The 2011 ESRD Prospective Payment System: Perspectives From a For-Profit Small- to Medium-Sized Dialysis Organization

Sometimes we stare so long at a door that is closing that we see too late the one that is open.
—Alexander Graham Bell

Nearly a year of eager anticipation and trepidation was culminated in summer 2010 by the release of the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule, closely followed by the proposed Quality Incentive Program (QIP) measure. As a small dialysis organization, on the whole, we are pleased with several provisions that differ from the initial proposed rule that was released in 2009. Notable changes seen in the final rule include: (1) re-evaluation of the proposed case-mix adjusters with reference to clarity, relevance, and relationship to costs resulted in a streamlined and less complex system; (2) concerns about the ability to provide nondialysis services in the dialysis facility, such as non–ESRD-related blood draws and use of antibiotics for infections not related to vascular access, were addressed by allowing these services to remain separately billed; and (3) oral-only medications were not included in 2011, though the Centers for Medicare & Medicaid Services (CMS) has left open the possibility of including ESRD-related oral-only medications in the bundle as soon as 2014. This editorial explores in greater detail the implications of the new expanded bundle on the ability of a smaller dialysis provider, consisting of 10 dialysis units in New York, to operate in a new bundled payment environment.

CASE-MIX ADJUSTMENT

As a small- to mid-sized dialysis organization, we believed that prior proposals for case-mix adjustment of the bundled payment were too complex. We feared loss of revenue due to undercoding comorbid conditions. The CMS incorporated many of the comments submitted in reference to the proposed final rule last year, opting to decrease the number of case-mix adjusters from 18 to 11. Newly excluded case-mix adjusters were sex, alcohol and drug dependence, cardiac arrest, human immunodeficiency virus (HIV)/AIDS, hepatitis B, sepsis, and cancer, reflecting the low predictive value of these adjusters for costs, potential for adverse incentives, violation of patient privacy, potential for coding abuse, vague definition, and problems with case-mix modeling. Further simplifications include the provision for only 1 case-mix adjuster to be applied per patient-month. If a patient has more than 1 case-mix-adjustable condition, only the adjuster with the highest index will be applied and paid. Not only do these changes reduce administrative complexity for providers, but they allow the base rate for all patients to be substantially higher than the proposed base rate ($229.63 vs proposed $198.64), decreasing financial risk to providers. Concern for undercoding remains, especially for hospital discharge diagnoses and diagnoses of myelodysplastic syndrome and monoclonal gammopathy.

NON-ESRD LABORATORY TESTS AND ORAL-ONLY MEDICATIONS

Potential inclusion of non-ESRD laboratory tests and medications in the bundled payment was another area of concern. Inability to perform courtesy blood draws for our patients represented a formidable challenge for both patients and providers. The final rule specifies a panel of 53 tests to be included in the bundled rate. Tests beyond this panel will continue to be separately billed with modifying codes. Facilities and laboratory service providers are responding with novel arrangements, including “bundled laboratory payments” within our ESRD bundled payments.

Inclusion of oral-only medications, specifically phosphorus-binding agents and cinacalcet, was proposed, but was greatly underfunded in the initial proposal. Significant administrative challenges relating to the inclusion of oral medications also were unaddressed, including mechanisms by which dialysis facilities could either make arrangements with pharmacies or become pharmacies themselves to dispense medications for home use. Accordingly, inclusion of these medications in the expanded bundle has been delayed until 2014, with the CMS intending to use the next 3 years to study proper pricing for oral-only medications. Our own priority in preparing for 2014 is to use the electronic medical record to have better knowledge of what oral-only medications are prescribed for our own patients, as well as to monitor patients’ adherence with therapy.
THE DECISION: MOST OPT IN

After the final rule was released, facilities had several weeks to decide whether to enter 2011 under fully bundled payments versus transitioning progressively from the prior system over 3 years. Our organization’s decision process began with the preparation and review of facility-by-facility models comparing our present Medicare reimbursement with minimum expected revenue under the PPS using a “naked bundle” analysis that considers only age group, body surface area, body mass index, and 120-day adjuster variables. From this financial analysis, it appeared that some of our 10 facilities, especially those using more separately billable medications, would have fared better under “phase in.” However, all our facilities have decided to opt in fully bundled. We recalled Joyce Jackson’s remark at the annual meeting of the National Renal Administrators Association (NRAA) in Huntington Beach, CA: “you can’t be half pregnant.” In other words, goals and incentives regarding separately billable medication differ in the old and the bundled systems, and it makes sense to move forward with a bundled mindset now.

What can we learn from the observation that, like us, most facilities have decided to opt in fully bundled? We believe that facilities and physicians have been paying attention to the rumblings from Washington and are gearing up to make their practices and facilities more efficient. The bundled payment system will go hand-in-hand with the QIP, which proposes to place a facility-level payment penalty on hemoglobin levels outside the target range of 10-12 g/dL. Many facilities have already seen their annual erythropoiesis-stimulating agent (ESA) use decrease since 2007, facilitating their opt-in decision. Further savings may be possible with increased use of intravenous iron, although optimal dose strategies, targets, and long-term safety are not established. Subcutaneous ESA may be considered, although the efficacy and cost-effectiveness of the subcutaneous route is unproved. It is becoming increasingly clear that escalating doses of ESA in the face of ESA hyporesponsiveness is associated with adverse outcomes, but how best to deal with the phenomenon of ESA hyporesponsiveness is unclear, with guidance from clinical trials sorely needed.

Use of blood transfusions may have a role in the management of anemia in ESRD in ESA-hyporesponsive patients, but again, appropriate use needs to be defined. In sum, the expanded bundled payment system and QIP offer disincentive to the use of ESA without proven clinical response, but regimens for dose reduction, monitoring, and follow-up with regard to ESA response currently are not well formulated or studied.

QUO VADIS?

The realities of for-profit enterprise and the expectation of progressive growth will leave providers searching for the next area of cost savings. When ESA dosing has been optimized, to which areas can facilities turn next?

Bone disease management is an obvious target, with intravenous vitamin D representing the second costliest category of separately billable expenditure in the ESRD program. Optimal management of ESRD-related bone-mineral disorders is an area of uncertainty. With the prospect of bundling of oral-only medications in 2014, there is additional pressure to determine the best regimens for therapy. During the 3-year period preceding bundling of oral-only medications, we can anticipate decreased use of medications included in the bundle (ie, intravenous or oral active vitamin D) and possibly increased use of medications that fulfill similar goals and are not included in the bundle (ie, cinacalcet and phosphorus-binding agents). Treatment protocols that incorporate use of vitamin D, calcimimetic agents, and parathyroidectomy need to be studied with reference to appropriate end points, including such surrogate end points as calcium, phosphorus, and parathyroid hormone levels, as well as harder outcomes, such as bone pathologic state, fracture risk, cardiovascular outcomes, and mortality.

Care coordination will be critical in the bundled environment, with efficient hospital discharge planning and communication across care settings becoming even more important. Vascular access monitoring and coordination with outpatient vascular access centers likely will be an important element in providing seamless care with minimal missed treatments.

The bundled payment system incentivizes home therapies because equal payment will be given for home modalities, although the cost of providing home therapy may be substantially lower than in-center hemodialysis. Further incentive is provided by a training add-on adjustment of $33.88 (adjusted by area wages). Whether the add-on adjustment and bundled payment structure will serve to increase the use of home therapy remains to be seen.

AREAS OF CONCERN

Areas of concern remain. The hefty 3.1% “transition adjuster” was made on the assumption that 43% of facilities would opt to go fully bundled in 2011. With >90% of facilities opting in to the bundled payment system, we believe that the adjuster should be recalculated; in our estimate, this would amount
to an additional $6.75 per treatment. Although there is bipartisan support for adjustment of the base rate, as of this writing, we are awaiting final input from Congress regarding whether a legislative or a regulatory change is needed. Two other unresolved issues compromise the ability of small- and mid-sized dialysis organizations to survive in the bundled environment: CROWNWeb and the status of the Medicare Administrative Contractors (MAC). The 2008 Conditions for Coverage mandate entry of patient-level data for several clinical performance measures into a web-enabled network (CROWNWeb). Currently, the CMS has allowed only 3 large dialysis organizations (LDOs) to electronically batch submit their data. However, if non-LDO providers must submit data manually, even for a limited period, this represents a substantial burden that threatens the ability of smaller dialysis organizations to adapt to the new payment system. The CMS recently agreed to allow the NRAA to develop a production pilot that will allow all other interested providers, regardless of type of electronic medical record, to submit data electronically using health information exchange. Small providers without electronic medical records will still have to enter patient data manually. The 15 regional MACs, also known as fiscal intermediaries, are contracted to accept and process claims for Medicare services. Our MAC, as well as several others, appears unprepared to accept and adjudicate claims submitted in February 2011 under the new system. At the time this editorial was written, it is only days before the expected submission of the first new claims, and the absolute silence maintained by our MAC in this matter is bothersome. As of this writing, we have not been able to test run our claims and there is a real possibility that many facilities may face cash flow problems if the system does not work properly.

Now that the PPS has been finalized, we see some pitfalls, but many more opportunities to improve the care we deliver to our patients. It has been a benefit to the renal community that the ESRD PPS was enacted as part of the Medicare Improvements for Patients and Providers Act in 2008, before the Health Care Reform Act of 2010. During the past 2 years, the dialysis industry has had the opportunity to work with the CMS in shaping the final bundle. Although we are optimistic about the impact of the PPS on the overall care provided to dialysis patients, we are less sanguine about the prospects of smaller entities in the dialysis business. We note that there has been some recent consolidation in the dialysis industry, with mid-size providers merging in anticipation of the PPS. Although LDOs and larger mid-size providers are positioned well, smaller chains, single independent centers, and hospital-based facilities may find it difficult or impossible to make the short-term “stretches” that seem to be required—adapting to CROWNWeb and other reporting burdens, dealing with possible cash-flow problems—or to establish the economies of scale needed for long-term survival. Dialysis has always been at the forefront of prospective payment models for Medicare, and we can expect that the impact of the expanded PPS on our practices and outcomes, as well as on trends in the national dialysis market and industry, will be of continued widespread interest in view of the current legislative environment and health care reform.

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**ACKNOWLEDGEMENTS**

We thank Diane Wish, Edward Dowling, and William Cundiff for their comments.

**Financial Disclosure:** Dr J.G. Bhat is owner and principal of Atlantic Dialysis Management Services LLC and is on the Speakers Bureau for Amgen and Genzyme. Dr P. Bhat is Medical Director of Home Programs at Ridgewood Dialysis Center, an affiliate of Atlantic Dialysis Management Services LLC.

**REFERENCES**