Policy Update

Medicare Announces Changes to ESRD Program for 2013 and Beyond

By Rachel Shaffer

The Centers for Medicare and Medicaid Services (CMS) announced final plans for modifications to the End-Stage Renal Disease (ESRD) Program. The payment-related revisions set forth in its rulemaking will affect the ESRD Prospective Payment System (PPS) beginning in 2013, and quality-related changes will affect the ESRD Quality Incentive Program (QIP) in 2014, 2015, and beyond.

ASN was among the 55 commenters that submitted input to CMS regarding its preliminary proposals for changes to the ESRD PPS and QIP during the summer of 2012. The majority of ASN's feedback focused on how CMS's proposed alterations related to the QIP might affect patient access to the highest quality dialysis care—and many, though not all, of the society's recommendations were reflected in CMS's November final rule. "We appreciate that CMS responded to several of our key concerns in this rulemaking cycle," stated ASN Public Policy Board Chair Thomas H. Hostetter, MD, "and we look forward to continuing to work with the agency in the coming months and years to shape a QIP program constituting not only measures that ensure a minimum standard of care, but measures that catalyze improvement in meaningful patient outcomes."

Mineral Metabolism Reporting Requirements for Payment Year 2014

One of the key ASN recommendations that CMS adopted in the final rule was that facilities should exclude patients who received fewer than seven dialysis sessions in a month from QIP data reporting for the mineral metabolism measure that month. CMS originally proposed that data from patients receiving just two sessions should be included in QIP data reporting, but ultimately concurred with ASN—and other commenters—that treating a patient twice may not provide enough time to ensure (or assess) high-quality patient outcomes. Similarly, CMS responded to concerns that requiring facilities to obtain and report data for patients who received dialysis treatments in other environments may be overly burdensome and not accurately reflect patient care provided in the facility. In the final rule, CMS stated that it recognizes "it may be difficult for facilities to coordinate with hospitals and other care providers in order to obtain lab values" and would not require reporting for those patients.

Home Dialysis

ASN urged CMS to ensure, to the extent possible, that all QIP measures include patients who dialyze via peritoneal dialysis or home hemodialysis (HHD). The society specifically recommended expanding the existing National Health Safety Network infection reporting measure to PD and HHD patients. While CMS did not implement the recommendation, it stated that it "will take these suggestions into consideration during future measure development and rulemaking." Notably, CMS did integrate a peritoneal dialysis measure into the composite dialysis adequacy measure for the QIP in 2015. ASN will continue to advocate for equitable, evidence-based QIP measures that apply to patients who dialyze at home.

Additions and Changes to QIP Measures for 2015

CMS finalized that, parallel to previous years, it will use all of calendar year (CY) 2013 as the performance period for payment year (PY) 2015. In 2015, CMS will continue to use five of the six QIP measures from PY 2014, but made changes to two measures and added four new ones:

- Clinical Measure for Dialysis Adequacy, a composite of three measures:
  - o Hemodialysis Adequacy Minimum Delivered Dose (NQF # 0249)
  - o Peritoneal Dialysis Adequacy Delivered Dose Above Minimum (NQF #0318)
  - o Minimim spKt/V for Pediatric Hemodialysis Patients (NQF #1423)
- Anemia Management Reporting Measure

In 2011, the U.S. Food and Drug Administration changed the erythropoiesis stimulating agent (ESA) label, removing the recommended hemoglobin level of 10–12 g/dL, stating it could not identify a minimum safe target. CMS followed suit by eliminating a QIP measure ensuring a minimum hemoglobin level of 10 g/dL. Since then, many in the nephrology community have been concerned about potential for compromised patient access to ESA therapy or increased transfusions to treat anemia.

CMS acknowledged these concerns in its November ruling. While it recognized that there has been a slight but noticeable increase in transfusion rates since FDA and PPS modifications, the agency noted that any possible associations between the changes "are not yet known." CMS explained that it is "working through our ESRD QIP monitoring and evaluation program to further assess the effects of the ESRD PPS." Moreover, CMS finalized its proposal to implement an Anemia Management Reporting Measure, requiring facilities to report ESA dosage (if applicable) and hemoglobin/hematocrit values on at least one monthly claim. Similar to the mineral metabolism reporting measure for 2014, and in alignment with recommendations from ASN and others, CMS determined that it would exclude any patient who is treated by a facility fewer than seven times in the reporting month.

Addressing ASN's most significant concern, CMS did not finalize a proposed clinical hypercalcemia measure. Citing, and agreeing, with commenters that the performance standards, benchmarks, and achievement thresholds were not calculated using data from all facilities—and could therefore contain a systemic bias—CMS determined not to require reporting for the measure. ASN's concerns stemmed from the fact that insufficient evidence exists to support the proposed serum calcium and serum phosphorus targets. CMS stated that it "intend[s] to use this measure in subsequent payment years." However, ASN will continue to strongly urge CMS not to implement this or other measures incentivizing providers to achieve performance targets that have not been scientifically validated.

In addition to the four new measures, CMS finalized its proposals to modify the National Health Safety Network Dialysis Event Reporting Measure (implementing more frequent reporting) and finalized the PY 2014 exclusions for the Mineral Metabolism measure for 2015 and beyond.

Future QIP Years

Looking ahead to future years of an expanded QIP, CMS requested comment on potential Standardized Hospitalization Ration (SHR) for Admissions, a Risk-Adjusted Standardized Mortality Ratio (SMR), and a 30-day Hospital Readmission measure. In the final rule, CMS stated that most commenters—including ASN—"strongly opposed" the SHR and SMR measures, given that it is "a measure over which facilities have little control" and due to concerns that SMR could promote cherry-picking patients. While CMS did not finalize any of these measures as part of the QIP at this time, it will be reporting SHR and SMR via the Dialysis Facility Compare Website.

In the coming months, ASN will be working with CMS and the greater kidney community to ensure that subsequent additions to the QIP are appropriate and evidence-based, and critically important, to ensure that the impending addition of oral-only drugs to the PPS bundle is fair and maintains patient access. Read more about ASN's comments to CMS about the ESRD program online at www.asn-online.org/policy, and stay tuned to *Kidney News* in 2013.

Innovators Place Unveiled at Kidney Week 2012

Among the new features introduced at Kidney Week 2012 in San Diego was Innovators Place: a dedicated space to exhibit medical technologies not yet approved by the U.S. Food and Drug Administration (FDA). Inaugural exhibitors were selected by an ASN committee based on a set of criteria including the technology's relevance to curing kidney disease and the exhibit's educational value for Kidney Week attendees.

The exhibitors—mostly U.S. and European start-up companies, as well as nonprofit academic labs—presented innovations ranging from a benchtop instrument for early detection of severe acute kidney injury (AKI) to a compression device to reduce postdialysis clotting time. For most participants, Innovators Place provided an opportunity to secure potential partners and investors.

One exception was Semprus Biosciences, which was acquired 5 months before Kidney Week 2012 by Teleflex, Inc., and whose vascular access catheter received 501(k) clearance from the FDA 2 weeks after the meeting. Designed to reduce thrombus accumulation inside and outside the device, the catheter was exhibited at Innovators Place to generate awareness of the new technology, according to a Semprus Biosciences representative. Based on biomaterial discoveries by Robert Langer, ScD, of the Massachusetts Institute of Technology, the catheter received European market clearance in July 2012.

Other exhibitors presented innovations that are in the early stages of development. Joris Rotmans, MD, PhD, from the Leiden University Medical Center (LUMC) in the Netherlands