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## ESRD Payment Reform: First Do No Harm

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“Bureaucracy defends the status quo long past the time when the quo has lost its status – Laurence J. Peter (*American educator & writer; 1919–1988*)”

The continued growth of the number of patients receiving RRT levies not only a personal toll on families and communities, but also an increasing financial burden on Medicare. With patients with ESRD accounting for <1% of the total Medicare population but consuming nearly 7% of Medicare costs,<sup>1</sup> there is a crucial need to explore new strategies to advance value-based care. The challenge of balancing cost constraints while maintaining quality of care continuously lingers over the nephrology community. The introduction of new health care policies and regulations are designed to enhance the value of care by improving patient outcomes and/or reducing costs. To ensure there are not unintended consequences of such policies (*Primum non nocere* – first, do no harm), a careful evaluation of their impact is needed. Even if there are formal evaluation strategies in place, it is often incumbent on the medical community to conduct independent analyses, especially when there could be conflicting effects of policies on patient and financial outcomes. In this issue of the *Journal of the American Society of Nephrology (JASN)*, Chertow *et al.* take on such a challenge.<sup>2</sup>

In an effort to balance quality of care and costs to optimize the value of renal health care delivery, the US Congress passed the Medicare Improvements for Patients with Providers Act (MIPPA HR 6331) in 2008, which mandated reform of Medicare reimbursement policies. The Centers for Medicare and Medicaid Services (CMS) released a final ruling for implementation of the

ESRD prospect of payment system in July of 2010<sup>3</sup> that was subsequently implemented in January of 2011.<sup>4,5</sup> This new, bundled payment for ESRD was developed on the same principles that led to the original “Composite Rate” dialysis payment introduced in 1983 and transformed reimbursement to one set payment per dialysis treatment, including ESRD lab tests, intravenous medications (*e.g.*, erythropoiesis stimulating agents [ESAs], vitamin D, and iron), and oral medications with intravenous equivalents.<sup>6</sup> To lower Medicare expenditures, the 2011 bundled payment for ESRD reduced payments to ESRD facilities by 2% overall and eliminated incentives to the overuse of previously profitable, separately billable drugs. In particular, ESAs changed from being separately billable to being part of the bundled payment. This was prompted, in part, due to the high costs of ESA treatment, and in part because controlled trials demonstrated that targeting hemoglobin levels of  $\geq 13$  g/dl led to higher rates of mortality, cardiovascular events, and stroke in patients with CKD.<sup>7–9</sup> These studies also led to the US Food and Drug administration to require a modification of ESA product labels, which were released in June of 2011. This replaced the conventional hemoglobin target of 10–12 g/dl with recommendations to reduce or interrupt dosing as the hemoglobin approaches or exceeds 11 g/dl.<sup>10</sup>

Thus, the combination of the introduction of Medicare ESRD payment reform (in January of 2011) and changes in ESA product labeling (in June of 2011) rapidly led to a 29%–52% reduction in the use of ESAs in dialysis patients across different dialysis organizations.<sup>11</sup> However, the new bundled payment model also raised many concerns about the impact of managing trade-offs that could affect facility and/or provider behaviors and lead to unintended adverse consequences,<sup>12</sup> including worse outcomes for patients with ESRD due to the potential for undertreatment in terms of dialysis time, anemia management, and mineral and bone disorders.<sup>4</sup> In fact, the American Society of Nephrology (ASN) called for close monitoring of not only intermediate quality care outcomes such as lab values, but downstream clinical outcomes such as hospitalizations and mortality.<sup>4</sup> Several studies have subsequently examined the impact of bundled payment on intermediary outcomes and suggest that overall, the nephrology community has done an excellent job in maintaining the quality care for patients with ESRD. A recent analysis by Swaminathan *et al.* found the reduction in ESA use among dialysis patients was limited to those with a hematocrit >36%, with little change in use among patients with hematocrit  $\leq 36\%$ , suggesting that the impact on ESA reduction has appropriately been among patients who are least likely to benefit from the use of these agents.<sup>13</sup> In a cross-sectional analysis, Turenne *et al.* reported trends in ESRD quality care measures in 132 facilities in the Dialysis Outcomes and Practice Patterns Study from August of 2010 to December of 2011.<sup>14</sup> Not unexpectedly, they found that not only did mean hemoglobin levels fall from

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11.5 to 11.0 g/dl, along with erythropoietin doses falling by >25%, but mean serum parathyroid hormone levels rose from 340 to 435 pg/ml. Of note, they found no meaningful differences by race regarding the rates of change of management practices or laboratory measures following payment reform. Thus, several studies of intermediary outcomes have suggested the bundle payment has not led to adverse clinical outcomes.

Under the existing bundled payment for ESRD regimen, the above early findings allay many of the concerns that providers might maximize profits by injudiciously lowering the use of medications such as ESAs, since they receive the same bundled fee regardless of the dose administered, leading to worse patient outcomes. Further, CMS also instituted another rule in January of 2011, establishing three quality performance measures that included reduction in payments related to the proportion of patients with hemoglobin <10 g/dl, tempering the drive to underdose ESA. However, the impact of bundled payment for ESRD on the more downstream clinical outcomes that the ASN recommended be monitored, such as death or cardiovascular events, had yet to be reported. In this issue of *JASN*, Chertow *et al.*<sup>2</sup> provide us with the first detailed analysis of observed rates of death (all-cause and cardiovascular mortality) and major cardiovascular events (stroke, myocardial infarction [MI], a composite end point [death, stroke, or MI], heart failure, venous thromboembolic disease [VTE], and red blood cell transfusion) during the 2 years following the implementation of bundled payment (2011–2012) in comparison to rates during the period of 2005–2010, in approximately 250,00 patients receiving maintenance hemodialysis treatments each year. To isolate the potential impact of bundled payments, they not only accounted for differences in numerous patient characteristics, but assessed comorbid conditions using a multiple category variable that integrated both the timing and source of the claims information (*e.g.*, inpatient/outpatient), potential regional variations based on renal network, and adjustment for influenza virulence (by tracking outpatient visits for influenza-like illness in the general population) as a surrogate for the effect of seasonal diseases on the dialysis population. They found, as expected, a dramatic fall in ESA use in 2011 associated with a decline in hemoglobin concentrations and an increase in the use of blood transfusions. Importantly, they found no initial evidence of an unintended relative increase in death or any major cardiovascular events during this early follow-up period. Mortality declined consistent with secular trends but stroke, VTE, and heart failure rates declined more than expected, suggesting the new hemoglobin targets and ESA practices have, in fact, improved the value of ESRD care by lowering costs and possibly improving, and at a minimum not worsening, major clinical outcomes.

Although the authors controlled for many variables, they were unable to control for factors including new public health or governmental initiatives in health and health care, such as hospital admission and disposition practices. The Affordable Care Act included hospital quality improvement payment policy changes (2010–2012) that may have influenced clinical outcomes, and while the CMS-directed Hospital Re-admissions

Reduction Program started in 2012, with a focus on reducing acute MI, congestive heart failure, and pneumonia readmissions,<sup>15</sup> practice patterns may have begun during the 2011–2012 observation period in anticipation of legislatively mandated incentives and penalties. Also, the authors were unable to adjust for changes in several aspects of dialysis patient care, such as the use of intravenous iron or vitamin D analogs, oral medications (including iron or vitamin D), and the rates of catheter use, all of which can impact patient outcomes. Finally, changes in the 2011 guidelines for the prevention and treatment of stroke and VTE may also have impacted cardiovascular outcomes. Despite these limitations, this report provides a thoughtful and comprehensive approach to examining the potential impact of policy changes on major clinical outcomes over time. In particular, it provides an excellent insight into the impact of bundled payment for ESRD on death and major cardiovascular outcomes, and provides a high level of confidence that the change in 2011 to bundled payments for ESRD has not led to overt unintended consequences in patient outcomes. Clearly these findings will require follow-up to see how longer term exposure to lower rates of ESA use and lower hemoglobin levels, coupled with the other changes in care influenced by the bundled payment plans, may alter the outcomes of patients receiving RRT with hemodialysis, including potential increased rates of HLA sensitization from increased blood transfusions leading to decreased rates of kidney transplantation.<sup>16</sup> Until then, the findings of Chertow *et al.* serve as a barometer for the status of ESRD following the introduction of the bundled payment plan, and we are happy to find their report reflects an increase in the value of care for patients with ESRD, that is, no change or improved outcomes in the setting of fiscal constraints.

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## DISCLOSURES

None.

## REFERENCES

1. United States Renal Data System: *2015 USRDS annual data report: Epidemiology of kidney disease in the United States*, Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2015
2. Chertow GM, Liu J, Monda KL, Gilbertson DT, Brookhart MA, Beaubrun AC, Winkelmayer WC, Pollock A, Herzog CA, Ashfaq A, Sturmer T, Rothman KJ, Bradbury BJ, Collins AJ: Epoetin Alfa and Outcomes in Dialysis amid Regulatory and Payment Reform. *J Am Soc Nephrol* 27: XXX–XXX, 2016
3. Charytan C: Bundled-rate legislation for Medicare reimbursement for dialysis services: implications for anemia management with ESAs. *Clin J Am Soc Nephrol* 5: 2355–2362, 2010

4. Iglehart JK: Bundled payment for ESRD—including ESAs in Medicare's dialysis package. *N Engl J Med* 364: 593–595, 2011
5. Swaminathan S, Mor V, Mehrotra R, Trivedi A: Medicare's payment strategy for end-stage renal disease now embraces bundled payment and pay-for-performance to cut costs. *Health Aff (Millwood)* 31: 2051–2058, 2012
6. Centers for Medicare and Medicaid Services: Medicare program; end-stage renal disease prospective payment system. Final rule. *Fed Regist* 75: 49029, 2010
7. Besarab A, Bolton WK, Browne JK, Egrie JC, Nissenson AR, Okamoto DM, Schwab SJ, Goodkin DA: The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin. *N Engl J Med* 339: 584–590, 1998
8. Singh AK, Szczech L, Tang KL, Barnhart H, Sapp S, Wolfson M, Reddan D; CHOIR Investigators: Correction of anemia with epoetin alfa in chronic kidney disease. *N Engl J Med* 355: 2085–2098, 2006
9. Pfeffer MA, Burdmann EA, Chen CY, Cooper ME, de Zeeuw D, Eckardt KU, Feysi JM, Ivanovich P, Kewalramani R, Levey AS, Lewis EF, McGill JB, McMurray JJ, Parfrey P, Parving HH, Remuzzi G, Singh AK, Solomon SD, Toto R; TREAT Investigators: A trial of darbepoetin alfa in type 2 diabetes and chronic kidney disease. *N Engl J Med* 361: 2019–2032, 2009
10. Fishbane S, Jhaveri KD: The new label for erythropoiesis stimulating agents: the FDA'S sentence. *Semin Dial* 25: 263–266, 2012
11. Thamer M, Zhang Y, Kaufman J, Kshirsagar O, Cotter D, Hernán MA: Major declines in epoetin dosing after prospective payment system based on dialysis facility organizational status. *Am J Nephrol* 40: 554–560, 2014
12. Weeks WB, Rauh SS, Wadsworth EB, Weinstein JN: The unintended consequences of bundled payments. *Ann Intern Med* 158: 62–64, 2013
13. Swaminathan S, Mor V, Mehrotra R, Trivedi AN: Effect of Medicare dialysis payment reform on use of erythropoiesis stimulating agents. *Health Serv Res* 50: 790–808, 2015
14. Turenne MN, Cope EL, Porenta S, Mukhopadhyay P, Fuller DS, Pearson JM, Dahlerus C, Lantz B, Tentori F, Robinson BM: Has dialysis payment reform led to initial racial disparities in anemia and mineral metabolism management? *J Am Soc Nephrol* 26: 754–764, 2015
15. Joynt KE, Jha AK: A path forward on Medicare readmissions. *N Engl J Med* 368: 1175–1177, 2013
16. Yabu JM, Anderson MW, Kim D, Bradbury BD, Lou CD, Petersen J, Rossert J, Chertow GM, Tyan DB: Sensitization from transfusion in patients awaiting primary kidney transplant. *Nephrol Dial Transplant* 28: 2908–2918, 2013