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RESEARCH ARTICLE

Reforming Medicare's Dialysis Payment Policies: Implications for Patients with Secondary Hyperparathyroidism

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Objective. To demonstrate how expanding services covered by a “bundled payment” can also expand variation in the costs of treating patients under the bundle, using the Medicare dialysis program as an example.

Data Sources/Study Setting. Observational claims-based study of 197,332 Medicare hemodialysis beneficiaries enrolled for at least one quarter during 2006–2008.

Study Design. We estimated how resource utilization (all health services, dialysis-related services, and medications) changes with intensity of secondary hyperparathyroidism (sHPT) treatment.

Data Extraction Methods. Using Medicare claims, a patient-quarter level dataset was constructed, including a measure of sHPT treatment intensity.

Principal Findings. Under the existing, narrow dialysis bundle, utilization of covered services is relatively constant across treatment intensity groups; under a broader bundle, it rises more rapidly with treatment intensity.

Conclusions. The broader Medicare dialysis bundle reimburses providers uniformly, even though patients treated more intensively for sHPT cost more to treat. Absent any payment adjustments or efforts to ensure quality, this flat payment schedule may encourage providers to avoid high-intensity patients or reduce their treatment intensity. The first incentive harms efficiency. The second may improve or worsen efficiency, depending on whether it reduces appropriate or inappropriate treatment.

Key Words. Bundled reimbursement, Medicare, end-stage renal disease, secondary hyperparathyroidism, dialysis

Payment reform has become a central feature of recent efforts to reduce US health care costs and alleviate federal budget pressures (Crowley and Golden 2014; Sommers, Kenney, and Epstein 2014). A primary target of these efforts is the overtreatment problem often associated with fee-for-service (FFS) reimbursement, which compensates providers for doing more, but not

necessarily for doing better (Lee et al. 2013b). In contrast to FFS reimbursement, bundled payments reimburse providers with a single fee for treating a specific episode of illness or patient. For instance, a physician may be paid a flat fee to treat each patient with diabetes, rather than fees for each office visit, blood test, and so on. Under bundled payment schemes, providers have incentives to provide care as economically as possible, since they retain any difference between the bundled payment and the actual costs to treat.

A key element of bundled payment design is the bundle “width,” or the number of activities, treatments, and procedures covered under a single payment. While a relatively narrow bundle covering only a few activities during a short episode of care may be simple to implement, it limits the ability of providers to substitute across alternative treatments and thus find the most efficient and appropriate bundle of care. A wider bundle covering a broader scope of activities presents more substitution opportunities and thus may result in greater cost savings. However, wider bundles may also lead to greater variation in the costs of providing clinically appropriate care, and such variation can strengthen providers’ incentives to under-provide care, or avoid high-cost patients, particularly if no specific treatment quality targets are imposed.

A simple example helps illustrate the point. Imagine a disease that can be treated either with a set of inexpensive behavioral interventions—for example, nutritional counseling and a range of exercise programs—or an expensive prescription drug. Imagine further that Type A patients respond well to the behavioral interventions alone, but Type B patients require the addition of the expensive drug. A bundle for the disease is being designed, covering either behavioral interventions alone, or behavioral *and* drug treatments together. It is straightforward to set a bundled payment rate for the behavioral interventions alone, because the rate can be set equal to the relatively low and uniform cost of providing these interventions. However, setting a bundled payment rate for the combination of behavioral interventions and drugs is more difficult. To achieve any cost savings, the bundled payment would need to be set at a level below the costs of the interventions plus drugs.

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Yet, at this level, providers face incentives not to prescribe the drug for Type B patients who need them, or to avoid Type B patients altogether. On the positive side, they also face greater incentives to avoid overprescribing drugs for Type A patients. The net effect on welfare is uncertain, but expanding the bundle clearly encourages a range of complex behavioral responses by providers.

While this logic is fairly simple, relatively little attention has been paid in the literature to the relation between a bundle's "width" and the incentive effects it produces. Significantly, the potential for such effects depends on the variation in costs across patients whose treatment is covered under the bundle, and can be identified before bundle implementation. Thus, effective bundle design must consider the competing incentive effects that will occur under different bundle widths, and their associated welfare consequences. In this article, we present an empirical example of this issue in the context of bundled payments for Medicare dialysis patients and discuss the various countervailing incentive effects and their policy implications.

Payment policy for the treatment of kidney failure is an important issue for the Medicare program. Since 1973, Medicare has provided coverage as either the primary or secondary payer for all patients with end-stage renal disease (ESRD), irrespective of age or disability. In 2010, the 410,000 patients on dialysis constituted only 1.3 percent of Medicare beneficiaries, yet ESRD-related payments constituted 6.3 percent, or \$32.9 billion, of Medicare expenditures (United States Renal Data System 2012).

Until 2011, Medicare reimbursed dialysis via a composite rate (adjusted based on patient age, body surface area, and body mass index), and many laboratory services and treatments associated with ESRD—such as erythropoiesis stimulating agents (ESAs), vitamin D analogs, and intravenous iron—were reimbursed on a FFS basis. However, the substantial and growing costs of treating ESRD prompted the Centers for Medicare and Medicaid Services (CMS) to implement new ESRD reimbursement rules, most of which went into effect in 2011 (the ESRD Prospective Payment System, or PPS) (Swaminathan et al. 2012). Under the new payment rules, *all* dialysis-related services and treatment delivered during a particular session are reimbursed through a bundled payment at a standard base rate, which is then adjusted using additional clinical factors related to the cause and severity of anemia. Providers receive a fixed amount per patient per dialysis session (equal to \$240.36 per session in 2013), regardless of the specific treatments administered (Centers for Medicare and Medicaid Services [HHS] 2012). Included in the current bundle—referred to hereafter as the narrow bundle—are all parenteral drugs used in dialysis care or their oral equivalents. Currently, oral-only drugs are excluded from the bundled payment

and covered in large part by pharmacy insurance providers (HHS 2013). For the next stage of policy implementation, CMS is considering the inclusion of oral-only drugs (HHS 2010, 2013), which are used to treat a common sequela of kidney failure called secondary hyperparathyroidism (sHPT) (de Francisco 2004).

In this article, we show that per-patient treatment costs covered by the broad bundle vary more than those covered by the narrow bundle. Specifically, per-patient treatment costs covered by the broad bundle will vary depending on how intensively a patient is treated for sHPT. While the broad bundle might improve efficiency by reducing or eliminating incentives for unnecessarily intensive sHPT treatment, it may also lead providers to avoid patients requiring more care or to provide less-than-appropriate sHPT therapy like calcium-binding agents. In the latter case, greater downstream complications for patients who do not receive appropriate treatment for their sHPT could result (Block et al. 2004).

The general issue of bundle width merits more attention in policy discussions of bundled payment design because the right choice will vary across disease contexts. For instance, if broader bundles reduce appropriate use, or cause providers to avoid patients requiring intensive sHPT treatment, then more sophisticated risk-adjustment strategies and quality metrics for providers could improve efficiency. On the other hand, if broader bundles reduce inappropriate use, then more sophisticated risk adjustment would actually limit the efficiency gains from bundled payments. Hence, it is important to investigate three sets of issues when determining the ideal breadth of a bundled payment policy:

1. Does the broader bundle incorporate therapies that are used differentially across the covered population of patients?
2. Are these therapies clinically overused or underused?
3. Are providers able to easily identify patients at greater risk of incurring high costs, if they wished to avoid such patients?

Our analysis focuses primarily on answering the first question. As we discuss later, addressing the second requires clinical data that lie beyond the scope of this study. We also provide some insight into the third by exploring the extent to which dialysis vintage, which is easily observed, could be used to predict sHPT treatment intensity.

We begin our analysis with a description of clinical background, followed by a description of our data and methods. We then present our empirical results on how variation in per-patient resource utilization differs across bundles of different widths. We conclude with a discussion of implications for bundled payment policy.

Clinical Background

In the United States, more than 115,000 patients annually start dialysis because of kidney failure, with the current dialysis population standing at roughly 410,000 (United States Renal Data System 2012). One of the most common sequelae of ESRD is sHPT, a mineral and bone disorder that accompanies a progressive loss of kidney function and is characterized by elevated plasma concentrations of the parathyroid hormone (PTH), and abnormal calcium and phosphorus metabolism. Clinical manifestations include bone and joint pain, muscle weakness, and increased risk of fracture, cardiovascular events and mortality, among others (National Kidney Foundation 2003; Block et al. 2004; Kalantar-Zadeh et al. 2006; St Peter et al. 2009). While most ESRD patients also have sHPT, the severity of sHPT and degree to which it progresses (with or without therapy) vary considerably across patients (de Francisco 2004).

Effective management of sHPT in ESRD patients typically requires dialysis, restriction of dietary phosphorus, and provision of oral phosphate binders and oral or intravenous vitamin D. In many patients with moderate to severe sHPT, cinacalcet, an oral-only calcimimetic agent, is also required, and for some, surgical therapy (typically subtotal parathyroidectomy [PTX]) may be necessary (National Kidney Foundation 2003). For additional clinical background, see the technical appendix.

A number of prior studies have concluded that resource utilization is higher for dialysis patients with sHPT than without it. For example, several studies have examined the direct treatment costs of sHPT (Joy, Karagiannis, and Peyerl 2007) and the costs of sHPT-related clinical events (Doan et al. 2007). Others have considered the additional therapy costs for sHPT (Schumock et al. 2009) and the epidemiologic evidence linking sHPT to high-cost clinical outcomes (de Francisco 2004; Lee et al. 2013a).

DATA AND METHODS

Data

We analyzed data from the United States Renal Data System (USRDS), a nationwide registry funded by the National Institute of Diabetes and Digestive and Kidney Diseases. The USRDS tracks information on the entire U.S. ESRD population, with detailed information on patient demographics, treatment methods and outcomes. USRDS standard analytic files were linked with Medicare claims files—Part A inpatient, Part B outpatient, and Part D prescription

drug claims from January 1, 2006, through December 31, 2008 (United States Renal Data System 2011). While all patients on dialysis are enrolled in the Medicare ESRD program, patients on Medicare Advantage plans are excluded. For detailed information about study methods, see the technical appendix.

Population and Sample Selection

To ensure data completeness and the inclusion of only patients undergoing dialysis, we restricted our sample to patients who received in-center hemodialysis during periods of continuous coverage for at least one quarter by both Medicare Parts A and B as primary payer and enrollment in the Part D prescription program. Patients were observed on a quarterly basis for up to 12 quarters. The final sample consisted of 197,332 patients and a total of 1,333,144 patient-quarters. Table 1 presents descriptive statistics for the sample.

Heterogeneity in sHPT Treatment Intensity

The vast majority of dialysis patients present with some degree of sHPT; those with greater underlying severity will tend to be treated more aggressively. We develop a measure of sHPT treatment intensity as a means of assessing patient heterogeneity under both the broad and narrow bundles, and of evaluating how spending may vary under an expanded dialysis bundle.

Our sHPT treatment intensity index comes from the claims data and comprises two dimensions. The first is based on the patient's dosage of cinacalcet, which is typically given in more advanced or complicated sHPT cases and may be considered a medical alternative to PTX (Narayan et al. 2007). The second dimension of sHPT treatment intensity is based upon provision of vitamin D analogs and their dosage: none; low-dose; and high-dose (see technical appendix for details). Note that vitamin D dosage is not always monotonic in sHPT severity (Fine and Zacharias 2002; National Kidney Foundation 2003).

Estimation of Relation between Dialysis Vintage and sHPT Treatment Intensity

To investigate whether providers can easily identify prospective patients likely to require intensive sHPT treatment, we use dialysis "vintage" as a potential predictor of sHPT treatment intensity. We determined prevalence of cinacalcet treatment and PTX history for all patients in our sample based on number of quarters since dialysis initiation.

Table 1: Summary Statistics for the Study Sample

<i>Characteristics of Study Population (n = 197,332)</i>	<i>Mean or Percent</i>	<i>Standard Deviation or Frequency</i>
Average age at first service date	61.4	14.9
Average age at beginning of study period	63.6	14.5
Average duration in study period (months)	20.0	12.0
Average BMI	28.3	8.8
% Female	50.1	98,765
% Hispanic	13.8	27,197
% Dual eligibility at first service date (Medicare and Medicaid)	24.0	47,312
% Incident (new to dialysis)	43.4	85,543
Race		
% Native American	1.6	3,077
% White	54.4	107,391
% Black	40.0	78,860
% Asian	3.5	6,965
% Other/unknown	0.5	1,039
End reason		
% End of Medicare continuous coverage	5.1	10,099
% Death	34.1	67,334
% Lost to follow-up	0.3	540
% Recovered kidney function	0.7	1,348
% Still in sample	59.8	118,011
Comorbidities at first service date		
% Diabetes	55.2	108,929
% Congestive heart failure	32.6	64,383
% COPD	7.7	15,251
% Cancer	5.0	9,855
% Alcohol dependence	1.7	3,292
% Cerebrovascular disease	9.7	19,210
% Drug dependence	1.6	3,220
% Hypertension	84.8	167,365
% Other cardiac disease	29.1	57,345
% Peripheral vascular disease	13.6	26,785
% Tobacco use	6.7	13,125
Census Division		
% Pacific	11.4	22,567
% Mountain	4.0	7,895
% West North Central	5.7	11,207
% East North Central	14.6	28,711
% West South Central	14.1	27,834
% East South Central	8.8	17,441
% South Atlantic	23.9	47,148
% Middle Atlantic	13.8	27,140
% New England	3.5	6,811
% Other	0.3	578

Statistical Analysis

As described above, the potential for incentive effects—both good and bad—under bundled payment schemes depends on whether and how the costs of using bundled services vary across patients. We are interested specifically in how the bundle width affects variation in the costs of covered services. Since the broader bundle covers expensive sHPT treatment, while the narrower bundle does not, costs may then vary across patients who are treated more or less intensively for sHPT.

To isolate the sHPT treatment intensity effect, we employ a panel data regression model at the patient-quarter level with patient-level fixed effects to control for time-invariant patient-specific factors. For example, if frailer patients are both more difficult to treat and more likely to require intensive sHPT treatment, failure to account for frailty might overstate the relationship between sHPT treatment intensity and cost. Including a patient-specific fixed effect addresses this type of problem. We used White’s robust standard errors to adjust for heteroskedasticity.

Since the bundled payment is made on a per-session basis, we focus correspondingly on per-dialysis session health care utilization for treatments and services covered under the narrow and broad bundles. Table 2 outlines the differences in the set of services covered by these two bundles. We calculate utilization variables from final claim amounts paid by Medicare at a time when services were paid via FFS reimbursement, measured in 2008 \$US. We also consider total utilization for all health services, by aggregating claims to

Table 2: Health Care Services Covered under Two Alternative Bundling Schemes

<i>Narrow Bundle</i>	<i>Broad Bundle</i>
<ul style="list-style-type: none">• Non physician services and materials previously included in prebundle composite rate (as of December 31, 2010)• ESRD-related laboratory tests• ESRD-related intravenous drugs and their oral equivalents, including:<ul style="list-style-type: none">○ vitamin D analogs○ erythropoiesis stimulating agents (ESAs)○ intravenous iron	<p>All treatments and services in the narrow bundle, plus:</p> <ul style="list-style-type: none">• Oral-only ESRD-related medication, including:<ul style="list-style-type: none">○ cinacalcet○ phosphate binders

Source. Centers for Medicare and Medicaid Services (HHS) 2010.

generate a measure of utilization over a patient-quarter. This outcome is examined in alternate specifications of the fixed effects regression model.

The explanatory variables of interest are categories of sHPT treatment intensity, which provide a means of assessing the relevant heterogeneity across patients. Time-varying covariates include dialysis vintage (calculated in quarters and months), age, age squared, and quarterly components of the Charlson Comorbidity Index. All time-invariant patient-level factors (such as race) are accounted for by the patient-level fixed effects.

Modeling Bundled Payment on Potential Incentive Effects

Using the regression results, we predict the per-patient cost of providing the narrow and broad bundles of services. We then stratify these predicted costs across patients with different sHPT treatment intensity levels. Recall that the regression is based on final claims paid under a FFS regime. Therefore, our predictions represent the cost of providing services under the assumption that the bundled payment policy does not influence physician behavior. In the terminology of welfare economics, this represents the “first-order effect” of the policy. This is the relevant calculation: If costs equal the FFS reimbursement under both bundles without any behavioral change, there is no incentive to change behavior from the initial FFS baseline, and vice-versa.

The process of predicting costs under both bundles begins with identifying the therapies and services that would be covered under a given bundle. Using the results of our fixed effects panel regressions, we estimate utilization of covered services and its variation across patient types. If pre-bundle treatment intensity is relatively constant across patients, there is little reason to believe that providers will alter their treatment patterns once a bundle is implemented. On the other hand, if prebundle utilization is higher for a specific patient type, this raises the possibility of behavioral effects by providers, which may help or harm patients depending on the clinical particulars.

Testing for Facility Specialization in sHPT Care

If our results indicate higher prebundle utilization for a particular patient type, the potential for behavioral effects by providers is less of a policy concern if that patient type is concentrated among a few highly specialized facilities. Using variations in treatment intensity to define patient types, we measure the extent to which facilities specialize in high-intensity sHPT patients.

A simple way of doing this is to measure the degree to which high-intensity and low-intensity patients are “segregated” across different facilities. This is analogous to a standard empirical problem in real estate economics, which attempts to measure the degree of racial and ethnic segregation across neighborhoods (Rugh and Massey 2010; Stoll and Covington 2012). In that literature, a “dissimilarity index” is used to measure segregation; the index ranges from 0 to 1, with 0 representing complete integration and 1, complete segregation. As an example, if a city’s white-black index were 0.75, the interpretation is that 75 percent of whites would need to move to another neighborhood for whites and blacks to be evenly distributed across neighborhoods. Convention in the economics literature on segregation considers values of the index below 0.3 to indicate low dissimilarity; from 0.3 to 0.6, moderate; above 0.6, high; and above 0.75, extremely high (Rugh and Massey 2010).

RESULTS

Estimating Health Care Utilization across sHPT Treatment Intensity Levels

We begin by describing the variation in total quarterly resource utilization across patients with different levels of sHPT treatment intensity, based on fixed effects regressions. Total utilization includes all health services and medications, including sHPT-specific medications, whether covered under a bundle or not. Detailed regression results are available in the online technical appendix. Figure 1 graphs the results across groups. The most expensive groups cost roughly \$4,500, or 24 percent, more than the least expensive groups. For all services, quarterly utilization tends to rise with increasing sHPT treatment intensity.

The top panel of Figure 2 charts predicted per-session utilization for covered sHPT medications. Under the narrow bundle, covered sHPT medications include only intravenous vitamin D and their oral equivalents, and their predicted utilization is relatively constant across patient types, ranging from \$2 to \$14. But under the broad bundle, in which cinacalcet and phosphate binders are also covered, per-session utilization of covered medications varies considerably across patients, ranging from \$11 to \$133.

This difference in covered drug costs translates into total cost differentials under the bundle, as shown in the bottom panel of Figure 2, which charts predicted per-dialysis session utilization for all covered services under alternative bundles, by sHPT treatment groups. Under the narrow bundle, resource utilization ranges from \$379 to \$422, for a maximum difference across groups

Figure 1: Mean Quarterly Resource Utilization (Per-Patient, Per-Quarter) for All Services across sHPT Treatment Intensity Groups

Notes. The figure shows how total quarterly resource usage for all services varied with sHPT treatment intensity prior to the implementation of bundled payment reforms. “CH” is cinacalcet hydrochloride; “VD” is vitamin D. *denotes predicted mean is statistically significantly different from the mean of reference group “no CH, no VD” at the 1-percent level. Bootstrapped standard errors are in parentheses.

of \$43. In contrast, under the broad bundle, the range is \$428 to \$535, for a maximum difference of \$107, 2.5 times larger than the difference under the narrow bundle. Note that current per-session Medicare reimbursement is roughly \$240. Costs were higher prior to the bundle implementation, as our estimates demonstrate.

In addition, note that, under the narrow bundle, less intensively treated patients are more costly per dialysis session than their more intensively treated peers; this is likely due to differences in the number and intensity of treatment sessions. We found that patients treated more aggressively for sHPT tend to receive more frequent hemodialysis sessions. Specifically, the number of treatment sessions per quarter is 37.0, 37.3, 37.5, and 37.6, for the 30, 60, 90, and 120-mg cinacalcet groups, respectively. This variation in sessions could be due to a number of factors: hospitalizations, skipped sessions, or the need for more frequent dialysis among certain patients. With longer dialysis vintage, patients lose residual kidney function, sometimes requiring additional sessions; sHPT tends to become more severe in parallel. Such patients are more likely to undergo hemodialysis four or more times per week but receive intravenous vitamin D and ESAs at only three of these.

Figure 2: Mean Per-Session Utilization of Covered Services under Alternative Bundles

Notes. The top panel shows how resource usage—for sHPT-specific medications in two alternative bundles—varied with sHPT treatment intensity prior to the implementation of bundled payment reforms. The bottom panel shows the same for total covered services. Medications include intravenous vitamin D and their oral equivalents under the narrow bundle, and the addition of phosphate binders and cinacalcet under the broad. “CH” is cinacalcet hydrochloride; “VD” is vitamin D. * denotes predicted mean is statistically significantly different from the corresponding mean of reference group “no CH, no VD” at the 1-percent level. Bootstrapped standard errors are in parentheses.

Under the broad bundle, in contrast, less intensively treated patients are less costly. The narrow bundle thus provides incentives to reduce treatment for, or potentially avoid, healthier patients, while the broad bundle provides incentives to reduce treatment for or avoid sicker ones. While the overall welfare effects of changing treatment patterns remain uncertain, this result suggests that under the narrow bundle, those effects are borne or enjoyed by healthier patients, while under the broad bundle they are borne or enjoyed by sicker ones.

Finally, a correlation between dialysis vintage—an easily observable patient trait—and the need for more intensive sHPT treatment may enable providers to identify patients likely to be sHPT treatment-intensive. Figure 3 illustrates the distribution of sHPT treatment intensity in every patient-quarter at a given time since initiating dialysis. Taking treatment with cinacalcet or use of PTX as a marker of moderate to severe treatment intensity, the proportion of patients with any such treatment increases monotonically from 1.8 percent one quarter after initiating dialysis to 31.1 percent thirty-three quarters after initiation.

Facility Specialization in sHPT Care

The above results suggest that the broad bundle may generate incentives for providers to adjust their behavior when caring for sHPT treatment-intensive patients. This effect might be less relevant for policy if care for such patients is concentrated among a few highly specialized facilities.

We assess the degree of segregation of high- and low-intensity sHPT patients across facilities, using a dissimilarity index, which takes on a value of 0 when patients are fully “integrated” and 1 when fully “segregated.” Using cinacalcet treatment or PTX as a marker of more intensive sHPT treatment, we find a dissimilarity index of 0.26 (details described in the technical appendix), suggesting that care of more complex sHPT patients is not segregated in a few facilities. In fact, in the average facility, 15 percent of treated patients receive more intensive treatment, with over 86 percent of facilities treating at least some high-intensity sHPT patients.

LIMITATIONS

Our study has several limitations. First, our data are from 2006 to 2008, prior to the introduction of the bundled payment system designed to

Figure 3: Relationship between Time on Dialysis and sHPT Treatment Intensity

Note. PTX used as abbreviation for parathyroidectomy.

address the potential overuse of certain intravenous drugs. Our estimates thus compare the narrow and broad bundles to FFS reimbursement, not directly to each other. For example, implementation of the narrow bundle may have reduced the use of intravenous drugs. Moving subsequently to the broad bundle would thus have a smaller effect than the “full” move from FFS to the broad bundle.

Second, we measure health care utilization based on Medicare final claim amounts, but our data do not include information about providers’ actual costs for labor or supplies. Thus, we cannot estimate the actual profit providers receive from particular patient types, nor the size of potential incentives to alter treatment.

Additionally, since we do not observe postreform utilization, we can only estimate first-order effects on provider incentives and not the resulting changes in provider behavior or actual health care utilization. Nevertheless, our results do allow us to identify how changing bundled payment schemes will affect the incentives providers face in treating particular kinds of patients; the first-order effects analyzed here suggest the presence of incentives to change behavior that grow stronger with the broader bundle. We suggest an analysis of utilization patterns pre- and postreform as an area for future research.

Finally, neither others nor we have adequately examined clinical outcomes associated with changes in therapeutic choices or patient access. Emerging clinical evidence on cinacalcet efficacy (Chertow et al. 2012), for example, should be incorporated along with real-world estimates of effectiveness for other sHPT treatment strategies.

DISCUSSION

We analyzed how expanding a dialysis payment bundle affects variation in the utilization of bundled services. Specifically, we analyzed how expanding the bundle to include oral-only medications that treat sHPT affect variation across patients who are treated more or less intensively for sHPT. Under the narrow bundle, utilization of in-bundle services was more homogeneous across sHPT treatment intensity levels. In contrast, the range of variation was 2.5 times larger for the broad bundle. Thus, the broad bundle may provide stronger incentives to reduce treatment or avoid patients requiring highly intensive sHPT treatment. Reducing treatment intensity may be socially harmful or beneficial, depending on whether providers reduce current use that is appropriate or

inappropriate. Avoiding patients who require treatment is always socially harmful.

A bundled payment system may be helpful for controlling dialysis-related costs and promoting efficient care; however, these benefits should be weighed against competing, adverse incentive effects. Variation in the costs of treating different patient types may create incentives for providers to skimp on the use of appropriate but expensive treatments, particularly in the absence of quality metrics that gauge appropriateness of care. Providers may even choose to avoid treating severe sHPT patients altogether. Indeed, we have shown that patients likely to have severe sHPT can be easily identified by a simple screen based on dialysis vintage. Even more troubling, providers may have greater incentives to deny treatment to African Americans relative to whites, because African Americans tend to have more severe sHPT (Winkelmayer and Chertow 2011). These findings underscore the importance of policy mechanisms, like risk-adjustment and quality-based compensation, designed to mitigate incentives for inappropriate use.

Our analysis highlights the kinds of questions policy makers must ask when deciding on the appropriate breadth of a bundle. In particular, when incorporating an additional therapy or set of therapies into a bundle, one needs to know:

1. Are the additional therapies used differentially across the population of patients covered by the bundled payment?
2. Are the additional therapies more likely to be underused or overused?
3. Are providers able to easily identify patients at greater risk of incurring high costs, if they wished to avoid such patients?

If the answer to the first question is no, then expanding the bundle width is straightforward. If the answer is yes, the subsequent questions need to be answered. For the second question, if the additional therapies are overused, the expansion of the bundle is likely to be welfare-improving, and risk-adjusted payments are unnecessary. If underused, the expansion of the bundle might harm welfare, unless payment is appropriately risk-adjusted to eliminate incentives that might exacerbate underuse. If the answer to the third question is yes, then the bundle might also harm welfare, again unless appropriate risk-adjustment is incorporated into the payment structure.

Poorly designed bundled payment schemes that exacerbate underuse might simultaneously increase costs to the health care system and/or to public payers. One example relevant to dialysis is the use of PTX, an expensive

procedure that remains outside either the narrow or broad bundle. Under a broad bundle, providers might opt against treating severe sHPT patients with cinacalcet (which is expensive and covered under the broad bundled payment), but instead opt for more PTX procedures. Clinically, PTX can be an appropriate and cost-effective treatment for sHPT in some patients, but dominated by cinacalcet for others, particularly those with very poor health or with a shorter life expectancy (Narayan et al. 2007). The more general point is that exacerbating underuse need not lower total costs, and vice-versa.

Another relevant example demonstrates the consequences for Medicare. Suppose the broad bundle leads to inadequate control of sHPT. Clinically, this can result in costly adverse events such as heart failure, myocardial infarction, or a peripheral vascular event (Chertow et al. 2012). The costs of treating these adverse events are not covered under the dialysis bundle, but would be borne by CMS.

These examples illustrate a general challenge faced by bundled payment designers, namely that “unbundled” services exist alongside the bundled ones. Therefore, bundled payment significantly changes the relative costs faced by providers of bundled versus unbundled treatments. While a fully capitated payment system that accounts for all treatment costs and all clinical outcomes would address this issue more holistically, such a system faces an even more extreme problem of variation across patients in cost.

Despite these challenges, few would argue that cost-based reimbursement for medical care leads to efficient outcomes. Most would agree, for example, that hospital payments based on diagnosis-related groups (DRGs) are superior to simple FFS payments, despite the well-known pitfalls of DRGs. Similarly, bundled payments have important efficiency advantages over a fully unbundled alternative, and the challenge is how best to avoid their pitfalls. For example, underuse of within-bundle services could be ameliorated by incorporating enhanced risk-adjustment, quality metrics, or performance-based payments for providers into payment policy. Current case mix adjusters in the dialysis bundle include several anemia-related clinical factors; our analysis suggests that bundled payment designers may wish to consider additional case mix adjusters that account for sHPT severity, if underuse of sHPT treatment is a concern. As part of the dialysis bundle reform, Congress has mandated a Quality Incentive Program, which will result in payment reductions to providers who do not meet certain measures, related to dialysis dosing and reporting of hemoglobin levels (Chambers et al. 2013). Expanding such quality metrics could mitigate the potential for adverse incentive effects. These kinds of incentives have been shown to work in other clinical contexts. For

example, a pay-for-performance program for physicians was found to significantly improve compliance to glycosylated hemoglobin testing recommendations among patients with diabetes (Coleman, Reiter, and Fulwiler 2007). The Centers for Medicare and Medicaid Services is working to develop a comprehensive quality monitoring program to avoid problems associated with incentives to ration care. While a number of implementation issues remain to be worked out, this type of approach could be a valuable tool for mitigating the challenges identified in this study (United States Government Accountability Office 2011).

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

- Appendix SA1: Author Matrix.
- Data S1: Technical Appendix.