ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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May 25, 2012

The Honorable David Camp, Chairman
U.S. House of Representatives
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Re: April 27, 2012 Request to Ronald J. Falk, President, American Society of Nephrology

Dear Chairman Camp and Members of the Committee on Ways and Means:

On behalf of the American Society of Nephrology, thank you for the opportunity to provide comments regarding value-based measures and practice arrangements that can improve health outcomes and efficiency in the Medicare program, including identifying a fiscally responsible, long-term solution to the Sustainable Growth Rate (SGR). ASN represents nearly 14,000 physicians, scientists and healthcare providers dedicated to providing the best care to kidney patients and developing future cures for kidney diseases. ASN and the professionals it represents are strongly committed to maintaining the integrity of the physician-patient relationship, and to providing equitable patient access to optimal quality, efficient care regardless of socioeconomic status, geographic location, or demographic characteristics.

The society recognizes and appreciates the Committee's interest in learning about physicians' experience with and opinions on bundled payments, shared savings models, and other value-based purchasing arrangements that may advance patient outcomes and promote greater efficiency, as a part of its larger effort to develop a solution to the SGR. As nephrology care professionals, ASN members' practices are disproportionately represented by patients covered by Medicare—primarily through the Medicare End-Stage Renal Disease (ESRD) Program—than other healthcare providers. Accordingly, ASN's members are dedicated to ensuring that any changes to the payment system first and foremost protect the highly vulnerable kidney disease patient population, as any unintended consequences would have a disproportionately large effect on these patients.

Mandated by the Medicare Improvements for Patients and Providers Act of 2008, the Medicare ESRD Program implemented a bundled payment system for dialysis care (the Prospective Payment System, or PPS) in 2011 and implemented the first-ever mandatory value-based purchasing program (the Quality Incentive Program, or QIP) in 2012. This letter will focus on nephrology's early experiences and 'lessons learned' about the pros and cons of bundled payments and value-based purchasing as they affect clinical practice and patient access. That said, ASN remains open to considering other types of alternative payment models to the SGR formula; this letter is not intended to suggest that the society's scope is necessarily limited to options discussed here.

Executive Summary

ASN sincerely appreciates the Committee's interest in seeking input from the physician community and other stakeholders regarding potential solutions to resolve the SGR situation. This letter provides in-depth detail regarding ASN's recommendations and recent experiences with novel payment systems, but in summary, the society suggests that Congress:

- Consider nephrology's early experience with a bundled payment system and mandatory pay-for-performance program, evaluating the benefits of these models and identifying pitfalls that could result in unintended consequences to avoid in the design of future alternative payment systems.

- Prioritize preserving patient choice and flexibility for physicians to individualize care.

- Assess and empirically test the effects of multiple new payment models—for physician reimbursement as well as other types of payments—prior to implementing them in the wider Medicare environment.

- Prevent bundling physician reimbursement with bundled payments provided to publicly held, for-profit entities.

- Continue to interact and pursue partnerships with ASN and other members of the medical community to conceptualize fiscally responsible alternative payment models to the current SGR system.

Early Experiences in the Medicare ESRD Program

It is important to clarify that neither hospitalizations, dialysis vascular access procedures for dialysis patients, or physician payments are included in the bundled payment system. Nonetheless, the society believes that some of the lessons learned in the ESRD Program are highly translatable to other alternative payment models and are important for the Committee to consider. The nephrology community's experience suggests that bundled payments and value-based purchasing models are potentially viable alternatives to fee-for-service that can reduce costs while maintaining quality. Establishing such systems requires a cautious approach with constant attention to preventing potential unintended consequences for patients. It should be noted that physician payment for the dialysis care of ESRD patients is, and long has been, a capitated per-patient payment paid on a monthly basis rather than the fee for service model. Those capitated payments to physicians are entirely separate from the bundle that provides reimbursement to dialysis facilities.

Notably, no pilot programs or demonstration projects were conducted prior to implementation of the PPS or the QIP. Consequently, the nephrology community had—and continues to have—scant up-front understanding of the potential implications, positive or negative, of these novel approaches to payment and quality measurement on patient outcomes and access to health care services. ASN strongly recommends that any future alternative payment models be tested and evaluated in a controlled capacity prior to full-scale implementation. If possible, they should be evaluated in a prospective environment and otherwise evaluated and assessed in as close to real-time as possible. The resulting information would be invaluable in helping healthcare providers of all types better prepare to prevent and address unintended consequences and would likely contribute to providers' willingness to participate in the model.

A bundled payment system that prospectively sets a fixed reimbursement amount for a certain service or range of services (such as dialysis) promotes judicious use of healthcare resources. It simultaneously creates an environment in which lower utilization will generate a greater financial margin for providers (such as dialysis providers). Under such a system, it is necessary to also develop incentives to reward provision of high quality care and mitigate the risk that bundling services results in withholding care in order to maximize the providers' financial gain.

In the ESRD Program, the QIP was designed to provide that incentive. However, the QIP, like any other approach that establishes standards appropriate for *most* patients, runs the risk of hampering individualized patient care. Balancing the benefits of quality thresholds with the risk of overly generalizing care practices may be particularly challenging in a population with limited life expectancy or multiple comorbidities, where conservative goals may be more appropriate for some patients. It is crucial to construct value-based purchasing systems with sufficient latitude to preserve physicians' and patients' choice and their flexibility to appropriately customize care.

It is also important to note that the QIP is a "stick" program rather than a "carrot" program in that the program implements payment reductions for failure to meet standards but no payment increases for achieving higher-than-average patient outcomes. Rather than enforce only a baseline minimum of quality for all patients via a payment reduction, also rewarding providers who meaningfully elevate the quality of care with a bonus could spur investment and innovation in care delivery and practice patterns and may be worth considering.

Another important consideration the nephrology community has identified within the bundled payments and value-based purchasing programs is the potential for new patient access barriers, via "cherry-picking" of patients who minimize provider financial risk (or avoiding patients who may elevate risk). This was an acknowledged practice under prior payment systems and in a shared-risk environment becomes an even greater concern. While CMS developed an algorithm to adjust the bundled payment based on a handful of risk factors, it remains unclear whether this solution will adequately preserve equitable access to care. Identifying strategies to minimize cherry-picking should be a key consideration in development of payment models that are alternatives to the fee-for-service system. ASN is especially concerned about the effects of policy changes on African-American patients, who disproportionately suffer with ESRD in the Unites States, as the treatment of certain ESRD-related conditions (e.g., anemia, secondary hyperparathyroidism) may be more expensive, in general, in this particularly vulnerable group.

Perhaps the most important lesson learned thus far is the vital necessity of a system to monitor patient access to care and care utilization changes in as close to real-time as possible, in any novel payment environment. Robust patient data collection and analysis capability should be established prior to implementing changes in reimbursement that have the potential to alter practice patterns or affect patient outcomes. Access to this type of data is still lacking in the ESRD program and, consequently, it is still too early to make conclusive statements regarding the effect of bundled payments and the QIP on patient care, cost, and access.

Despite the potential challenges discussed above, there are also a number of potential pros to bundled payments and value-based purchasing aside from their effectiveness at containing costs that may serve as positive examples in other areas of medical practice. For instance, these alternative payment models may promote better streamlining and coordinating processes of care as providers strive to meet quality measures while minimizing costs. Dialysis providers have placed an increased emphasis on patient education prior to kidney failure in order to make

the transition to kidney replacement therapy more efficient for the healthcare system and less burdensome to patients. Studies show that increased use of evidence-based protocol driven care—a trend that has been on the rise under the PPS—can reduce errors and increase utilization of effective medications.

One concrete example of positive change that reduces cost while maintaining, or even improving, the quality of care may be increased use of dialysis at home rather than in-center hemodialysis. In the past, provider revenue for peritoneal dialysis was lower than for hemodialysis, because peritoneal dialysis patients use drugs that were reimbursed on a fee-for-service basis at lower rates. Now that providers receive one bundled payment for those previously separately billable drugs, financial incentives are realigned to make home dialysis more profitable and, thus, should increase its utilization. Data suggest that patients on home dialysis enjoy a higher quality of life with comparable outcomes to patients who dialyze in-center.

Consolidation and Physician Payments

ASN recognizes the need for physicians and professional societies to help responsibly address this cost crisis by developing fee structures that promote collaboration, higher quality, and more efficient use of limited resources. ASN suggests that bundled payments—if implemented cautiously, thoughtfully, and with adequate monitoring systems in place—could be an overall effective alternative payment model to the current fee-for-service systems. Depending on its design, a bundled payment system could even potentially incorporate physician payments in the future. However, ASN has serious concerns about the structure of a bundled payment system that includes physician payments in the current nephrology practice environment.

Reduced provider diversity in any area of medicine may affect flexibility of delivery, innovation in care, and choice for patients, particularly in areas where there is little provider diversity. In recent years, there has been unprecedented consolidation among dialysis providers in the United States: two entities now provide care for more than 70% of patients on dialysis. Especially given the increased financial pressures under the bundled payment system, the society would have significant reservations about physician payment being incorporated into the bundle that dialysis providers receive for dialysis care. This arrangement has the potential to limit physicians' flexibility to make independent treatment decisions with patients.

For-profit entities should not control physician payments, which may potentially give them undue leverage to advocate for clinical decisions that could result in sub-optimal care and outcomes for patients. Because they are not paid directly by dialysis organizations, nephrologists should have the flexibility provide pushback to any clinical decisions large dialysis organizations put forth that may disadvantage patient outcomes.

If bundling of physician payments moves forward in any area of medicine—including nephrology—it is imperative that regulations be put in place to ensure that if multiple parties are receiving reimbursement from the same bundled payment that payment is divided equitably as intended by CMS. The society would be somewhat more comfortable if physician reimbursement were bundled with payments to a non-profit institution, such as an academic center or multispecialty clinic. That said, in that model it would be unclear how nephrologists in private practice who are not affiliated with an entity of this kind would receive reimbursement. While ASN does not possess a fully-developed alternative recommendation, the society is open working with Congress and policymakers to devise strategies for bundled and other approaches to physician payments.

ASN also suggests that—unlike the PPS and QIP programs—new payment models be empirically tested prior to being implemented. The society would favor testing an array of alternative payment strategies simultaneously in a manner that allow rigorous evaluation of their effects on clinical practice, patient access, and the diversity of the provider market. With this evidence base, Congress, CMS, and the medical community could jointly identify a menu of the most cost-effective, appropriate payment mechanisms to put in place moving forward. A nephrology-specific integrated care delivery model is among the alternatives that could potentially be considered for testing. ASN has already developed a set of principles related to the design of such a possible integrated care delivery model, which is available at http://www.asn-online.org/policy_and_public_affairs/docs/ASNPrinciplesforIntegratedNephrologyCareDeliveryModels.pdf. ASN stands ready to work with Congress and CMS to help design, implement, and test novel payment demonstration projects.

Conclusion

Thank you again for your time and consideration. The society's members are committed to providing the best possible care for patients with kidney disease and believe that a permanent, sound payment system is a necessity to ensure that every patient has access to the care they need. ASN welcomes the opportunity to continue to collaborate with the Committee and Congress to help address the current SGR situation. The society believes that many challenges remain in developing a permanent solution, but offers several recommendations for your consideration in this letter and stands ready to discuss any of these suggestions and observations at your convenience. To discuss ASN's comments please contact ASN Manager of Policy and Government Affairs Rachel N. Shaffer at rshaffer@asn-online.org or at (202) 640-4659.

Sincerely,

Ronald J. Falk, MD, FASN
President

CC: Thomas H. Hostetter, MD, Chair, Public Policy Board
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