ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Renal Week Edition

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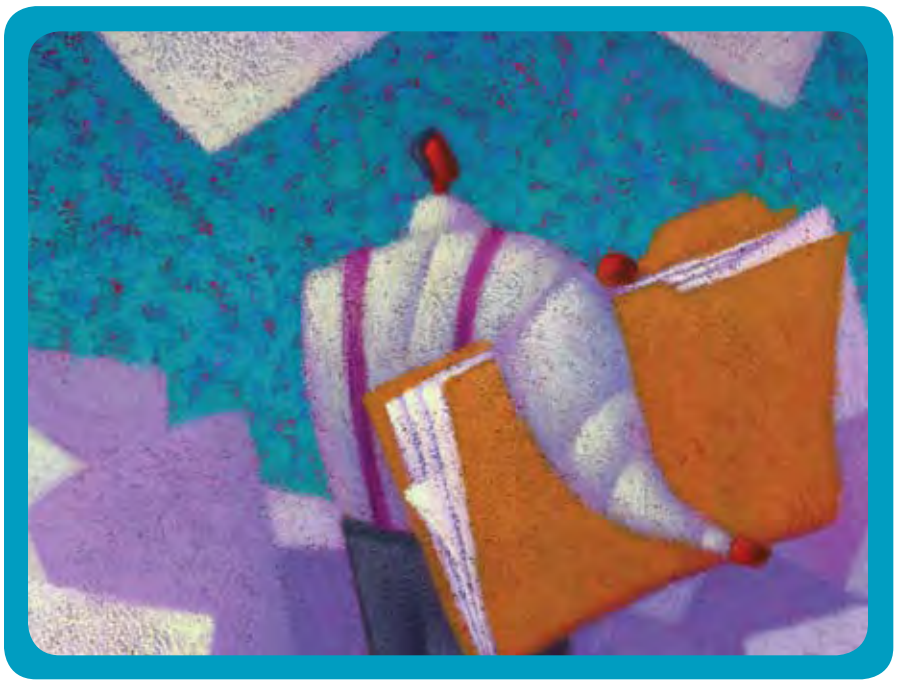
Pay for Performance on the Way: ASN Aims to Improve the Inevitable



By Rachel Shaffer

The Medicare End-Stage Renal Disease (ESRD) program will implement the first-ever pay-for-performance system in the entire Medicare system on January 1, 2012. Before the Affordable Care Act is fully implemented, the nephrology community will play a leading role in piloting this model for health reform.

Prior to rolling out this groundbreaking payment system—entitled the Quality Incentive Program (or QIP)—the Centers for Medicare and Medicaid Services (CMS) issued a QIP Proposed Rule in July and solicited public comment. Released alongside the agency's final rule on ESRD bundled payments, the QIP Proposed Rule outlined CMS's conceptual model for the program.

Under the QIP, CMS will tie facilities' payments to care quality standards. Facilities that fail to achieve specified performance scores for quality of dialysis care will see payment reductions of up to two percent. The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 mandated CMS to institute both bundled payments and a pay-for-performance program for ESRD care. While MIPPA outlined the key aspects of the pay-for-performance program, it left many details to be finalized by CMS.

Given the unprecedented nature of the QIP, ASN formed a QIP Task Force to analyze the proposed rule and, with the support of the ASN Public Policy Board and President Sharon Anderson, MD, FASN, submitted a detailed comment letter on behalf of the society. Foremost among the concerns articulated in ASN's letter was the preservation of equitable patient access to optimal quality dialysis care and all related services.

ASN responds

ASN's comment letter to CMS emphasized the society's strong support for CMS's goal of monitoring the quality of care provided to patients with ESRD. In the context of a novel bundled payment environment, evaluation of quality and unencumbered access to dialysis services and prescribed medications will be of utmost importance. However, given the scientific evidence currently available, the society has reservations about some aspects of the proposed regulations, the letter noted. As the first pay-for-performance program in Medicare, the QIP is fundamentally an experiment—an experiment in a realm of medicine for which nephrologists are still developing evidence-based guidelines for patient management. As such, ASN offered the following overarching suggestions regarding the QIP:

1. Because of limited evidence supporting the QIP measures, the three finalized measures should be subject to replacement by new measures when scientifically validated performance

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targets are developed.
2. The QIP should be redesigned to account for facility-level differences in case-mix.
3. In the interim, careful monitoring in as close to real-time as possible will be crucial to the success of the QIP by minimizing adverse unintended consequences, including compromises in access to care.

Limitations of quality measures

As mandated by MIPPA, CMS will adjust dialysis facilities' payments based on their performance, with the first payment reductions beginning January 1, 2012—with a reduction of up to 2 percent for facilities that do not meet or exceed the standards. To determine payment reductions, CMS proposed calculating a performance score for each facility, based on three quality measures. CMS finalized the three quality measures that facilities will be measured against during the first year of the QIP in the ESRD Final Rule:

- Hemodialysis sdequacy: percentage of Medicare patients with an average urea reduction ratio (URR) of 65 percent or more
- Anemia management: controlled anemia, as shown in two measures:
  - The Medicare percentage of patients at a facility whose hemoglobin levels were <10 g/dL
  - The percentage of Medicare patients at a facility whose hemoglobin levels were >12 g/dL

Facilities already report these three measures to CMS as part of the dialysis facility compare. CMS further proposes to weight the total performance score for each facility such that the percentage of Medicare patients with hemoglobin less than 10 g/dL makes up 50 percent of the score, and the other hemoglobin measure and the hemodialysis adequacy measure each comprise 25 percent of the score. Facilities whose scores do not meet or exceed performance standard would see payment reductions ranging from 0.5 percent to 2 percent of total payments (Figure 1).

Although these three quality measures have been finalized, ASN took the opportunity to call attention to the limitations of the scientific evidence upon which the measures are based. In general, ASN conveyed concerns that incentivizing providers to achieve performance targets that have not been scientifically validated could potentially lead to unintended consequences for patients. For instance, had the current QIP been in place several years ago, with the hemoglobin targets promulgated in clinical practice guidelines at that time (pre-CREATE, CHOIR, and TREAT), performance-based payment may have prompted excess deaths instead of improving patient care.

While acknowledging that CMS is mandated by MIPPA to implement a QIP—and therefore must select quality measures based on currently available information—ASN emphasized that it is important for CMS to recognize the scarcity of scientifically validated performance targets and create opportunities to change and replace these QIP measures in the future as new, more robust evidence becomes available. Nonetheless, the society noted that these three measures—particularly the proposed weighted 10 g/dL hemoglobin measure—seem reasonable at this time, until they can be revised with better scientific evidence.

Case-mix adjustors: a vital addition to the QIP

ASN also conveyed that the quality measures selected may penalize facilities with a large percentage of patients in whom it can be difficult to achieve the specified outcomes. In certain areas of the country, particularly in regions with socioeconomically or medically disadvantaged patients, it is difficult to achieve the most desirable intermediate quality metrics despite the best efforts of nephrologists.

Defining quality based on intermediate quality metrics does not take into account variation between compliance level and vascular access across patient populations, nor does it necessarily reflect the efforts of nephrologists and other providers to provide high-quality care. So ASN strongly encouraged CMS to implement case-mix adjustments when calculating performance scores. Case-mix adjustment is vital to preserving equal access to nephrology care for all patients, regardless of geographic location or socioeconomic status—which must be a foremost goal for the agency under the QIP, ASN said. Besides instituting case-mix adjustors, CMS should also establish mechanisms to monitor patient access patterns before the January 1, 2012, QIP start date.

ASN also noted that quality data from facilities with few patients may be skewed owing to the small sample size, negatively (or positively) affecting their overall performance score. The letter stated that CMS should consider removal of statistical outliers more than a certain number of standard deviations from the mean in all facilities (small or large) in either direction, in order to achieve a better sense of overall performance—and moderate the focus on a single absolute threshold score.

Performance standards

CMS proposes two potential performance standards—the baselines against which facilities will be judged—during the first year of the QIP. CMS would compare facilities' data during the performance period to the lesser of the two following standards:

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1. the facilities' own performance on each measure during 2007, or
2. the national performance rates of all dialysis providers (calculated from 2008 data)

CMS proposes judging facilities against the most lenient of the standards according to facility-specific data. A facility that performed worse than the national average in 2008 would be held to a lower performance standard (its own performance on each measure during 2007) than a facility whose performance in 2007 was better than or equal to the national average in 2008 (which would be held to the 2008 national average). The 2008 national performance rates (percentage of Medicare patients who had the following average values) for each measure are shown here:

- hemodialysis adequacy: 96 percent
- hemoglobin <10 g/dL: 2 percent
- hemoglobin >12 g/dL: 26 percent

Given the variability of patient characteristics across regions and facilities, ASN commented that it is most reasonable to compare facilities to their own patient population, rather than a national average. Supporting CMS's proposal to hold facilities accountable to standards specific to their patient populations, the society noted that the goal of the QIP should not be to rank dialysis units based on performance standards, but rather to bring every unit up to its highest level of function.

ASN also expressed concern regarding CMS's proposal that floors for the performance standards will never be lower than those set for the previous year (i.e., never lower than the performance rates shown earlier), and urged CMS to establish a formal way to evaluate the appropriateness of these metrics—leaving open the option to change the floors in light of new evidence.

Performance period

With payment reductions set to begin January 1, 2012, CMS said the performance period—the period from which CMS will examine providers' data to establish payment reductions—must occur before then to allow time to collect, review, and calculate the performance scores that will determine the extent of each facility's reductions. CMS proposes establishing the performance period as the entire calendar year of 2010, reasoning that it needs a full year (all of 2011) to calculate applicable payment reductions—which will go into effect on January 1, 2012. Under this proposal, providers would see payment reductions in 2012 (the payment consequence year) for care provided during 2010 (the performance period). See Figure 2 for a timeline.

ASN expressed concern that many facilities may not be aware that the care they provide today will be evaluated—and potentially subject to payment reductions—two years from now. Were CMS to finalize the proposed performance standards, facilities would be penalized for patient results that were largely (or wholly) recorded prior to the finalization of the QIP. ASN is concerned that CMS would set a precedent of creating ex post facto regulations and strongly urged the agency to reconsider this proposal. ASN proposed that CMS instead make the first half of 2011 the performance period—assuming the agency publishes the final rule in 2010—and conduct data processing during the final six months of 2011.

Public reporting

Each facility must post information regarding performance under the QIP, as mandated by MIPPA. The information must also be made available to the public through a CMS-maintained website. In the proposed rule, CMS suggests that each facility would share data that shows how well the facility's total performance score, and scores on each of the three measures, compares to the national total performance score average.

ASN conveyed its appreciation for CMS's commitment to transparency and openness in the provision of dialysis care. But the society also noted that executing public reporting programs in a way that is both accurate and meaningful from a patient perspective is challenging. CMS notes that it will provide "appropriate comparisons of providers and facilities to the national average with respect to such scores." ASN suggested that developing methods of meaningful comparison for patients is an activity that would best be conducted collaboratively between the agency and the nephrology community.

ASN encouraged the agency to work with the renal community to obtain a better understanding of stakeholder needs and adjust the public reporting system accordingly, including case-mix adjustors.

Future measures

CMS notes that it will be developing measures that "reflect performance goals widely recognized by the ESRD medical community as demonstrating high quality care." While recognizing that CMS is bound by MIPPA to develop more measures, ASN noted that in the absence of hard study outcomes (rather than observational or patient-reported outcomes) it is difficult to identify quality metrics certain to reflect, and improve, the quality of care.

ASN suggested that CMS consider supporting efforts to generate necessary evidence in this arena. The Children's Oncology Group (COG) offers one such potential model of improving care over time. In the COG, every child with cancer is entered into a protocol and, through studying which patients do better over time, survival rates have improved. While translation of this model to the ESRD environment is neither direct nor problem-free, the approach may warrant consideration as a cost-effective method to generate evidence, ASN said.

Next Steps

CMS staff will review public comments submitted to the agency and will likely release a final rule on the QIP before the close of 2010. Many of the concerns ASN conveyed in December 2009 to CMS regarding its ESRD Bundling Proposed Rule were addressed in the final ESRD bundling rule released this summer, and ASN looks forward to a similar outcome for the QIP program. ASN will continue working with the agency as it shapes the final rule and addresses how this new pay-for-performance system will be updated in future years.

Please visit ASN's policy webpage for ASN's complete comments on the QIP Proposed Rule as well as more information about the new bundled payment system and pay-for-performance proposals.

Figure 1

Summary of proposed scoring methodology

1. Measure Performance Scores

- Performance scores will range from 0 to 30 points, based on three measures:
  - o Hgb <10 g/dL
  - o Hgb >12 g/dL
  - o URR >65%
- 10 total possible points are awarded per measure
- 2 points subtracted for every 1.0% below the performance standard

2. Total Weighted Performance Score

- Measured performance scores are weighted, then summed to create a total performance score:
  - o Hgb <10 g/dL: 50% (of total score)
  - o Hgb >12 g/dL: 25%
  - o URR >65%: 25%

Points Awarded (per measure)	Proposed Model
10	Performance Standard
8	-1%
6	-2%
4	-3%
2	-4%
0	-5%

For more detailed information on CMS's proposed scoring, please visit ASN's public policy website.

Figure 2

Timeline of proposed performance period and payment reductions