the 2008 CMS Report to Congress on the ESRD Bundle PPS, Secretary Leavitt noted that payments for home dialysis training have not been updated since 1983 and demonstrably do not reflect actual training costs.

In addressing the provider costs for training, the proposed rule postulates that training costs are one of the contributors to the increased costs of treating patients in their first 120 days on dialysis. On analysis, however, only 15% of patients training for home hemodialysis are within their first 120 days on dialysis, and less than half of peritoneal dialysis patient are trained within the first 120 days. Therefore, the proposed adjustor for new dialysis patients would not apply to the vast majority of patients undergoing dialysis training. Conversely, patient preferences should drive the timing of initiation of home dialysis training rather than reimbursement policy. To truly address the costs of this material, non-routine clinical service, that can occur at any point in a patient's dialysis journey, a unique payment adjustor should be paid on a per training session basis.

Analysis of CMS 2006 Cost Reports for ESRD facilities reporting any home hemodialysis treatments or training volume (representing 216 centers) demonstrated per training session costs of approximately \$394 (not including separately billable pharmaceuticals and labs), representing an approximate \$240 cost premium to ongoing therapy per session (Source: Estimation of Costs for Home Hemodialysis by the Moran Company, June 2008). Yet, the proposed rule incorporates training into the routine bundle for all facilities, regardless of whether they provide home therapies. Eliminating the specific payment mechanism for training services will discourage the discrete and

necessary investment to provide this essential first step to home dialysis access, and will instead reward clinics that choose not to offer home dialysis training.

Training clearly occurs in identifiable periods of time, and is associated with a noticeable higher cost structure than ongoing care. Moreover, this activity is easily traced even within current reporting procedures. Separate payment should be created for the training episode based on best available cost information, whether from existing cost report information (similar to the Moran Company study mentioned) or a pilot study. Whether this payment is implemented as a single payment for episode of training services or as an adjustor to the bundled payment during the training period(s) should be based on administrative efficiency.

Quality Improvement Measures

MIPPA requires that CMS include Quality Improvement elements in the ESRD PPS. The proposed rule specifically stipulates that an adequacy quality measure will be created. It is essential that CMS re-evaluate historical adequacy measures to ensure that they are consistent with the variations in clinical practice that have evolved. Adequacy for more frequent dialysis is not appropriately captured in the current URR%, as required on the claims forms and included in Dialysis Facility Compare. As is now the practice in excluding PD data from the current Dialysis Facility Compare tracking, and until such a time as a measure can be validated for the reporting of adequacy in home or more frequent dialysis patients, it is appropriate to exclude patients with any home treatments reported on the claims from the penalty phase of the QIP.

As CMS moves to expand the elements in the QIP over time, it is critical that CMS evaluate any measure considered against current and evolving practice patterns. Not all elements considered will be applicable to all modalities or all patients. MIPPA references development of a patient satisfaction measure. This is an important component of the patient's experience of care and should be considered. The Home Hemodialysis Work Group would like to be a resource to CMS as you move to expand elements that may impact home therapy.

ESRD Laboratory Tests

MIPPA requires that lab tests "used in the treatment of ESRD" be in the bundle. The Proposed Rule exceeds the MIPPA mandate by including all labs for a dialysis patient, ordered by any nephrologist, in the bundle. Home patients often see their nephrologist for primary care needs. Without further definition of labs to be included, the proposed rule may cause confusion and tension between the nephrologist and the dialysis facilities. Further, due to the potential for increased lab costs for non-ESRD related labs now ordered by the nephrologist, in the role of primary care physician, we are concerned, that this proposal will interfere with established patient:physician:facility relationships. To address these concerns, CMS should revisit the lab component of the PPS, and include only a discrete list of ESRD-related labs in the bundle.

Conclusion

Patients should have access to the treatment modality that best fits their changing medical conditions, at any point in their dialysis journey. Offering a unique payment for training treatments, through an adjustor or other methods, would protect patient access to home hemodialysis. The adjustor construct would be consistent with the methodology CMS used for other identifiable, non-

routine episodes of care. A training adjustor would not render any additional administrative burden on clinics or CMS contractors, as the training is already clearly reported on the claim forms.

Access to quality care is the expectation of all current and future Medicare beneficiaries. We support CMS's intent to monitor and improve the care provided to ESRD patients and encourage CMS to validate the outcome measures used to assure that they reflect a complete and accurate view of the care provided. Further, to help achieve the goal of fostering a greater use of home therapies, we support the development of measures that encourage home therapy.

For home dialysis patients, the nephrologist often serves as the primary care physician. Inclusion of all labs ordered by the MCP physician in the PPS bundle exceeds the mandate in MIPPA and may interfere with the continuity of the physician to patient relationship. A better approach would be to develop a discrete list of ESRD-specific labs for inclusion in the PPS.

Thank you for your consideration of our input to the Proposed Rule. Please let us know if you need additional information as you work to finalize the ESRD PPS.

Sincerely,

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