

ASN End-Stage Renal Disease Task Force: Perspective on Prospective Payments for Renal Dialysis Facilities

John R. Sedor,^{*†‡} Suzanne Watnick,[§]
Uptal D. Patel,^{¶**} Alfred Cheung,^{††}
William Harmon,^{‡‡} Jonathan Himmelfarb,^{§§}
Thomas H. Hostetter,^{|||} Jula K. Inrig,^{¶¶}
Rajnish Mehrotra,^{***†††‡‡‡} Emily Robinson,^{§§§}
Paul C. Smedberg,^{||||} and Rachel N. Shaffer,^{||||}
for the American Society of Nephrology
ESRD Task Force

*Department of Medicine, MetroHealth System Campus, Cleveland, Ohio; †Case Western Reserve University Center for the Study of Kidney Disease and Biology, Cleveland, Ohio; ‡School of Medicine, Case Western Reserve University, Cleveland, Ohio; §Portland VA Medical Center, Portland, Oregon; ¶Duke Clinical Research Institute and Departments of ¶Medicine and **Pediatrics, Duke University, Durham, North Carolina; ††Division of Nephrology & Hypertension, University of Utah School of Medicine, Salt Lake City, Utah; ‡‡Department of Pediatrics, Children's Hospital Boston, Boston, Massachusetts; §§Kidney Research Institute, Department of Medicine, Division of Nephrology, University of Washington School of Medicine, Seattle, Washington; |||Department of Medicine, Albert Einstein College of Medicine, Bronx, New York; ¶¶Department of Medicine, Division of Nephrology, University of Texas Southwestern Medical Center, Dallas, Texas; ***Department of Medicine, Harbor-UCLA Medical Center, Los Angeles, California; †††Los Angeles Biomedical Research Institute at Harbor-UCLA, Torrance, California; ‡‡‡Department of Medicine, David Geffen School of Medicine at UCLA, Los Angeles, California; §§§Division of Renal Medicine, Brigham and Women's Hospital, Boston, Massachusetts; and ||||American Society of Nephrology, Washington, DC

J Am Soc Nephrol 21: 1235–1237, 2010.
doi: 10.1681/ASN.2010060656

For the first time in nearly 30 years, the Centers for Medicare and Medicaid Services (CMS) will implement a new payment system for dialysis patients. Since 1983, Medicare has reimbursed each dialysis session with a prospective payment—known as the composite rate—designed to cover the cost of center or home dialysis.¹ Since implementation of the composite rate, however, new therapies—including erythropoietin, vitamin D, and iron—have emerged as new additional

costs for standard dialysis care. These therapies are reimbursed separately from the composite rate and now compose approximately 40% of the total Medicare payment for each dialysis treatment.²

To improve the efficiency and flexibility of the ESRD Program, the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 mandated implementation of a comprehensive, case mix–adjusted, bundled-rate payment system for ESRD that includes therapies currently reimbursed outside the composite rate.³ The ESRD Prospective Payment System will be phased in on January 1, 2011, and fully implemented by 2014. Although MIPPA outlines the basic approach to bundling, the legislation grants CMS authority to finalize the components of the bundle and generate a detailed implementation plan. In September 2009, CMS released for public comment a proposed rule on ESRD bundling and is expected to issue a final rule on ESRD bundling in 2010. In addition, CMS is projected to release a proposed rule on a quality improvement program for ESRD care.

AMERICAN SOCIETY OF NEPHROLOGY ESRD TASK FORCE

Given the monumental significance of the new payment system, the American Society of Nephrology (ASN) formed an ESRD task force to assess and respond comprehensively to the proposed rule changes. Eight ASN members from diverse specialties and practice settings served on this task force, including early-career and established nephrologists as well as ASN policy staff. ASN's foremost concerns relate to preservation of patient access to optimal dialysis care and related services, regardless of socioeconomic status, geographic location, or local demographic characteristics, and protection of reasonable latitude for physicians to make clinical decisions.

Between September and December 2009, working groups convened several weekly conference calls and one in-person meeting to analyze sections of the proposed rule and their potential effect on the practice of nephrology and ESRD care. The Task Force drafted a 30-page comment letter summarizing its analysis that was vetted by the ASN Advisory Group, the Public Policy Board, and Council. ASN President, Sharon Anderson, submitted the letter to CMS on behalf of the Society in December 2009. Conclusions from the task force are summarized below and can be read in full on the policy portion of ASN's website (http://asn-online.org/policy_and_public_affairs/esrd-bundling.aspx).

MAJOR CONCLUSIONS FROM THE ASN TASK FORCE ANALYSES

The task force recognizes that many aspects of the proposed rule represent true payment reform for the ESRD Program

Published online ahead of print. Publication date available at www.jasn.org.

Correspondence: Dr. Thomas H. Hostetter, Division of Nephrology, Albert Einstein College of Medicine, Room 615, Ullmann Building, 1300 Morris Park Avenue, Bronx, NY 10461. Phone: 718-430-3158; Fax: 718-430-896; E-mail: thostett@acom.yu.edu

Copyright © 2010 by the American Society of Nephrology

and the first fully implemented global payment rule.^{4,5} Implementation of the ESRD Prospective Payment System will demonstrate the effects of bundled payments for care of patients with chronic disease and may act as a model for other health care payment reforms. Besides the potential risks and benefits of the novel payment system, the task force focused on the unique vulnerabilities of the patient with ESRD to adverse selection and limited choice of dialysis provider.

Equitable Access to Quality Care

Given the frequency of dialysis treatments, the vast majority of patients with ESRD obtain care at a facility as close to home as possible.⁶ For many patients with ESRD, there is little available choice: Currently, two organizations provide dialysis services to more than 60% of patients. Moreover, dialysis companies supply the majority of dialysis equipment, and one of these organizations owns and markets drugs commonly administered to dialysis patients. Dialysis facilities of all sizes and types will likely encourage staff and physicians to operate with greater efficiency under the new bundle. Administrative requirements could result in financial pressures that smaller dialysis organizations may not be able to withstand, potentially further reducing the choice of options for dialysis care. We believe it is important to support the independence of a variety of dialysis organizations to preserve patient choice and access.

We are also deeply concerned that the proposed rule underestimates the complexity of providing dialysis for pediatric patients. The rule would impose substantial reductions in the payments for pediatric patients, potentially severely impeding the ability of dialysis centers that provide pediatric care. To avoid jeopardizing access to dialysis care for children and adolescents with ESRD, we believe CMS should postpone the application of bundled payments for pediatric patients until more accurate data can be collected on actual costs of caring for this vulnerable population.

Integrity of the Patient–Physician Relationship

In the current business environment for dialysis patient care, we are concerned that some aspects of the proposed regulations—in particular, bundling of all drugs and diagnostic laboratory tests that were formerly separately billed—may have unintended adverse consequences on the flexibility of the patient–physician relationship. We believe this relationship requires reasonable latitude for physicians to prescribe and order medications and diagnostic laboratory tests as part of complete care.

Access to the Range of Appropriate Therapies

In some circumstances, expanded bundling of dialysis-related medications may lead to pressures to prescribe selected drugs within each facility, primarily on the basis of financial considerations or contractual arrangements necessitated by facility affiliations. We strongly believe in the importance of maintaining physician responsibility to make decisions independent of dialysis providers and prescribe treatments appropriate for the individual

patient. Including only medications that are pointedly related to renal dialysis care in the bundle preserves patient access to necessary therapies and provides optimal patient care.

Regardless of which medications CMS includes in the bundle, the final rule must ensure all appropriate classes and types of drugs be readily accessible to all patients and providers, in all facilities, nationwide. The choice of medications for patients is often based on data that may not be readily apparent through administrative claims; customization of treatment regimens is sometimes necessary to meet variable patient needs. Regimens should not be fixed or based on algorithms that use narrowly limited formularies.

Access to the Range of Necessary Laboratory Tests

We are also concerned about maintaining provider flexibility to order diagnostic laboratory tests. Many nephrologists serve as the principal care provider for dialysis patients and commonly order non–dialysis-related tests, such as hemoglobin A_{1c} values, transplant-related laboratory tests, and other diagnostic tests not directly pertinent to dialysis care, yet the proposed rule includes in the bundled payment all diagnostic tests ordered by the nephrologist. This would create significant new costs for facilities, potentially creating a deterrent to obtaining certain non–dialysis-related tests that are an important component of care. We are concerned the rule would shift blood draws for all non–dialysis-related tests from the dialysis unit to non-nephrology offices, with the unintended consequence of undermining vein protection for future vascular access needs. We believe CMS should include in the bundle only laboratory tests directly related to dialysis and develop an alternative mechanism for nephrologists to order other, necessary non–dialysis-related tests. We suggest CMS work with the nephrology community to identify dialysis-related tests appropriate for the bundle.

Ongoing Monitoring and Evaluation

The new payment system will almost surely catalyze changes in practice and prescribing patterns. Lack of data on the effects of commonly used treatments for dialysis patients makes it unclear whether changes in payment policy will be to the benefit or detriment of patient outcomes and access. Regardless of the services and medications CMS includes under the bundle, the agency should prospectively monitor the influence of bundled payments on access to care and the use of dialysis-related medications and services important to preserving patient health. Ongoing, real-time monitoring and evaluation will ensure that a bundled payment system—whatever its scope—not exert unintended adverse effects on safety or quality of care.

Reiterating the task force's concerns, the Government Accountability Office (GAO) released a report in May 2010 stating that CMS should begin monitoring access to and quality of dialysis care as soon as possible after implementation of the new payment system. This is especially important for beneficiary groups that have above-average costs of care, including black patients and patients with additional coverage through

Medicaid.⁷ The GAO also suggests that CMS use the information to help refine the system over time.

Further Research to Evaluate Treatment Effectiveness

Potential outcomes of the new payment system highlight the lack of evidence on effectiveness of treatments in dialysis patients. Given the influence of CMS in shifting prescribing patterns and drug use *via* bundled payments, CMS should fund, commission, and collaborate on comparative effectiveness research for efficacy of drugs commonly used in ESRD care. As the bundle is implemented, physicians must have access to clinical trials and comparative effectiveness research that examine the full array of pharmaceutical products and renal replacement therapies. The availability of such data is vital to protecting patient well-being and allowing physicians the information they need to prescribe the most cost-conscious therapies under the bundled payment.

CONCLUSIONS

Bundling is an initial step to helping control the high costs of dialysis treatment; however, for bundled payments to be safe and result in improvements in care, the new system must include substantial safeguards to protect patient access, physician decision-making responsibility, and inclusion of appropriate drugs for responsible patient care. CMS proposes an implementation process in its proposed rule, but much remains to be specified before the new system can be enacted safely or successfully.

We reiterate ASN's ongoing interest in collaborating with the renal community, the Department of Health and Human Services (particularly CMS), and Congress to ensure that the new prospective payment system for renal dialysis facilities promotes accessible, high-quality patient care during the phase-in period and beyond.

ACKNOWLEDGMENTS

U.D.P. is supported by the National Institutes of Health (NIH) grant K23DK075929; W.H. receives grants from NIH/National Institute of Allergy and Infectious Diseases; and J.K.I. is supported by NIH grant K23 HL092297.

DISCLOSURES

J.R.S. serves on the CKD Advisory Board for Eli Lilly. A.C. has consulting agreements with Amgen, Baxter, CorMedix, PharmaNet, Shire, and Sorbent and receives honoraria from American Renal Management and Renal Advantage. W.H. serves as a consultant to Genzyme and serves on the ASN Public Policy Board. J.H. has consulting agreements with Alder Biopharmaceuticals, Shire Scientific, Nephron/Cytopheryx Medical Advisory Board, Kai Pharmaceuticals, Gilead, Genzyme, and Resolvx Pharmaceuticals; receives research funding from Fresenius Medical Services of North America; and serves on a scientific advisory board or is a member of the International Society of Renal Nutrition and Metabolism Council, Department of Veterans Affairs, Food and Drug Administration, International Society of Blood Purification 2010 Program Committee (note: all honoraria and consulting fees were donated to the Kidney Research Institute at the University of Washington). T.H.H. serves as a consultant to Eli Lilly, AstraZeneca, Wyeth, and Genzyme. J.K.I. receives industry grant/research support from Genzyme. R.M. receives grant support from Amgen, Baxter, Shire, DaVita, and Genzyme and serves as an *ad hoc* consultant for Novartis, Novashunt, Baxter, Shire, and Mitsubishi.

REFERENCES

1. MedPAC: Payment Basics: Outpatient Dialysis Services Payment System, 2008. Available at: http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_dialysis.pdf. Accessed April 28, 2010
2. Centers for Medicare and Medicaid Services: End Stage Renal Disease (ESRD) Payment Overview, 2010. Available at: <http://www.cms.gov/ESRDpayment>. Accessed April 28, 2010
3. Department of Health and Human Services Centers for Medicare and Medicaid Services: 42 CFR Part 410, 413 and 414. *Medicare Programs; End-Stage Renal Disease Prospective Payment System*, Washington, DC, US Government Printing Office, 2009
4. Liu CF, Subramanian S, Cromwell JJ: Impact of global bundled payments on hospital costs of coronary artery bypass grafting. *Health Care Finance* 27: 39–54, 2001
5. Hackbarth G, Reischauer R, Mutti A: Collective accountability for medical care: Toward bundled Medicare payments. *N Engl J Med* 359: 3–5, 2008
6. Brooks D, Irwin C, Hunsicker L, Flanigan M, Chrischilles E, Pendergast J: Effect of dialysis center profit-status on patient survival: A comparison of risk-adjustment and instrumental variable approaches. *Health Serv Res* 41: 2267–2289, 2006
7. US Government Accountability Office: *End-Stage Renal Disease: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System*, Washington, DC, US Government Printing Office, 2010