New proposed rule from the Centers for Medicare & Medicaid Services (CMS) lays out changes to how it reimburses dialysis care, as well as how it will assess the quality of dialysis care. Released on Friday, June 26, and open for comment from stakeholders through Tuesday, August 25, the proposal includes several anticipated adjustments to the bundled payment and modest tweaks to the Quality Incentive Program (QIP).

Highlights of the proposed rule related to the Prospective Payment System (PPS) bundle included a reduction to the base rate, overhaul to the low-volume and case-mix adjustments to the base rate, and clarification on how new products might be added to the bundle. Many of the changes to the payment system were anticipated, as Congress had mandated that CMS reassess several PPS elements.

Proposals to Adjust Medicare’s Payment System: (see box) is analyzing the proposed rule and will provide comments to CMS on behalf of the society.

Prospective Payment System proposed changes

CMS proposed changing the base bundled payment rate from $239.43 to $230.20 (a reduction of $9.23 per treatment), yet total payments to all dialysis facilities are projected to increase 0.3%. While the rule calls for a modest cut to monthly bundled payment rates, changes to low-volume, case-mix, and other adjustors may offset that reduction. Overall, CMS projects that the adjustments to the Medicare ESRD Program will be budget neutral.

Originally, CMS had established six patient conditions for which it would adjust the bundled payment. In this rule, the agency proposes to reduce that to just four conditions (with larger payment multipliers). The rule also proposes to provide low-volume payment adjustors only to facilities at least 5 miles from the next closest facility; formerly, that threshold was 25 miles. A Government Accountability Office (GAO) report showed that many of the facilities to which CMS was providing a low-volume payment boost were near each other and prompted Congress to call on CMS to re-examine this policy. While the new low-volume payment adjustor would apply to fewer facilities, those facilities would see a larger additional payment. The rule also proposes establishing a novel payment adjustment that would give facilities in very rural areas an increase in payment.

Since the inception of the bundled payment system, CMS has withheld paying out 1% of total claims, reserving the withheld dollars for new technologies to the fixed-payment bundle. Notably absent from the rule was any discussion regarding home dialysis. Numerous stakeholders in the community have called for increases to the home dialysis training rate as well as changes related to payment for more frequent dialysis care. In August 2014, Medicare contractors issued notice that they would not pay for dialysis more than three times per week except in cases of emergency—presenting a clear barrier to those on nocturnal and other home dialysis modalities. Despite the controversy, CMS declined to adjust the definition of a category or add a new category. As CMS makes this determination, the agency would pay for the new drug at a rate of average sale price (ASP) plus 6% for at least 2 years.

CMS Releases Proposed Changes to Bundled Payment and Quality Measures

By Rachel Meyer and Mark Lukaszewski

Many in the kidney community are apprehensive of the lack of clarity regarding future payments has created a disincentive for industry to innovate in the ESRD space. In this rule, CMS included guidance on this topic. CMS also proposed that oral drugs with no IV equivalents that are not currently in the bundle would be added to the bundle if IV equivalents become available. If new injectable drugs fit into the 12 existing product categories, they would be included in the bundle and considered already reimbursed under the system. CMS proposes to pay an add-on payment for novel pharmaceutical products (or other types of technologies that could affect dialysis) as they assess how these products are adopted. If a totally new type of drug is created or does not fit into any category it would not be included in the bundle. CMS mandated the determine whether it needs to adjust the definition of a category or add a new category. As CMS makes this determination, the agency would pay for the new drug at a rate of average sale price (ASP) plus 6% for at least 2 years.

Proposed Replacement of the Four Measures Currently in the Dialysis Adequacy Clinical Measure

CMS is proposing to replace four measures in the Kt/V Dialysis Adequacy measure topic—(1) Hemodialysis Adequacy: Minimum delivered hemodialysis dose; (2) Peritoneal Dialysis Adequacy: Delivered dose above minimum; (3) Pediatric Hemodialysis Adequacy: Minimum spKt/V; and (4) Pediatric Peritoneal Dialysis Adequacy—with a single, comprehensive clinical measure (the Dialysis Adequacy clinical measure) covering the patient populations previously captured by these four individual measures. The measure will be determined based on the total number of qualifying patients treated at a facility. Thus, any facility with at least 11 total qualifying patients will report to assess the quality of care.

CMS proposes to weight the single Dialysis Adequacy clinical measure at 18 percent of a facility’s Clinical Measure Score Domain, which is the same percentage for the current Dialysis Adequacy measure topic. The agency proposes no other changes to the weighting for the remaining clinical measures and measure topics.

Proposed New Reporting Measures Beginning with the Payment Year 2019 ESRD QIP: Ultrafiltration

CMS proposes to add an ultrafiltration rate reporting measure. However, the National Quality Forum has not yet endorsed an ultrafiltration measure and no consensus organization on ultrafiltration rates currently exists. That said, CMS proposes adopting a measure that “is based on” the “Ultrafiltration Rate Greater than 13 mL/kg/h.” Facilities would be required to report an ultrafiltration rate for each qualifying patient at least once per month.

CMS proposes adopting a full season influenza vaccination measure as a reporting measure. Facilities would be scored on whether they successfully report the data, not on measure results.

Future Achievement Threshold Policy under Consideration

CMS stated that increasing the achievement threshold from the 15th percentile to the 25th percentile of national performance during the baseline period would improve patient care, maintaining that the increased achievement threshold would add additional incentives for facilities to improve performance and quality of care. During the proposed rule-making process, ASN will continue to emphasize that CMS work in a transparent and collaborative way with the kidney community. The society will continue to urge CMS to focus on meaningful measures from a patient perspective rather than diluting the QIP and distracting dialysis providers with numerous measures of less substantial importance. CMS will likely release the final rule in early November at which time ASN will provide a detailed analysis of the final decisions and their implications for patients and the nephrology community.