National Kidney Foundation™

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National Kidney Foundation Summary of the 2016 ESRD PPS and 2017-2019 QIP Final Rule.

On Thursday, October 29, the Centers for Medicare & Medicaid Services (CMS) released the final Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program rule. The rule affects payment to dialysis facilities for 2016 and the quality metrics that are tied to payment in 2017-2019.

The National Kidney Foundation (NKF) commented on the proposed rule in August 2015 and focused on issues that may impact patient's access and quality of care. Below is a summary of the final rule and how CMS responded to NKF's concerns.

CMS finalized a base rate payment to dialysis facilities of $230.39. This is a decrease of about 3.9% from 2015. This payment rate is adjusted up or down based on a patient's condition and medical needs and the type of dialysis facility providing treatment. Despite this decrease, CMS predicts that payments to dialysis facilities will be 0.3% higher in 2016 than 2015.

This is because CMS will increase payments to facilities that care for patients who require more costly services. By paying more, CMS's intent is to help protect patients from being discharged from the facility, or prevented from receiving dialysis. This will ensure patients receive the additional care they need.

However, after reviewing independent data analyses and speaking with professionals who work in dialysis facilities, NKF expressed concern over some of these patient characteristic payment adjustments.

Age

Unfortunately, CMS will not adjust payment for patients in the age group 70-79. While age does not always reflect higher costs, many clinicians believe it is an appropriate substitute for factors that do tend to afflict older patients such as malnutrition, falls, and blood stream infections . CMS states their analysis of this group reflected lower costs on average. At the same time, CMS recognized limitations in its ability to analyze data because it has to rely mostly on what the providers submit as claims to Medicare. While facilities do submit cost reports to CMS to show additional expenses not covered by CMS, not all of these costs are captured in these reports. While we don't anticipate that this policy will lead to discrimination against the 70-79 age group, we note that it's likely payment is not aligning with a population that dialysis facility staff feel may be more costly to care for.

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Body Surface Area (BSA) and Body Mass Index (BMI)

CMS retained its policy to use both BSA and BMI to calculate a patient level adjustment, despite independent analyses that showed the interaction between the two adjustments was voiding any increase in payment for patients who have a low BMI and may be malnourished. NKF had recommended that CMS just use BMI as an adjuster for increasing payments for patients who are overweight and underweight as defined by the National Institutes of Health. CMS denied this request for now saying it was too big of a policy change and would have to consider it for future rulemaking to allow for public comment. Given this keeps current policy as it has been, we don't anticipate there will be discrimination against overweight or underweight patients, but we note that the payment is likely not aligning with higher costing underweight, malnourished patients who may need more medications, personal attention and support during their dialysis treatment.

Low-volume payment adjustment (LVPA) and rural adjuster

CMS finalized its proposal to establish a rural adjuster of .08% for facilities in rural locations (defined as an area outside of a Metropolitan Statistical Area or a Metropolitan division). CMS also finalized a proposal that would reduce the number of miles a facility had to be from the next nearest facility from 25 driving miles to 5 miles. All facilities, including those previously grandfathered out of this rule, will now have to meet this requirement to receive the LVPA. NKF issued comments stating that rather than establish a rural adjuster, the LVPA should be tiered and used to increase payments where facilities are of critical access to the community. CMS stated they would analyze other approaches in future years to better target payment to facilities that, if closed, would leave patients with very limited options to receive dialysis. NKF remains concerned that facilities in isolated areas serving predominately Medicare and Medicaid beneficiaries would be the first to be targeted for closure even with a rural payment adjuster. In addition, the LVPA modifications still encourage the establishment of low-volume dialysis facilities within close proximity to one another – while this provides patients with more options for where they can receive dialysis, it also may result in patients having to pay a higher copayment to dialyze at facilities that receive a higher Medicare reimbursement rate for remaining a low volume facility.

Home dialysis training

While payment for home dialysis training was not addressed in the proposed rule, a number of commenters requested additional payment for training and raised concerns that payment was undervalued for the time. NKF did not request more dollars for training, but did ask for greater evaluation of costs of training to ensure they are adequately paid. A

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number of other commenters stated various session durations and training times of anywhere from 2-6 weeks. CMS expressed concern with the large variation in training and indicated it will conduct further analysis of the training adjuster. CMS did note that since implementation of the ESRD PPS (the bundle) that use of home dialysis has increased.

Payment for New Medications

CMS finalized its proposal to not pay separately for new injectable medications that fit into existing drug categories paid under the bundle. CMS did modify its existing categories, reflected in the chart below. If a new intravenous or injectable drug is brought to market that does not fit into one of these categories, CMS will pay for it separately for two years at its average sales price (ASP) plus 6%. NKF remains concerned that this process will discourage innovation of new drugs in these categories that improve outcomes for patients, or a subset of patients, over the current medications.

TABLE 8B: ESRD PPS FUNCTIONAL CATEGORIES

Category	Rationale for Association
DRUGS ALWAYS CONSIDERED USED FOR THE TREATMENT OF ESRD	
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetrics
Cellular Management	Drugs used for deficiencies if naturally occurring substances needed for cellular management. This category includes levocarnitine.
DRUGS THAT MAY BE USED FOR THE TREATMENT OF ESRD	
Antiemetic	Used to prevent or treat nausea and vomiting *related to* dialysis. Excludes antiemetics *used for purposes unrelated to dialysis, such as those*

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	used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat *vascular access-related and peritonitis* infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple actions. *Use within an ESRD functional category* includes treatment for itching *related to* dialysis.
Anxiolytic	Drugs in this classification have multiple actions. *Use within an ESRD functional category* include treatment of restless leg syndrome *related to* dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/fluids used to treat fluid and electrolyte needs
Pain Management	Drugs used to treat *vascular access* site pain and to treat pain medication overdose, *when the overdose is related to medication provided to treat vascular access site pain.*

Quality Incentive Program (QIP)

NKF largely supported the continued use of quality measures used for the payment year 2018 in payment year 2019. However, NKF requested that hypercalcemia be used only as a reporting measure and not a clinical measure because performance is so high it's unlikely the measure is encouraging any improvements in care. Initially NKF had a concern that that once dialysis facilities were required to pay for phosphorus binders for patients through the bundled payment those facilities may steer patients to lower-costing options that tend to be higher in calcium. A hypercalcemia measure may discourage that practice. However, oral medications like phosphorus binders will not be included in the bundle payment until 2025. Therefore, NKF does not feel this measure is serving any quality improvement purpose currently.

In addition, CMS finalized its proposal to remove the four separate dialysis adequacy measures and replace it with a pooled measure of dialysis adequacy that measures facilities

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for hemodialysis patients that dialyze 3-4 times per week, PD patients and pediatric patients. NKF opposed this change out of concern that a pooled measure masks how well the facility is performing on achieving dialysis adequacy goals for smaller populations, like pediatrics. However, CMS decided that it was more beneficial to have an adequacy measure that also includes pediatrics given that they were excluded from the current adequacy measures.

CMS did not finalize two measures it proposed, ultrafiltration rate >13 ml/kg and a patient seasonal influenza vaccination measure. In both cases, CMS was proposing measures where an alternative measure existed. The National Quality Forum (NQF) has endorsed a seasonal influenza vaccination measure developed by the Kidney Care Quality Alliance (KCQA) and is likely to endorse the KCQA developed ultrafiltration measure. Some commenters encouraged CMS to adopt these versions of the measures, but CMS declined to do so.

The final 2019 measures areas are:

- Dialysis adequacy
- Vascular Access Type
    - Fistula
    - Catheter for at least 90 days
- Hypercalcemia
- Standardized Transfusion Ratio
- Standardized Hospital Readmissions Ratio
- Bloodstream Infections in Hemodialysis Outpatients
- Patient experience based on responses to the In-Center Hemodialysis (ICH) Consumer Assessment of Healthcare Providers and Systems (CAHPS)
- Mineral Metabolism Reporting
- Anemia Management Reporting
- Screening for Depression and Follow Up Reporting
- Pain Assessment and Follow-Up Reporting
- Healthcare Personnel Influenza Vaccination Reporting

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Future measurement development

Many commenters suggested ideas for new measures for future years, including patient reported measures and measures for home dialysis patients. Some of the patient reported measures suggested included: whether patients have a "voice" during dialysis, patient informed consent of anemia treatment including patient quality of life data; measures on cramping and "washed out" feeling, and healthy days at home. CMS did not indicate if they would consider these measures for the future. However, CMS did site concern on lack of clinical evidence to support more home dialysis measures.

For questions regarding the ESRD PPS and QIP final rule please email tonya.saffer@kidney.org.