Issues for an Expanded Medicare PPS for Outpatient ESRD Dialysis Services

Phase II Segment 1 Report

I. Introduction

The Center for Medicare and Medicaid Services (CMS) has contracted the Kidney Epidemiology and Cost Center (KECC) of the University of Michigan (UM) to complete two phases of the Design, Development, and Implementation of an Improved Medicare Outpatient End Stage Renal Disease (ESRD) Prospective Payment System project (PPS). The three major goals of Phase I of this project are now complete: a) identification and assessment of available data, b) review of literature concerning case-mix adjustment, and c) development of analytical files for hypothesis testing, data validation, and concept modeling. The Phase I effort also supported a Report to Congress submitted by CMS. The complete report for Phase I is now available on-line at http://www.med.umich.edu/kidney/. The Report to Congress is available on-line at http://www.cms.hhs.gov/providers/esrd/.

Phase II of this research is intended to inform CMS about the feasibility and implications of various potential modifications to the ESRD PPS. Phase II is comprised of three segments, each addressing diverse issues with regard to an expanded PPS. Segment 1 will address hemodialysis services. Segment 2 will address peritoneal dialysis services and laboratory services. Segment 3 will address options for prospective monitoring of the revised PPS.

The primary purpose of this interim report for Segment 1 of Phase II is to provide relevant background information to the Technical Expert Panel (TEP) that has been engaged by the UM research team to guide the final phase of the research effort. The TEP has been selected to provide expertise from within the dialysis community in order to complement the expertise and perspectives of the UM research team. Their advice will help ensure that the resulting research will be as informative as possible to CMS in facilitating the design of a payment system that promotes the delivery of high quality care, equitably reimburses providers for the costs inherent in delivering such care, and places reasonable demands on the Federal budget.

II. Background on Dialysis Payment

The Medicare program covers more than 265,000 dialysis patients. Payments for dialysis services make up approximately $5 billion of the estimated $13 billion spent on ESRD patients annually. While changes in technology and increased delivery of anti-anemia drugs such as erythropoeitin (EPO) and intravenous iron have led to improved survival rates and a better quality of life for Medicare ESRD beneficiaries, they have added considerably to expenditures and to the complexity of what is considered routine patient care.

Currently, in the outpatient setting, payment for maintenance dialysis is based on a fixed prospective payment, called the composite rate (CR). Facilities receive the composite rate for each hemodialysis (HD) treatment they furnish. Facilities receive composite rate payments for PD patients at a rate equal to three times the applicable hemodialysis composite rate, for each week a patient is on PD. The composite payment rates do not vary among the different types of PD.

The composite payment rates, first adopted August 1, 1983, were developed from Medicare ESRD facility cost data for fiscal years ending in 1977, 1978, and 1979.[1] Different payment rates apply to hospital based and freestanding facilities classified as urban or rural, with the labor-related portion of each rate adjusted for area differences in wage levels using a wage index. For hospital-based facilities the base outpatient payment rate that is used to calculate the composite rate payment is currently $130.32; for freestanding facilities it is $126.33. The basic composite rate is adjusted to reflect geographic variations in wages, subject to a “floor” and a “ceiling” limiting the extent of the wage adjustment. Unlike other Medicare PPSs, the ESRD composite payment rates are not subject to an annual inflation adjustment. The Congress has increased the composite rate on three occasions since its inception ($1.00 in 1991, 1.2% in 2000, and 2.4% in 2001).

The composite rate covers routinely provided drugs, tests, and supplies in connection with outpatient dialysis related services. Other services, such as the provision of EPO, laboratory tests considered non-routine because of frequency of occurrence, or due to medical necessity, are separately billable. The ESRD facility, laboratory, or supplier can receive payment for these services in addition to the composite rate.

CMS’s outpatient ESRD payment system is in need of updating and revision. The system has aspects of both a PPS for routine services and a fee-for-service reimbursement system for separately billable services. The base year costs from which the payment rates were developed are over 20 years old, and do not reflect current treatment practices. Inflation updates have been infrequent, and little effort has been made to design a system that could direct higher payments to facilities treating costlier, more resource intensive patients except through a cumbersome, now repealed, exceptions process.

The Congress has expressed its desire to revise the current ESRD payment system in section 422 of Pub. L. 106-554, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). The enactment of BIPA on December 21, 2000 greatly accelerated the need for research to determine whether a truly prospective system could be developed for ESRD payments, one which expands the bundle of routine services reflected in the composite rate to include separately billable laboratory tests and drugs.

In its March 2001 report, the Medicare Payment Advisory Commission (MEDPAC) questioned the appropriateness of the current composite rate payment system, and supported Congress’ directive to broaden the payment bundle in an expanded ESRD PPS.

MEDPAC issued four recommendations that are directly relevant to redesigning the ESRD payment system:

- The Congress should instruct the Secretary to broaden the composite rate payment bundle to include widely used services currently excluded from it. The Secretary should continue to emphasize quality monitoring and quality improvement efforts to ensure that patients have access to high-quality dialysis care.
- The Congress should instruct the Secretary to evaluate whether the composite rate's unit of payment—a single dialysis session—should be revised to reflect better the way dialysis is furnished.
- The Congress should instruct the Secretary to revise the outpatient dialysis payment system to account for factors that affect providers' costs to deliver high-quality clinical care, including dialysis method, dose, frequency, and patient acuity.
- The Congress should instruct the Secretary to develop a wage index based on market wage rates for occupations typically used in furnishing dialysis.

In order to move toward an improved system of payment that overcomes these limitations, CMS is investigating the feasibility of developing a redesigned PPS for outpatient renal dialysis services. Such a system could bundle routine dialysis related services with some or all of those that are currently separately billable, potentially target greater payments to facilities treating more costly patients through an empirically developed risk or case mix adjustment, provide incentives to encourage efficiency, establish payment levels which would promote desired clinical outcomes, and provide for a regular means of updating, recognizing inflation, variation in input costs, and other factors.

III. Goals of the Technical Expert Panel (TEP) Meeting

This first meeting of the TEP is intended to provide KECC with insights into how our research should proceed. Hence, *the overall objective of this meeting is for our research team to hear your thoughts on the research we should be conducting on behalf of CMS to facilitate its deliberations regarding recommendations on a revised bundled payment system*. To achieve this objective, we have structured the meeting to achieve a set of sub-objectives.

In the first part of the meeting (1 and 2 in the agenda), we shall describe our project and our key data sources. We will also review our preliminary analyses of cost and payment data. Our objectives here are:

1. To provide you with an overview of the project's history and objectives;
2. To provide you with information on the data we have identified as potentially useful;
3. To show you how we have used these data in preliminary analyses;
4. To get your impressions of the results of these preliminary analyses.

In the second part of the meeting (3-7 in the agenda), we'll build on the discussion of our preliminary analyses and policy options. We have developed a set of payment policy questions that we think drive research questions and therefore inform our research going forward. We will also continue our discussion of preliminary analyses by focusing on case-mix adjustment and templates for the analysis of the financial impact of payment redesign. Our objectives here are:

1. To present our list of payment policy questions;
2. To get your reaction to our list;
3. To have you add questions to our list;
4. To arrive at a consensus as to the key policy questions to inform our research;
5. To develop a research agenda relevant to key policy questions.

To stimulate your thoughts prior to the meeting, below is a partial list of policy questions we have developed:

1. What should be the basic unit of payment? Should it be the dialysis session? Should it be the patient-month? What are other alternatives? We might discuss the information necessary to support different approaches to the unit of payment. We would then discuss the research necessary to inform CMS about the feasibility of various approaches.

2. How should the payment system deal with patients who are relatively costly to care for? One approach is to employ a system to measure the severity of patient condition and to adjust payment for the cost implications of severity. Another, not necessarily mutually exclusive approach, is to employ an outlier payment system. This second approach might require a definition of routine care versus non-routine care. Our discussion might focus on (1) the importance of this policy question and (2) the research necessary to develop a fact basis for CMS in deciding what to recommend.

3. How might the system deal with incentives for underprovision or overprovision of services to patients? This question depends on the likely response of dialysis and other providers to changes in the payment system. What research should KECC do to assess these likely responses? What information might be used to measure provider responses to incentives once a new payment system is instituted? What quality assurance measures should be monitored?

4. Which services should be bundled? Should the bundle include items such as laboratory and vascular access services currently billed to Medicare Part B?

IV. Key Phase II Tasks

One major goal of this project is to provide the research necessary to update the elements that are included in the expanded PPS and the methods for adjusting the level of the PPS payment to reflect changes in the delivery of care. Research thus far has addressed a number of issues including variation in volume of services delivered (practice patterns)

among facilities, variation in costs among patients of different types, and variation in allowed reimbursements among fiscal intermediaries and carriers. Meanwhile, routine dialysis services are provided by independent laboratories, physicians, and other providers outside the outpatient setting. The potential for bundling payments for these services will also be considered.

Phase II of this research project is divided into three segments. We are currently completing the first segment, with preliminary findings summarized in this report. Segment 1 includes analyses for hemodialysis patients, who comprise the majority of dialysis patients, focusing upon EPO and other injectable drugs, which comprise the bulk of Medicare payments for separately billable services for dialysis and which are nearly always dialysis related.

For Segment 2, we expand our analyses in two potentially important directions: inclusion of laboratory services and coverage of peritoneal dialysis (PD) services. We will deliver a set of analyses permitting evaluation of multiple options for the establishment of a bundled PPS for ESRD service covering both HD and PD, where the options will reflect variation in the inclusion of EPOGEN (EPO), non-EPO injectable drugs, and laboratory services.

For Segment 3, we will deliver a set of analyses supporting the development of a monitoring system based on the attainment of specific clinical results. Our analyses will conclude with a recommendation on the structure of the monitoring system.

The achievement of the objectives of Phase II will be supported by the input and guidance of a Technical Expert Panel (TEP). The TEP is composed of persons with a range of expertise, including persons with clinical, managerial, policy, and academic perspectives.

V. Ongoing Analyses

Overview

An update on data processing and preliminary findings from ongoing analyses are provided below. Please note that all results that are included in this report should be considered preliminary. These results include descriptive data for the most current Medicare outpatient dialysis claims from July 2000 - June 2002 and dialysis facility cost reports from 2001. Other preliminary analyses have extended analyses performed during the Phase I study exploring the variability in both Medicare payments and costs per session among dialysis facilities and the role of patient case mix in explaining this variability. It will also be possible to use existing data resources to simulate the impact of alternative prospective payment systems on both patients and facilities.

Data Sources and Processing

The data sources used by KECC are described in detail in the Database Report that is included in the Final Report for Phase I of the PPS project. All analyses were carried out using data extracted by KECC through Data Use Agreements 9155 and 10671. The

analyses outlined in this report used data from Medicare Outpatient Claims (Version I) dated between July 2000 and June 2002 (from the Standard Analytical Files of June 2002 and March 2003, respectively), the Medical Evidence Form (CMS 2728, extracted on April 8, 2003), Freestanding Dialysis Facility Cost Reports (Renal Release 1.0, July 22, 2003), and Hospital Cost Reports (Release 1.0, May 8, 2003).

The KECC links, screens, cleans, and processes the data to create working analysis files. Dialysis-related outpatient claims for all ESRD patients from all dialysis providers are included in these analyses. Some of these ESRD patients also have Medicare bills from sources other than dialysis providers (e.g. hospital outpatient units), but the services listed on these claims were not dialysis-related, so these claims were excluded from these analyses. Similarly, bills indicating ESRD as a diagnosis (using the ICD 9 code for ESRD) but not including payments for dialysis-related services were excluded from these analyses. Dialysis-related services are identified for ESRD patients by billing source (bills of type 72X), revenue center codes, and HCFA common procedure coding system (HCPCS) codes. Data were cleaned to remove records that have impossible, misleading, or missing values for key variables. Descriptions of selected data are provided in this report.

Analyses focus upon ESRD patients receiving in-center hemodialysis treatments and injectable drugs. As described in the work plan for Phase II of this project, analyses planned for Segments 2 and 3 will include data for other patients and services, including peritoneal dialysis patients (though descriptive data on the number of peritoneal dialysis sessions are provided in this report) and other separately billable items such as lab services. Based upon meetings with the TEP, these analyses may be reprioritized.

Descriptive Statistics

Tables 1 through 3 provide descriptions of both patient and facility data used for the analyses presented in this report. Tables 1a-1b show the distribution of hemodialysis (HD)-equivalent dialysis sessions per patient-month (a calendar month in which one or more outpatient claims for dialysis-related services were identified for an individual patient) from January to June 2002. The vast majority (77-79 percent) of patient-months have bills for 12-14 dialysis sessions. When accounting for factors such as Medicare Secondary Payer, training, start of dialysis, hospitalization and death, which would explain lower numbers of sessions per month, 91 percent of patient months include bills for 12-14 sessions (Table 1b). Tables 2a-2d show trends in the counts of dialysis patients, sessions, facilities and payments by modality from dialysis-related outpatient claims. Patients, sessions, facilities, and payments are relatively consistent across years overall, as seen in Table 2a.

Table 3 reports costs for all freestanding facilities, freestanding facilities providing HD only, and hospital-based facilities during 2001. Data from hospital cost reports will have limited use in the current study.

Current Analyses of Case Mix

The possibility that case mix may explain some of the variation across facilities in Medicare payments and costs per session is being addressed through preliminary analyses at both the patient and facility level, further developing analyses that were presented in the final report of the Phase I project.

Facility-Level Regression Analyses

At the facility level case mix is measured as the percent of patients diagnosed with a given condition at start of dialysis (source: CMS 2728 form).

Methods

Average Medicare payments and costs per session were obtained for freestanding facilities. Dependent variables in multiple linear regression models include average costs per session, average payments per session, net income per session and payment to cost ratio. Separate models were estimated for all outpatient dialysis services as well as for composite rate and separately billable services, including EPO. Models were adjusted for wage index alone and wage index plus case mix. Wage indices were obtained from the Federal Register (Federal Register, July 31, 2001). Case mix variables that were aggregated from the CMS 2728 form included age, time since first dialysis, and several lab values:

- Hematocrit
- Serum albumin
- BUN
- Creatinine clearance
- GFR

The models also included the following comorbidities:

- Ischemic heart disease
- Myocardial infarction
- Cardiac arrest
- Cardiac dysrhythmia
- Pericarditis
- Cerebrovascular disease
- Peripheral vascular disease
- Diabetes
- Hypertension
- Chronic obstructive pulmonary disease
- Current smoker
- Alcohol dependence
- Drug dependence
- HIV
- AIDS
- Inability to ambulate
- Inability to transfer
- Weight

Results

Table 4 summarizes the results, through R-squared statistics, for a series of regression models that include successively more predictive factors. The R-square statistic measures the fraction of the variation in per session costs or payments that can be attributed to the predictive factors in the model. A higher value of R-square indicates that the costs or payments are more accurately predicted by the factors included in a model. The R-square statistic increases when more predictive factors are added to the model.

As expected, wage index alone explains most of the variation in composite rate payments (65 percent), but relatively little of the variation in any other payment measures (0 to 10

percent). Case mix accounts for an additional 2 to 10 percent of the variation among facilities.

Discussion

This analysis is an update of prior analyses that used a wider set of factors to predict variation in per session payments and costs. Further analyses will explore additional facility characteristics that may be considered for case mix adjustment (e.g. patient gender and race mix). The potential value of using other clinical diagnoses that are recorded at the time of service (e.g., a hospital stay) as additional case mix indicators are also being explored.

Patient-Level Regression Analyses

A separate set of analyses further explored the impact of case mix on variation in Medicare payments among both patients and facilities. While the unit of observation in this case is the individual patient and the predictor variables are patient characteristics, the approach that is used allows us to estimate both the magnitude of the patient-to-patient variation in payments that is explained by case mix, as well as the magnitude of the facility-to-facility variation in per session costs that remains after accounting for differences in case mix across facilities.

Methods

Payments were calculated using outpatient claims as described above. Patient case mix information was obtained from CMS 2728 form data. Case mix indicators included age, time since first dialysis, and the lab values and comorbidities listed above for the facility-level regression analyses. Wage indices were obtained from the Federal Register (Federal Register, July 31, 2001). Facility characteristics, including chain, hospital-based versus freestanding, profit status, facility size, region, and urban/rural classification were obtained from the database used to generate the annual Dialysis Facility Reports.

Random effects mixed models were used to estimate the variability in payments among both patients and facilities. These models were also adjusted for 1) wage index alone, 2) wage index and case mix, and 3) wage index, case mix and facility characteristics. Separate models were estimated for major groups of outpatient services.

Results

Table 5 reports estimates of the patient-to-patient variation in payments per session that is explained by factors such as case mix that are included in the model (labeled “Predicted patient variation”) as well as the facility-to-facility variation in payments per session (labeled “Facility variation”) and the variation that remains *unexplained* after accounting for the factors in the model (labeled "Unexplained variation within facilities"). Only $0.02 of the variation in separately billable payments per session is explained by differences in the wage index, while $6.65 per session is a result of case mix differences (i.e., $6.67-0.02=6.65). An additional $2.99 is explained by facility characteristics (i.e., $9.66–6.67=2.99). Similar results hold for EPO, the largest component of separately billable items. There is notable facility-to-facility variation in payments for separately billable services. The amount of variation attributed to the facility (random effect)

decreases as case mix is added, whereas the variation attributed to the patient (fixed effects) increases, suggesting that patient case mix does account for facility-to-facility variation in payments per session.

Discussion

This preliminary analysis demonstrates one approach to measuring the magnitude of both the patient-to-patient and facility-to-facility variation in payments that can be attributed to differences in patient case mix. Comparison of the parameter estimates for the covariates included in both the patient- and facility-level analyses will provide validation of the case mix adjustment factors at either level. Facility-to-facility variation in payments or costs that can be attributed to case mix differences is one factor to be considered in developing options for a new bundled PPS, whether at the patient or the facility level. These analyses are ongoing, and we anticipate that input from the TEP will be helpful in developing these analyses further.

Evaluating the Impact of Proposed Payment Methods: Costs Versus Payments

Using existing payment and cost data, the potential financial impact on dialysis facilities of implementing an alternative PPS that might include a broader bundle of dialysis services can be evaluated. This would include comparisons of average costs and average payments at the facility level under both the current payment system and any proposed payment systems. The impact of payment reform on the variation in average reported costs, average payments, and average net income across facilities could also be evaluated based in part on existing data.

Methods

Costs and treatment counts for freestanding facilities were obtained from calendar year 2001 cost reports and were used to calculate costs per session. Since only aggregate data are reported in the cost reports, this calculation was based upon all dialysis sessions, both Medicare and non-Medicare. Payments per session were calculated using payments and treatment counts for these facilities obtained from Medicare outpatient claims (Version I) for the same time period, assuming recovery of the entire patient co-pay responsibility. Groups of services that are reported in the cost reports include all dialysis services, composite rate services, separately billable services, and EPO. Costs per session for each group of services were then subtracted from payments per session to yield the net income for each facility for Medicare covered services. The net income was also calculated under the assumption that each facility would receive the average payment but accrue costs as usual. Spearman Correlations were used to validate the correspondence between the cost report data and the payment data.

Costs Versus Payments

In Tables 6a and 6b, results of the Spearman correlations show that the number of treatments reported in the cost reports are highly correlated with the number of dialysis sessions for which Medicare paid during 2001 for each facility ($r=0.97$, $p< 0.0001$). This is an encouraging validation of the cost report and billing data. However, the total costs reported under the current system do not correlate highly with the total payments ($r=0.41$,

$p<0.0001$). The reason for this is apparent. Total costs are made up of composite rate costs and costs for separately billable services. As shown in Tables 6a and 6b, composite rate costs are poorly correlated with composite rate payments ($r=0.17$, $p< 0.0001$), while separately billable costs are highly correlated with separately billable payments ($r=0.78$, $p< 0.0001$).

Table 7a documents the variation across facilities in reported costs per dialysis session, while Table 7b documents the variation in payments per session. On average, freestanding facilities report costs of $214.66 per dialysis session and collect payments of $208.91 from Medicare patients (assuming full recovery of patient co-payments). However, there is substantial facility-to-facility variation in both average costs and average payments, especially for separately billable services.

Table 8 provides a preliminary template that can be used to evaluate the financial impact of various bundling options or payment systems. Estimates of the average net income as well as the distribution of net income among facilities under both the current payment system and a proposed payment system can be compared using Table 8. This would allow for an assessment of the change in the variation in net income among facilities that is expected under a proposed payment system.

The distribution of the impact (i.e., the difference in net income between the current system and a proposed system) can also be described for various subgroups of facilities. For example, the impact of a proposed change in the PPS can be evaluated to detect differences by facility size, profit status, or urban/rural classification. In addition, regression models can examine the simultaneous relationship between net income and several facility characteristics.

Recommendations for Further Analyses Involving Alternative Payment Approaches

Modeling the effects of different payment approaches on payments and net income for various types of dialysis providers is essential to inform policy concerning the new bundled payment system. This modeling is done assuming budget neutrality. Many routine dialysis-related laboratory and supply services as well as vascular access services are currently covered by other Medicare payment systems. The inclusion of these services in a new bundled payment may be problematic. The extent to which the payment systems may overlap will be evaluated.

Payment approaches that will be evaluated over the course of Phase II include the following:

1. Elimination of wage index floor and ceiling
2. Inclusion of EPO
3. Inclusion of EPO and other drugs
4. Inclusion of all outpatient separately billable services
5. Inclusion of case mix adjustment (with and without race and gender)
6. Inclusion of Physician/Supplier laboratory services and supplies

7. Inclusion of Vascular Access from Outpatient, Physician/Supplier, and Inpatient sources

The viability of each of these approaches remains a topic for discussion with CMS and with the TEP. We will continue to investigate the many facets of the proposal to bundle payments for outpatient dialysis-related services.

[1] See May 11, 1983 Federal Register at 48 FR 21262.