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END STAGE RENAL DISEASE PAYMENT SYSTEM:

RESULTS OF RESEARCH ON CASE-MIX ADJUSTMENT FOR AN EXPANDED BUNDLE

FEBRUARY 2008

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RESEARCH UNDER CONTRACT NO.

HHSM-500-2006-00048C

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Executive Summary

The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC), under contract to the Centers for Medicare and Medicaid Services (CMS), performed research to inform the design and specification of an expanded prospective payment system for end stage renal disease (ESRD) dialysis services as mandated in the Medicare Prescription Drug and Modernization Act of 2003 (1). UM-KECC has developed a model payment system that is described in this report.

A. BUNDLE OF SERVICES

To test the feasibility of developing and implementing a prospective payment system that encompasses the entire bundle of outpatient ESRD dialysis services, a specific bundle of services was selected in consultation with CMS as the basis of most of the analyses. The bundle definition employed includes services that are currently reimbursed through the composite rate system and the following types of services that were billed separately by either dialysis facilities or other providers on Medicare claims:

- Injectable drugs billed by dialysis facilities (including erythropoiesis stimulating agents, iron, vitamin D analogs, commonly used parenteral antibiotics, alteplase)
- Laboratory services
  - Billed by freestanding laboratory suppliers and ordered by physicians that received monthly capitation payments for treating ESRD patients, or
  - Billed by the dialysis facilities
- Other services billed by dialysis facilities (e.g. dialysis supplies)

B. DATA SOURCES

The descriptive statistics, case-mix models and other analyses used in this report are based primarily on CMS claims files for Medicare dialysis patients and the Medicare Cost Reports for dialysis facilities. Resource utilization for separately billable services was based on patient level Medicare outpatient claims for the years 2001-2005. Since composite rate cost information is available only at the facility level, resource utilization for composite rate services was measured using the Independent Renal Dialysis Facility Cost Reports and Hospital Cost Reports. The most complete current annual cost report data were available through 2004. Case-mix models for both separately billable items and composite rate costs, which are described in detail in this report, use Medicare claims and Cost Reports for the years 2002-2004.

Several data sources were used to measure patient and facility characteristics. These data sources include the Medicare Enrollment Database and the CMS Medical Evidence Form (CMS Form 2728), which is completed at onset of renal replacement therapy. Patient body size measures were derived from the height and weight values reported on CMS Form 2728. Patient comorbidities were measured using a combination of CMS Form 2728 and diagnoses reported on Medicare claims. The claims diagnoses were used both to identify comorbidities that were not abstracted using CMS Form 2728 and to capture changes in patient condition since the start of renal replacement therapy. Dialysis facility characteristics were measured using a combination of the ESRD Standard Information Management System (ownership type and geographic location), the Medicare Cost

Reports (facility size), the Online Survey and Certification and Reporting System (hospital affiliation for satellite units) and other information obtained from CMS (composite rate payment exceptions).

C. STRUCTURE OF CASE-MIX MODELS

As noted above, the level at which resource use can be measured differs for the two principal components of an expanded bundle. Given the available patient level data on resource use for separately billable services and facility level data on resource use for composite rate services, a modeling approach could be based on either one or two estimating equations:

- Two equation approach: Facility level model for composite rate services and patient level model for separately billable services
- One equation approach: Facility level combined model for composite rate and separately billable services

By utilizing patient to patient variation in both case-mix and resource use, a patient level model for separately billable services has the advantage of reducing potential bias related to unobserved facility characteristics, producing more precise coefficient estimates and yielding greater stability in coefficient estimates over time. Further, a patient level model for separately billable services can be combined with a facility level model for composite rate services to yield a single payment model for an expanded bundle. A two equation modeling approach was therefore used in examining potential risk adjusters for use with an expanded prospective payment system.

D. CASE-MIX VARIABLES

Evaluation of patient characteristics for use as case-mix variables in the models began with the CMS Form 2728 comorbidities, demographics, and anthropometrics to which previously defined comorbidity categories developed for the Medicare Advantage managed care project were added. Patient characteristics were considered for inclusion in our models based on the magnitude and statistical significance of relationship to cost (composite rate costs and dialysis separately billable Medicare Allowable Payments), the potential for adverse incentives, and social acceptability. Whenever possible, the list of potential case-mix variables identified as having statistically significant associations with cost was refined by combination of clinically similar comorbidity categories having similar effect on cost. Several patient comorbidities having statistically significant, low magnitude association with cost in our preliminary models and additional comorbidities with ambiguous definition, high prevalence, or both, were excluded to facilitate development of a parsimonious case-mix model. The refined list of case-mix comorbidities were evaluated for persistence of effect on cost. These analyses allowed identification of acute or short-lived cost associations for some case-mix categories and chronic or long-lived cost associations for others. Time-specific case-mix variable definitions were used in the models reported in Table A below and in the body of this report.

E. CASE-MIX ADJUSTED MODELS

The table below illustrates the potential case-mix adjusters, their estimated multipliers based on a two equation approach, and a single payment multiplier for each patient characteristic based on its relationship to resource use for both composite rate and separately billable services.

Table A. Modeled case-mix adjustment for an expanded bundle (EB) of composite rate (CR) and separately billable (SB) services

	Estimated case-mix multipliers based on a two equation model				Modeled case-mix adjustment*
	Composite rate services		Separately billable services		
Variable	Multiplier	P value	Multiplier	P value	Multiplier
Age <18	1.421	<.0001	0.449	<.0001	1.091
Age 18-44	1.314	<.0001	1.005	0.0626	1.209
Age 45-59	1.014	0.6951	0.991	<.0001	1.006
Age 60-69	1.000	reference	1.000	reference	1.000
Age 70-79	1.059	0.0929	0.962	<.0001	1.026
Age 80+	1.230	<.0001	0.931	<.0001	1.128
Female	1.049	0.0315	1.163	<.0001	1.088
Body surface area (per 0.1 m^2)	1.034	<.0001	1.038	<.0001	1.035
Underweight (BMI <18.5)	1.066	0.3059	1.031	<.0001	1.054
Duration of renal replacement therapy: <4 months	1.605	<.0001	1.445	<.0001	1.551
Alcohol/drug dependence (any)	1.121	0.0003	1.125	<.0001	1.122
Cardiac arrest: (any)	1.000^	n.s.	1.090	<.0001	1.031
Pericarditis (from 0-3 months ago)	1.000^	n.s.	1.609	<.0001	1.206
HIV/AIDS (any)	1.000^	n.s.	1.125	<.0001	1.042
Hepatitis B (any)	1.000^	n.s.	1.041	<.0001	1.014
Septicemia (from 0-3 months ago)	1.071	0.0052	1.701	<.0001	1.285
Bacterial pneumonia and other pneumonias/opportunistic infections (from 0-3 months ago)	1.000^	n.s.	1.469	<.0001	1.159
Gastrointestinal tract bleeding (from 0-3 months ago)	1.000^	n.s.	1.884	<.0001	1.300
Hereditary hemolytic or sickle cell anemias (any)	1.000^	n.s.	1.155	<.0001	1.053
Cancer since 1999 (any diagnosis, excluding non-melanoma skin cancer)	1.000^	n.s.	1.088	<.0001	1.030
Myelodysplastic syndrome (any)	1.000^	n.s.	1.280	<.0001	1.095
Monoclonal gammopathy (any)	1.382	0.0009	1.099	<.0001	1.286

*The case-mix multipliers for an expanded bundle were calculated as 0.661*Composite Rate Multiplier + 0.339*Separately Billable Multiplier.
^A multiplier of 1.000 is used for factors that were not determined by regression to have a statistically significant association with measures of resource use.

The payment multipliers in the third column of Table A ($Mult_{EB}$) were calculated as the weighted average of the composite rate and separately billable multipliers. The weights that were used reflect each component's proportion of the total estimated costs, so that the resulting case-mix adjustment reflects the overall relationships between patient characteristics and estimated costs for an expanded bundle of services.

The payment multipliers reported in Chapter IX, A Combined Case-mix Adjusted Model for Composite Rate and Separately Billable Services, can be used to derive case-mix adjusted payment rates for individual patients. The principal step is to calculate a patient specific multiplier. The patient multiplier is then applied to a wage-adjusted base rate to calculate the per session payment. If additional payment adjustments are needed to account for outliers, they are made once the per

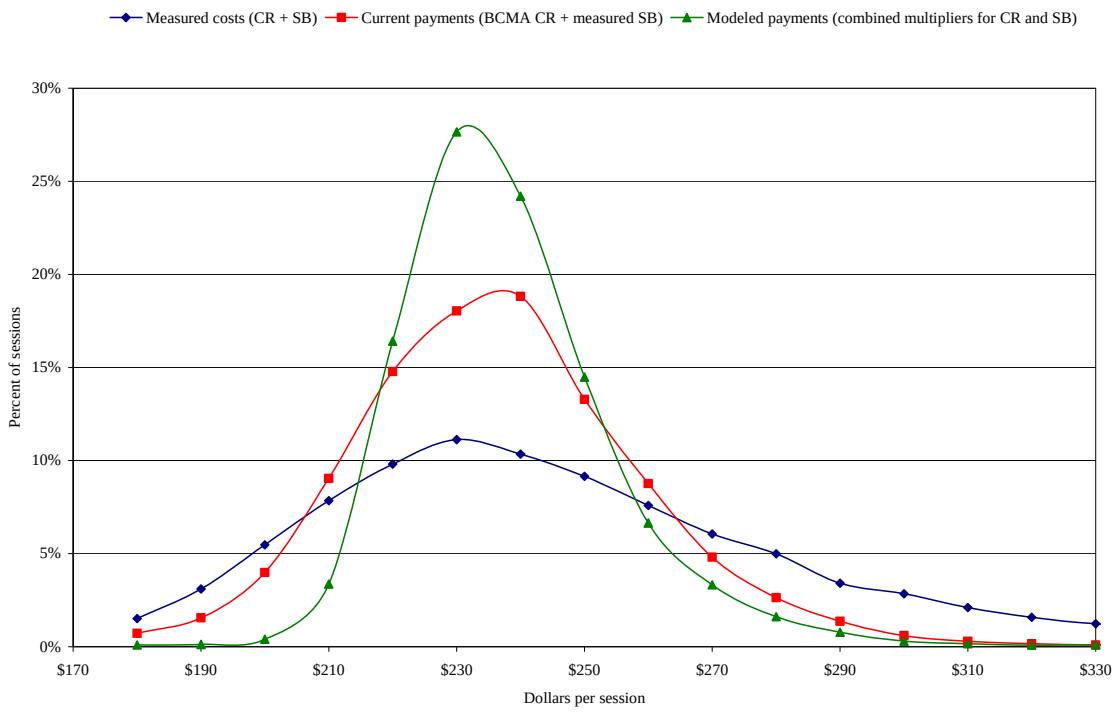
session rate has been determined.[1] Given the limited ability of patient characteristics to explain differences in cost across patients and facilities, exploration of an outlier payment mechanism may be advisable. One possible mechanism pays facilities a fraction of their costs for injectable medications and laboratory tests to the extent that those costs exceed a threshold. Less than 1% of total payments to dialysis facilities would be devoted to this hypothetical outlier payment system, and it would result in a meaningful decrease in the risk to facilities' revenues due to very high cost patients. Examples of the application of this modeling approach and outlier mechanism can be seen in Chapter XI, Hypothetical Examples of Case-mix Adjusted Payment Calculation.

F. IMPACT ANALYSIS

Figure 1 shows the distribution of current measured costs, current payments, and modeled payments per dialysis session. The variation in modeled payments is much lower than the variation in measured costs and current payments. This reduction is due to the current bundling of composite rate services and the substantially lower variation in composite payment rates compared to costs across facilities. The variation in the modeled payments is also lower than the variation in the current payments. Most of this reduction is explained by expanding the payment bundle to include separately billable services instead of reimbursing facilities separately. These comparisons reflect differences among measured costs, current payments, and modeled payments, not the fit of the statistical models.

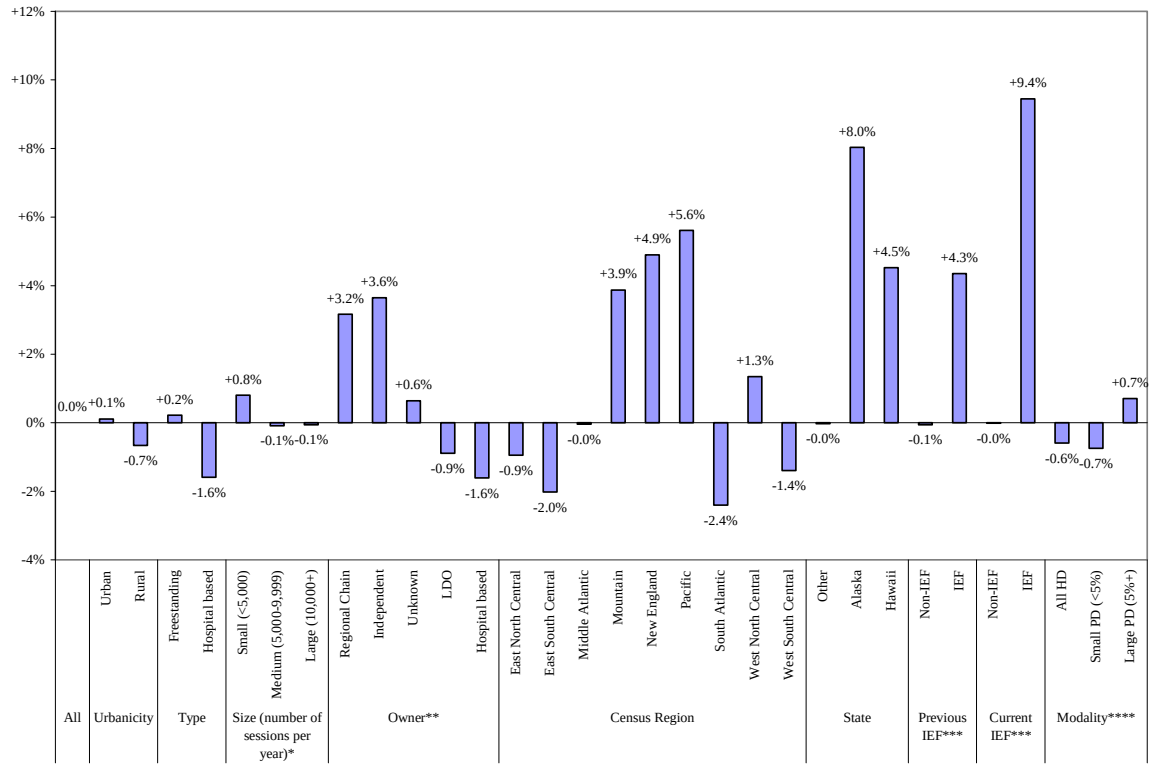
[1] Another budget neutrality adjustment is necessary to reflect the fact that the average patient multiplier adjustment is larger than 1 or for potential outlier adjustments for very high cost patients.

Figure 1
Frequency distributions of measured costs, current payments, and modeled payments per dialysis session, 2002-2004



The predicted cost per session for an expanded bundle explained 34 percent of the variation in the measured cost per session. Facility control variables accounted for 31 percent of the variation, while the included patient characteristics contributed an additional 3 percentage points to the R-squared. Figure 2 shows the average change in the per session payments to different types of dialysis facilities. The overall average change is constrained to be zero. In other words, both systems use the same number of facilities, the same number of dialysis sessions, and the same total dollars. Each facility type has an average change of less than 6%, except for the small groups of facilities in Alaska (4 facilities, represented by 6 facility-years) and those currently receiving composite rate exception payments as isolated essential facilities (4 facilities, represented by 10 facility-years).

Figure 2
Average change in payments to facilities per dialysis session, 2002-2004



* Number of sessions from the facility cost report where available. Otherwise, source was annual facility survey (432 facility-year records) or sum of sessions from claims (106 facility-year records).
** Of the 1,378 facility-year records reporting hospital based status, 57 also indicated form of ownership (e.g., LDO or regional chain). Those 57 records were included with the reported ownership categories. The remaining 1,321 facility-year records for hospital based units without ownership information are presented as a separate category.
*** Isolated essential facilities: the previous IEF category includes facilities that recently gave up their special payment rate and facilities continuing to receive a special payment rate. The current IEF category includes only facilities that continue to be paid their special rate. The current IEF category is a subset of the previous IEF category.
**** Excludes 93 facility-year records where information on modality was unavailable.

Urban facilities, freestanding facilities, facilities with fewer than 5,000 sessions per year, facilities owned independently, facilities owned by a regional chain, facilities with unknown ownership, facilities designated as isolated essential facilities, and facilities that provide a relatively large amount of peritoneal dialysis tend to have higher payments in the model system compared to the current system. On the other hand, rural facilities, facilities with at least 5,000 sessions per year, facilities owned by a large dialysis organization, facilities not designated as isolated essential facilities, and facilities that provide little or no peritoneal dialysis tend to have lower payments in the model system compared to the current system. Hospital based facilities also receive a $3.89 lower payment under the model system, assuming the current $4 payment differential between hospital based and freestanding facilities built into the composite rate system does not continue.

Facilities in the East North Central, East South Central, South Atlantic, and West South Central census regions tend to have lower payments in the model system when compared to the current system.

G. IMPLEMENTATION ISSUES

A key policy decision is whether to pay facilities per dialysis session or per month. This report presents an analysis of the merits of both units of payment, as well as methods of implementing both. A monthly payment system has a conceptual advantage of enhancing flexibility in treatment schedules, but introduces additional complications involving accounting for partial months of outpatient dialysis (e.g., months of hospitalization) and for patients treated at multiple facilities (e.g., patients who switch facilities, or receive transient treatments while traveling).

Other issues regarding the implementation of case-mix adjusted payments for an expanded bundle include increased data reporting requirements and contracting between services providers. Continued reporting of key utilization and outcome measures should be required to facilitate quality monitoring and evaluating and updating the proposed payment system. Attention should focus on the regulatory specification of definitions and reporting guidelines for the patient comorbidities used as payment adjusters.

A payment system including an expanded bundle of services changes the incentives facing dialysis providers. This report discusses incentives and provides some suggestions for managing incentives, including quality monitoring and pay-for-performance systems. The construction of the potential payment model has attempted to account for the potential for adverse incentives (e.g., over-reporting of nebulously defined comorbidities, indirectly rewarding providers for poor outcomes), but care should be taken to continue monitoring for adverse incentives, and to revise the payment model as necessary.

H. CONCLUSION

Building an expanded prospective payment system for renal dialysis-related services is possible given existing CMS data. A case-mix adjustment model is also feasible using existing data. Development of an outlier payment mechanism should be considered to ensure that those patients who require extraordinary resources to achieve appropriate clinical outcomes are not disadvantaged by the payment system. In addition, the model presented in this report should not be applied to pediatric patients. Several implementation challenges exist, and, following implementation, ongoing monitoring of comorbidity reporting, provider costs, access to care, quality of care, and new technologies is crucial.

I. INTRODUCTION

The Medicare Prescription Drug and Modernization Act of 2003 (MMA-2003) (1) required both the development and implementation of a basic case-mix adjustment for the composite rate payment system for outpatient dialysis and the design and demonstration of a fully case-mix adjusted bundled ESRD payment system. The Centers for Medicare and Medicaid Services (CMS) contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to examine potential case-mix adjustments for composite rate payments that consist of a "limited number of patient characteristics" in accordance with the MMA 2003. A methodology to apply a basic case-mix adjustment to composite rate payments was developed, and was implemented on April 1, 2005 (2).

In addition to the short term basic case-mix adjustment to the existing bundle of composite rate services, the statute requires a Report to Congress that delineates the elements and features for the design and implementation of a fully bundled ESRD prospective payment system (PPS). This report is in support of that Report to Congress. The methods and elements examined in this report may also serve as the basis for the mandated three-year demonstration of a fully case-mix adjusted bundled ESRD PPS.

A. PURPOSE OF THIS REPORT

The purpose of this report is to describe legislative and administrative options for design of a fully bundled ESRD PPS that encompasses the entire bundle of outpatient ESRD dialysis services, excluding vascular access, furnished to Medicare beneficiaries. The report is based on work by CMS's Center for Medicare Management and by its contractor, UM-KECC. This report builds on research that has been conducted in several phases over the period 2001-2007. Earlier phases of this research explored the feasibility of using available data to develop a fully bundled ESRD PPS (3,4,5) and supported the development and evaluation of a basic case-mix adjustment for the composite rate system (6,7,8,9). Recent work has examined factors that affect the cost of outpatient ESRD services to support the development of case-mix adjustment methods for a fully bundled ESRD PPS (10,11,12,13,14). The overall goal of this multi-phase project is to suggest and develop improvements to the current Medicare payment policy for outpatient ESRD care.

In the broadest terms, the objectives for a revised dialysis payment system are to promote the delivery of high quality dialysis related services, economic efficiency in the delivery of these services, and sufficient reimbursement to health care providers to ensure that an efficient provider can deliver high quality services. Accomplishing these sometimes conflicting objectives requires a careful analysis of the workings and shortcomings of the existing payment system, an analysis of how well existing data are able to inform decisions about the costs incurred by an efficient provider delivering high quality services, and analyses of the relationships between dialysis modality, case-mix, and costs. These analyses are required to devise a system that ensures access to quality care for more complex patients and ensures equitable reimbursement to those facilities that serve them.

Currently, the Medicare ESRD system provides reimbursement for selected outpatient dialysis services under a prospective composite rate payment system ($4.8 billion in 2005), while providing reimbursement for other separately billed outpatient ESRD services through a fee-for-service system ($3.1 billion in 2005). Broadening the bundle of services included in the composite rate can simplify the billing process and remove incentives for excessive use of separately billable services. However, broadening the bundle necessitates increased attention to quality assurance measures to ensure that

the expanded outpatient ESRD PPS does not result in an inappropriate reduction in the use of some services that were formerly billed separately (e.g., erythropoiesis stimulating agents (ESAs)). Further, case-mix adjustments may be important in designing equitable reimbursement levels for dialysis providers. Finally, a broader bundle makes facility revenues more predictable, but also places facilities at risk for the costs of providing a wider array of services to a variety of patients. If the risks are substantial, particularly for small, independent facilities who cannot allocate the risk of unusually costly outliers over many patients, a mechanism to incorporate outlier payments into an expanded outpatient ESRD PPS might be warranted.

The information presented will help determine the feasibility of an expanded ESRD PPS which reflects the costs of appropriate treatment for patients with different clinical characteristics and includes all outpatient dialysis services, drugs, laboratory services, and supplies.

II. GENERAL CONSIDERATIONS FOR PROGRAM DESIGN

The key issue in defining a bundle of services to be paid prospectively is to ensure the creation of incentives for the efficient delivery of high quality care and to avoid incentives for inappropriate or inefficient actions by providers. The decision about any set of services included or excluded from a bundle definition necessarily involves balancing competing objectives. For example, including a broad set of services in a bundle creates desirable incentives for efficiency but may require a system to monitor use of services or the concurrent implementation of pay-for-performance (P4P) incentives to avoid undesirable limitations to care. Before we present data analyses in subsequent sections of this report, conceptual issues are considered here.

A. BREADTH OF SERVICE BUNDLE

The first consideration is the breadth of bundled services in two crucial and interrelated dimensions: 1) the clinical indication for which the service is used, and 2) which providers order and deliver the service. In terms of clinical indication, the narrowest bundle definition incorporates only services directly related to the delivery of dialysis sessions. Such a definition, which closely approximates the existing composite rate bundle, excludes care for other conditions (e.g., anemia) even if they are closely associated with ESRD. Broader definitions include conditions that are very common in ESRD patients and the broadest definitions bundle services for the treatment of a wide variety of non-ESRD comorbidities. At the extreme, full capitation would pay the dialysis unit, a physician, or some other provider to take responsibility for delivery or financing all of the patient's medical care, regardless of the clinical indication. Note that as the list of clinical indications and related services is expanded, the question arises as to which provider is the most appropriate locus for the bundled payment and hence the management of care. In the case of the narrow bundle definition, with focuses on direct dialysis sessions, the recipient of the bundled payment is most certainly the dialysis unit. Broader definitions of the bundle make it possible to consider a nephrologist or other physician, or perhaps another type of provider or health care financing organization (e.g., insurer, managed care plan) as the recipient of the bundled payment and therefore the manager of the care.

In terms of providers, the narrowest bundle definition includes only services delivered in the dialysis unit. With this definition the dialysis unit is not responsible for any services delivered elsewhere. A slightly broader definition includes services routinely ordered by the nephrologist who receives the

Medicare monthly capitation payment for the patient's dialysis related, outpatient care, even if those services are performed outside the dialysis unit (e.g., laboratory tests). A yet broader bundle definition adds more services performed in the dialysis unit, but not directly or routinely related to the dialysis session itself or to the care of mainly ESRD related services, and additional services provided elsewhere in the health care system (e.g., imaging or procedures related to vascular access).

When a service is included in the bundle, an additional decision must be made as to how a bill for that service submitted by a provider other than the dialysis unit should be handled. One option is to define the service as part of the ESRD bundle, regardless of where it is provided. This option effectively disallows billing by other providers and requires payment arrangements between the dialysis facility and other providers. A second option is to prohibit separate billing by dialysis units for a given service in the bundle, but to continue to pay claims from other providers. Disallowing billing by other providers results in greater administrative complexity for the dialysis units who have to manage the prospective payment and places dialysis units at risk of being held responsible for services for which they have little control. In addition, patient access to needed care could be inappropriately restricted. However, to allow billing from other providers places CMS at risk of paying twice for the same services if dialysis units collect the prospective payment that presumably includes specified services while arranging for other providers to actually deliver and bill for them. Similarly, to allow other providers to bill separately places patients at risk of receiving fragmented, uncoordinated care. Hence, some of the most difficult decisions of bundle design involve services that are often prescribed by dialysis units for ESRD related purposes, but are also prescribed by other providers in the community for non-ESRD related purposes.

A second consideration is the existing pattern of utilization by renal dialysis patients. A service is an ideal candidate for bundling if it is widely used at consistent frequencies in the ESRD population. For example, a laboratory test performed on every patient on a fixed quarterly time interval could be paid prospectively without creating any risk for the provider and saving the administrative costs of submitting and processing four annual claim line items. However, services that are used inconsistently, either in terms of the percentage of patients who use them or in terms of the frequency of use among those patients who receive them, should not necessarily be excluded from the bundle. Many of the objectives of bundling are best achieved by including a broad range of services. Therefore, a supportable working assumption is that dialysis services should be included in the bundle unless there are strong grounds for their exclusion. Inclusion of services should be strongly considered if at least one of two criteria is met. The first is concern that services are being overused for some patients or by some providers. The change in incentives from the existing fee-for-service (FFS) billing to a prospective system may encourage efficiency and allow payments to be reduced. Second, even if service use varies across patients in a way consistent with appropriate clinical care, the service could be bundled if the financial risk to providers is limited and case-mix adjustments to the prospective payment system are developed to sufficiently limit the risk to providers and creates incentives to treat patients whose care is more costly than average.

Consequent to these concerns, metrics to assess the risk faced by providers under alternative bundle definitions and alternative case-mix adjustment systems are being developed and assessed by UM-KECC. The most important of such metrics is the distribution of gains and losses under a hypothetical budget neutral, bundled payment system relative to the existing FFS system. In order to assess the ability of payment systems to account for the risk of patients who are more costly than average, gains and losses are calculated at several levels of aggregation, which include the patient month, the patient year, and the facility year.

These conceptual considerations will be made operational through analysis of data on utilization patterns in the historical Medicare claims. Effectively, using historical data to forecast the cost of services included in a bundle relies on the strong assumption that costs under a prospective, bundled

payment system will remain similar to those in the historical FFS system. This assumption may be violated due to the time lag in the availability of complete claims files, which implies that recent trends in utilization patterns will not be reflected in the available data. Similarly, changes in the payment system (e.g., the new method of pricing injectable medications implemented by CMS on January 1, 2005) and subsequent changes in utilization would not be reflected in pre-2005 data. Such payment changes could be simulated using the historical data. Perhaps more importantly, the assumption would be violated if, as expected, providers reduce utilization below historical rates in response to the incentives created by prospective payment. The extent of such changes in behavior would be difficult to forecast.

An alternative approach may help address these limitations, at the cost of being less well-grounded in broad, national claims data. Expert opinion could be sought to determine the level of services that would constitute good quality of care. For example, care prescribed in order to comply with widely accepted clinical guidelines (e.g., KDOQI) or therapy targets (e.g., anemia management criteria) could be assessed. To base payments on historical claims data (vs. expert opinion on clinically appropriate care) has several advantages and disadvantages. Historical usage can readily be determined with Medicare claims data and may appropriately reflect a mix of practice patterns where patient needs vary or clinical guidelines are not well established. However, historical usage may not reflect current practice or represent clinically ideal care, and data for services not currently covered by Medicare are not available.

Measures based on expert opinion of clinically appropriate care also have several pros and cons. Clinical guidelines which define best practice recommendations for the care of chronic dialysis patients are available from diverse sources. These guidelines include practice guidelines from USA based organizations as well as several international efforts. Most utilize standardized literature review by medical expert panels to define practice guidelines based on consensus expert opinion, although at least one source of practice pattern information comes from an ongoing international, prospective, observational study (Dialysis Outcomes and Practice Patterns Study (DOPPS)). Although there is substantive agreement among these various guidelines, differences remain. Some of these differences likely relate to the varied reimbursement policies, political and cultural variation and differences in patient population and comorbid condition distribution from country to country. Additionally, many best practice recommendations have been made without adequate evidentiary support, given the lack of adequate clinical trials in many areas. Expert opinion could be used to establish adequate reimbursement for ideal care if even the ideal is not reflected by current practice or available evidence in the medical literature. However, such an approach may include services that are not currently covered by Medicare, may not be budget neutral, and may result in practices ultimately shown to be ineffective as data from ongoing and future research becomes available.

B. BEHAVIORAL RESPONSES CREATED BY BUNDLING

Any change in the method by which dialysis units are paid will affect their incentives in terms of care delivery and patient selection. As a practical matter, several types of behavioral responses should be considered, with appropriate monitoring and data collection to assess their magnitudes and ensure access to care and the delivery of appropriate services to the dialysis population. Substitution of services excluded from the bundle for those included is one behavioral response. For example, if only one antibiotic that could be used to treat a specific type of infection is included, providers would have a strong incentive to circumvent the intent of bundling by substituting an alternative antibiotic that could still be billed separately from the bundle. Consequently, when several services or drugs are close clinical substitutes, it is advisable to include all or none in the bundle. In many cases, the set of close substitutes can readily be identified (e.g., all antibiotics in a particular drug class for the

treatment of a specified type of infection; EPO, iron and blood transfusions for the treatment of anemia). In other cases, it may be more difficult to specify the set of substitutes (e.g., laboratory tests performed for a variety of indications).

Similarly, involvement of multiple providers has the potential to create administrative burdens and risks. Even a nephrologist caring for a unit's patients is not under the control of the unit. However, unit wide protocols for high cost care such as anemia management developed in conjunction with the medical director, other nephrologists, and nursing staff are likely to influence physician practice and/or limit physician autonomy, thereby limiting the risk that units will be held financially responsible for decisions they can not control. Services provided outside the dialysis facility and ordered by physicians other than the nephrologist are likely to pose greater risks that the unit will be held financially accountable for clinical decisions partially or totally outside their control. Certain services currently provided by dialysis units, but not essential to the core of ESRD related care, might by offloaded to other providers in the community if they remain separately billable by other providers. In particular, the dialysis unit might now serve as a collection point for specimens needed for laboratory testing for a variety of conditions. Patients benefit from such a practice both in terms of convenience and because it may preserve vascular access sites by protecting them from unnecessary venipuncture. In such cases, it may be advisable to continue to allow separate billing to avoid creating an incentive to take services out of the unit.

C. SERVICE BUNDLE VALUATION

To identify and measure the utilization of services that may be added to the PPS bundle, several decisions must be made. To ensure that payment is adequate to cover the actual costs incurred by providers, it is ideal to measure the cost of the inputs required to deliver each service in an efficient manner (e.g., labor costs, drug acquisition costs). However, available claims data reliably include Medicare payments, from which we calculate the Medicare Allowable Payments (MAP). Use of such a calculation to determine the payment to include the service in a bundle implicitly assumes that MAP is a reasonable proxy for the cost of providing the service (plus a sufficient mark-up to allow the provider an adequate rate of return on their investment). Alternatively, the utilization data derived from Medicare claims can be multiplied by a price other than the historical MAP if it is believed the alternative price is a better proxy for cost. For example, the changes in drug reimbursement implemented on January 1, 2006, could be incorporated in this manner.

III. OVERVIEW OF DATA SOURCES

Although CMS provides and UM-KECC maintains several comprehensive ESRD databases (see Appendix A), the descriptive statistics, case-mix models and other analyses used in this report are based primarily on Medicare claims for Medicare dialysis patients and the Medicare Cost Reports for dialysis facilities. Resource utilization for separately billable services was based on patient level Medicare outpatient claims for the years 2001-2005. Since composite rate cost information is available only at the facility level, resource utilization for composite rate services was measured using the Medicare Cost Reports for each facility. As of the date of this report, the most complete annual cost report data were available from Healthcare Cost Report Information Systems (HCRIS) through 2004. Case-mix models for both separately billable items and composite rate costs, which are described in greater detail in a later section, use Medicare claims and Cost Reports for the years 2002-2004.

Several data sources were used to measure the patient and facility characteristics that were used in the case-mix analyses. Patient demographic information was obtained from the Renal Management Information System (REMIS)/Consolidated Renal Operations in a Web-Enabled Network (CROWN) and the ESRD Standard Information Management System (SIMS). These data sources include the Medical Evidence Form (CMS Form 2728), which is completed at onset of renal replacement therapy (RRT). Patient body size measures were derived from the height and weight values reported on CMS Form 2728. Patient comorbidities were measured using a combination of CMS Form 2728 and diagnoses reported on Medicare claims. The claims diagnoses were used both to identify comorbidities that were not collected by using CMS Form 2728 and to capture changes in patient condition since the start of renal replacement therapy. Dialysis facility characteristics were measured using a combination of SIMS (ownership type and geographic location), the Medicare Cost Reports (facility size), Online Survey, Certification and Reporting (OSCAR; hospital affiliation for satellite units) and other information obtained from CMS (composite rate payment exceptions). The specific patient and facility measures that are used in the case-mix analyses are described in later sections of this report.

A. PATIENT CLAIMS DATA

The universe of CMS paid patient claims data is used to aggregate payments of separately billable services (injectable drugs, laboratory and other dialysis services) and all claim types are used to find comorbid conditions (see Chapter VIII and Appendix B for discussion of comorbid conditions and codes used to define these conditions). Data are collected for institutional claims covering inpatient hospitals, outpatient facilities, skilled nursing facilities, hospices, and home health agencies. Similarly, claims data are collected for physicians, other non-institutional carrier, and durable medical equipment providers.

The outpatient facility paid claims file is the primary source of information for payments dialysis facilities receive for treatment of ESRD patients. All payments made to the dialysis facility are detailed on these records. Type 72 bills provide detailed data for dialysis payments. UM-KECC receives these bills quarterly. The last data file for the data calendar year contains all claims for ESRD patients (including bill type claims other than type 72). Claims files used for analyses in this report are based on final full year claims and include all bill types, unless indicated otherwise below. To be included, patients must have at least one claim record for dialysis.

Carrier claims and durable medical claims are used to enumerate dialysis related payments made to other providers such as freestanding laboratories. Claims for injectable drugs provided and paid through other carriers and durable medical providers are also collected. These claims are aggregated to the patient-month level and joined to the patient-month facility dialysis record.

As the case mix analyses were generated, the most current, complete annual data available were for calendar year 2004. To date, 2005 claims have become available and are included in trend analyses. Claims data counts are reported in Table 3-1.

Table 3-1
Medicare Dialysis Patients, Sessions, Facilities and Claims by Year, 2001 – 2005

	2001	2002	2003	2004	2005
Medicare Dialysis Patients	270,026	284,654	298,048	307,805	317,511
Hemodialysis Equivalent Dialysis Sessions	27,910,493	29,919,658	31,943,850	33,602,322	33,438,754
Facilities	4,069	4,255	4,419	4,571	4,671
Patient Month Claims	2,528,429	2,689,067	2,827,373	2,929,831	3,030,048

B. MEDICARE COST REPORTS

Facility level cost and treatment data were obtained from CMS Medicare Independent Renal Dialysis Facility Cost Reports (CMS Form 265-94) and the Medicare Hospital Cost Reports (CMS Form 2552-96). CMS updates the cost report files quarterly. Case-mix analyses use the most current available HCRIS data for 2002-2004 facilities as of May 2006. The files contain Cost Reports through March 31, 2006.

Table 3-2
Available Cost Reports by Facility Type and Year as of March 31, 2006

Facility Type	2002	2003	2004	2005
Freestanding	3,426	3,730	3,806	174
Hospital Based	441	420	396	0
Total	3,867	4,150	4,202	174

Based on the Cost Reports that include necessary cost and treatment data, it was possible to define measures of resource use for composite rate services for the following facilities:

Table 3-3
Available Cost Reports by Facility Type Used in 2002-2004 Sample

Facility Type	2002	2003	2004
Freestanding	3,379	3,663	3,739
Hospital Based	430	408	387
Total	3,809	4,071	4,126

For most facilities, a single cost report encompasses the entire calendar year. In cases where Cost Reports spanned two calendar years (e.g., October through September rather than January through December), data from multiple Cost Reports spanning the same calendar year were used to calculate a weighted average of the numerical values from those Cost Reports, where the weight was the fraction of the reporting period that spanned the calendar year.

C. PATIENT CLAIM AND COST REPORT SUMMARY DATA 2002-2004

Case-mix analyses are based on datasets that link claims and cost report data for each year from 2002 through 2004. Patient level claims data were merged with annual facility Cost Reports by facility identifier. Claims data for patients treated in hospital satellite facilities were linked to the parent hospital (using OSCAR), since Cost Reports are submitted by only the parent facility. The table below describes the resulting analysis files that include both claims data and cost report data to measure resource utilization.

Table 3-4
Medicare Dialysis Patients, Sessions, Facilities and Claims
For Facilities with Cost Reports by Year, 2002-2004

	2002	2003	2004
Medicare Dialysis Patients	267,790	287,906	296,058
Hemodialysis Equivalent Dialysis Sessions	28,682,933	31,277,947	32,338,626
Facilities	3,772	4,035	4,120
Patient Month Claims	2,470,813	2,692,914	2,778,339

D. DATA FOR THE PRIMARY CASE-MIX ANALYSES, 2002-2004

The case-mix analyses require data for several patient and facility characteristics (see Chapter VI, Section B, Independent Variables) and exclude statistical outliers for cost per session (largely for composite rate costs; see Chapter VII, Section C, Statistical Outliers for the Average Cost per Session). The table below summarizes the data used in the primary analyses for both composite rate and separately billable services.

Table 3-5
Medicare Dialysis Patients, Sessions, Facilities and Claims
Final Analysis Sample by Year, 2002-2004

	2002	2003	2004	Pooled, 2002-2004
Medicare Dialysis Patients	253,149	274,010	282,049	809,208
Hemodialysis Equivalent Dialysis Sessions	27,004,308	29,637,613	30,709,881	87,351,802
Facilities	3,508	3,796	3,870	11,174

The primary case-mix analyses used pooled data for 2002-2004, which include 809,208 Medicare dialysis patient years and 11,174 facility years. Based on the patient counts in the above tables, the case-mix analyses include 90.9% of patients with Medicare outpatient dialysis claims during 2002-2004.

IV. CURRENT MEDICARE PAYMENT SYSTEM FOR END STAGE RENAL DISEASE

Legislation that supports a bundled ESRD PPS provides an opportunity to reexamine the overall Medicare approach to payment for dialysis related services and other services provided to dialysis patients. Key attributes of the current Medicare dialysis payment system are:

- Outpatient dialysis facilities are paid for a specified set of dialysis related services, including the dialysis session itself, either in-center or home dialysis, under the composite rate. This amounts to a limited bundled payment system.

- Outpatient dialysis facilities are paid for services not covered by the composite rate, referred to as separately billable services, on a fee-for-service basis.

- Nephrologists and other physicians who manage the care of patients on dialysis are paid separately for their services, according to the Medicare fee schedule. Basic, outpatient physician management of dialysis related services is paid as a monthly capitation payment, pro-rated if fewer than four patient encounters per month.

- Other providers are paid separately for dialysis related and non-dialysis related services provided to dialysis patients. Some of these providers are paid on a fee-for-service basis (e.g., physicians and clinical laboratories) while others are paid prospectively (e.g., hospitals). In some cases, such as laboratory tests covered by the composite rate system for dialysis facilities but performed by independent laboratories, the laboratory is paid under arrangement by the dialysis facility.

- Oral medications provided to dialysis patients on an outpatient basis were not covered by Medicare during the time period for which the data used in this report were available. However, beginning January 1, 2006, Medicare Part D covered a percentage of the cost of outpatient prescription medications. This prescription drug coverage is administered through private health plans and enrollment is voluntary. Given the high prescription drug costs faced by most ESRD patients, enrollment for this new benefit by those who had not previously been eligible for prescription drug coverage (e.g., through Medicaid or an employer) is expected to be high.

The current Medicare system uses multiple methods to pay for services delivered by different types of providers. This situation is further complicated by the existence of other financing sources that pay for care received by dialysis patients (e.g., coordination of benefits with Medicaid or private health insurers).

A. INEFFICIENCIES IN AND OPPORTUNITIES TO IMPROVE THE CURRENT PAYMENT SYSTEM

The current Medicare ESRD payment system presents opportunities to reduce inefficiencies, eliminate beneficiary confusion, improve quality, and possibly make care more accessible. To understand these opportunities fully it helps to understand, in some detail, the limitations of the current payment system.

The involvement of multiple payment systems creates a major inefficiency. Because some services (i.e., composite rate services) are bundled and others (i.e., separately billable services) are paid on a fee-for-service basis, where the fees paid for items billed separately from the composite rate system generally exceed providers' marginal costs of delivering these services, there is an incentive to shift the service delivery process toward separately billable services and away from composite rate services. This incentive may raise the cost of producing services and distort the mix of services provided to patients. Given the recent controversy regarding data on mortality risks associated with high hematocrit among chronic kidney disease patients (15,16,17), this incentive may also have adverse clinical consequences.

A second type of inefficiency in the process of producing dialysis services arises from the involvement of multiple care providers that may exacerbate gaps in coverage. A key example here is the frequent failure to secure permanent vascular access, particularly via arteriovenous fistula, at the initiation of renal replacement therapy. For many patients, an arteriovenous fistula is the preferred route of vascular access, enabling lower cost, higher quality dialysis, and fewer complications (18). Delayed placement of permanent vascular access can arise for several reasons including failure to identify chronic kidney disease prior to ESRD, lack of pre-ESRD referral for nephrology care, and the likelihood that vascular access placement is often performed by a surgeon not affiliated with the dialysis facility. The fact that Medicare coverage for those patients not otherwise qualified (i.e., non-disabled patients under age 65) does not begin until three months after the determination of ESRD also contributes to these delays.

A third type of inefficiency is the higher administrative costs inherent in a situation with multiple providers and multiple insurance arrangements. These higher costs are borne by the dialysis facilities and other providers and are sometimes passed on to payers. Some of these administrative costs are borne by patients, as they are forced to navigate the complex payment situation.

B. CONSTRAINTS TO AN IDEAL PAYMENT SYSTEM

Ideally, Medicare would have the necessary latitude to eliminate inefficiencies and confusion while optimizing quality and access. This latitude might involve a comprehensive redesign of the system of financing ESRD care. However, constraints to the design of the ideal payment system must be recognized.

- The Medicare benefits structure specifies covered services, the eligibility conditions, patient cost-sharing, and the rules of coordination and subrogation of benefits between Medicare and other insurers. Of particular interest is the fact, discussed above, that there is a three-month waiting period once ESRD has been established before Medicare benefits are in force.

- Medicare Part A and Part B are separate programs. Most dialysis related services are covered under Medicare Part B. However, Medicare Part A covers hospital inpatient services. Some services for dialysis patients are or can be provided in the hospital. The best example is surgery to create vascular access. In addition to relating to different types of providers, Parts A and B have different funding mechanisms and different systems of paying providers for care provided to Medicare beneficiaries. Given their separation, it will not currently be possible to design a bundled payment system that includes services covered by both Part A and Part B. Hence, the scope of the potential changes to the dialysis payment system covered in this report is limited to those services covered under Medicare Part B.

- It is unlikely that substantial additional funds for the ESRD program will be made available. Therefore, the most plausible changes to the system will be those that result in no net cost increase to the Medicare Program. A good case could be made for applying a broad concept of budget neutrality under which increases in dialysis payment could be supported by savings accrued elsewhere in the Medicare program (e.g., reduced hospitalizations). This approach would bridge Parts A and B of Medicare. However, it is possible that a narrower concept of budget neutrality would be invoked wherein no additional funds for the Part B portion of Medicare ESRD costs would be made available.

Despite these constraints, there remain substantial opportunities to promote efficiency, access and quality through improvements to the payment situation. Such improvements can include some combination of redefining the bundle, adjusting for patient severity, and assuring and rewarding quality of care.

V. DEVELOPING AN EXPANDED BUNDLE BASED ON MEDICARE SPENDING FOR DIALYSIS SERVICES

A. MEDICARE SPENDING BY SERVICE CATEGORY AND PROVIDER TYPE

Table 5-1 presents total Medicare Allowable Payments (MAP), by provider type, for the years 2001-2005. In 2005, Medicare spent a total of $7.9 billion for outpatient dialysis and the related outpatient services shown in Table 5-1, up from $6.1 billion in 2001. This reflects an annualized rate of growth of about 9 percent.

Table 5-1

Medicare Allowable Payments* (in Millions) by Provider, 2001-2005

Continued on next page

	2001				2002				2003			
	Dialysis Facilities			Other	Dialysis Facilities			Other	Dialysis Facilities			Other
Service category	Freestanding	Hospital Based	All	Providers **	Freestanding	Hospital Based	All	Providers **	Freestanding	Hospital Based	All	Providers **
Outpatient Dialysis and Other Composite Rate Services	3,068.5	534.8	3,603.3	n.a.	3,329.0	532.0	3,861.0	n.a.	3,603.8	516.0	4,119.8	n.a.
Separately Billable Services												
Drugs and Biologicals	1,924.8	304.1	2,229.0	1.3	2,204.5	341.3	2,545.8	1.3	2,406.8	351.4	2,758.2	5.0
Epoetin	1,298.8	199.9	1,498.7	1.0	1,465.2	203.4	1,668.6	0.9	1,648.7	198.9	1,847.6	1.0
Darbepoetin	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.9	<0.1	0.9	3.7
Iron	218.9	28.7	247.6	<0.1	261.7	43.0	304.7	<0.1	292.9	51.0	343.9	<0.1
Iron Dextran	51.0	16.0	67.0	<0.1	13.8	8.6	22.4	<0.1	5.3	3.6	8.9	<0.1
Iron Sucrose	0.0	0.0	0.0	0.0	110.0	12.7	122.7	<0.1	168.5	21.7	190.2	<0.1
NA Ferric Gluconate	167.9	12.7	180.6	<0.1	137.8	21.7	159.5	<0.1	119.2	25.8	144.9	<0.1
Vitamin D	329.1	56.9	386.0	<0.1	409.4	75.8	485.2	<0.1	407.5	83.2	490.7	<0.1
Calcitriol	45.9	20.2	66.1	<0.1	27.2	15.3	42.4	0.0	20.3	11.2	31.6	<0.1
Doxercalciferol	0.0	<0.1	<0.1	0.0	28.5	2.9	31.4	<0.1	35.5	6.3	41.8	<0.1
Paricalcitol	283.2	36.7	319.9	<0.1	353.7	57.7	411.4	0.0	351.6	65.7	417.3	<0.1
Levocarnitine	39.6	3.8	43.4	0.0	36.9	4.1	40.9	0.0	18.5	2.6	21.1	0.0
Alteplase	0.7	1.9	2.6	0.1	4.2	3.6	7.8	0.1	13.4	5.6	19.0	0.0
Vancomycin	3.5	1.0	4.5	<0.1	4.3	1.2	5.5	<0.1	4.6	1.1	5.7	<0.1
Vaccines (flu and Hepatitis B)	13.3	1.8	15.1	0.2	14.4	2.3	16.6	0.2	14.9	2.5	17.4	0.3
Other Injectables	21.0	10.0	30.9	n.a.	8.5	8.0	16.4	n.a.	5.5	6.4	11.9	n.a.
Laboratory Tests	6.1	13.5	19.5	193.4	5.6	14.4	20.1	232.9	5.3	15.1	20.4	265.3
Supplies & Other Services	17.0	3.5	20.5	n.a.	17.4	4.8	22.2	n.a.	18.4	6.3	24.7	n.a.
Total Separately Billable services	1,947.8	321.1	2,268.9	194.7	2,227.6	360.5	2,588.1	234.2	2,430.5	372.8	2,803.3	270.4
Total Composite Rate and Separately Billable Services	5,016.3	855.9	5,872.2	194.7	5,556.6	892.5	6,449.1	234.2	6,034.4	888.7	6,923.1	270.4
Total All Providers				6,067.0				6,683.3				7,193.5
Hemodialysis-equivalent dialysis sessions (millions)	23.9	4.0	27.9	n.a.	25.9	4.0	29.9	n.a.	28.1	3.9	31.9	n.a.

*MAP, except labs and vaccine, include full patient co-pay. MAP do not include the Part B deductible, which was $100 per patient per year in 2004.

Payments to dialysis facilities based on claims with at least one session in a month, and monthly hemodialysis equivalent dialysis sessions were capped at 20.

**MAP to all other providers include outpatient institutional claims (excluding type 72 claims), carrier claims, and durable medical equipment claims.

Medicare Allowable Payments* (in Millions) by Provider, 2001-2005

Continued from previous page

	2004				2005			
	Dialysis Facilities			Other Providers **	Dialysis Facilities			Other Providers **
Service category	Freestanding	Hospital Based	All		Freestanding	Hospital Based	All	
Outpatient Dialysis and Other Composite Rate Services	3,808.1	529.6	4,337.7	n.a.	4,238.2	550.4	4,788.5	n.a.
Separately Billable Services								
Drugs and Biologicals	2,782.5	409.8	3,192.3	5.3	2,423.2	337.3	2,760.5	3.3
Epoetin	1,883.1	195.3	2,078.4	0.2	1,807.3	130.6	1,937.8	<0.1
Darbepoetin	24.9	20.8	45.7	4.7	35.3	65.4	100.7	2.8
Iron	333.0	65.2	398.3	<0.1	195.4	45.1	240.5	<0.1
Iron Dextran	2.9	2.0	4.9	<0.1	1.2	0.9	2.1	<0.1
Iron Sucrose	206.8	28.3	235.1	<0.1	122.7	24.8	147.6	<0.1
NA Ferric Gluconate	123.3	34.9	158.3	<0.1	71.4	19.4	90.8	<0.1
Vitamin D	463.9	105.7	569.6	<0.1	328.9	75.3	404.2	<0.1
Calcitriol	12.0	8.8	20.8	<0.1	5.8	4.1	9.9	0.0
Doxercalciferol	96.3	15.8	112.1	<0.1	58.3	19.6	77.9	<0.1
Paricalcitol	355.5	81.1	436.6	<0.1	264.7	51.6	316.3	<0.1
Levocarnitine	29.5	4.8	34.3	0.0	12.0	4.4	16.4	0.0
Alteplase	19.8	6.3	26.1	<0.1	21.1	7.1	28.2	<0.1
Vancomycin	5.1	1.5	6.7	<0.1	2.4	1.4	3.8	<0.1
Vaccines (flu and Hepatitis B)	16.8	3.2	20.0	0.3	16.8	2.4	19.2	0.3
Other Injectables	6.2	7.1	13.3	n.a.	4.1	5.6	9.7	n.a.
Laboratory Tests	4.0	17.1	21.1	296.2	4.1	16.4	20.5	312.7
Supplies & Other Services	19.0	6.8	25.7	n.a.	31.2	9.0	40.2	n.a.
Total Separately Billable Services	2,805.5	433.6	3,239.1	301.5	2,458.5	362.7	2,821.2	316.0
Total Composite Rate and Separately Billable Services	6,613.6	963.2	7,576.8	301.5	6,696.7	913.1	7,609.8	316.0
Total All Providers				7,878.2				7,925.8
Hemodialysis-equivalent dialysis sessions (millions)	29.6	4.0	33.6	n.a.	29.7	3.8	33.4	n.a.

*MAP, except labs and vaccine, include full patient co-pay. MAP do not include, which was $100 per patient per year in 2005.
Payments to dialysis facilities based on claims with at least one session in a month.
**MAP to all other providers include outpatient institutional claims (excluding type 72 claims), carrier claims, and durable medical equipment claims.

Nearly all of the payments in Table 5-1 went to dialysis facilities. Figures 5-1 and 5-2 present the distribution of total MAP by provider type for 2001 and 2005. These data indicate that a bundle that includes payments only for services provided by dialysis facilities would cover 96 percent of these composite rate and separately billable services. Payments to other providers, mainly freestanding laboratories for laboratory tests provided to dialysis patients, accounted for the remaining four percent of the total.

Comparison of the figures for 2001 and 2005 indicates a small shift over time in the distribution of payments toward freestanding dialysis facilities and other providers and away from hospital based dialysis facilities.

Figure 5-1
Total Medicare Allowable Payments
by Service Provider Type, 2001

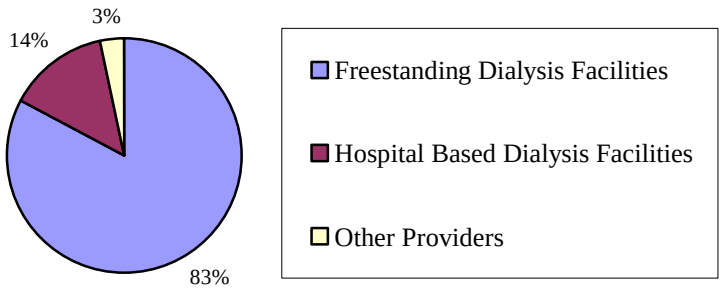


Figure 5-2
Total Medicare Allowable Payments
by Service Provider Type, 2005

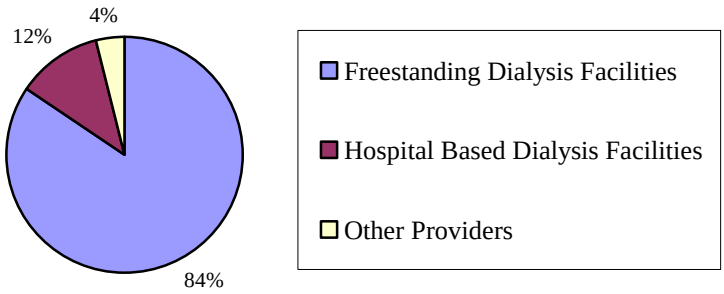


Table 5-1 also presents total Medicare Allowable Payments, by service category, for the years 2001-2005. The separately billable service category includes all services that were billed by outpatient dialysis facilities and certain services that were billed by other providers but are likely to be used in conjunction with dialysis or in treating and evaluating ESRD related conditions (e.g., anemia, bone disease). Services billed by other providers include laboratory tests and the specific injectable drugs shown in Table 5-1. The distributions of payments by service category for 2001 and 2005 are presented in Figures 5-3 and 5-4, respectively.

Figure 5-3
Total Medicare Allowable Payments (in Millions)
by Type of Service, 2001

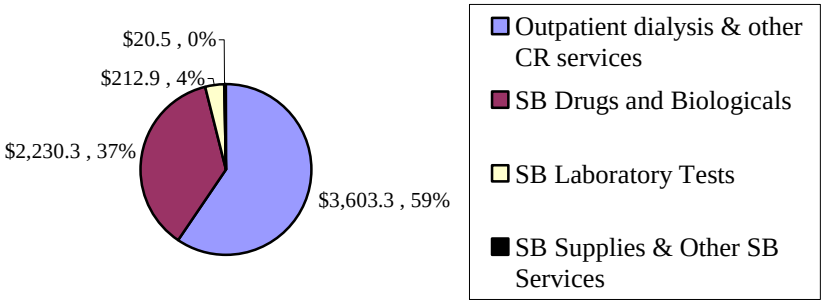
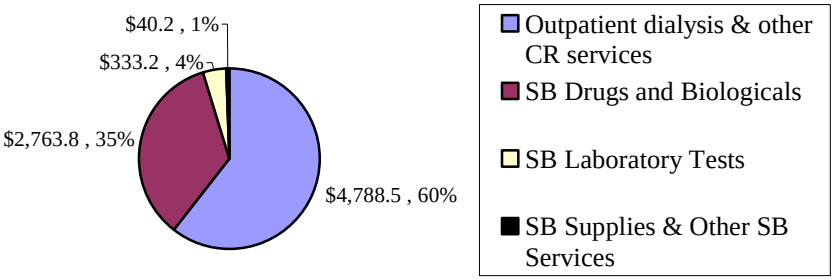


Figure 5-4
Total Medicare Allowable Payments (in Millions)
by Type of Service, 2005



Separately Billable (SB), Composite Rate (CR)

More than half of payments in 2005 (about 60 percent) cover dialysis composite rate (CR) services. The remainder cover separately billable (SB) services. Through 2004, the distribution of payments shifted toward separately billable services and away from composite rate services. This shift occurred as payments for separately billable services increased at an average annual rate of about twice the average annual rate experienced by payments for composite rate services. SB payments accounted for 37 percent of total payments in 2001 and 43 percent in 2004 (Table 5-1). In 2005 this redistribution was reversed in response to changes in the pricing of composite rate and separately billable services mandated by the MMA.

Table 5-2 presents Medicare Allowable Payments per session, by provider type, for 2001-2005. In 2004, composite rate payments averaged $129.09 per session, while separately billable payments averaged $105.37 per session. Separately billable payments per session to dialysis facilities were $96.39. The remaining nearly $10 per session was to laboratories for tests.

Table 5-2
Per Session Medicare Allowable Payments* by Provider, 2001-2005
Continued on next page

	2001				2002				2003			
Service category	**Freestanding Dialysis Facilities**	**Hospital Based Dialysis Facilities**	**All Dialysis Facilities**	**All Dialysis Facilities+ Other Providers ****	**Freestanding Dialysis Facilities**	**Hospital Based Dialysis Facilities**	**All Dialysis Facilities**	**All Dialysis Facilities+ Other Providers ****	**Freestanding Dialysis Facilities**	**Hospital Based Dialysis Facilities**	**All Dialysis Facilities**	**All Dialysis Facilities+ Other Providers ****
Outpatient Dialysis and Other Composite Rate Services	$128.46	$132.90	$129.10	$129.10	$128.42	$133.09	$129.05	$129.05	$128.41	$133.04	$128.97	$128.97
Separately Billable Services												
Drugs and Biologicals	$80.58	$75.57	$79.86	$79.91	$85.04	$85.38	$85.09	$85.13	$85.76	$90.60	$86.35	$86.50
Epoetin	$54.37	$49.68	$53.70	$53.73	$56.52	$50.89	$55.77	$55.80	$58.74	$51.28	$57.84	$57.87
Darbepoetin	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.03	$0.01	$0.03	$0.14
Iron	$9.16	$7.14	$8.87	$8.87	$10.09	$10.75	$10.18	$10.18	$10.44	$13.15	$10.77	$10.77
Iron Dextran	$2.13	$3.98	$2.40	$2.40	$0.53	$2.15	$0.75	$0.75	$0.19	$0.92	$0.28	$0.28
Iron Sucrose	$0.00	$0.00	$0.00	$0.00	$4.24	$3.18	$4.10	$4.10	$6.00	$5.59	$5.95	$5.95
NA Ferric Gluconate	$7.03	$3.16	$6.47	$6.47	$5.32	$5.43	$5.33	$5.33	$4.25	$6.64	$4.54	$4.54
Vitamin D	$13.78	$14.14	$13.83	$13.83	$15.79	$18.97	$16.22	$16.22	$14.52	$21.46	$15.36	$15.36
Calcitriol	$1.92	$5.03	$2.37	$2.37	$1.05	$3.82	$1.42	$1.42	$0.72	$2.90	$0.99	$0.99
Doxercalciferol	$0.00	<$0.01	<$0.01	<$0.01	$1.10	$0.73	$1.05	$1.05	$1.27	$1.62	$1.31	$1.31
Paricalcitol	$11.86	$9.11	$11.46	$11.46	$13.65	$14.42	$13.75	$13.75	$12.53	$16.94	$13.06	$13.06
Levocarnitine	$1.66	$0.95	$1.56	$1.56	$1.42	$1.01	$1.37	$1.37	$0.66	$0.67	$0.66	$0.66
Alteplase	$0.03	$0.48	$0.09	$0.10	$0.16	$0.90	$0.26	$0.27	$0.48	$1.44	$0.59	$0.59
Vancomycin	$0.15	$0.25	$0.16	$0.16	$0.17	$0.29	$0.18	$0.18	$0.16	$0.29	$0.18	$0.18
Vaccines (flu and Hepatitus b)	$0.56	$0.44	$0.54	$0.55	$0.55	$0.56	$0.56	$0.56	$0.53	$0.64	$0.54	$0.55
Other Injectables	$0.88	$2.48	$1.11	$1.11	$0.33	$1.99	$0.55	$0.55	$0.20	$1.66	$0.37	$0.37
Laboratory Tests	$0.25	$3.34	$0.70	$7.63	$0.22	$3.60	$0.67	$8.45	$0.19	$3.89	$0.64	$8.95
Supplies & Other Services	$0.71	$0.88	$0.73	$0.73	$0.67	$1.19	$0.74	$0.74	$0.65	$1.63	$0.77	$0.77
Total Separately Billable Services	$81.55	$79.79	$81.29	$88.27	$85.93	$90.17	$86.50	$94.33	$86.60	$96.12	$87.76	$96.22
Total Composite Rate and Separately Billable Services	$210.01	$212.70	$210.39	$217.37	$214.36	$223.26	$215.55	$223.37	$215.01	$229.17	$216.73	$225.19

*MAP, except lab and vaccine, include full patient co-pay. MAP do not include the Part B deductible, which was $100 per patient per year in 2004.
Payments to dialysis facilities based on claims with at least one session in a month, and monthly hemodialysis equivalent dialysis sessions were capped at 20.
**MAP to all other providers include outpatient institutional claims (excluding type 72 claims), carrier claims and durable medical equipment claims.

Table 5-2
Per Session Medicare Allowable Payments* by Provider, 2001-2005
Continued from previous page

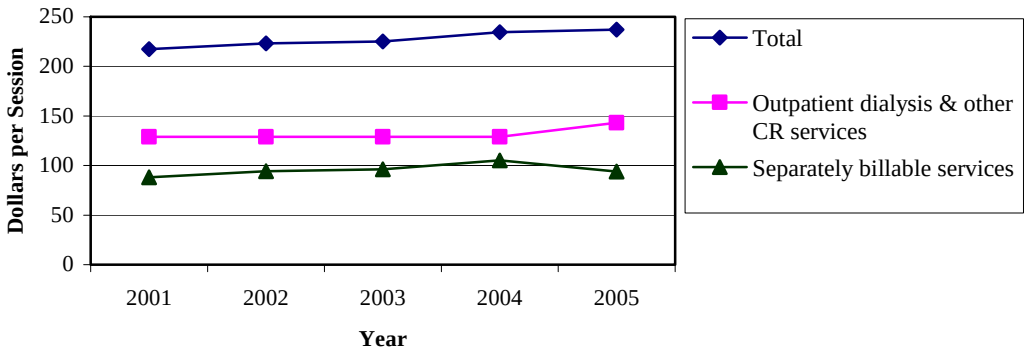
	2004				2005			
Service category	**Freestanding Dialysis Facilities**	**Hospital Based Dialysis Facilities**	**All Dialysis Facilities**	**All Dialysis Facilities+Other Providers ****	**Freestanding Dialysis Facilities**	**Hospital Based Dialysis Facilities**	**All Dialysis Facilities**	**All Dialysis Facilities+Other Providers ****
Outpatient Dialysis and Other Composite Rate Services	$128.48	$133.64	$129.09	$129.09	$142.77	$146.66	$143.20	$143.20
Separately Billable Services								
Drugs and Biologicals	$93.88	$103.41	$95.00	$95.16	$81.63	$89.89	$82.55	$82.65
Epoetin	$63.53	$49.28	$61.85	$61.86	$60.88	$34.80	$57.95	$57.95
Darbepoetin	$0.84	$5.25	$1.36	$1.50	$1.19	$17.44	$3.01	$3.10
Iron	$11.24	$16.46	$11.85	$11.85	$6.58	$12.02	$7.19	$7.19
Iron Dextran	$0.10	$0.50	$0.15	$0.15	$0.04	$0.23	$0.06	$0.06
Iron Sucrose	$6.98	$7.15	$7.00	$7.00	$4.13	$6.62	$4.41	$4.41
NA Ferric Gluconate	$4.16	$8.81	$4.71	$4.71	$2.41	$5.18	$2.72	$2.72
Vitamin D	$15.65	$26.67	$16.95	$16.95	$11.08	$20.06	$12.09	$12.09
Calcitriol	$0.41	$2.21	$0.62	$0.62	$0.20	$1.09	$0.30	$0.30
Doxercalciferol	$3.25	$3.99	$3.34	$3.34	$1.97	$5.21	$2.33	$2.33
Paricalcitol	$11.99	$20.47	$12.99	$12.99	$8.92	$13.75	$9.46	$9.46
Levocarnitine	$1.00	$1.20	$1.02	$1.02	$0.40	$1.17	$0.49	$0.49
Alteplase	$0.67	$1.58	$0.78	$0.78	$0.71	$1.89	$0.84	$0.84
Vancomycin	$0.17	$0.39	$0.20	$0.20	$0.08	$0.38	$0.11	$0.11
Vaccines (flu and hep b)	$0.57	$0.80	$0.60	$0.60	$0.57	$0.63	$0.57	$0.58
Other Injectables	$0.21	$1.79	$0.40	$0.40	$0.14	$1.50	$0.29	$0.29
Laboratory Tests	$0.14	$4.30	$0.63	$9.44	$0.14	$4.37	$0.61	$9.96
Supplies & Other Services	$0.64	$1.71	$0.77	$0.77	$1.05	$2.41	$1.20	$1.20
Total Separately Billable Services	$94.65	$109.42	$96.39	$105.37	$82.82	$96.66	$84.37	$93.82
Total Composite Rate and Separately Billable Services	$223.13	$243.05	$225.48	$234.45	$225.58	$243.33	$227.57	$237.02

*MAP, except lab and vaccine, include full patient co-pay. MAP do not include the Part B deductible, which was $100 per patient per year in 2004. Payments to dialysis facilities based on claims with at least one session in a month, and monthly hemodialysis equivalent dialysis sessions were capped at 20.

**MAP to all other providers include outpatient institutional claims (excluding type 72 claims), carrier claims and durable medical equipment claims.

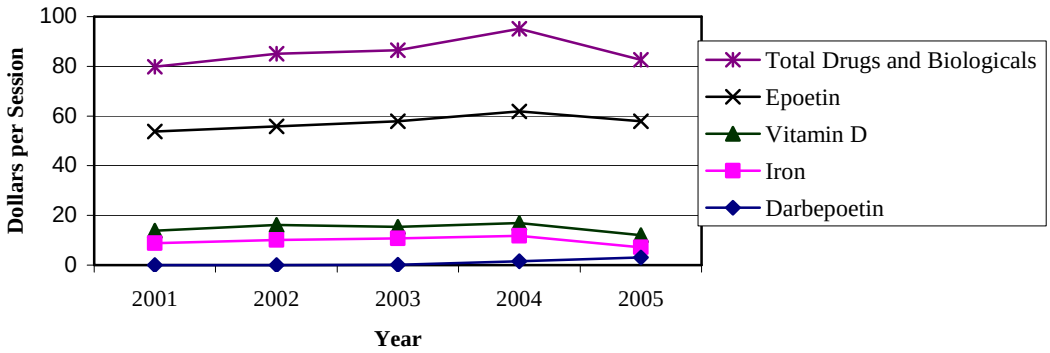
Figure 5-5 reports Medicare dialysis payments over the period 2001 to 2005. Total payments per session rose steadily over this period. Payments per session for separately billable services rose substantially through 2004 and declined in 2005. Payments per session for composite rate services were fairly constant through 2004 and increased markedly in 2005.

Figure 5-5
Trends in Medicare Allowable Payments per Session



Most of the growth in separately billable payments per session was due to increases in payments for injectable drugs. Figure 5-6 displays trends in payments per session for drugs and biologicals. The largest fraction of per session payments was for epoetin. Payments for all types of drugs increased steadily through 2004. In 2005, because of a change in payment policy mandated by MMA that reduced prices paid by Medicare, payments per session for these drugs and biologicals, except for darbepoetin, decreased.

Figure 5-6
Trends in Medicare Allowable Payments per Session for Drugs and Biologicals



B. A BUNDLE FOR ANALYTICAL PURPOSES

A necessary requirement in the development of models to predict ESRD dialysis resource utilization was definition of services for inclusion in an expanded payment bundle. A core group of Medicare reimbursed services separate from the composite rate payment for ESRD under the current reimbursement system was identified. Categories of services included several classes of injectable medications used in the majority of dialysis patients to treat specific medical conditions resulting from kidney failure and dialysis, including anemia, ESRD related bone disease, and thrombosis or infection of vascular access. These injectable medications are administered almost exclusively in dialysis facilities, and include erythropoiesis stimulating agents (ESAs), injectable iron, injectable vitamin D analogs (paricalcitol, doxercalciferol, calcitriol), and miscellaneous injectable medications (antibiotics, thrombolytic agents). As shown in Table 5-1, the MAP for these injectable medications reached $3.4 billion in 2005, accounting for 41% of total MAP to dialysis facilities. Along with payment for separately billed laboratory services and vascular access related procedures discussed below, these services account for virtually all dialysis related Medicare payments.

1. Dialysis related laboratory tests

Frequent laboratory testing of serum chemistries and blood counts is performed as part of the regular monitoring of dialysis patients. Payment for some of these tests, performed at specified frequencies, is included in the dialysis facility composite rate. When performed above the ESRD payment system specified frequency, these laboratory services may be separately billed by specific diagnostic indication, based on the presumptive diagnosis determined by the treating nephrologist. In addition, many of these same common laboratory tests are ordered by non-dialysis medical providers in the course of their care of other medical conditions in chronic dialysis patients. Finally, some laboratory tests, separately billed by Medicare, are ordered by nephrologists to monitor response to treatment of ESRD related conditions and to guide prescription of injectable medications. We attempted to identify for inclusion in the expanded bundle only those specific lab tests and frequencies ordered by physicians to monitor dialysis related conditions, including response to separately billed injectable medications. The specificity of lab inclusion by dialysis indication was complicated by the need to develop a model which achieved administrative simplicity. This task was complicated by the practice of some, but not all, dialysis providers to include primary medical care to dialysis patients as part of their Medicare Capitated Payment (MCP) services.

We used several strategies to identify the subset of labs generally associated with dialysis related care. First, we identified a group of freestanding laboratory providers who perform the bulk of outpatient laboratory tests on chronic dialysis patients. In addition, we identified individual outpatient laboratory tests performed in these laboratory facilities on known chronic dialysis patients and ordered them by frequency. These analyses demonstrated that most laboratory tests performed in this patient group, based on both frequency and total cost, were related to core dialysis services (anemia, bone disease, infection prevention and/or treatment). Separate analyses demonstrated that approximately 89% of all diagnostic laboratory tests performed on dialysis outpatients by the 50 largest freestanding laboratory facilities in 2003 were ordered by physicians identified as receiving an MCP for dialysis management. Furthermore, more than 90% paid by Medicare in 2003 for these physician MCP ordered labs, was for labs related to anemia, bone disease, dialysis or infection prevention and/or treatment.

Given the significant administrative burden to Medicare fiscal intermediaries involved in evaluating separately billable laboratory claims, as well as to providers in documentation of the presumptive diagnosis for the claims, inclusion of dialysis related laboratory charges in the expanded bundle should reduce the administrative costs for both providers and the Medicare program. The vast

majority of these lab tests were performed in support of performance of core services by dialysis facilities as noted above. Thus, we included all outpatient labs performed on Medicare dialysis patients which were ordered by MCP physicians as identified by their Unique Physician Identification Number (UPIN). For a small number of labs billed at inpatient hospitals, we were unable to distinguish whether the lab was ordered by an MCP physician or another physician. MCP physician ordered lab tests, as defined here, were included as part of the expanded bundled payment.

2. Exclusion of vascular access payments from expanded bundle

We considered inclusion of payments for vascular access creation and maintenance in our expanded prospective payment models. This aspect of ESRD management is important to optimize outcomes in Medicare ESRD patients and is a significant cost contributor to the ESRD program. Inclusion of vascular access management in the PPS would provide opportunities to create financial incentives favoring creation of arteriovenous fistulae, potentially contributing to the success of the Fistula First initiative currently in progress.

While exploring the feasibility of including vascular access management in the expanded PPS, we identified several complicating issues. First, most incident dialysis patients should have initial vascular access created prior to initiation of chronic dialysis. Approximately 50% of these incident patients are not Medicare eligible during this critical period. Therefore accurately identifying costs associated with creation of access in these individuals is not possible. Furthermore, development of a Medicare payment model which promotes optimal vascular access choices in individual patients not yet participating in Medicare would be problematic.

A second issue relates to the multiple medical and facility providers involved in creation and maintenance of vascular access. In some situations nephrologists, vascular surgeons, interventional radiologists, dialysis facilities, freestanding vascular access clinics and inpatient and outpatient hospital facilities are all participants in creation or restoration of functionality of a vascular access. Inclusion of payments for vascular access management in the expanded PPS for dialysis facilities would create significant administrative burdens for these facilities. In addition, the scope of vascular access management spans both Medicare parts A (inpatient) and B (outpatient). For the purposes of research in support of CMS' development of an expanded PPS for outpatient dialysis, we have not included vascular access management in our models. There may be opportunity to revisit this important component of the Medicare ESRD program in the future if the barriers outlined above are satisfactorily addressed.

3. Bundle definition for analyses

To determine the feasibility of development and implementation of a PPS that encompasses an expanded bundle of outpatient ESRD dialysis services, we selected a specific bundle of services as the basis of the analyses which follow. This selection was made in consultation with CMS, and was informed by analyses of the data described above. The bundle definition for the case-mix models and other analyses includes services that are currently reimbursed through the composite rate system and the following types of services that were billed separately by either dialysis facilities or other providers (as specified below) on Medicare claims:

- Injectable drugs billed by dialysis facilities
- Laboratory services
    - billed by freestanding laboratory suppliers and ordered by physicians that received monthly capitation payments for treating ESRD patients, or
    - billed by dialysis facilities
- Other services billed by dialysis facilities (e.g., dialysis supplies)

C. DETERMINING THE UNIT OF PAYMENT FOR AN EXPANDED BUNDLE: PER DIALYSIS SESSION OR PER UNIT OF TIME?

In the current Medicare payment system for dialysis and related services, the unit of payment varies by type of service. Payments for bundled services (those included under the composite rate) are based on the number of dialysis sessions actually delivered subject to a cap of three hemodialysis sessions (or the PD equivalent) per week. Under rare circumstances, facilities can request a medical exception to allow for payment for four sessions per week. Payment for services that are not bundled into the composite rate is based upon actual utilization. Finally, dialysis related, outpatient physician care is based on a monthly capitation payment. Under an expanded bundle, the services now billed separately could be bundled with composite rate services on either a per session basis, or a per unit of time basis.

Although different units of time (e.g., day or week) could be chosen as the basis for payment, we will use the month to illustrate how existing data could be used to develop a time based payment. A monthly payment is analytically convenient because dialysis bills are currently submitted monthly, with facilitates calculating historical costs on a monthly basis. In addition, this approach would align with the unit of time used to determine physician payment for dialysis related services, and the typical unit of time for capitated payments in managed care settings ("per member per month").

To base payment for an expanded bundle on a unit of time rather than on a delivered dialysis session has several potential advantages as well as several potential drawbacks. Key advantages of a monthly payment are the alignment with the method of physician payment, simplification of the payment system, and neutrality with respect to the schedule of dialysis sessions. Neutrality with respect to scheduling could allow greater flexibility in selecting between the standard, three times per week schedule versus shorter, more frequent sessions. However, it should be noted that a bundled payment system, regardless of whether the unit of payment is the session with a maximum number of allowable paid sessions or per month with a maximum payment per month, could encourage more frequent dialysis. Such an incentive would be present to the extent that more frequent dialysis sessions generate savings in the utilization of current separately billable items. Under a bundled payment system, the facility would absorb the costs of delivering the extra sessions, and it would retain any resulting savings on other dialysis related services.

One key disadvantage of a monthly payment compared to a per session payment is the possibility of creating adverse incentives which encourage fewer than three sessions per week and indifference toward missed sessions. Therefore, it may be useful to require a minimum number of delivered sessions to qualify for the full monthly payment, with a pro-rated reduction for months with fewer sessions. This requirement would function analogously to the physician MCP payment formula which requires at least four visits to receive the full, monthly capitation payment. Unlike payment based on sessions, a monthly payment would be complicated in months in which the patient received dialysis in multiple facilities (either due to switching to a new facility, or due to receiving transient dialysis while away from home), or in which intervening events occurred causing the patient to be ineligible to receive outpatient dialysis for part of the month (e.g., hospitalization). Therefore, monthly payment would involve several considerations that would not be present under a per session payment approach. These issues include identifying a "home" facility and making the home facility responsible for arranging payment to facilities providing transient dialysis, and appropriately pro-rating the monthly payment in months with intervening events. See the Implementation Issues section for further discussion of issues in a per month payment system.

1. Payment per session

If the dialysis session is chosen as the unit of payment, the payment rate for a particular patient could be determined on the basis of a case-mix adjustment model that uses cost per session as the dependent variable. To use the model as the basis for a payment per session, one would take a base budget neutral payment price and apply the model coefficients for comorbid conditions and other patient characteristics as multiplicative payment adjusters. Under this per session payment approach, aggregate payments per month would equal the case mix adjusted payment per session multiplied by the number of sessions the patient actually receives (potentially up to a specified limit on the number of sessions, like the current system).

Estimation of both the base payment price per session and case-mix adjustment coefficients would be based on annual data describing composite rate costs, monthly data on separately billable payments, and information about patient characteristics reflecting different time periods. Methods used to develop these estimates are described later in this report.

2. Payment per month

Under a per month payment system, a standard "per member per month" base payment amount must be determined. In order to use historical cost report and claims data to derive an empirical basis for a monthly payment system, it is necessary to aggregate costs over time and to account for time at which the patient was not at risk for incurring outpatient dialysis related costs. Below, we describe two approaches that could be taken to develop a payment rate based on unit of time (patient month) rather than dialysis session. Either of these approaches requires that we first calculate "time at risk" for partial months of dialysis in order to prorate the monthly payment for patients who experienced one or more events that result in less than a full month of outpatient dialysis.

The events that lead patients to be "at risk" for less than a full month of outpatient dialysis services include hospitalization, initiation of dialysis, death, withdrawal from dialysis, recovery of renal function, transplantation, and returning to dialysis after a transplant graft failure. The occurrence of these events would presumably reduce the payment in proportion to the fraction of the month they reduce the patient's time "at risk." (A patients' skipping sessions does reduce time at risk.)

Patients who receive partial months of outpatient services due to such events could have their monthly payment prorated by the percentage of days in the month during which they are eligible for outpatient services. Under a per month payment system, the special cases of partial months due to transient care and between-facility transfers would create additional administrative and operational costs for dialysis facilities, possibly introducing disincentives to patient access to care and patient choice.

Table 5-3 describes the frequency of patient months that are partially or fully eligible for outpatient dialysis reimbursement. Eighty one percent of patient months are eligible for a full month of payment. For the other 19 percent of patient months, the treating facility would receive a fraction of the full month payment proportional to the fraction of the month in which they were eligible for outpatient dialysis services. Available dialysis claims data include only a range of dates covered (typically a calendar month), and do not indicate the specific dates on which services were delivered. Further, an examination of the timing of the intervening events revealed a variety of complex patterns of multiple and recurrent events. For example, the data currently do not allow us to determine whether a patient received outpatient dialysis on the admission date or discharge date for a hospitalization, the most common type of event. Therefore, the data do not allow us to determine whether these days should be considered at risk for outpatient dialysis. Therefore, using the claims

data to determine time at risk involves some uncertainties that necessitate making assumptions and as well as substantial programming and data analysis efforts.

Table 5-3
Distribution of Medicare Dialysis Patient Months, 2002-2004

Month Type	2002 (n=2,480,430)	2003 (n=2,646,551)	2004 (n=2,774,764)
Percent of patient-months eligible for full month of payment			
No events	81.35	81.50	81.48
Percent of patient-months eligible for partial month of payment			
Start of dialysis	0.35	0.34	0.34
Hospitalization	15.42	15.30	15.37
Transplant	0.01	0.01	0.01
Transplant failure	0.02	0.02	0.02
Recovered renal function	0.04	0.05	0.05
Death or withdrawal from dialysis	0.43	0.43	0.41
Start of dialysis + hospitalization	0.98	0.96	0.94
Transplant + hospitalization	0.26	0.25	0.26
Transplant failure + hospitalization	0.05	0.05	0.05
Death/withdrawal + hospitalization	1.03	1.03	1.01
Other combination of events	0.05	0.05	0.05

Rather than make assumptions that can not be tested and impose rules to account for the complex patterns in the data, we followed a simpler approach. For patient months with an intervening event, the approach is to infer time at risk based on the number of outpatient dialysis sessions for that month. For example, if a patient had 9 sessions during a month in which he or she was hospitalized, the time at risk during the month would be 9 * 7/3 = 21 days, which in a 30-day month would correspond to 70 percent of the month. Hence, the payment for this patient would be 70 percent of the full month base rate. The utility of this approach is enhanced by its applicability to the estimates of the composite rate portion of dialysis related costs (based on Cost Reports) as well as to the separately billable portion (based on utilization reported in paid claims). Because the Cost Reports are at the facility level, are annual, and include all patients (not just Medicare patients), any feasible calculation of aggregate time at risk for the accrual of these measured costs would have to be based on a transformation from the total number of sessions to the estimated time at risk.

This time at risk estimate could be employed with either of the following approaches for calculating monthly payments.

2a. Approach 1: Adjust average cost per session to reflect a full month of dialysis

This approach estimates case-mix adjustment models using the same cost per session model that would serve as the basis of a system using the session as the basis of payment, but it would scale up the per session costs to estimate the monthly cost. To use the model as the basis for a payment per month for a patient with a given set of characteristics who has a full month of outpatient sessions, multiply the case mix adjusted payment per session multiplied by the typical number of sessions per month received by outpatient dialysis patients. This typical number could reflect the current average of 12.8 sessions, or the current standard protocol of 13 sessions. To ensure adequate therapy, a minimum number of sessions may be required. When a patient does not receive the minimum number of sessions in months where no intervening event occurred, a downward adjustment could

be made to the monthly payment, similar to the current MCP reimbursement system for physician services. A hypothetical case mix adjusted per session payment of $250 multiplied by the current standard protocol of 13 sessions per month would result in a monthly payment of $3,250. Alternatively, using the current average of 12.8 sessions per month would result in a monthly payment of $3,200. The chosen base amount would be the maximum that would be paid on a monthly basis.

2b. Approach 2: Estimate models of cost per month

An alternative approach is to estimate a model of cost per month for use as a case-mix adjuster. The costs for patients who are at risk for less than a full month would be represented as dollars per full month equivalent. The time at risk calculation for partial months, described as Approach 1, also applies to this approach. Hence, the dependent variable is actual cost observed in the partial month divided by the proportion of the month at risk. This creates the cost per full month equivalent. In the analysis, each patient month is weighted by the proportion of the month at risk to ensure that these partial months receive weight in proportion to the actual time at risk represented. For example, consider a patient incurring $2,100 in costs during a month in which he or she was at risk for 21 of 30 days (70 percent). The full month equivalent cost of $2,100/0.70 = $3,000 would then be used, and the observation would receive a weight of 0.70 in the regression model.

3. Comparison of per session and per month case-mix adjustments

Table 5-4 compares the results for per session and per month case-mix adjustment models for separately billable services. These models are consistent with the case-mix adjustment payment models developed later in this report. The models presented here focus on separately billable services because patient level data are not available for composite rate services. Hence, these separately billable models serve to indicate the similarity of case-mix adjustment results in the two types of approaches and thereby to inform the selection of a unit of payment.

The approach employed to estimate the per month case-mix adjustment model is that described above in Approach 2. The approach used to estimate the per session case-mix adjustment model is that described generally as payment per session. More detail on these estimation procedures is presented in later sections of this report. The cases identified as statistical outliers vary slightly between the two models.

The average separately billable payment in the per month model is $1,066.50, compared to the average separately billable payment in the per session model of $83.18. As shown in Table 5-4, among the 22 potential case-mix adjustment payment variables, 12 multipliers do not change, nine change by 0.01, and one, duration of RRT less than 4 months, changes by 0.03. All of the control variables have multipliers that change by no more than 0.01 (not shown). The small differences in multipliers and statistical significances likely arise from definitions used for time at risk in the per month model.

Given the very small differences in multipliers observed in the two models, the choice of unit of payment can be based on other criteria. Some of these criteria have been introduced above. We cover these and other issues in more detail in Chapter XIII, Implementation Issues.

The next several sections describe the development of a per session payment model. As described above, a per month model can easily be adapted from a per session model. Therefore, the remainder of this report focuses on a per session model.

Table 5-4. Per session versus per month estimation models for separately billable services, 2002-2004

Variable	Per session model: adjusted SB MAP per session* (n=809,208) R-sq: 8.82% Average $83.18/session		Per month model: adjusted SB MAP per month at risk* (n=809,210) R-sq: 8.71% Average $1,066.50/month	
	Estimated Multiplier	p-value	Estimated Multiplier	p-value
Age <18	0.45	<.0001	0.45	<.0001
Age 18-44	1.00	0.0626	1.00	0.3101
Age 45-59	0.99	<.0001	0.99	<.0001
Age 60-69	1.00	ref	1.00	ref
Age 70-79	0.96	<.0001	0.96	<.0001
Age 80+	0.93	<.0001	0.93	<.0001
Female	1.16	<.0001	1.17	<.0001
Body surface area (per 0.1 m^2)	1.038	<.0001	1.039	<.0001
Underweight (BMI <18.5)	1.03	<.0001	1.02	<.0001
Duration of RRT: <4 months	1.45	<.0001	1.42	<.0001
Alcohol/drug dependence: claims since 1999 or reported on 2728 (any)	1.12	<.0001	1.11	<.0001
Cardiac arrest: claims since 1999 or reported 2728 (any)	1.09	<.0001	1.10	<.0001
Pericarditis from same month to three months ago	1.61	<.0001	1.62	<.0001
HIV/AIDS: claims since 1999 or reported on 2728 (any)	1.13	<.0001	1.12	<.0001
Hepatitis B since 1999	1.04	<.0001	1.04	<.0001
Septicemia from same month to three months ago	1.70	<.0001	1.70	<.0001
Bacterial pneumonia and other pneumonias/opportunistic infections from same month to three months ago	1.47	<.0001	1.46	<.0001
Gastro-intestinal tract bleeding from same month to three months ago	1.88	<.0001	1.89	<.0001
Hereditary hemolytic or sickle cell anemias since 1999	1.16	<.0001	1.16	<.0001
Cancer since 1999 (excludes non-melanoma skin cancer)	1.09	<.0001	1.09	<.0001
Myelodysplastic syndrome since 1999	1.28	<.0001	1.28	<.0001
Monoclonal gammopathy since 1999	1.10	<.0001	1.10	<.0001

*The per session model was weighted by the number of hemodialysis equivalent dialysis sessions. The per month model was weighted by the proportion of time at risk. Models also included several facility characteristics and year as control variables. Observations with outlier values for either average MAP/session or average MAP/month at risk were excluded from the per session and per month models, respectively.

VI. PER SESSION PAYMENT SYSTEM AND IDENTIFICATION OF DEPENDENT AND INDEPENDENT VARIABLES

A. DEPENDENT VARIABLES

The analytic approach used to examine potential case-mix adjusters for an expanded PPS includes a facility level regression model for composite rate services and a patient level regression model for separately billable services. The rationale for using this two equation modeling approach is discussed in Chapter VII, Section A. The dependent variables measuring resource utilization for each of the two equations are defined below.

1. Average cost per session for composite rate services

Resource use for the bundle of services included in the composite rate was measured at the facility level since no patient level measures of resource use are available. While the patient level Medicare claims include the composite rate payment amounts, which are adjusted for certain classes of facilities (e.g., based on area wage indexes and for hospital-based facilities) and patients (i.e., based on the basic case-mix adjustment), these payments do not vary according to the level of services or other resources used to treat individual patients within a facility.

The cost of resources used to deliver composite rate services was measured with facility level data obtained from the Cost Reports for freestanding dialysis facilities (CMS Form 265-94) and hospital based facilities (CMS Form 2552-96) for each year from 2002-2004. A more detailed description of the Cost Reports is included in Chapter III, Overview of Data Sources. The average composite rate cost per session at each facility was calculated by dividing the total reported Medicare allowable costs for composite rate services (Worksheet B, column 11, rows 7-16 on CMS 265-94; Worksheet I-2, column 11, rows 2-11 on CMS 2552-96) by the total number of dialysis sessions (Worksheet C, column 1, rows 1-10 on CMS 265-94; Worksheet I-4, column 1, rows 1-10 on CMS 2552-96). CAPD and CCPD patient weeks were multiplied by 3 to yield hemodialysis equivalent sessions, as other researchers have done (19,20,21).

To explore the relationship between area wages and costs, we performed some analyses where the average composite rate cost at each facility was adjusted for regional differences in the cost of labor by dividing the estimated labor share of composite rate costs, 53.711% (22), by the wage index that was developed for the 2006 payment system for skilled nursing facilities (SNFs) (23,24). This wage index has also been used to adjust composite rate payments for area wage differences (22). Regression models were then used to explain variation in the average wage adjusted costs. For other analyses, no wage adjustment was made to calculate the average composite rate cost per session. Instead, the SNF wage index was included as an independent variable in the regression models (see Section B, Independent Variables, below). No floor or ceiling was imposed on the SNF wage index in either case. For further discussion on the wage index methodology, see Chapter IX, Section B.

Resource use for composite rate services was therefore measured using the average annual composite rate cost per session. A log transformation was used in most analyses to account for the skewness in the cost data and to derive multiplicative payment adjustments (see Chapter VII, Section B,

Logarithmic versus Linear Model), and was calculated as the natural logarithm of the average annual composite rate cost per session. Potential outlier values for average facility costs were identified and excluded from the case-mix analyses. See Chapter VII, Section C, for a discussion of the methods used to identify statistical outliers and the impact of the exclusion.

2. Average Medicare Allowable Payment per session for separately billable services

Resource use for separately billable dialysis related services was measured at the patient level using the Medicare claims. Patient level measures of resource use were defined for each year during 2002-2004. This time period corresponds to the most recent three years of cost report data that were available to measure resource use for composite rate services.

Measures of resource use include the following separately billable services: injectable drugs billed by dialysis facilities; laboratory services provided to ESRD patients, billed by freestanding laboratory suppliers and ordered by physicians who receive monthly capitation payments for treating ESRD patients, or billed by dialysis facilities; and other services billed by dialysis facilities. Chapter V, Section B (A Bundle for Analytical Purposes), describes these services in greater detail, and discusses the rationale for this bundle definition.

Medicare claims data for separately billable services were obtained for patient months in which outpatient dialysis was provided and Medicare was the primary payer. Measures of resource use were based on Medicare Allowable Payments (MAP), which were calculated using the payment data on the claims. Medicare payments were inflated by a factor of 1.25 for services that have a 20% patient obligation (e.g., most injectable drugs) to yield MAP. For services that have no patient obligation (e.g., laboratory tests and vaccines), the Medicare payment is identical to the MAP. The MAP amounts do not include the portion of the annual Part B deductible ($100 per patient per year) applied to these separately billable services.

For the case-mix analyses, MAP based on the 2002-2004 claims were adjusted to approximate the relative costs of these separately billable services under the current Medicare payment system. Medicare reimbursement levels were recently adjusted to reflect the typical facility acquisition costs for the top injectable drugs (2,22). We adjusted MAP for the top injectables to reflect reimbursement levels during the first quarter of 2006 (25). MAP for each injectable was multiplied by the ratio of the Medicare payment rate in the first quarter of 2006 to the prevailing Medicare payment rate (e.g., 2006 Quarter 1 payment rate / 2004 payment rate). Repricing was done for the following injectables: epoetin alfa, darbepoetin alfa, iron dextran, iron sucrose, sodium ferric gluconate, calcitriol, doxercalciferol, paracalcitol, levocarnitine, alteplase recombinant and vancomycin. The MAP reflects the volume of services provided to each patient and the relative cost of each service based on prevailing Medicare reimbursement rates.

For the primary analyses, the adjusted MAP was standardized to the number of Medicare outpatient dialysis sessions reported on the claims. This approach is consistent with the current composite rate unit of payment which reimburses facilities on a per session basis. For patients who received peritoneal dialysis (PD) during the month, the number of PD days reported on Medicare claims was multiplied by 3/7 to yield the number of hemodialysis equivalent sessions (e.g., 7 days PD are converted to 3 HD equivalent sessions, since HD is typically performed 3 times per week). Monthly HD equivalent dialysis sessions reported on the claims were capped at 20; values exceeding 20 are implausible under the current composite rate payment system.

The ratio of adjusted MAP for separately billable services to the total number of HD-equivalent sessions was used to calculate the average adjusted MAP per session. The average MAP per session for epoetin alfa was capped to reflect no more than 30,000 units of EPO per session, since higher

doses may be clinically implausible or inappropriate. Medicare currently places a relatively similar limit on EPO reimbursement of 500,000 units per patient per month (26). As with the analyses of composite rate services, a log transformation was used for most analyses of separately billable services (see Chapter VII, Section B, Logarithmic versus Linear Model). The exclusion of potential outliers is described in Chapter VII, Section C, Statistical Outliers for the Average Cost per Session.

B. INDEPENDENT VARIABLES

Payment and control variables are the two types of independent variables included in models of resource utilization. Payment variables may be used to adjust payments for the expanded PPS. The patient characteristics that were examined as potential payment variables based on models of resource use included patient demographics, measures of body size, duration of renal replacement therapy and patient comorbidities. These patient characteristics were measured using several CMS data sources (see Chapter III). The use of regression analysis and other criteria to specify a preliminary case-mix adjustment model is discussed in Chapter VII, Structure of the Model, and Chapter VIII, Definition and Measurement of Patient Characteristics for Case-mix Adjustment.

Measures were defined for patient age, duration of renal replacement therapy (RRT) at time of session, and gender. Patient weight and height recorded at the start of RRT were used to calculate body mass index (BMI, kg/m^2) and body surface area (BSA, m^2). BSA was calculated as a function of height (H, in centimeters) and weight (W, in kilograms) using the following formula (27):

$$BSA = 0.007184 \times H^{0.725} \times W^{0.425}$$

BMI values below 18.5 kg/m^2 were used to identify patients who were underweight (28). BSA and low BMI (<18.5) are currently used as part of the basic case-mix adjustment for the composite rate system. For patients who had no weight or height measurements available from the CMS Form 2728 because they started RRT before April 1995 (i.e., when the CMS Form 2728 began collecting weight and height measurements), we used the average values among patients of the same age group and gender.

Comorbidity measures were defined for the following conditions: specific types of heart disease (cardiac arrest, congestive heart failure, cardiac dysrhythmia, myocardial infarction, ischemic heart disease, and pericarditis), cerebrovascular disease, diabetes, peripheral vascular disease, chronic obstructive pulmonary disease, AIDS, HIV positive status (without AIDS), Hepatitis B, other hepatitis, specific types of infections (septicemia, bacterial pneumonias, pneumococcal pneumonias and opportunistic infections), specific types of bleeding conditions (gastro-intestinal tract bleeding and esophogeal varices), specific types of anemias (acquired hemolytic anemias, hereditary hemolytic anemias, and sickle-cell anemia), cancer (excluding non-melanoma skin cancers and subset into lung, upper digestive tract, and other severe cancers; lymphatic system, head, and other major cancers; metastatic cancers; breast, prostate, colorectal, and other cancers and tumors; lymphoma; multiple myeloma; and leukemia then recombined), inability to ambulate, inability to transfer, alcohol dependence, drug dependence, tobacco use, gastro-intestinal ulcer, hyperparathyroidism, monoclonal gammopathy, myelofibrosis, and myelodysplastic syndrome. The measurement of specific comorbidities depended on factors such as whether the conditions were relatively chronic or acute and whether certain related conditions might be combined to form a single measure. These comorbidity measurement issues are discussed in Chapter VIII.

Some analyses also include a measure of local wages (SNF wage index that has been used to adjust composite rate payments for differences in labor costs) as an independent variable. The wage

adjustments vary according to the location of the facility in a specific metropolitan statistical area (of a core based statistical area, CBSA) or a rural area of a specific state for facilities not in a metropolitan statistical area. By accounting for area wage differences, the inclusion of the wage index as an independent variable also allows the estimates for the other payment variables (case-mix) to be determined based on the variation in provider costs for which there is no separate payment adjustment.

Control variables were included to obtain more accurate estimates of the effects of the payment variables. In the absence of control variables, the relationship between the payment variables and measures of resource utilization may be biased. The control variables were defined using several data sources (see Chapter III, Overview of Data Sources) and included the following facility characteristics: hospital based versus freestanding; facility size (less than 5,000, 5,000-10,000 and greater than 10,000 dialysis sessions); facility ownership (independent, large dialysis organization, regional chain, unknown); composite rate payment exception; percent of patients having a urea reduction ratio (URR) less than 65 percent; and rural versus urban location. Calendar year was included as an additional control variable in analyses that pooled three years of data. The rationale for including these specific control variables is discussed in Chapter VI, Section C, Dialysis Facility Characteristics and Control Variables.

A similar set of independent variables was included in the composite rate and separately billable equations. To define the independent variables for each equation, it was necessary to link patient and facility level data. For example, measures for patient characteristics (e.g., female) are included as potential payment variables in the facility level composite rate equation, while measures for facility characteristics (e.g., hospital based) are included as control variables in the patient level separately billable equation. For the composite rate equation, we defined case-mix measures using data for all Medicare dialysis patients treated in each facility. Specifically, we determined the percentage of a facility's patients having each patient characteristic. For example, sex was measured as the percentage of patients that were female. Since separate Cost Reports are not submitted for hospital satellite facilities, case-mix data for patients treated in satellite facilities were linked to the parent hospital using CMS (OSCAR) data. For the model of separately billable MAP, we defined measures for facility characteristics using data for all facilities that treated each Medicare dialysis patient.

These patient and facility variables were calculated as the weighted average value across multiple observations, where the weight was based on the number of Medicare hemodialysis equivalent dialysis sessions at each facility. This weighting process was used to give greater emphasis to patient and facility observations that accounted for more of the care that was delivered, based on the number of dialysis sessions. For example, in defining facility level case-mix measures, the characteristics of patients who were treated by the facility for twelve full months (e.g., with 13 sessions each month) were given twelve times as much weight as the characteristics of patients who were treated by the facility for only one full month (e.g., with 13 sessions). Similarly, to define patient level measures for the facility control variables, the characteristics of the facility that treated the patient for nine full months were given three times as much weight as the characteristics of the facility that treated the patient for the remaining three full months. The resulting case-mix variables were examined as potential payment variables in the composite rate equation (e.g., % female and average body surface area among patients in each facility). This approach was also used to define the case-mix measures examined for the composite rate basic case-mix adjustment (4). The resulting facility variables were included as control variables in the separately billable equation (e.g., % of a patient's sessions provided in hospital based facilities).

Evaluation of specific control and payment variables for inclusion in a payment model involved extensive research to determine relations to cost. This research is described in the next section.

C. DIALYSIS FACILITY CHARACTERISTICS AND CONTROL VARIABLES

In addition to the patient case-mix factors that are potential risk adjusters, the case-mix models we estimated also include several facility characteristics. Facility characteristics can be used as either payment or control variables in a bundled case-mix adjusted payment system.

If costs are associated with facility characteristics that are considered to justify a payment adjustment, then the coefficient on that facility characteristic could serve as the basis for a payment adjustment. For example, if hospital based dialysis facilities are associated with higher costs of providing care by $10 per session, and there is a public policy to adjust for this cost differential, then hospital based facilities might receive a higher payment of $10 per session.

Alternately, some facility characteristics might be associated with cost of providing dialysis services, but they may not be considered as justifying a differential payment. These characteristics are included in the case-mix models to provide more accurate estimates of the causal effects of the case-mix measures on dialysis costs. Models that include only the case-mix measures suffer from omitted variables bias, so that the case-mix coefficients might capture not only the causal effect of case-mix but also part of the effect of those omitted variables that are correlated with case-mix. For example, hospital based facilities treat a higher percentage of relatively young (aged 18-44 years) patients. If hospital location is left out of the case-mix estimation model, some of the higher cost of hospital location would be attributed to young patient age. A payment model derived from this case-mix estimation model that adjusted payments for young age would then result in a payment adjustment that exceeded the true cost differential for patients of young age.

To assess the effects of including or excluding facility characteristics in estimating equations, we estimated several facility year linear regression models explaining total cost per session as a function of patient demographic and diagnostic characteristics, controlling for successively more facility characteristics (13). We used data from 2003 Medicare Cost Reports and Medicare claims files (n= 4,275 facility years, corresponding to 212,034 patients and 23,411,303 dialysis sessions). Facility characteristics in these analyses included size, urban-rural location, chain ownership, and hospital based versus freestanding status. Results are summarized in Table 6-1 below.

Our analyses demonstrate that inclusion of facility characteristics changes the coefficients for some of the patient characteristics. For example, youngest and oldest patients tend to be the most expensive to treat. When facility characteristics are included in the model, the relationship becomes less pronounced by about half. Some diagnoses become insignificant when facility variables are included. An example is cardiac arrhythmia. Still other diagnoses, such as bacterial pneumonia, become significant. All three groups of control variables affected the magnitudes of many potential patient characteristics coefficients. A notable example is cancer. For other variables such as hepatitis B, controlling for hospital based facility versus freestanding facility had the most substantial impact on the estimate of the potential patient level adjuster. Controlling for facility size also influenced several potential adjusters, such as duration of RRT, substantially. Controlling for chain membership also changed the values of several patient adjusters (e.g., ischemic heart disease).

Table 6-1
Linear model parameter estimates predicting total cost per session (CR+SB), with various facility level controls, 2003

	Controls: none	Controls: Hospital-based	Controls: Hospital-based, # of sessions	Controls: Hospital-based, # of sessions, chain
Ages <18 yrs	$246.95 ***	$148.41 ***	$102.20 ***	$102.13 ***
Ages 18-44 yrs	$72.30***	$44.80 ***	$58.65***	$50.99 ***
Ages 45-59 yrs	$8.11	$7.74	$22.99	$10.94
Ages 70-79 yrs	$6.19	-$5.32	-$2.58	-$5.26
Ages 80+ yrs	$55.51 ***	$21.18	$19.37	$9.35
Female	$18.86	$21.26 *	$18.10 *	$23.40 **
Ages 18-44, female	-$54.56	-$5.42	$7.42	$2.75
Body surface area	$160.40 ***	$155.15 ***	$110.72 ***	$112.14 ***
Underweight (BMI <18.5)	$69.58 **	$64.82 **	$37.91	$32.46
< 1 year of RRT	$9.94	$2.35	-$18.92 *	-$20.37 *
Arrhythmia	$25.7 *	$19.06	$21.56	$11.12
Ischemic heart disease	$25.37	$30.3 **	$29.81 **	$16.62
HIV/AIDS	$13.26	$5.43	$7.58	$3.52
Bacterial pneumonia	$65.28	$102.34 *	$93.04 *	$96.59 *
Hepatitis B	$17.30 *	$10.19	$10.22	$10.28
Hereditary hemolytic or sickle cell anemia	$45.01	$13.84	$8.99	$6.17
Cancer	$20.81	$18.12	$33.01 *	$43.92 **
Hospital-based facility		$63.36 ***	$73.71 ***	$63.01 ***
Facility size (sessions)			-$18.69 ***	-$19.15 ***
Chain 1				$9.73 ***
Chain 2				$18.49 ***
Chain 3				$29.30 ***
Chain 4				-$12.21 ***
Chain 5				-$1.66
Chain 6				$16.20 ***
Regional chain				-$1.26
Unknown				$15.53 ***
R-squared	0.0857	0.2867	0.3548	0.4304

***p<0.001; **p<0.01; *p<0.05.

The changes in coefficient estimates resulting from inclusion of facility characteristics arise because patients with particular characteristics tend to receive dialysis at certain types of facilities. As suggested above, unless facility characteristics associated with cost are controlled for, facility effects may be incorrectly attributed to patient characteristics.

Facility characteristics that might be considered for use in estimating equations include the CMS wage index used to adjust Medicare payments to skilled nursing facilities. This variable helps to account more accurately for differences in labor costs. Facility size could be included to account for differences in efficiency due to economies of scale, as the lower average costs among larger facilities are well documented (19,20). The models might control for whether the facility was hospital based or freestanding, and for chain ownership (e.g. indicators for the six largest chains and smaller chains versus independent). Hospital based providers tend to have substantially higher self-reported composite rate costs than freestanding providers, which may partly reflect the methods used to allocate joint costs to hospital outpatient dialysis units. Chain membership could be used to account for differences across chains (e.g., due to differences in reporting) as well as similarities among facilities within chains. Urban versus rural location likewise can account for efficiency and other cost drivers related to geography.

The percentage of Medicare patients achieving the KDOQI guideline for urea reduction ratio (URR ≥65 percent) has been used as a measure of quality of care at each facility. URR values were obtained from Medicare outpatient dialysis claims, and were weighted by the number of HD equivalent dialysis sessions reported on the claim. The resulting case-mix coefficients will be less biased by any relationship that exists between quality of care and facility costs.

Estimation models also might control for whether the facility was granted a payment exception to the composite rate system (e.g., as a pediatric facility or isolated essential facility). The resulting higher reimbursement levels may enable facilities to sustain higher average costs relative to those that would be sustainable by an otherwise similar facility that did not receive an exception to the composite rate payment. Facilities that were granted a payment exception between November 1993 and July 2001 were identified using a list obtained from CMS.

Regardless of whether policy makers adjust payments for facility characteristics, it is important to consider facility characteristics in the model used to estimate case-mix adjusters. This is particularly true if the models are estimated at the facility level rather than the patient level.

VII. STRUCTURE OF THE MODEL

A. ONE VERSUS TWO EQUATION MODELING APPROACH

To determine the structure of the case-mix models for an expanded ESRD PPS, it is imperative to consider the unit of analysis. This is because the level at which resource use can be measured differs for the two principal components of an expanded bundle. Resource use for separately billable (SB) services can be measured for individual patients using several types of Medicare claims. In contrast, the available measures of resource use for composite rate (CR) services are reported on the Freestanding Dialysis Facility and Hospital Cost Reports, which combine session costs for all of the patients treated in each facility. Given the available data on resource use, a modeling approach could be based on either one or two estimating equations:

- One equation approach: Facility level combined model for composite rate and separately billable services
- Two equation approach: Facility level model for composite rate services and patient level model for separately billable services

The relative strengths and limitations of these modeling approaches are discussed below.

A third modeling approach, a single equation at the patient level, was also considered in preliminary work. However, as detailed below that approach was determined not to be statistically valid and was dropped from consideration.

1. Accuracy, precision and stability of estimates

The major difference between the two primary modeling approaches is that a patient level model is used to explain the variation in separately billable services under the two equation approach and a facility level model (of combined SB+CR services) is used under the one equation approach. The first approach therefore has the advantage of utilizing the patient level variation in separately billable services that is available from the Medicare claims. The second approach has the relative simplicity of deriving the case-mix adjustment based on a single statistical model that is estimated at the facility level. The main similarity between the two modeling approaches is that the form of the resulting payment model is the same and will not depend on the form of the estimation model (one or two equation). That is, a two equation estimation model can be converted into a one equation payment model.

To understand the differences between these two modeling approaches, we evaluated patient level and facility level models that were limited to separately billable services. By using the same patient level data in both models, we isolate the effect of aggregating the patient level data to the facility level. These analyses are used to compare patient level models and facility level models for separately billable services (Table 7-1).

Based on both models in Table 7-1, predictors of higher SB MAP per session include younger age, female, body surface area, and most comorbidities. Despite using the same data and same set of predictors, large differences emerged in the estimated coefficients for several case-mix factors, especially rare conditions having large effects on SB MAP. For example, the coefficient estimate for other cancers based on the facility level data is $27.49, while the estimate based on the patient level data is $5.39. Both coefficients are statistically significant, and were estimated with sufficient precision that their 95 percent confidence intervals are non-overlapping. Therefore, it must be determined which of these coefficients represents an unbiased estimate of the true, underlying relationship between other cancers and dialysis costs.

One theoretical source of bias in the coefficient estimates arises if a correlation exists between case-mix measures and unobserved facility characteristics. The nature of this bias is explained intuitively here, and is described in more detail in Appendix A. The theoretical equations in that appendix guide an empirical analysis that demonstrates the bias. Unobserved facility characteristics can be considered a "latent" variable. The biasing effects of this latent variable can be minimized in a patient level analysis by estimating a model that uses as a dependent variable the difference between patient level cost and facility mean cost, and uses as predictor variables the difference between the patients' characteristics and the mean value of the characteristics at the facility level. This patient level model will be unbiased by omitted facility characteristics. The facility level model will be biased unless the latent variable is uncorrelated with case-mix. Estimating these two models yields quite different coefficients for a number of case-mix variables, confirming the presence of bias in the facility level model.

Theoretically, the bias is greatest when the correlation between the case-mix measure and the latent variable is high, the effect of the latent variable on cost is large, the standard deviation of the latent variable is large, and the standard deviation of the case-mix measure is small. Empirically, as the latent variable can not be observed implies that the first three factors cannot be directly estimated. However, the standard deviation of the case-mix measure across facilities can be measured. For rare conditions, this standard deviation is low, which helps explain why the bias is often large in the case of rare conditions (e.g., gastrointestinal bleeding, pericarditis and esophageal varices).

Table 7-1.
Comparison of patient level and facility level models of separately billable services, 2002-2004

	Linear models of SB MAP per session*			
	Facility level model n=12,142 R-sq=0.1511		Patient level model n=848,331 R-sq=0.0882	
Case Mix Factor	Parameter Estimate	p-value	Parameter Estimate	p-value
Age <18	-$42.31	0.0014	-$15.40	<.0001
Age 18-44	$1.31	0.729	$5.50	<.0001
Age 45-59	$8.71	0.0183	$2.36	<.0001
Age 60-69	$0.00	ref	$0.00	ref
Age 70-79	-$14.58	<.0001	-$4.30	<.0001
Age 80+	-$15.09	<.0001	-$7.59	<.0001
Female	$18.40	<.0001	$10.74	<.0001
Body surface area (per 0.1 m^2)	$6.34	<.0001	$3.25	<.0001
Underweight (BMI <18.5)	$29.07	<.0001	$3.45	<.0001
Less than 4 previous months of RRT	$14.62	0.0365	$24.05	<.0001
Alcohol/drug dependence: claims since 1999 or 2728 (any)	$7.59	0.0002	$6.41	<.0001
Cardiac arrest: claims since 1999 or 2728 (any)	$8.95	0.2316	$7.94	<.0001
Pericarditis within one year	$105.30	<.0001	$21.32	<.0001
HIV/AIDS: claims since 1999 or 2728 (any)	$13.46	<.0001	$9.78	<.0001
Hepatitis B since 1999	$1.03	0.4571	$2.27	<.0001
Specified infection (includes 4 categories) within 1 month	$88.36	<.0001	$84.03	<.0001
Gastro-intestinal tract bleeding within 1 month	$406.51	<.0001	$109.37	<.0001
Esophageal varices within 6 months	$13.12	0.7704	$58.91	<.0001
Acquired hemolytic anemias within one year	-$5.94	0.0359	$9.80	<.0001
Hereditary hemolytic or sickle cell anemias since 1999	$17.55	0.0006	$14.68	<.0001
Specified cancer (includes 6 categories) since 1999	$19.51	<.0001	$9.21	<.0001
Other cancers since 1999	$27.49	<.0001	$5.39	<.0001
Myelodysplastic syndrome since 1999	$27.77	0.0153	$25.73	<.0001
Monoclonal gammopathy since 1999	$45.95	<.0001	$7.64	<.0001

*Includes adjustments for facility characteristics. Models are weighted by the number of hemodialysis-equivalent dialysis sessions. MAP=Medicare Allowable Payments from Medicare claims.

Table 7-2 provides information about the precision and stability of the parameter estimates from both facility level and patient level models. Coefficients from the patient level model are more precisely estimated and more stable over time. Precision is demonstrated using the 95 percent confidence intervals reported for the pooled 3-year models. As an illustrative example, we use hereditary hemolytic or sickle cell anemias, which has relatively similar point estimates from the patient level and facility level models, but has much wider confidence intervals based on the facility level model. Regarding stability, coefficient estimates for each individual year from 2002-2004 are reported for both patient and facility models. As an illustrative example, myelodysplastic syndrome is statistically significant and has a similar coefficient based on patient level and facility level models using pooled 2002-2004 data, but is highly unstable from year to year in the facility level model. Cardiac arrest provides another example where the two pooled models yield similar point estimates, but the facility level model demonstrates greater instability in the estimates over time.

Table 7-2
Confidence intervals and yearly estimates for case-mix coefficients, facility level versus patient level linear models of MAP/session for separately billable services, 2002-2004*

	Facility level						Patient level					
	2002-04 (n=12,142)			2002	2003	2004	**2002-04** (n=848,331)			2002	2003	2004
	Confidence intervals		Estimated coefficient	n=3,840	n=4,066	n=4,236	Confidence intervals		Estimated coefficient	n=266,700	n=285,032	n=296,599
Variable	95% Low	95% High					95% Low	95% High				
Age <18	-$68.31	-$16.32	-$42.31	-$46.59	-$56.40	-$34.54	-$18.88	-$11.93	-$15.40	-$12.31	-$13.86	-$18.68
Age 18-44	-$6.08	$8.69	$1.31	$4.38	-$1.24	$1.36	$5.13	$5.88	$5.50	$5.16	$5.82	$5.55
Age 45-59	$1.47	$15.94	$8.71	$1.02	$1.30	$22.75	$2.03	$2.68	$2.36	$1.95	$2.57	$2.53
Age 70-79	-$21.51	-$7.65	-$14.58	-$11.52	-$18.90	-$12.91	-$4.62	-$3.97	-$4.30	-$3.58	-$4.70	-$4.58
Age 80+	-$22.42	-$7.77	-$15.09	-$11.43	-$21.93	-$12.03	-$7.99	-$7.19	-$7.59	-$6.61	-$8.05	-$7.98
Female	$13.89	$22.91	$18.40	$18.70	$19.10	$17.96	$10.50	$10.98	$10.74	$10.67	$10.42	$11.07
Body surface area (per 0.1 m²)	$5.67	$7.02	$6.34	$5.48	$5.56	$7.77	$3.20	$3.30	$3.25	$3.05	$3.14	$3.50
Underweight (BMI <18.5)	$16.20	$41.95	$29.07	$9.65	$17.99	$60.54	$2.86	$4.05	$3.45	$3.35	$3.06	$3.93
<4 previous months of RRT	$0.92	$28.33	$14.62	$4.95	$10.65	$29.65	$23.39	$24.72	$24.05	$19.58	$25.80	$26.53
Alcohol/drug dependence: claims since 1999 or 2728 (any)	$3.55	$11.62	$7.59	$9.01	$6.35	$7.03	$6.05	$6.77	$6.41	$5.51	$6.02	$7.45
Cardiac arrest: claims since 1999 or 2728 (any)	-$5.72	$23.63	$8.95	$24.41	$10.41	-$6.51	$7.28	$8.61	$7.94	$6.74	$7.81	$9.05
Pericarditis within one year	$80.36	$130.23	$105.30	$77.16	$97.21	$141.14	$20.14	$22.50	$21.32	$17.17	$21.85	$24.90
HIV/AIDS: claims since 1999 or 2728 (any)	$9.43	$17.48	$13.46	$21.07	$10.08	$11.40	$9.20	$10.35	$9.78	$10.11	$9.40	$9.90
Hepatitis B since 1999	-$1.69	$3.76	$1.03	-$0.91	$3.20	$0.39	$1.82	$2.71	$2.27	$1.66	$2.96	$1.97
Specified infection (includes 4 types) within 1 month	$74.03	$102.69	$88.36	$74.15	$104.10	$90.12	$82.87	$85.20	$84.03	$72.94	$84.55	$93.77
Gastro-intestinal tract bleeding within 1 month	$322.49	$490.53	$406.51	$380.97	$371.85	$452.42	$106.03	$112.71	$109.37	$95.85	$108.50	$121.17
Esophageal varices within 6 months	-$74.98	$101.22	$13.12	$60.89	-$51.87	$56.38	$55.30	$62.51	$58.91	$53.96	$58.64	$63.40
Acquired hemolytic anemias within one year	-$11.49	-$0.39	-$5.94	-$8.17	-$0.10	$0.50	$8.78	$10.81	$9.80	$5.08	$14.53	$14.32
Hereditary hemolytic or sickle cell anemias since 1999	$7.48	$27.61	$17.55	$20.98	$16.50	$15.86	$13.95	$15.40	$14.68	$13.86	$14.80	$15.26
Specified cancer (includes 6 categories) since 1999	$11.71	$27.31	$19.51	$21.68	$19.47	$14.17	$8.76	$9.65	$9.21	$8.63	$9.10	$9.82
Other cancers since 1999	$21.12	$33.87	$27.49	$19.70	$23.50	$39.42	$5.02	$5.76	$5.39	$4.73	$5.01	$6.44
Myelodysplastic syndrome since 1999	$5.32	$50.23	$27.77	-$16.35	$48.07	$40.66	$24.64	$26.82	$25.73	$23.53	$26.99	$26.30
Monoclonal gammopathy since 1999	$26.36	$65.55	$45.95	$37.95	$28.97	$67.18	$6.67	$8.60	$7.64	$7.35	$6.65	$8.78

*Includes adjustments for facility characteristics. Models are weighted by the number of hemodialysis-equivalent dialysis sessions. MAP=Medicare Allowable Payments from Medicare claims.

2. Potential refinement for the two equation approach

To determine the relationship between case-mix and resource use for separately billable services, a patient level model relies on a combination of the variation occurring among individual patients within the same facility and the variation occurring among patients in different facilities. Since the number of facility observations (~12,000) is small relative to the number of patient observations (~800,000), the impact of unobserved facility characteristics in a patient level model will be limited relative to a facility level model (i.e., as with the one equation approach). However, the case-mix coefficients may still be influenced by unobserved facility characteristics.

As an alternative modeling approach for separately billable services that fully controls for unobserved facility characteristics, we tested individual facility effects in a patient level model. This approach includes individual facility intercepts, or essentially a separate indicator variable for each of the approximately 4,000 facilities. This analysis includes one observation per patient per facility, for each year from 2002-2004.

The inclusion of individual facility fixed effects (versus including several measurable facility characteristics in the model) increased the explanatory power of the model from 8.4 percent to 18.3 percent (Table 7-3). This increase in explanatory power reflects the addition of approximately 4,000 individual facility indicator variables. The case-mix multipliers estimated by the two models, however, are generally very similar, varying within one percentage point for most factors. Those factors that had somewhat larger differences tended to represent relatively small numbers of patients (e.g., pediatric, pericarditis, HIV/AIDS). The difference in multipliers was largest for the pediatric variable, and may reflect the concentration of many pediatric patients in facilities that specialize in treating these patients. The ability to distinguish the effect of being a pediatric patient and the effect of being a patient in a largely pediatric facility may be limited if there are relatively few pediatric patients treated in other facilities. For pediatric facilities, the individual facility effects may be at least partly capturing the effect of what is inherently a patient characteristic (pediatric), and thereby removing it from the payment adjustment for pediatric patients. This is a possible disadvantage of controlling for individual facility effects. Since the adjustment for individual facility effects had a limited effect on most multipliers, it was not explored further as part of a patient level separately billable equation.

3. An alternative form of the one equation approach

Given the available resource use data, another possible form of a one equation modeling approach is a patient level combined model for composite rate and separately billable services. Such an approach requires combining patient level costs for separately billable services with the average cost for composite rate services for the facility in which the patient is treated (i.e., as a proxy for the cost of providing composite services to each patient). This approach would both allow the variation in separately billable services to be used (as with Approach 2) and require only one estimating equation (as with Approach 1). However, this approach potentially leads to a substantial bias in the estimated case-mix coefficients.

Table 7-3
Impact of adjusting patient level analyses of separately billable services for individual facility effects, 2002-2004

	Model 1: Includes facility characteristics R-sq: 0.0841		Model 2: Includes individual facility intercepts R-sq: 0.1834	
Variable	**Estimated Multiplier**	**p**	**Estimated Multiplier**	**p**
Age				
<18	0.64	<.0001	0.80	<.0001
18-44	1.01	0.0005	1.01	<.0001
45-59	0.99	<.0001	0.99	<.0001
60-69	1.00	ref	1.00	ref
70-79	0.96	<.0001	0.97	<.0001
80+	0.93	<.0001	0.94	<.0001
Female	1.16	<.0001	1.15	<.0001
Body surface area (per 0.1 m^2)	1.04	<.0001	1.04	<.0001
Underweight (BMI <18.5)	1.04	<.0001	1.03	<.0001
Duration of RRT <4 months	1.41	<.0001	1.42	<.0001
Alcohol/drug dependence: claims since 1999 or 2728 (any)	1.08	<.0001	1.07	<.0001
Cardiac arrest: claims since 1999 or 2728 (any)	1.09	<.0001	1.09	<.0001
Pericarditis from same month to three months ago	1.62	<.0001	1.55	<.0001
HIV/AIDS: claims since 1999 or 2728 (any)	1.13	<.0001	1.10	<.0001
Hepatitis B since 1999	1.03	<.0001	1.03	<.0001
Specified infection (4 categories) from same month to three months ago	1.64	<.0001	1.65	<.0001
GI tract bleeding from same month to three months ago	1.83	<.0001	1.78	<.0001
Hereditary hemolytic or sickle cell anemias since 1999	1.16	<.0001	1.15	<.0001
Specified cancer (includes 6 categories) since 1999	1.10	<.0001	1.09	<.0001
Other cancers since 1999	1.07	<.0001	1.06	<.0001
Myelodysplastic syndrome	1.29	<.0001	1.29	<.0001
Monoclonal gammopathy since 1999	1.09	<.0001	1.08	<.0001

n=1,112,456 patient-facility-year observations. Models of the average separately billable Medicare Allowable Payment per session from the Medicare claims were weighted by the number of hemodialysis-equivalent dialysis sessions.

Although we expect the true cost to provide composite rate services to vary among patients in each facility, there is no variation in our measure of composite rate costs among patients within each facility. The result is a positive measurement error for patients whose true composite rate cost per session is greater than their facility average and a negative measurement error for patients whose true composite rate cost per session is less than their facility average. To the extent that this measurement error is correlated with case-mix, which unlike composite rate costs is measured at the patient level, we would systematically understate or overstate the cost of treating certain types of patients in each facility. For example, the average facility cost for composite rate services is likely to understate the cost of treating patients who have a body surface area (BSA) that is greater than their facility average. The measurement error in composite rate costs is therefore likely to be correlated with BSA, and potentially with other patient characteristics. The result is a form of nonrandom measurement error

in the composite rate cost component of the dependent variable which will tend to bias the case-mix coefficients towards zero. As a result of this potentially substantial bias, this form of a one equation approach was not used.

4. Conclusion

The two primary modeling approaches that were possible given the available resource use data differ with regard to whether a facility level model or a patient level model was used to explain variation in separately billable services. By utilizing patient-to-patient variation in both case-mix and resource use, a patient level model has the advantage of reducing potential bias related to unobserved facility characteristics, producing more precise coefficient estimates and yielding greater stability in coefficient estimates over time. Further, a patient level model for separately billable services can be combined with a facility level model for composite rate services to yield a single payment model for an expanded bundle. A two equation modeling approach was therefore used to examine potential risk adjusters for use with an expanded PPS.

B. LOGARITHMIC VERSUS LINEAR MODEL

Models of resource use for composite rate services and separately billable services could be estimated as either logarithmic models or linear models. Logarithmic models are useful with skewed data. Typically, health care cost data feature a skewed distribution in which a relatively small fraction of individuals account for a disproportionate fraction of costs. The cost distribution for both composite rate and separately billable services exhibits this type of skewness.

However, since the skewness in costs for outpatient dialysis related costs is not as pronounced as with other cost data, we examined both logarithmic and linear forms of the case-mix models. For these analyses, the dependent variable was the average cost per session in the linear models and the log of the average cost per session in the logarithmic models, while the independent variables were the same in all models. For both composite rate and separately billable services, the explanatory power of the logarithmic models was either similar to or slightly lower than that of the linear models (Table 7-4).

The explanatory power of the logarithmic models was assessed using two separate R-squared values. The R-squared statistic from the logarithmic model, which is labeled as R-sq (log dollars) in Table 7-4, measures the ability of the model to explain variation in resource use in terms of log dollars rather than in dollars. However, the extent to which a model explains variation in resource use measured in dollars will be more relevant to providers, since they are reimbursed in dollars. A separate R-sq value, R-sq (dollars), is based on a linear model in which the average cost per session (in dollars) was the dependent variable and the predicted cost per session from the log-linear model (i.e., retransformed to dollars) was used as the only independent variable. When evaluated in terms of dollars, the explanatory power was not affected by which functional form was used for composite rate services (39.8%) and remained slightly lower with the logarithmic form for separately billable services (9.1% vs. 10.3%).

Based on the factors that had a statistically significant association with costs (not shown here; see Chapter IX, A Combined Case-mix Adjusted Model for Composite Rate and Separately Billable Services), the list of potential case-mix adjusters implied by the two functional forms was very similar, although the magnitude of the payment adjustments varied for individual factors. A secondary analysis of residuals showed that the logarithmic form of the separately billable model had a modest advantage in better satisfying the assumptions of the model (e.g., normality and

homoskedasticity of residuals). By reducing the influence of individual observations that reflect unusually high levels of resource use, logarithmic models yield more stable estimates.

Table 7-4

Explanatory power of linear and log-linear models of resource utilization, 2002-2004

		Functional form		
		Linear	Log-linear	
Measure of resource utilization	n	R-sq	R-sq (log dollars)*	R-sq (dollars)**
Composite rate cost per session	11,174	39.8%	38.7%	39.8%
Separately billable MAC per session	809,208	10.3%	8.8%	9.1%

*R-sq (log dollars) is the R-sq statistic from the log-linear model, and measures the ability of the case-mix model to explain variation in log dollars.

**R-sq (dollars) is a measure of the ability of the log-linear model to explain variation in dollars. This statistic is the R-sq value from a linear model in which the average cost/session is the dependent variable and the predicted cost/session from the log-linear model (i.e., retransformed to dollars) is used as the independent variable.

In addition to the skewness in the cost data, there may be other factors to consider when choosing between logarithmic and linear models. A log transformation was applied to the resource utilization measure that was used to develop the current basic case-mix adjustment (BCMA) for the composite rate system (7). The log-transformed dependent variable allows the case-mix adjustments to be applied multiplicatively to the wage adjustment which reflects a multiplier in the composite rate system (i.e., results in a larger case-mix adjustment for facilities in higher wage areas). Hence, a logarithmic form is consistent with prior methods employed by CMS to adjust payment for dialysis services.

One potential disadvantage of a logarithmic model is a by-product of the multiplicative nature of the case-mix adjustments. A given upward payment adjustment based on body surface area will be larger for dialysis patients who also have a costly comorbidity. An example from the composite rate BCMA shows that larger patients who are younger (18-44 years) receive a greater incremental payment for their large size than do large patients in the middle age category (60-69 years). This is not necessarily inappropriate, but it does represent a different policy choice than using an additive adjustment that would pay the same number of extra dollars for each characteristic regardless of which other characteristics are present.

Logarithmic models have both advantages and disadvantages relative to linear models. Separate analyses of composite rate and separately billable services suggest that the choice of functional form does not substantially affect overall model performance. Based on the somewhat skewed cost data for composite rate and separately billable services, and based on prior methods used to adjust payment for dialysis services, we applied a log transformation to both measures of resource use for the primary case-mix analyses.

C. STATISTICAL OUTLIERS FOR THE AVERAGE COST PER SESSION

Regression models of the average cost per session were used to estimate the typical increment in cost associated with each case-mix factor. However, the average cost per session may be influenced by individual facilities and exceptionally high cost patients. We explored methods to restrict the study samples so that the resulting models would characterize the patterns seen among a broad spectrum that included most facilities and patients, rather than being unduly influenced by a few exceptional, non-representative, and perhaps erroneously reported cases. For example, extreme values for the average composite rate cost per session may reflect unique circumstances for some facilities (e.g., a new dialysis facility that treated a very small number of patients) or differences in reporting across facilities (e.g., a hospital that uses different methods for allocating costs to a dialysis unit on its cost report). In addition, to the extent there is variation over time in the characteristics of facilities or patients with extreme average costs, individual outliers may lead estimates of the relationship between case-mix factors and cost per session to be less stable over time.

This section describes the methods used to identify statistical outliers for the average cost per session and the impact on case-mix analyses of excluding potential outlier observations. Since a two equation modeling approach was used, potential outliers for the average cost per session were examined separately for composite rate and separately billable services.

It should be noted that this section focuses on identifying statistical outliers for average costs in order to estimate accurate and stable models to develop the case-mix adjustment for an expanded bundle. The possibility of using an outlier payment methodology for dialysis providers who incur exceptionally high session costs under an expanded PPS is addressed in Chapter X, Section D, Outlier Payments.

The distribution of the average cost per session for outpatient dialysis related services is shown in Table 7-5. Average composite rate costs are between $121 per session and $305 per session for 90% of facility observations (i.e., based on the 5th and 95th percentiles, respectively). However, some facilities reported extreme values for average cost per session. For example, one percent of facilities report average costs below $100 per session and another one percent of facilities report average costs exceeding $639 per session.

A standard outer fence method was examined for facilities with extreme average costs. The upper outer fence is defined as the 75th percentile plus three times the interquartile range (IQR, which is the 75th percentile – the 25th percentile); while the lower outer fence is the 25th percentile minus three times the IQR. The outer fences for average cost per session were calculated on the log scale, since a log transformation was used to estimate the models. When retransformed to dollars, the lower outer fence for composite rate costs was $58 per session and the upper outer fence was $457 per session. However, a model that applied these exclusion criteria yielded especially large prediction errors for facilities with reported costs below $100 per session. Approximately 95 percent of the facilities with average costs between $58 per session and $100 per session had studentized residuals less than -2, and approximately 50 percent had studentized residuals less than -4. Based on this analysis of studentized residuals, a slightly more restrictive lower limit of $100 per session was applied.

Table 7-5

Distribution of average costs for outpatient dialysis-related services, 2002-2004

Measure of resource use	n	Average cost per session at selected percentiles of facilities or patients						
		1	2	5	50	95	98	99
Facility composite rate costs	11,499	$104.08	$111.39	$120.79	$159.42	$304.73	$459.67	$639.01
Patient separately billable MAP	818,558	$5.90	$11.89	$21.93	$75.50	$206.08	$260.44	$297.48

The impact of these exclusion criteria on regression models of average composite rate costs is summarized in Table 7-6. When using the slightly more restricted sample that excluded 2.8% of facilities, there was a substantial improvement in the overall explanatory power of the model. There were relatively large changes in the estimated multipliers for several factors (e.g., age 18-44, monoclonal gammopathy) and a few factors which either gained or lost statistical significance (e.g., female, underweight, and septicemia). Supporting analyses showed that the excluded facilities tended to be smaller and were more likely to be hospital based relative to other facilities. As a result of their typically smaller size, the 2.8% of facilities that were excluded as potential outliers reflected only 1.3% of Medicare dialysis patient years. When exploring the use of even more restrictive criteria for average composite rate costs, there were much smaller changes in both the overall model fit and in the estimated multipliers for most factors.

Extreme values for the average cost per session were also identified for separately billable services. First, the average monthly cost for EPO, which is by far the largest component of separately billable costs, was capped to reflect no more than 30,000 units of EPO per session; more than that may reflect clinically implausible doses. CMS currently places a similar limit on EPO reimbursement of 500,000 units per patient per month (26). As a result of capped average EPO costs, the remaining extreme values for average separately billable costs described in Table 7-5 largely reflect services other than EPO.

As shown in Table 7-5, the average MAP per session for separately billable services ranged from $22 to $206 for 90% of patients, and exceeded $297 for 1% of patients. The outer fence method yielded an upper cutoff ($1,358 per session) that represents an unusually high level of resource use. This very high upper limit excluded only eight patient observations from the model (from n=818,558 to n=818,550), with virtually no change in the analysis results. Supporting analyses that used more restrictive criteria did not substantially improve the performance of the model and yielded similar case-mix multipliers (i.e., typically varying by no more than 0.01). In order to base potential case-mix adjusters on the largest possible number of Medicare dialysis patients while still placing a limit on extreme values, the upper outer fence method was used for average separately billable costs, as it was for average composite rate costs. No lower limit on separately billable costs was established for the purpose of identifying statistical outliers. It is plausible for a patient to incur no separately billable costs in a particular month.

Analyses of the effects of patient characteristics on the average cost per session for outpatient dialysis and related services have the potential to be sensitive to individual facilities or patients with extreme costs. Their inclusion may lead the resulting estimates to be less reflective of the typical increment in

cost associated with individual patient characteristics and to be less stable over time. Exclusion criteria can be used to develop methods that are as inclusive as possible with regard to the underlying Medicare dialysis patient population that is the basis for determining a case-mix adjustment, but are not unduly influenced by individual facilities or patients having extreme costs. Exclusion criteria were used for the average cost per session for both composite rate and separately billable services, and relied principally on a standard outer fence method, with one refinement based on an analysis of studentized residuals. The use of these exclusion criteria led to a substantial improvement in model performance for composite rate costs, while there was a relatively limited effect for models of separately billable costs.

Table 7-6
Sensitivity of analyses to potential outliers for average composite rate costs, 2002-2004

	Log-linear models of average CR cost per session			
	Includes all facilities in the 50 states and D.C. n=11,499 Mean $ 162.83 per session R-sq: 0.2727 R-sq, controls only: 0.2559		**Excludes potential outliers** n=11,174 Mean $ 162.00 per session R-sq: 0.3871 R-sq, controls only: 0.3695	
Variable	**Est. Multiplier**	**p**	**Est. Multiplier**	**p**
Age				
<18	1.33	0.0009	1.42	<.0001
18-44	1.70	<.0001	1.33	<.0001
45-59	1.11	0.0352	1.02	0.6175
60-69	1.00	ref	1.00	ref
70-79	1.13	0.0097	1.06	0.0688
80+	1.34	<.0001	1.24	<.0001
Female	1.07	0.0304	1.05	0.0457
Body surface area (per 0.1 m^2)	1.019	<.0001	1.033	<.0001
Underweight (BMI <18.5)	1.22	0.0146	1.06	0.3219
Duration of RRT: <4 months	1.80	<.0001	1.60	<.0001
Alcohol/drug dependence: claims since 1999 or 2728 (any)	1.12	0.0092	1.13	0.0001
Cardiac arrest: claims since 1999 or 2728 (any)	*1.00^*	*n.s.*	*1.00^*	*n.s.*
Pericarditis from same month to three months ago	*1.00^*	*n.s.*	*1.00^*	*n.s.*
HIV/AIDS: claims since 1999 or 2728 (any)	*1.00^*	*n.s.*	*1.00^*	*n.s.*
Hepatitis B since 1999	*1.00^*	*n.s.*	*1.00^*	*n.s.*
Specified infection within 3 months				
Septicemia	*1.00^*	*n.s.*	1.07	0.0034
Bacterial pneumonia	*1.00^*	*n.s.*	*1.00^*	*n.s.*
Other pneumonias/opportunistic infections	*1.00^*	*n.s.*	*1.00^*	*n.s.*
Gastro-intestinal tract bleeding from same month to three months ago	*1.00^*	*n.s.*	*1.00^*	*n.s.*
Hereditary hemolytic or sickle cell anemias since 1999	*1.00^*	*n.s.*	*1.00^*	*n.s.*
Cancer since 1999 (excludes non-melanoma skin cancer)	*1.00^*	*n.s.*	*1.00^*	*n.s.*
Myelodysplastic syndrome since 1999	*1.00^*	*n.s.*	*1.00^*	*n.s.*
Monoclonal gammopathy since 1999	2.03	<.0001	1.38	0.0010

Models also include facility control variables (not shown).

As noted earlier, this section does not address the possibility of using an outlier payment mechanism to target higher payments to providers who incur exceptionally high costs under an expanded PPS. The use of potential outlier payment methodologies with the model payment system is discussed in Chapter X.

VIII. DEFINITION AND MEASUREMENT OF PATIENT CHARACTERISTICS FOR CASE-MIX ADJUSTMENT

Selection of case-mix adjustment patient characteristics from the extensive Medicare databases (see Chapter III, Overview of Data Sources) required careful consideration. As we developed predictive models suitable for implementation in a case-mix adjusted prospective payment system, we considered whether specific patient characteristics should be included in the model, based on both magnitude and statistical significance of relationships between cost and the characteristic. In addition, the potential for creation of adverse incentives or social inequity by inclusion of a patient characteristic was considered. Subsequent research informed CMS decisions about which patient characteristics to include in payment models. Case-mix measures were reviewed for accuracy and objectivity of diagnostic criteria, temporal relationship between comorbidity appearance and cost, and model parsimony. It will be particularly important to consider how the comorbidity measures identified retrospectively in our models can be translated into comorbidity measures that can be reported prospectively for a future payment system.

A. CONSIDERATIONS FOR SELECTION OF PATIENT CHARACTERISTICS

1. Inclusion in basic case-mix adjustment

The basic case-mix adjustment (BCMA) recently instituted for the payment of CR services reflects several patient characteristics: age category, body surface area (BSA), and low body-mass index (BMI). These patient characteristics have demonstrated relations to CR costs. Prior to implementing the BCMA, the specific measures of these patient characteristics were subject to extensive analyses. These analyses resulted in the selection of the specific age categories described in Chapter VI of this report (Section B, Independent Variables). They also resulted in selection of a specific measure of body size, BSA using the DuBois formula (27), among many considered. Finally, these analyses verified a commonly used definition of underweight status: BMI under 18.5. The analysis underlying these selections is presented fully in "Methodology for Developing a Basic Case Mix Adjustment for the Medicare ESRD Prospective Payment System" (7). Given the results of this prior work, and to be consistent with the consequent changes in Medicare payment policy, these patient characteristics are included in the case-mix models described throughout this report.

2. Magnitude and statistical significance of relationship to cost

Given the very large number of ESRD patients with Medicare claims, statistical significance is a necessary but not a sufficient criterion for including a variable in a case-mix adjustment system. Variables with very small relationships to cost are likely to be statistically significant in patient level analyses. Such variables add little to the explanatory power of the models, and facilities caring for patients with those conditions will not receive meaningful increases in payments. To achieve these minor benefits in terms of explanatory power and actual payment changes, it may not be worth the additional complexity and administrative burden to collect and report variables with small, though statistically significant, relationships to cost. Therefore, each potential case-mix adjuster should be examined to ensure not only that its relationship to cost is statistically significant, but also that the magnitude of the relationship is economically meaningful.

3. Potential for adverse incentives

Some comorbidities or clinical measures may themselves be adverse outcomes of dialysis related care. For example, recent or current measures of hematocrit may be strongly associated with ESAs and iron dosing, with lower hematocrit predicting higher subsequent costs. Therefore, using recent or current hematocrit in a payment model would effectively reward facilities achieving lower hematocrit. Preliminary analyses showed that measures of recent hematocrit had a strong effect on costs, with lower hematocrit predicting higher subsequent costs. For example, adding a measure of the average hematocrit six to eight months prior to the current month to the case-mix adjustment model raised the R-squared of preliminary models by approximately five percent. Although these measures have been excluded from the focal models discussed in this report due to concerns regarding incentives, they could be considered for a payment system provided that adequate quality assurances could be implemented.

4. Social acceptability

Some variables may have statistical relationships with costs but may be judged to not be appropriate for differential payments. Patients' race and ethnicity are examples of variables that may be excluded from a payment model by policy makers.

B. SELECTION OF PATIENT CHARACTERISTICS

We began with a long list of patient characteristics that might be included in a bundled case-mix adjusted payment system. In addition to age, patient demographic characteristics included gender, race and Hispanic ethnicity. Physical characteristics included measures of body size and underweight status. Duration of renal replacement therapy was also examined as a potential payment adjuster. In addition, we considered an extensive list of patient comorbidities. Table 8-1 lists the comorbidity variables and data sources that were considered. The original list was based on diagnostic categories developed for the Medicare Advantage managed care program (listed in Table 8-1) and categories developed for the comorbidities in the CMS Form 2728.

Comorbidity measures based on diagnoses reported in Medicare claims used all available claims (e.g., inpatient, dialysis and other outpatient, skilled nursing facility, physician/supplier, and laboratory). It should be noted that some diagnoses reported on laboratory claims may represent a condition being "ruled out" by the test, rather than an established diagnosis. Therefore, the use of laboratory claims to identify comorbidities may overestimate the frequency of certain conditions. Conversely, excluding laboratory claims from the comorbidity identification process may underestimate the frequency of certain conditions if the laboratory diagnosis reflects the presence of the condition and other claims do not identify the condition. In ongoing research, UM-KECC is re-estimating the case mix models without using diagnoses reported on laboratory claims in the comorbidity identification process. These alternative estimates of the prevalence of comorbidities and the resulting case mix multipliers will be compared to those in this report.

Table 8-1 also shows which of the comorbidity measures considered made the refined list of comorbidities included in most of the case-mix models described in this report. The refined list is the result of applying the considerations described above and the application of several analytical approaches.

Table 8-1: Original and Refined Comorbidity Measures

Original Comorbid Conditions Considered for a Case-mix Model	Source	Included in Final Models	Comments
Cardiac Arrest	2728 or claims	Yes	Explored alternative definition with automatic implantable cardiac defibrillator (AICD) procedure codes but the use of AICD placement did not overlap substantially with cardiac arrest diagnosis. Source and time frame used in model: claims since 1999 or 2728, any occurrence.
Pericarditis	2728 or claims	Yes	See Table 8-2. Potentially ambiguous definition. In clinical practice, pericarditis classically presents with characteristic chest pain, physical exam findings (including friction rub) and often will have associated fluid in the pericardial sac which can be imaged with cardiac ultrasound. The problem is that pericardial fluid alone is probably not adequate to define pericarditis. The clinical features noted above are somewhat subjective. Not all patients will manifest all of the signs and symptoms and some patients may present in atypical manner. In ESRD patients, pericarditis can be a uremic manifestation. In addition, some literature suggests that the intermittent anticoagulation associated with dialysis may contribute to development of pericarditis in chronic dialysis patients. In theory, chronic poor dialysis could cause uremia and potentially increase the risk of uremic pericarditis. There are solutions for this potential problem (e.g., monitor facility for adequate dialysis provision; pay for pericarditis only if patient was adequately dialyzed by URR criteria). Source and time frame used in model: claims, same month to 3 months ago.
Alcohol Dependence	2728 or claims	Yes	Combined with Drug Dependence to form Substance Abuse category. Requires strict definition as current claims diagnoses likely represent specific diagnostic severity (e.g. Inpatient Rehab admission). Source and time frame used in model: claims since 1999 or 2728, any occurrence.
Drug Dependence	2728 or claims	Yes	Combined with Alcohol Dependence to form Substance Abuse category. Without specific definition, potential for significant expansion of diagnostic frequency. In addition, many ESRD patients are regularly prescribed potentially habit forming medications to treat uremic sleep disturbances, chronic pain, restless leg syndrome, and anxiety related to chronic illness. This further emphasizes the need for a specific definition. Source and time frame used in model: claims since 1999 or 2728, any occurrence.
HIV Positive Status	2728 or claims	Yes	Combined with AIDS diagnosis (essentially either HIV and/or AIDS) Source and time frame used in model: claims since 1999 or 2728, any occurrence.

Table 8-1: Original and Refined Comorbidity Measures			
Original Comorbid Conditions Considered for a Case-mix Model	Source	Included in Final Models	Comments
AIDS	2728 or claims	Yes	Combined with HIV diagnosis (essentially either HIV and/or AIDS) Diagnostic criteria are available through CDC and other agencies for AIDS; HIV exposure can be objectively defined by antibody tests with reasonable accuracy. Providers may be able to order screening HIV studies, potentially expanding defined HIV positive pool. This may not be a bad thing, since effective treatments are available to slow the progression from asymptomatic HIV to AIDS with early diagnosis, but raises patient privacy issues. Source and time frame used in model: claims since 1999 or 2728, any occurrence.
Gastro-Intestinal Tract Bleeding	claims	Yes	Including severity in the definition is one issue. See Table 8-4 In theory, unethical practitioners could increase their use of aspirin, non-steroidal anti-inflammatory drugs or even warfarin. This may be far-fetched, but many dialysis patients have at least a relative indication for use of one or more of these agents. More likely, facilities could increase their screening efforts (obtain fecal occult blood testing on a regular basis (or more frequent basis if already using this as part of their anemia management program). Such testing would result in the identification of additional cases, probably of lower than average severity. Source and time frame used in model: claims, same month to 3 months ago.
Lung, Upper Digestive Tract, and Other Severe Cancers	claims	Yes	Combined with multiple other cancer diagnoses. Starting with all cancers except for non-melanoma skin cancers, we split them into the groups of cancers used by the Medicare Advantage Program. After further analysis we recombined the categories as they had very similar coefficients. Source and time frame used in model: claims, any occurrence since 1999
Lymphatic System, Head, and Other Major Cancers	claims	Yes	Combined with multiple other cancer diagnoses Source and time frame used in model: claims, any occurrence since 1999
Metastatic Cancers	claims	Yes	Combined with multiple other cancer diagnoses Source and time frame used in model: claims, any occurrence since 1999
Breast, Prostate, Colorectal, and Other Cancers and Tumors	claims	Yes	Combined with multiple other cancer diagnoses Source and time frame used in model: claims, any occurrence since 1999
Septicemia/Shock	claims	Yes	Use of separate category from pneumonias. See Table 8-3 Catheters have been shown to increase the risk of sepsis. Hypothetically, paying for blood infections is financial incentive to ignore permanent vascular access planning. See hepatitis B for infection control practices issue. Several quality assurance mechanisms currently in place (particularly Fistula First at Network level) or under development could counter this misaligned incentive. Source and time frame used in model: claims, same month to 3 months ago

Table 8-1: Original and Refined Comorbidity Measures			
Original Comorbid Conditions Considered for a Case-mix Model	Source	Included in Final Models	Comments
Opportunistic Infections (Pneumonias)	claims	Yes	Combined with other Pneumonia categories. See Table 8-3 Source and time frame used in model: claims, same month to 3 months ago
Aspiration and Specified Bacterial Pneumonias	claims	Yes	Combined with other Pneumonia categories. See Table 8-3 Source and time frame used in model: claims, same month to 3 months ago
Pneumococcal pneumonia, emphysema, lung abscess	claims	Yes	Combined with other Pneumonia categories. See Table 8-3 Source and time frame used in model: claims, same month to 3 months ago
Monoclonal Gammopathy	claims	Yes	Any diagnosis since 1999 Technically, fairly objective lab diagnosis available. This is a spectrum of diseases, ranging from clinically unimportant to life-threatening (malignant form is known as multiple myeloma). The presence of a monoclonal gammopathy is a lab definition which encompasses this very diverse set of clinical entities. Defining severity of monoclonal gammopathy will be important issue as we move forward. Source and time frame used in model: claims, any occurrence since 1999
Myelodysplastic Syndrome	claims	Yes	Source and time frame used in model: claims, any occurrence since 1999
Leukemia	claims	Yes	Combined with multiple other cancer diagnoses Source and time frame used in model: claims, any occurrence since 1999
Hereditary Hemolytic Anemias	claims	Yes	Combined with sickle cell anemia as both are hereditary anemias with similar impact on MAP Definitions are straightforward in many of the diseases in this category (alpha thalassemia may be an exception to this statement). As with other co-morbidities, defining which hereditary hemolytic anemias were identified with historical billing codes and writing the regulations to reflect those conditions or levels of severity will be important. Unlikely that all "hereditary hemolytic anemia diagnoses were identified with our analytic strategy. For example, UpToDate electronic textbook estimates that 8-10% of African Americans have sickle cell trait (generally asymptomatic). Carrier states for other hereditary hemolytic anemias exist. If dialysis facilities begin widespread screening for these carrier states, the diagnostic frequency for hereditary hemolytic anemias could expand greatly. Defining severity will be critical in developing a fair payment model. Source and time frame used in model: claims, any occurrence since 1999
Sickle-Cell Anemia	claims	Yes	Combined with sickle cell anemia as both are hereditary anemias with similar impact on MAP Source and time frame used in model: claims, any occurrence since 1999

Table 8-1: Original and Refined Comorbidity Measures

Original Comorbid Conditions Considered for a Case-mix Model	Source	Included in Final Models	Comments
Lymphoma	claims	Yes	Combined with multiple other cancer diagnoses Source and time frame used in model: claims, any occurrence since 1999
Hepatitis B	claims	Yes	Any diagnosis since 1999 Objective lab diagnosis is available. Need to align diagnostic criteria with historical billing code diagnostic criteria. In theory, facilities could stop vaccinating patients against hepatitis B, resulting in more cases. Alternatively, facilities could become more lax in infection control processes. This is not likely to happen as hepatitis B positive patients are difficult to dialyze (strict criteria from CDC for isolation), the facility surveyors could focus on infection control practices, staff are averse to providing care to patients with potentially highly contagious severe viral illness and CMS has discussed separate payment for vaccines, which would positively influence providers to continue vaccinating patients. Facilities could order screening tests more frequently, although they would end up bearing the cost in a widely bundled payment system. Source and time frame used in model: claims, any occurrence since 1999
Multiple Myeloma	claims	Yes	Combined with multiple other cancer diagnoses Source and time frame used in model: claims, any occurrence since 1999
Congestive Heart Failure	2728 or claims	No	Diagnostic criteria are vague and would make implementation difficult. Potential for misaligned incentives as congestive heart failure term is used for clinical diagnosis of symptomatic fluid overload, potentially caused by poor dialysis care. Also CHF is very common claims comorbidity, diluting effectiveness in payment model.
Ischemic Heart Disease	2728 or claims	No	Diagnostic criteria are vague and addition of this comorbidity to a payment model would likely result in increased coding.
Myocardial Infarction	2728 or claims	No	Diagnostic criteria are vague and addition of this comorbidity to a payment model would likely result in increased coding
Cardiac Dysrhythmias	2728 or claims	No	Claims comorbidity definition is too vague to allow definition of a regulation for payment variable. Significant potential for increased frequency of claims if used in a payment model, given the frequency of arrhythmias in ESRD patients
Cerebrovascular Disease	2728 or claims	No	Common conditions and claims comorbidity definition too vague to allow creation of a regulation defining payment variable based on available detail level in claims data.
Peripheral Vascular Disease	2728 or claims	No	Excluded both because of high prevalence of this comorbidity in claims and because of poor specificity in claims. Excluded from BCMA model in past for similar reasons.
History of Hypertension	2728 or claims	No	Extremely high prevalence limits its value as a risk adjuster. In addition, control of hypertension is an outcome of dialysis treatment (related to control of volume overload). Use of hypertension as a comorbidity in a payment model would result in misalignment between quality and payment incentives.

Table 8-1: Original and Refined Comorbidity Measures

Original Comorbid Conditions Considered for a Case-mix Model	Source	Included in Final Models	Comments
Type I Diabetes (Primary or Contributing)	2728 or claims	No	Accurate differentiation of Type 1 from Type 2 diabetes is difficult clinically and from claims. Combined diagnostic category of diabetes mellitus is very common (when longest look-back period is used) limiting it's effectiveness as a payment variable. In addition, magnitude of effect in models is small. Excluded to enhance model parsimony.
Chronic Obstructive Pulmonary Disease	2728 or claims	No	Claims diagnosis is relatively subjective. More objective definition of COPD could be developed if additional diagnostic testing (spirometry/pulmonary function testing) was required to define condition, but this would be difficult to implement and potentially add significant cost. COPD is also common condition and inclusion could result in significant increased frequency of reporting. More severe forms might be identified based on whether chronic oxygen therapy was required (as described later in this section), but the administrative burden of verifying home oxygen use would be significant, and this possibility was dropped from consideration.
Hyperparathyroidism	2728 or claims	No	Very common condition in chronic dialysis patients. Small magnitude effect on cost.
Inability to Ambulate	2728	No	Diagnosis is subjective. May be underreported in source data, which is limited to the 2728 Form.
Inability to Transfer	2728	No	Excluded by stepwise regression.
Tobacco Use	2728	No	Excluded by stepwise regression.
Other infections	claims	No	Claims comorbidity definition includes infections not otherwise classified. Extremely vague, and there is potential for significant increase in reporting. Currently, this diagnostic category includes over 1,000 specified infections, limiting its practical use as a payment variable.
Myelofibrosis	claims	No	Very rare.
Type II or unspecified Diabetes (Primary or Contributing)	claims	No	Accurate differentiation of Type 1 from Type 2 diabetes is difficult clinically and from claims. Combined diagnostic category of diabetes mellitus is very common (when longest look-back period is used) limiting it's effectiveness as a payment variable. In addition, magnitude of effect in models is small. Excluded to enhance model parsimony.
Other Hepatitis (not B)	claims	No	Excluded by stepwise regression.
Acquired Hemolytic Anemias	claims	No	The conditions are uncommon, the coefficients are small and the relationship with cost varied depending on the specific look-back period that was used (with multipliers varying above and below 1.00 depending on which month a relevant diagnosis was reported in the last year of claims).
Other Anemias	claims	No	Claims comorbidity definition is non-specific. How could this diagnosis be differentiated from anemia of CKD in dialysis patients?
Gastrointestinal Ulcer not Hemorrhaging	claims	No	Difficult to accurately diagnose without costly diagnostic study (UGI barium study or UGI endoscopy) and unclear relationship to GI bleeding. Analytic team, including clinicians at UM-KECC and CMM were concerned that this claims diagnosis might be present as a claims diagnosis in patients recently evaluated for GI bleeding. More analysis needed to define relationship between this category and GI bleeding
Esophogeal Varices	claims	No	Very rare. Specific diagnosis requires UGI endoscopy or other costly diagnostic imaging. Estimation of accurate coefficient limited by rarity of condition in claims.

We performed stepwise regression analyses to identify patient characteristics having a statistically significant association with measured costs.[2] Comorbidity measures that were excluded as potential case-mix adjusters on the basis of not having positive significant relations to measured costs included inability to transfer, smoking, and other Hepatitis.

C. REFINING THE DEFINITIONS OF PATIENT CHARACTERISTICS

We conducted several analyses to refine the definition and measurement of patient characteristics. These analyses were motivated by several types of measurement concerns.

1. Extent to which future reporting is likely to differ from measured historical prevalence

The available comorbidity data are collected for purposes other than making case-mix adjustments to dialysis payments. CMS Form 2728 is used to establish renal failure for program eligibility. Because the presence or absence of specific comorbidities does not factor into the ultimate eligibility decision, underreporting is expected and has been verified empirically by comparison to conditions reported in patients' medical records (29,30,31). Claims based comorbidity measures are more current and are likely to be more complete because they are drawn from claims submitted by many types of providers over a period of time. But even here there may not be a strong financial incentive for complete reporting. Therefore, policy makers should be aware that if a variable is included in a case-mix adjustment model, it is possible that reporting will increase above the levels seen historically. This is particularly likely if the condition varies greatly in severity (e.g., mild cases may not have been reported historically) or if the presence of the diagnosis is relatively subjective.

Chronic obstructive pulmonary disease (COPD) is one example of a condition with subjective diagnostic criteria, and for which severity of reported cases is likely to vary substantially. To explore the extent of such variation in severity and to determine if an observable marker for more severe cases could be identified, a measure of chronic oxygen therapy was derived from the Medicare claims. We investigated whether this measure could supplement or replace measures based on diagnosis codes for chronic obstructive pulmonary disease. Use of oxygen therapy was determined based on durable medical equipment (DME) claims and carrier claims. For the purposes of exploratory analyses, a patient was deemed to be receiving chronic oxygen therapy based on three or more months with oxygen therapy within the past year. Medicare employs a series of explicit criteria to determine whether a patient is eligible for oxygen therapy payment. To the extent that these criteria are enforced, concerns about inappropriate oxygen prescriptions to increase payments would be mitigated.

Chronic oxygen therapy occurred far less frequently than COPD diagnoses. However, the set of patients receiving chronic oxygen therapy is not strictly a subset of those with COPD claims diagnoses. This can be seen based on the relatively limited overlap between the two measures. A diagnosis of COPD was reported in the prior year of Medicare claims for 17.5 percent of patients and chronic oxygen therapy was identified for 5.6 percent of patients. Both COPD and chronic

[2] These analyses examined a relatively broad set of patient characteristics that included age, body surface area and underweight status at start of RRT, gender, race, ethnicity, duration of RRT, hematocrit at start of RRT, and most of the individual comorbidities listed in Table 8-1. A facility level analysis of composite rate costs that included facility control variables, composite rate BCMA factors, and other statistically significant patient characteristics yielded a model R-squared of 40.4%. A similar patient level stepwise regression analysis of separately billable MAP yielded a model R-squared of 12.5%.

oxygen therapy were indicated for only 1.5 percent of patients. Therefore, most patients with COPD did not receive chronic oxygen therapy and most patients receiving chronic oxygen therapy did not have a COPD diagnosis.

The explanatory power of the new measures was examined in a series of models of 2004 separately billable services. Four models were estimated using variants of these measures. Controlling for a large set of other patient characteristics and comorbidities, the first model included only COPD, the second included only chronic oxygen therapy, the third included both measures, and the fourth included a measure of patients with both a COPD diagnosis and chronic oxygen therapy. In the first two models, COPD and chronic oxygen therapy are significant predictors of cost and have similar multipliers (1.10 and 1.11, respectively). The explanatory power is slightly higher with the COPD measure due to its higher prevalence. In the model that includes both measures, each remains a significant and independent predictor of separately billable services, with multipliers similar to those in models one and two (1.09 for COPD, 1.10 for chronic oxygen therapy. In the fourth model which uses the combination of COPD reported *and* chronic oxygen therapy, the multiplier rises to 1.18. Therefore, the combination of these two variables may be an indication of the relative severity of pulmonary disease.

A related issue is how different "look-back" periods affect the prevalence of diagnoses (e.g., % of patients with a given diagnosis reported in the prior 6 months, year, or two years). One comorbidity for which unusually large differences existed between shorter and longer look back periods was diabetes. Sixty-five percent of patients were reported to have diabetes based on a longer look-back period (based on CMS Form 2728 and claims since 1999), while only 17 percent of patients had a diagnosis reported on claims within the last year. Since the more proximate diabetes mellitus prevalence is low relative to what we and others have previously reported in the literature (e.g., USRDS data), using only a recent diagnosis may inadequately represent the reporting prevalence of diabetes mellitus in an implemented payment model.

2. Persistence of effect on cost

Chronic conditions (e.g., sickle cell and hereditary hemolytic anemias) are likely to have a persistent effect on costs over time. Once such a condition is identified, it is likely to persist. Certainly, chronic conditions might have acute manifestations that lead to higher costs over a short period of time, but it is unlikely that such acute flare-ups can be predicted. Hence, it is likely to be appropriate to use a long time-frame to identify chronic conditions, with the resulting payment adjustments persisting for the patient. Conversely, acute conditions (e.g., GI bleeding) may result in elevated costs for only a short period of time. Therefore, various time-frames were examined to determine the length of time post-diagnosis that a payment adjustment should apply.

To illustrate the process of selecting a look back period, Table 8-2 presents the analysis of alternative look-back periods for pericarditis. The month-by-month analysis in the first column indicates that pericarditis in the same month, one month ago, and two months ago is significantly related to cost ($p<0.05$). There is also a significant relationship for pericarditis twelve months prior to the current month. Sensitivity analyses suggest that this result partly captures the effect of pericarditis occurring more than twelve months ago, which are not adjusted for in this model. The second, third, and fourth columns in Table 8-2 show analyses indicating pericarditis is positively associated with costs for any definition of look-back period. Furthermore, as we extend the look-back period two findings emerge: (1) more patients are classified as having pericarditis and (2) the coefficient indicating the strength of the relationship decreases. Therefore, the longer the look back period, the fewer dollars allocated to each patient with pericarditis.

Table 8-2
Analysis of alternative look back periods for pericarditis
Patient level log-linear regression model of MAP for separately billable services, 2002-2004 (n=847,660)

		Alternative look back periods							
		Same month to twelve months ago, by month		Same month to three months ago		Within two years		2728 Form or claims (since 1999)	
Diagnosis of pericarditis	% of patients	Multiplier	p	Multiplier	p	Multiplier	p	Multiplier	p
In same month	0.1%	1.50	<0.01	n/a	n/a	n/a	n/a	n/a	n/a
One month ago	0.1%	1.24	0.03	n/a	n/a	n/a	n/a	n/a	n/a
Two months ago	0.1%	1.40	0.00	n/a	n/a	n/a	n/a	n/a	n/a
Three months ago	0.1%	1.14	0.30	n/a	n/a	n/a	n/a	n/a	n/a
Four months ago	0.1%	1.30	0.05	n/a	n/a	n/a	n/a	n/a	n/a
Five months ago	0.1%	1.18	0.23	n/a	n/a	n/a	n/a	n/a	n/a
Six months ago	0.1%	1.05	0.73	n/a	n/a	n/a	n/a	n/a	n/a
Seven months ago	0.1%	0.99	0.94	n/a	n/a	n/a	n/a	n/a	n/a
Eight months ago	0.1%	1.01	0.94	n/a	n/a	n/a	n/a	n/a	n/a
Nine months ago	0.1%	1.18	0.31	n/a	n/a	n/a	n/a	n/a	n/a
Ten months ago	0.1%	0.96	0.81	n/a	n/a	n/a	n/a	n/a	n/a
Eleven months ago	0.1%	1.08	0.65	n/a	n/a	n/a	n/a	n/a	n/a
Twelve months ago	0.1%	1.61	<0.01	n/a	n/a	n/a	n/a	n/a	n/a
From same month to three months ago	0.4%	n/a	n/a	1.76	<0.01	n/a	n/a	n/a	n/a
Within two years	2.0%	n/a	n/a	n/a	n/a	1.22	<0.01	n/a	n/a
Based on 2728 Form or claims (since 1999)	4.4%	n/a	n/a	n/a	n/a	n/a	n/a	1.14	<0.01

Includes adjustment for control variables and other patient characteristics.

Tables 8-3 and 8-4 present similar analyses for specified infections and gastrointestinal bleeding, respectively.

Table 8-3
Analysis of alternative look back periods for specified infections
Patient level log-linear regression model of MAP for separately billable services, 2002-2004 (n=847,660)

		Alternative look-back periods			
		Same month to twelve months ago, by month		Same month to three months ago	
Diagnosis of specified infections (4 categories)	% of patients	Multiplier	p	Multiplier	p
In same month	4.9%	1.30	<0.01	n/a	n/a
One month ago	5.0%	1.22	<0.01	n/a	n/a
Two months ago	5.0%	1.26	<0.01	n/a	n/a
Three months ago	4.8%	1.11	<0.01	n/a	n/a
Four months ago	4.7%	1.08	0.00	n/a	n/a
Five months ago	4.5%	1.06	0.04	n/a	n/a
Six months ago	4.3%	1.05	0.08	n/a	n/a
Seven months ago	4.2%	1.03	0.28	n/a	n/a
Eight months ago	4.0%	0.99	0.71	n/a	n/a
Nine months ago	3.9%	1.01	0.82	n/a	n/a
Ten months ago	3.7%	0.97	0.31	n/a	n/a
Eleven months ago	3.6%	1.02	0.46	n/a	n/a
Twelve months ago	3.5%	1.14	<0.01	n/a	n/a
From same month to three months ago	13.3%	n/a	n/a	1.67	<0.01

Includes adjustment for control variables and other patient characteristics.

Table 8-4
Analysis of alternative look-back periods for gastrointestinal bleeding
Patient level log-linear regression model of MAP for separately billable services, 2002-2004 (n=847,660)

Diagnosis of GI bleeding	% of patients	Alternative look-back periods			
		Same month to twelve months ago, by month		Same month to three months ago	
		Multiplier	p	Multiplier	p
In same month	0.3%	1.82	<0.01	n/a	n/a
One month ago	0.4%	1.43	<0.01	n/a	n/a
Two months ago	0.4%	1.31	<0.01	n/a	n/a
Three months ago	0.4%	1.21	0.01	n/a	n/a
Four months ago	0.4%	1.21	0.01	n/a	n/a
Five months ago	0.3%	1.11	0.18	n/a	n/a
Six months ago	0.3%	1.18	0.04	n/a	n/a
Seven months ago	0.3%	1.12	0.17	n/a	n/a
Eight months ago	0.3%	1.03	0.70	n/a	n/a
Nine months ago	0.3%	1.00	0.97	n/a	n/a
Ten months ago	0.3%	1.14	0.14	n/a	n/a
Eleven months ago	0.3%	1.05	0.62	n/a	n/a
Twelve months ago	0.3%	1.83	<0.01	n/a	n/a
From same month to three months ago	1.2%	n/a	n/a	1.94	<0.01

Includes adjustment for control variables and other patient characteristics.

The results in Tables 8-2 through 8-4 were used to establish refined look back periods of up to two months ago and up to three months ago for pericarditis, specified infection, and gastrointestinal bleeding. These two refined look back periods were compared in separate models. For administrative ease, we recommend using the same look back period for each of these three comorbidities. The results indicated that a look back period of up to three months improved the fit of the model. Therefore, for these comorbidities, we recommend a look back period of up to three months.

3. Further refinements to patient characteristics

If a more parsimonious model is desired, clinically related conditions could be combined. For example, HIV and AIDS were combined into a single comorbidity measure in our models, as were sickle cell and hereditary hemolytic anemias. In some cases, diagnoses were combined based on *a priori* clinical judgments regarding their likely comparability of effects on the use of dialysis related services. In other cases, preliminary analyses allowed certain diagnoses or sets of diagnoses to enter the model separately, but they were combined after the preliminary models revealed that their relationships to costs were of similar magnitude.

The following example of measures of infection demonstrates how related diagnoses were grouped. Based on *a priori* clinical judgment, similar codes were grouped into three categories (septicemia, bacterial pneumonia, and a set of other specified infections, each with a look-back period of three months). Septicemia is the most common, present in 10.1% of patient months; bacterial pneumonia and the other specified infections occurred in 1.4% and 0.3% of months, respectively. Septicemia had a multiplier of 1.70 in preliminary analyses, bacterial pneumonia had a multiplier of 1.43, and

other specified infections had a multiplier of 1.50. Because the two relatively uncommon categories had similar multipliers, they were combined into a single category. In a more parsimonious specification, septicemia had a multiplier of 1.70 and the combined category had a multiplier of 1.47. This information is useful to develop more precise rules to define infection.

Similarly, two earlier groupings of cancer measures were combined into a single measure that includes all cancers except non-melanoma skin cancers. The two previous cancer measures had similar multipliers in analyses of both separately billable and composite rate services. Given this result and based on our review of the diagnoses in each category, there appeared to be no conceptual or empirical rationale to maintain separate categories. Combining the categories resulted in a more parsimonious model.

Additional research identified other opportunities to reduce the list of patient characteristics without major loss of predictive power. Any histories of alcohol or drug abuse were combined into one category of "substance abuse". We excluded multiple comorbidity categories based on several characteristics, including low economic impact, vague definition, coefficient instability or high prevalence. These were congestive heart failure, cardiac dysrhythmia, cerebrovascular disease, peripheral vascular disease, diabetes mellitus, COPD, other hepatitis, esophageal varices, hyperparathyroidism, other infection, and myelofibrosis.

IX. A COMBINED CASE-MIX ADJUSTED MODEL FOR COMPOSITE RATE AND SEPARATELY BILLABLE SERVICES

A. COMPONENTS OF CASE-MIX ADJUSTMENT MODEL

This section presents a case-mix adjustment model for a per session payment system. It is based on the refined list of patient characteristics developed using several criteria (Chapter VIII.). One of these criteria was the estimated relationship to cost. Since this was assessed using separate equations for composite rate and separately billable services (see Chapter VII, Section A), some factors may be proposed as payment adjusters for only one set of services.

The relevant patient characteristics are listed in Table 9-1. These patient characteristics include the factors that comprise the existing basic case-mix adjustment for the composite rate system (age, body surface area, and a measure of underweight status), gender, duration of renal replacement therapy (RRT), and 11 refined comorbidity measures. The relationships of these patient characteristics to measures of resource use for composite rate and separately billable services are examined below. We also provide results regarding the precision and stability of the estimates that determine the payment adjustments.

Table 9-1
Characteristics of Medicare dialysis patients, 2002-2004 (n=809,208)

Variable	% or mean
Age	
<18	0.2%
18-44	14.0%
45-59	25.2%
60-69	23.2%
70-79	25.1%
80+	12.3%
Female	47.3%
Body surface area (m^2)	1.87
Underweight (BMI <18.5 kg/m^2)	3.9%
Duration of RRT: <4 months	5.6%
Alcohol/drug dependence: claims since 1999 or 2728 (any)	9.2%
Cardiac arrest: claims since 1999 or 2728 (any)	3.1%
Pericarditis from same month to three months ago	0.4%
HIV/AIDS: claims since 1999 or 2728 (any)	4.1%
Hepatitis B since 1999	7.6%
Specified infection from same month to three months ago	
Septicemia	10.1%
Bacterial pneumonia and other pneumonias/opportunistic infections	1.7%
Gastro-intestinal tract bleeding from same month to three months ago	1.2%
Hereditary hemolytic or sickle cell anemias since 1999	2.4%
Cancer since 1999 (excludes non-melanoma skin cancer)	16.5%
Myelodysplastic syndrome since 1999	1.1%
Monoclonal gammopathy since 1999	1.4%

1. Adjustment for composite rate services

The relationships between patient characteristics and cost for composite rate services were estimated using a facility level regression model since patient level data are not available. This facility level model relates average patient characteristics to the reported facility costs. The BCMA was developed using a similar approach (7). As a result of the log transformation (see Chapter VII, Section B), the model estimates are reported as factors that can be applied multiplicatively to a base rate to derive a case-mix adjusted payment for individual patients. The models presented below were weighted by the number of dialysis sessions provided by the facility. Facility-year observations that account for a larger number of dialysis sessions will therefore have proportionately more influence in the analysis. Among the 11 refined comorbidity measures, potential payment variables were identified using a stepwise selection method. The criterion for selecting and retaining comorbidity variables was statistical significance at the $p<0.05$ level.

The analysis included 11,174 facility year observations during the three year period. The explanatory power of a model that included both facility control variables (described in Chapter VI, Sections B and C) and the patient characteristics in Table 9-2 was 38.74%. A separate model that included just

the facility control variables had an R-squared of 36.97%, while the inclusion of the patient characteristics shown in Table 9-2 contributed an additional 1.77% to the R-squared.

Table 9-2
Estimated case-mix multipliers for composite rate services, 2002-2004 (n=11,174)

	Facility-level log-linear model of average cost/session R-sq: 38.74% R-sq, control variables only: 36.97% Average $162.00/sess.		
Variable	Multiplier ($Mult_{CR}$)	p	95% CI (low, high)
Age			
<18	1.42	<.0001	(1.24, 1.63)
18-44	1.31	<.0001	(1.23, 1.41)
45-59	1.01	0.6951	(0.95, 1.09)
60-69	1.00	ref	ref
70-79	1.06	0.0929	(0.99, 1.13)
80+	1.23	<.0001	(1.15, 1.32)
Female	1.05	0.0315	(1.00, 1.10)
Body surface area (per 0.1 m^2)	1.034	<.0001	(1.027, 1.040)
Underweight (BMI <18.5)	1.07	0.3059	(0.94, 1.20)
Duration of RRT: <4 months	1.60	<.0001	(1.41, 1.82)
Alcohol/drug dependence: claims since 1999 or 2728 (any)	1.12	0.0003	(1.05, 1.19)
Septicemia from same month to three months ago	1.07	0.0052	(1.02, 1.12)
Monoclonal gammopathy since 1999	1.38	0.0009	(1.14, 1.67)

The U-shaped relationship of age with average composite rate session costs in Table 9-2 is similar to the pattern observed in previous research (7) and is reflected in the existing BCMA for the composite rate payment system. Based on age, the model indicates the largest increment in cost for pediatric patients. The estimated multiplier of 1.42 indicates that costs were 42% higher for pediatric patients compared to the reference group of patients aged 60-69. This estimate is somewhat smaller than the current pediatric payment adjustment that was developed by CMS using a different approach (1.62). Using the current regression-based approach, the precision of the pediatric multiplier is limited by the small fraction of pediatric patients in most facilities, as the 95% confidence interval ranges from 1.24 to 1.63 (Table 9-2).

Elevated costs were observed for the youngest and oldest adult age groups (ages 18-44 and 80+, respectively) compared to the reference age group (ages 60-69). Previous research suggested that higher costs for ages 18-44 may partly reflect unmeasured factors which are associated with patients in this age group (9). Our current research controls for several of these factors (male, drug dependence, urban) but not others (unexplained missed dialysis sessions, type I diabetes and HIV/AIDS). Relative to the BCMA, the current results include somewhat larger adjustments for both ages 18-44 and ages 80+. Differences among the three middle age groups were not statistically significant. The ability to detect modest differences in cost will be limited by the number of observations that are available for a facility level analysis.

The estimated BSA multiplier of 1.034 implies a 3.4% elevated cost for every 0.1m² increase in BSA, which is slightly smaller than the current adjustment in the BCMA (3.7% per 0.1m²). Previous research found this BSA measure, which was calculated using the DuBois formula (27), to be more highly predictive of composite rate costs than other measures of body size, such as weight or total body water. To be consistent with the BCMA, low BMI is included as a potential adjustment factor despite lacking a statistically significant relationship with CR cost in the current model (7).

The remaining patient characteristics in Table 9-2 have not previously been used to adjust composite rate payments. These would be new payment adjustments based on gender, duration of RRT (<4 months) and the presence of 3 comorbidities. The elevation in composite rate costs for females was marginally significant, while a much larger effect was observed for newly treated ESRD patients. The three comorbidity measures in Table 9-2 were selected by the stepwise regression as statistically significant predictors of cost. The remaining eight refined comorbidity measures were not found to be statistically significant. Based on this criterion, the model presented in Table 9-2 excludes them as potential payment variables.

We used separate analyses by year to consider the stability of the estimates during 2002-2004 (Table 9-3). These analyses included the same independent variables as the pooled model. The stability of the estimates varies for individual case-mix measures. For example, the multipliers ranged from 1.24 to 1.34 for ages 18-44 and 1.13 to 1.40 for ages 80+. The comorbidity measures tended to be less consistent predictors of composite rate costs, as the yearly comorbidity estimates varied in terms of both their magnitude and their statistical significance. The potential payment adjusters are based on the model that uses pooled data (Table 9-2), since it is expected to yield more stable estimates than separate models by year. Greater stability may lead payments to be more predictable for providers as the PPS is updated over time.

Table 9-3
Yearly case-mix multipliers for composite rate services, 2002-2004

	Facility level log-linear models of average cost per session					
	2002 (n=3,508) R-sq: 35.97% R-sq, controls only: 33.52%		**2003 (n=3,796)** R-sq: 39.16% R-sq, controls only: 37.15%		**2004 (n=3,870)** R-sq: 42.83% R-sq, controls only: 41.09%	
Variable	Multiplier	p	Multiplier	p	Multiplier	p
Age						
<18	2.10	<0.01	1.74	<0.01	1.04	0.71
18-44	1.24	<0.01	1.34	<0.01	1.33	<0.01
45-59	1.05	0.48	1.08	0.23	0.95	0.35
60-69	1.00	ref	1.00	ref	1.00	ref
70-79	1.01	0.92	1.10	0.10	1.08	0.19
80+	1.17	0.02	1.40	<0.01	1.13	0.03
Female	0.98	0.56	1.03	0.42	1.13	<0.01
Body surface area (per 0.1 m²)	1.034	<0.01	1.042	<0.01	1.025	<0.01
Underweight (BMI <18.5)	0.97	0.80	1.09	0.44	1.17	0.13
Duration of RRT: <4 months	2.00	<0.01	1.31	0.02	1.66	<0.01
Alcohol/drug dependence: claims since 1999 or 2728 (any)	1.11	0.06	1.05	0.43	1.23	<0.01
Septicemia from same month to three months ago	1.10	0.02	1.06	0.21	1.03	0.50
Monoclonal gammopathy since 1999	1.54	0.02	1.57	0.01	1.14	0.40

2. Adjustment for separately billable services

Since resource use for separately billable services can be measured using Medicare claims, a patient level model was used to identify potential payment adjusters for separately billable services. We specified a regression model, weighted by the number of dialysis sessions, which included the same control variables and examined the same refined list of patient characteristics as the model of composite rate costs.

The analysis included 809,208 patient year observations during the three year period. The R-squared for a model that included both control variables and the patient characteristics in Table 9-4 was 8.82%. Unlike the pattern seen in the composite rate model, the control variables accounted for only 0.84% of the variation in resource use, while the patient characteristics contributed an additional 7.98% to the overall R-squared.

Table 9-4
Estimated case-mix multipliers for separately billable services, 2002-2004 (n=809,208)

	Patient level log-linear model of Medicare Allowable Payments per session R-sq: 8.82% R-sq, controls only: 0.84% Average $83.18/session		
Variable	Multiplier ($Mult_{SB}$)	p-value	95% CI (low, high)
Age			
<18	0.45	<.0001	(0.43, 0.47)
18-44	1.00	0.0626	(1.00, 1.01)
45-59	0.99	<.0001	(0.99, 1.00)
60-69	1.00	ref	ref
70-79	0.96	<.0001	(0.96, 0.97)
80+	0.93	<.0001	(0.93, 0.94)
Female	1.16	<.0001	(1.16, 1.17)
Body surface area (per 0.1 m^2)	1.038	<.0001	(1.037, 1.039)
Underweight (BMI <18.5)	1.03	<.0001	(1.02, 1.04)
Duration of RRT: <4 months	1.45	<.0001	(1.43, 1.46)
Alcohol/drug dependence: claims since 1999 or 2728 (any)	1.12	<.0001	(1.12, 1.13)
Cardiac arrest: claims since 1999 or 2728 (any)	1.09	<.0001	(1.08, 1.10)
Pericarditis from same month to three months ago	1.61	<.0001	(1.55, 1.67)
HIV/AIDS: claims since 1999 or 2728 (any)	1.13	<.0001	(1.12, 1.13)
Hepatitis B since 1999	1.04	<.0001	(1.03, 1.05)
Specified infection from same month to three months ago			
Septicemia	1.70	<.0001	(1.69, 1.71)
Bacterial pneumonia and other Pneumonias/opportunistic infections	1.47	<.0001	(1.44, 1.49)
Gastro-intestinal tract bleeding from same month to three months ago	1.88	<.0001	(1.85, 1.92)
Hereditary hemolytic or sickle cell anemias since 1999	1.16	<.0001	(1.14, 1.17)
Cancer since 1999 (excludes non-melanoma skin cancer)	1.09	<.0001	(1.08, 1.09)
Myelodysplastic syndrome since 1999	1.28	<.0001	(1.26, 1.30)
Monoclonal gammopathy since 1999	1.10	<.0001	(1.08, 1.11)

The estimates reflect somewhat higher Medicare Allowable Payments for females and for ages 18-69 relative to ages 70+. These model results control for body size and the other patient characteristics which may vary by age and gender. The BSA multiplier of 1.038 indicates an increase in cost of 3.8% for every 0.1 increase in BSA. When we controlled for BSA, there was a modest increase in cost for patients who were underweight (BMI less than 18.5 (28)). Together, these results indicate that the lowest costs were observed for patients who were smaller but were not considered underweight.

A larger effect was observed for newly treated ESRD patients. MAP were 45% higher for patients in their initial 4 months of RRT. Supporting analyses showed that substantially higher doses of epoetin were administered during these initial months. Since this analysis is based on Medicare claims data, the elevated cost in these initial months largely reflects the experience of patients who are already covered by Medicare and do not need to wait 90 days for Medicare eligibility based on ESRD. This will primarily include patients who are at least 65 years of age. Similarly, this multiplier would largely be used to adjust payments for patients who are already Medicare-eligible at start of RRT.

All 11 comorbidity variables had statistically significant relationships to cost (Table 9-4). However, the magnitudes of the comorbidity effects varied substantially. The largest increase in cost was associated with GI bleeding, two categories of specified infections, and pericarditis (47% to 88% higher costs). These are the acute conditions where a recent diagnosis (i.e., no more than 3 months ago) leads to a temporary payment adjustment. For most of the remaining comorbidities, the model estimated much smaller effects on cost (4% to 16% for all other conditions except myelodysplastic syndrome). These are the chronic conditions for which a diagnosis leads to a permanent increase in payment based on the expectation that they will tend to have a more persistent effect on cost.

Because of the large number of patient observations, most case-mix multipliers for separately billable services are estimated relatively precisely. The lower and upper 95% confidence intervals for the estimated multipliers typically reflect no more than a 3% difference in payments (Table 9-4). The relationships between these patient characteristics and cost are relatively stable during 2002-2004, as the yearly multipliers are similar in most cases (Table 9-5).

Table 9-5
Yearly case-mix multipliers for separately billable services, 2002-2004

	Facility level log-linear models of Medicare Allowable Payments per session					
	2002 (n=253,149) R-sq: 8.01% R-sq, controls only: 0.78%		**2003 (n=274,010)** R-sq: 8.75% R-sq, controls only: 0.51%		**2004 (n=282,049)** R-sq: 9.28% R-sq, controls only: 0.77%	
Variable	Multiplier	p	Multiplier	p	Multiplier	p
Age						
<18	0.59	<0.01	0.46	<0.01	0.37	<0.01
18-44	1.01	0.06	1.01	0.08	1.00	0.91
45-59	0.99	<0.01	0.99	0.05	0.99	0.07
60-69	1.00	ref	1.00	ref	1.00	ref
70-79	0.97	<0.01	0.96	<0.01	0.96	<0.01
80+	0.94	<0.01	0.92	<0.01	0.93	<0.01
Female	1.17	<0.01	1.16	<0.01	1.16	<0.01
Body surface area (per 0.1 m^2)	1.037	<0.01	1.037	<0.01	1.040	<0.01
Underweight (BMI <18.5)	1.04	<0.01	1.03	<0.01	1.03	<0.01
Duration of RRT: <4 months	1.38	<0.01	1.49	<0.01	1.46	<0.01
Alcohol/drug dependence: claims since 1999 or 2728 (any)	1.11	<0.01	1.12	<0.01	1.14	<0.01
Cardiac arrest: claims since 1999 or 2728 (any)	1.08	<0.01	1.09	<0.01	1.10	<0.01
Pericarditis from same month to three months ago	1.53	<0.01	1.66	<0.01	1.64	<0.01
HIV/AIDS: claims since 1999 or 2728 (any)	1.14	<0.01	1.12	<0.01	1.12	<0.01
Hepatitis B since 1999	1.03	<0.01	1.06	<0.01	1.03	<0.01
Specified infection from same month to three months ago						
Septicemia	1.61	<0.01	1.73	<0.01	1.76	<0.01
Bacterial pneumonia and other pneumonias/opportunistic infections	1.43	<0.01	1.48	<0.01	1.48	<0.01
Gastro-intestinal tract bleeding from same month to three months ago	1.85	<0.01	1.89	<0.01	1.91	<0.01
Hereditary hemolytic or sickle cell anemias since 1999	1.15	<0.01	1.16	<0.01	1.15	<0.01
Cancer since 1999 (excludes non-melanoma skin cancer)	1.08	<0.01	1.09	<0.01	1.09	<0.01
Myelodysplastic syndrome since 1999	1.28	<0.01	1.29	<0.01	1.28	<0.01
Monoclonal gammopathy since 1999	1.10	<0.01	1.10	<0.01	1.10	<0.01

The potential impact of each of the model adjusters on facility payments will reflect both the magnitude of the adjustment (Tables 9-2 and 9-4) and the prevalence of the characteristic (Table 9-1). For example, some patient characteristics that were associated with a smaller increment in cost are relatively common, and will frequently be used to adjust payments (e.g., ages 18-44 and 80+, female). In contrast, the conditions that were associated with a larger increment in cost tend to be less common, and will be used less frequently as payment adjusters (e.g., pericarditis, GI bleeding, bacterial pneumonia and other pneumonias/opportunistic infections).

The case-mix adjustment model combines the separate adjustments for composite rate and separately billable services (Tables 9-2 and 9-4, respectively). Later in this chapter we show how these separate adjustments can be combined in a single payment formula for an expanded bundle.

B. WAGE ADJUSTMENT

It is common in Medicare payment policy to adjust payments to providers using an index that measures geographical differences in health care workers' wages relative to the national average. There are two conceptual approaches to applying such an adjustment. One adjusts a base payment rate by an area wage index before applying other appropriate adjustments that reflect patient characteristics (Approach 1). This approach is used to adjust payments in the current composite rate payment system. The other approach would develop a payment model that simultaneously estimates multipliers for patient characteristics and the wage adjustment (Approach 2).

To be consistent with current Medicare payment policy, we developed models using Approach 1. Therefore, the potential case-mix adjustment presented in the next section was based on analyses of measures of resource use that were adjusted to eliminate the effects of area wage differences on costs. This was accomplished by dividing the estimated labor share of the composite rate cost measure by an area wage index. The method that was used corresponds to the wage adjustment that is applied to composite rate payments (for details, see Chapter VI, Section A, Dependent Variables). No adjustment to the Medicare Allowable Payment amounts for separately billable services was necessary, since Medicare payments for these services are based on utilization levels and reimbursement rates which are currently not adjusted for area wage differences.[3]

The resulting regression models estimated case-mix adjustments that can be applied multiplicatively to a wage-adjusted payment amount. This is the approach used for the basic case-mix adjustment, which is applied to a SNF wage adjusted base rate. A similar wage adjustment may be applied to payments for an expanded bundle of outpatient dialysis services. A disadvantage of this method of accounting for wage differences is that it does not allow us to measure the extent to which adjustment for area wages accounts for variation in resource use for outpatient dialysis. We therefore performed analyses that address this question and also examine the sensitivity of the case-mix multipliers to another method of adjusting for area wages.

We re-estimated the current version of the models using the SNF wage index as a predictor variable on an unadjusted measure of composite rate cost per session. In addition, we re-estimated the current version of the separately billable model adding the wage index as a predictor variable. The results of these analyses are summarized in Table 9-6.

In the composite rate cost models, facility controls explained a smaller proportion of the variation when the dependent variable was not adjusted for the wage index. This result was expected because not adjusting for the wage index introduced more variation in the measure of composite rate costs. Adding the wage index raised the R-squared by 7.4%, from 34.3% to 41.7% (Table 9-6). The R-squared of the model with facility controls, wage index, and case-mix was 43.4%.

Adding the wage index had essentially no impact on the explanatory power of the separately billable model (Table 9-6) since Medicare Allowable Payments for separately billable services do not reflect an adjustment for the area wage index. In addition, measures of the actual costs of inputs such as labor are not available.

[3] If the actual costs of inputs (drugs, labor, etc.) could be measured for separately billable services, it would be feasible and appropriate to also adjust them for the area wage index. However, research by the CMS Office of the Actuary shows that the labor share of costs for separately billable items is quite small. Therefore, even if cost data were available, wage adjusting for separately billable services would not have a substantial effect.

Table 9-6
Comparison of R-squared values for log-linear models of resource use, 2002-04 (n=11,174)

Dependent Variable	Wage Adjustment Method	Independent Variables	R-squared
CR	Approach 1	Facility Controls	36.97%
CR	Approach 1	Facility Controls and Case Mix*	38.74%
CR	Approach 2	Facility Controls	34.30%
CR	Approach 2	Facility Controls and Wage Index	41.74%
CR	Approach 2	Facility Controls, Wage Index, and Case Mix	43.41%
SB	n/a	Facility Controls	0.84%
SB	n/a	Facility Controls and Case Mix*	8.82%
SB	n/a	Facility Controls and Wage Index	0.84%
SB	n/a	Facility Controls, Wage Index, and Case Mix	8.84%

*These models are the basis for the potential case-mix adjustment.

For both the composite rate and separately billable models, the estimated case-mix coefficients were not substantially different when adding the wage index as a predictor variable (Table 9-7). The largest difference was observed for the pediatric multiplier (1.48 vs. 1.42), which has limited precision due to the relatively small number of pediatric dialysis patients. Other multipliers varied by no more than three percentage points.

To measure how well the wage adjustment accounts for the variation in resource use for an expanded bundle, we estimated two log-linear models for composite rate and separately billable services which included control variables and the wage index, and calculated predicted composite rate and separately billable values based on the estimated multiplier for the wage index. We obtained actual bundle costs and predicted bundle costs by summarizing the actual and predicted separately billable costs for individual patients to the facility level and adding these two variables to the actual and predicted composite rate costs, respectively. Then, we regressed the predicted bundle costs on actual bundle costs. The R-squared of this model was 4.9%. This estimate suggests that the wage index accounts for 4.9% of the variation in provider costs for an expanded bundle of outpatient dialysis services. The results from this analysis demonstrate the extent to which a wage index adjustment accounts for variation in measured dialysis costs.

Table 9-7
Two approaches to adjust analyses of composite rate costs for area wages, 2002-2004

	Facility level log-linear models (n=11,174)*			
	Wage index used to adjust labor portion of CR cost measure**		Wage index (WI) included as an independent variable	
Variable	Multiplier	p-value	Multiplier	p-value
SNF wage index (per 0.1)	n.a.	n.a.	1.052	<.0001
Age				
<18	1.42	<.0001	1.48	<.0001
18-44	1.31	<.0001	1.32	<.0001
45-59	1.01	0.6951	1.01	0.7745
60-69	1.00	ref	1.00	ref
70-79	1.06	0.0929	1.06	0.0787
80+	1.23	<.0001	1.23	<.0001
Female	1.05	0.0315	1.04	0.0725
Body surface area (per 0.1 m^2)	1.034	<.0001	1.036	<.0001
Underweight (BMI <18.5)	1.07	0.3059	1.05	0.4276
Duration of RRT: <4 months	1.60	<.0001	1.63	<.0001
Alcohol/drug dependence: claims since 1999 or 2728 (any)	1.12	0.0003	1.13	0.0001
Cardiac arrest: claims since 1999 or 2728 (any)	1.00^	n.s.	1.00^	n.s.
Pericarditis from same month to three months ago	1.00^	n.s.	1.00^	n.s.
HIV/AIDS: claims since 1999 or 2728 (any)	1.00^	n.s.	1.00^	n.s.
Hepatitis B since 1999	1.00^	n.s.	1.00^	n.s.
Specified infection from same month to three months ago				
Septicemia	1.07	0.0052	1.08	0.0015
Bacterial pneumonia and other pneumonias/opportunistic infections	1.00^	n.s.	1.00^	n.s.
Gastro-intestinal tract bleeding from same month to three months ago	1.00^	n.s.	1.00^	n.s.
Hereditary hemolytic or sickle cell anemias since 1999	1.00^	n.s.	1.00^	n.s.
Cancer since 1999 (excludes non-melanoma skin cancer)	1.00^	n.s.	1.00^	n.s.
Myelodysplastic syndrome since 1999	1.00^	n.s.	1.00^	n.s.
Monoclonal gammopathy since 1999	1.38	0.0009	1.41	0.0004

^A multiplier of 1.00 is used for factors that were not selected by the stepwise regression as having a statistically significant association with costs (i.e., there would be no payment adjustment for these factors).

*Models also include facility control variables (not shown).

**This model is the basis for the potential case-mix adjustment. Composite rate costs were adjusted for area wage differences by dividing the assumed labor share of facility CR costs (53.711% based on the 2005 ESRD final rule) by the SNF wage index that corresponds to each facility's location (using the wage index published in the 2005 final rule for the SNF PPS).

C. COMBINING COMPOSITE RATE AND SEPARATELY BILLABLE CASE-MIX ADJUSTMENT MODELS

The selection of patient characteristics as payment variables was based on several criteria, including the relationship to resource use for outpatient dialysis services (see Chapter VIII). This was assessed using a modeling approach that used separate equations for composite rate and separately billable services as described earlier in this section. While the potential case-mix adjustment is based on separate estimating equations, they can be combined in a single payment formula for an expanded bundle.

Table 9-8 demonstrates a method to combine the estimated payment multipliers for composite rate and separately billable services. The first two columns repeat the model results from the Case-mix section ($Mult_{CR}$ and $Mult_{SB}$ in Tables 9-2 and 9-4, respectively). The third column presents a single payment multiplier for each patient characteristic based on its relationship to resource use for both sets of services.

Table 9-8
Modeled case-mix adjustment for an expanded bundle of composite rate and separately billable services

	Estimated case-mix multipliers based on a two equation model				Modeled case-mix adjustment*
	Composite rate services		Separately billable services		
Variable	$Mult_{CR}$	p	$Mult_{SB}$	p	$Mult_{EB}$
Age					
<18	1.421	<.0001	0.449	<.0001	1.091
18-44	1.314	<.0001	1.005	0.0626	1.209
45-59	1.014	0.6951	0.991	<.0001	1.006
60-69	1.00^	ref	1.00^	ref	1.000
70-79	1.059	0.0929	0.962	<.0001	1.026
80+	1.230	<.0001	0.931	<.0001	1.128
Female	1.049	0.0315	1.163	<.0001	1.088
Body surface area (per 0.1 m^2)	1.034	<.0001	1.038	<.0001	1.035
Underweight (BMI <18.5)	1.066	0.3059	1.031	<.0001	1.054
Duration of renal replacement therapy: <4 months	1.605	<.0001	1.445	<.0001	1.551
Alcohol/drug dependence (any)	1.121	0.0003	1.125	<.0001	1.122
Cardiac arrest: (any)	1.00^	n.s.	1.090	<.0001	1.031
Pericarditis (from 0-3 months ago)	1.00^	n.s.	1.609	<.0001	1.206
HIV/AIDS (any)	1.00^	n.s.	1.125	<.0001	1.042
Hepatitis B (any)	1.00^	n.s.	1.041	<.0001	1.014
Specified infection (from 0-3 months ago)					
Septicemia	1.071	0.0052	1.701	<.0001	1.285
Bacterial pneumonia and other pneumonias/opportunistic infections	1.00^	n.s.	1.469	<.0001	1.159
Gastro-intestinal tract bleeding (from 0-3 months ago)	1.00^	n.s.	1.884	<.0001	1.300
Hereditary hemolytic or sickle cell anemias (any)	1.00^	n.s.	1.155	<.0001	1.053
Cancer since 1999 (any diagnosis, excluding non-melanoma skin cancer)	1.00^	n.s.	1.088	<.0001	1.030
Myelodysplastic syndrome (any)	1.00^	n.s.	1.280	<.0001	1.095
Monoclonal gammopathy (any)	1.382	0.0009	1.099	<.0001	1.286

*The case-mix multipliers for an expanded bundle were calculated as $Mult_{EB}=0.661*Mult_{CR}+0.339*Mult_{SB}$.

^A multiplier of 1.000 is used for factors that were not selected by the stepwise regression as having a statistically significant association with measures of resource use.

The payment multipliers in the third column of Table 9-8 ($Mult_{EB}$) were calculated as the weighted average of the CR and SB multipliers. The weights reflect each component's proportion of the total estimated costs, so that the resulting case-mix adjustment reflects the overall relationship between patient characteristics and estimated costs for an expanded bundle of services. Measures of resource use for each component are reported in Table 9-9. The estimated MAP amounts for separately billable services were updated to reflect the revised payment rates for the top 11 injectable drugs as of the 1st quarter of 2006 (these drugs are listed in Chapter VI, Sections A, Dependent Variables). The weights were calculated using three years of pooled data. The average cost for composite rate services was $162.00 per session based on the Medicare Cost Reports for freestanding and hospital-based dialysis facilities. The average Medicare Allowable Payment for separately billable services was

$83.18 per session based on the Medicare claims. These average costs were estimated for the Medicare dialysis patients and facilities included in the case-mix analyses.

Table 9-9
Estimated costs for composite rate and separately billable services, 2002-2004

	2002		2003		2004		Pooled, 2002-2004	
Measure of resource use	n	Average $/sess.*	n	Average $/sess.*	n	Average $/sess.*	n	Average $/sess.*
Facility composite rate costs**	3,508	$162.03	3,796	$162.43	3,870	$161.55	11,174	$162.00
Patient separately billable Medicare Allowable Payments (repriced)***	253,149	$80.01	274,010	$81.48	282,049	$87.61	809,208	$83.18

*Weighted by the number of hemodialysis-equivalent dialysis sessions.

**Source: Medicare Cost Reports for freestanding and hospital-based dialysis facilities.

***Source: Medicare dialysis patient claims. MAP amounts were repriced to reflect 2006Q1 payment rates for the top injectable drugs.

Based on total estimated costs of $245.18 per session ($162.00+$83.18), the resulting weights are 0.661 for composite rate services ($162.00/$245.18) and 0.339 for separately billable services ($83.18/$245.18). Using these weights, the payment multipliers presented in the third column of Table 9-8 were defined as $Mult_{EB} = 0.661 \times Mult_{CR} + 0.339 \times Mult_{SB}$. These multipliers represent a single set of payment adjusters for an expanded bundle of outpatient dialysis services.

Several patient characteristics were identified as payment adjusters only for separately billable services. Based on the stepwise regression, these patient characteristics did not have a statistically significant association with composite rate costs. These include the nine comorbid conditions in Table 9-8 which have a composite rate multiplier of $Mult_{CR}=1$. For these patient characteristics, there is no payment adjustment for composite rate services, so that the payment adjustment multiplier is $(0.661 \times 1) + (0.339 \times Mult_{SB})$.

The modeled payment multipliers in the third column of Table 9-8 reflect the combined results from the two separate equations. The pediatric multiplier of 1.091 implies a 9.1% upward payment adjustment for patients under age 18 relative to the reference age group (ages 60-69). This reflects the net effect of an upward payment adjustment for composite rate services and a downward payment adjustment for separately billable services. The remaining age multipliers reflect a U-shaped effect that is a somewhat diluted version of the pattern that was observed for composite rate services only, since adult age did not have a strong relationship with the utilization of separately billable services. There are larger payment adjustments for ages 18-44 (20.9%) and 80+ (12.8%) and smaller payment adjustments for ages 45-59 (0.6%) and 70-79 (2.6%) relative to the reference age group of ages 60-69.

There are upward payment adjustments for females (8.8%), patients with a larger body surface area (3.5% per 0.1m^2 increase in BSA) and patients considered to be underweight (5.4%). Among the remaining factors, the largest payment multipliers generally reflect temporary adjustments to the payment amount. This includes upward adjustments for patients in the first 4 months of renal replacement therapy (55.1%) and for patients with the following diagnoses in the current month or

three previous months: pericarditis (20.6%), septicemia (28.5%), bacterial pneumonia, other pneumonias and opportunistic infections (15.9%), and gastrointestinal bleeding (30.0%). The remaining adjustments are for comorbidities that are relatively chronic, and will persist following an initial diagnosis. The upward payment adjustment for these comorbidities is frequently either less than 5% (cardiac arrest, HIV/AIDS, Hepatitis B, and cancer excluding non-melanoma skin cancer) or between 5% and 10% (hereditary hemolytic or sickle cell anemias and myelodysplastic syndrome). The payment adjustments exceed 10% for alcohol/drug dependence (12.2%) and monoclonal gammopathy (28.6%).

While the explanatory powers of the separate composite rate and separately billable equations were described earlier in this section, we also developed an overall measure of the explanatory power of the combined results from the two separate equations. This measure was based on a comparison between the measured cost per session for an expanded bundle and the cost per session that was predicted using both the composite rate and separately billable equations. Because no measure of composite rate cost exists at the patient level, the measure of overall explanatory power is constructed at the facility level. In other words, this explanatory power measure should be interpreted as reflecting the ability of differences in case mix across facilities to explain differences in average costs across facilities. We used the model estimates for both control variables and payment variables to calculate predicted costs for an expanded bundle including both composite rate services and separately billable services. The predicted costs were then retransformed to dollars, which as the unit of reimbursement will be more relevant to providers than log dollars. We calculated this for each patient in each month, and then summarized this data to determine the average predicted cost per session to the facility level for each year of data (2002-2004). A similar summarization approach was used to calculate each facility's measured cost per session.

We then examined the percent of facility level variation in measured costs that is explained by the predicted costs by using the R-squared value from a linear regression model. The predicted cost per session for an expanded bundle explained 34 percent of the variation in the measured cost per session. Facility control variables accounted for 31 percent of the variation, while the patient characteristics in Table 9-1 contributed an additional 3 percentage points to the R-squared.

X. DETERMINATION OF PER SESSION PAYMENT AMOUNT

The case-mix adjusted per session payment rate requires establishing a base payment rate and making adjustments for area wage index and patient characteristics. In addition, there will likely need to be an outlier adjustment for very high cost patients. The manner in which these payment components are combined to determine the per session payment amount is described below.

A. BASE PAYMENT RATE

To illustrate how payment amounts for an expanded bundle could be determined, we calculated a base payment rate in 2006 dollars. This base rate reflects estimates of the average Medicare Allowable Payment for composite rate and separately billable services in 2006. The average MAP for composite rate services was calculated using the 2006 base composite rates of $130.40 per session for freestanding dialysis facilities and $134.53 session for hospital-based facilities. We calculated a weighted average of these two rates based on the number of hemodialysis equivalent dialysis sessions

reported for each type of facility during 2002-2004. The basic case-mix adjustment was applied using Medicare dialysis patient characteristics during 2002-2004. The 2006 drug add-on and budget neutrality adjustments of 1.145 and 0.9116, respectively, were used. This resulted in an estimate of $151.48 for the average composite rate payment during 2006. The average MAP for separately billable services was calculated using Medicare claims during 2002-2004. The MAP amounts were adjusted to reflect payment rates for the top 11 injectable drugs during the 1st quarter of 2006. This resulted in an estimate of $83.18 per session for the average separately billable payment. The resulting base rate was $234.66 per session ($151.48+$83.18). This estimate will be used as the base rate in the hypothetical examples presented below.

B. WAGE ADJUSTMENT

The $234.66 base payment reflects the payment to a provider in an area where the wage index is equal to 1. For geographic areas with higher or lower wage indices, the labor portion of the base rate is adjusted by the wage index multiplier. The estimated labor related share for an expanded bundle of outpatient dialysis services is 39.278% based on analysis of the ESRD market basket by the CMS Office of the Actuary.

Using a hypothetical wage index of 1.10, the new labor portion of the base payment rate will increase by 10%. The wage-adjusted base rate is then formed by adding the labor portion, adjusted for the wage index, and the unadjusted non-labor portion. In this example, the wage-adjusted base payment rate is calculated as:

$$\$234.66*0.39278*1.10 + \$234.66*(1-0.39278) = \$243.88$$

A budget neutrality adjustment could be applied to this value if the average wage index differs from 1.

C. PATIENT MULTIPLIERS

The payment multipliers reported in Chapter IX, A Combined Case-Mix Adjusted Model for Composite Rate and Separately Billable Services, can be used to derive case-mix adjusted payment rates for individual patients. The principal step is to calculate a patient-specific multiplier (PM). The PM is then applied to the wage-adjusted base rate to calculate the per-session payment. If additional adjustments are needed to account for outliers, they are made once the per session rate has been determined.

Another budget neutrality adjustment is necessary to reflect the fact that the average patient multiplier adjustment (illustrated below) is larger than 1.[4]

[4] Based on an average patient multiplier of 1.21 during 2002-2004, an estimate of this adjustment is 0.83 (1/1.21). This adjustment is not used in the hypothetical examples.

D. OUTLIER PAYMENTS

The payment models described in this report are intended to adjust payment for patient characteristics associated with higher cost of care. In some cases, however, patients incur extremely high costs that are not adequately reflected in the payment model. To reduce the provider risk associated with very high cost patients, consideration of an outlier payment policy is recommended.

A limitation in defining an outlier payment mechanism is the lack of patient-level data on the cost of composite rate services. However, it is the bundling of services now separately billed that creates new financial risk for facilities, may impair access to appropriate care and could be addressed by an outlier payment system. We therefore defined high cost patients as those who use markedly more separately billable services than predicted by the case-mix adjusted payment model.

Given the absence of patient-level cost data, we used patient-level utilization data for separately billable services to identify "high cost" patients. The average acquisition costs to dialysis providers of the top 11 injectable drugs, which account for 87% of separately billable payments, have been studied and reported by the Office of Inspector General (OIG) (32,33). Medicare used the OIG data to establish payment rates that more accurately reflect the cost to facilities of acquiring and administering these medications. Patient-level separately billable costs were estimated by applying these Medicare payment rates to historical patient-level utilization. This approach is similar to that used to define outliers for Medicare's prospective payment system for hospital inpatient care. In that system, outliers are generally patients who utilize high amounts of diagnostic and therapeutic services, which are priced at national average cost-to-charge ratios.

We designed a hypothetical outlier payment system to show how such a system might work and to simulate the costs and impact of targeting extra payments for patient months whose costs exceeded a specified threshold. To define outlier cases, we identified patient months in which SB MAP per session exceeded the mean by 2 or more standard deviations. This process resulted in a threshold of $240 per session for SB MAP. The facilities treating these patients were assumed to receive an outlier payment of 60% of the difference between the SB MAP and the threshold amount. This outlier payment represents an add-on to the case-mix adjusted payment that they would normally receive.

Selection of the outlier payment percentage should balance concern with creating incentives for the use of separately billable services against the objective of minimizing financial risk. As long as the cost to facilities of the inputs required to deliver additional services is greater than 60% of the MAP, there will be no such incentive to increase utilization inappropriately to receive outlier payments. Sixty percent was chosen to yield an outlier payment that would not be likely to create such an incentive for facilities. Complete data on the cost incurred in delivering additional separately billable services are not available. Based on data presented earlier in this report, injectable drugs comprised 88% of SB MAP for outpatient dialysis related services in 2005. A recent OIG report on drug acquisition costs for the top 10 ESRD drugs indicates costs averaged 78% and 86% of MAP for the four largest dialysis organizations and for other dialysis facilities, respectively (32). The OIG later reported that costs for darbepoetin alfa averaged 73% of MAP as of the first quarter of 2005 (33). Starting in 2005, Medicare drug payment rates were reduced, resulting in an increase in these percentages. The vast majority of the input costs for injectable drugs are variable costs (e.g., drug acquisition costs and labor related to the administration of drugs) rather than fixed costs (e.g., facilities and equipment). These considerations support the conclusion that an outlier payment percentage of 60% or even higher will not create an adverse incentive. Note that the ultimate selection of an outlier payment percentage will influence the total dollars committed to outlier

payments as opposed to the base rate. As a point of reference, the Medicare hospital inpatient prospective payment system employs an outlier payment percentage of 80%.

Eligible separately billable costs can be determined through a number of different mechanisms. One model would require facilities to submit separately billable data to Medicare. Medicare would then apply a predetermined payment rate to the utilization data to approximate a dialysis facility's separately billable costs.

The outlier threshold for separately billable services may be revised based on updated billing data. If these data are not available, the threshold could be adjusted in other ways such as applying a price index or through the setting of a target percentage of outlier payments.

The following example illustrates the hypothetical outlier adjustment. The case-mix adjustment model generates a bundled payment of $325 per session for an example patient. This hypothetical patient incurred $300 per session of SB MAP and $150 per session of composite rate costs for a total of $450 per session. Based on an outlier payment percentage of 60%, the facility payment would then be the sum of the case-mix adjusted base payment and the SB outlier add-on payment, $325 + 0.6*($300-$240) = $361 per session for that month.

Application of any specific outlier payment model generates aggregate outlier payments that must be taken into account in setting payment rates to ensure budget neutrality. Using the hypothetical outlier payment model outlined above, we calculated aggregate outlier payments. Using this information, we determined how much the average payment per session would rise, and then deflated the average base payment to maintain budget neutrality. Following this method, 5.3% of patient months were identified as outliers. A reduction of 1.8% to the separately billable portion of the base payment rate, which corresponds to an estimated 0.7% of the base payment rate for an expanded bundle, was sufficient to fund hypothetical outlier payments for these patient months.

To assess the utility of an outlier payment model to reduce facility payment risk, one can compare the standard deviation of costs relative to payments before and after applying the model. As shown in Table 10-1, the standard deviation of SB MAP per session was $57.32. The standard deviation of the prediction error in the case-mix adjustment model was $54.92. Adding the outlier payment system with a 60% outlier payment percentage further reduced the standard deviation of the prediction error to $50.45. Therefore, adding the outlier payment system resulted in a larger reduction in the prediction error than the case-mix adjustment.

Table 10-1
Impact of a hypothetical outlier payment system on Medicare Allowable Payments (MAP) for separately billable services, 2004 (n=282,049)

No outlier payment system					
Actual MAP per session		Predicted MAP per session		Prediction Error	
Mean	*Std*	*Mean*	*Std*	*Mean*	*Std*
$87.61	$57.32	$87.61	$21.41	$0.00	$54.92

Hypothetical outlier payment system based on all SB services (budget neutral) using a 60% outlier payment percentage					
Actual MAP per session		Predicted MAP per session + outlier payment		Prediction Error	
Mean	*Std*	*Mean*	*Std*	*Mean*	*Std*
$87.61	$57.32	$87.61	$23.31	$0.00	$50.45

Hypothetical outlier payment system based on all SB services (budget neutral) using an 80% outlier payment percentage					
Actual MAP per session		Predicted MAP per session + outlier payment		Prediction Error	
Mean	*Std*	*Mean*	*Std*	*Mean*	*Std*
$87.61	$57.32	$87.61	$24.39	$0.00	$49.16

We also examined the effects of using an alternative hypothetical outlier payment model with a higher outlier payment percentage of 80%, which may not be sufficiently high to create an adverse incentive. Under this model, the facility payment for the same hypothetical patient described above would be increased to $325 + 0.8*($300-$240) = $373 per session for the month, reflecting the higher outlier payment (vs. $361 when using an outlier payment percentage of 60%). An 80% outlier payment percentage would further reduce the financial risk to facilities, as the standard deviation of the prediction error in the case-mix model declined to $49.16. In order to fund the higher outlier payments for the 5.3% of patient months identified as outliers, a slightly larger reduction of 2.5% to the separately billable portion of the base payment rate, or a 0.9% reduction to the base payment rate for the expanded bundle (vs. a 0.7% reduction with a 60% outlier payment), was needed.

To qualify for the outlier payment in this hypothetical system facilities would report all separately billable services delivered. This system would not result in administrative simplification of the billing process. To simplify the process, we defined outliers as patient months in which MAP for epoetin and darbepoetin exceeded the mean by 2 standard deviations or more. This simpler outlier method identified many of the same patient months. Of the patient months that were identified as an outlier by the original method, 82.5% were also identified as an outlier by the simpler method (Table 10-2). However, a substantial number of additional patient months were identified as outliers only by the simpler method (1.6% of all patient months, representing 26.3% of all outliers identified by the simpler method).

Table 10-2
Classification of patient months as outliers using two approaches

Outlier by EPO+darbepoetin	Outlier by all SB services		
	Yes	No	All
Yes	115,110 (4.4%)	41,221 (1.6%)	156,331 (5.9%)
No	24,404 (0.9%)	2,455,434 (93.1%)	2,479,838 (94.1%)
All	139,514 (5.3%)	2,496,655 (94.7%)	2,636,169 (100.0%)

XI. HYPOTHETICAL EXAMPLES OF CASE-MIX ADJUSTED PAYMENT CALCULATION

A. RELATIVELY HEALTHY, NO COMORBIDITIES

A 45 year old male (height: 187.96 cm, weight: 95 kg) with chronic glomerulonephritis and hypertension underwent AV fistula creation in 2000 and was diagnosed with ESRD in 2001. The patient also has secondary hyperparathyroidism.

The patient-specific multiplier (PM) for this example reflects adjustments for age and BSA.[5] The BSA multiplier is calculated in the same manner employed by the basic case-mix adjustment for the Medicare ESRD prospective payment system (4). A patient with the average BSA of 1.87 m² will not receive any upward or downward adjustment to the patient-specific multiplier based on their specific BSA. Patients having a BSA value above average (1.87 m²) will receive an upward adjustment and those below will receive a downward adjustment. This does not preclude other adjustments (age, gender, or other comorbidities) from changing the overall patient specific multiplier.

$$PM = M_{age} * M_{BSA}$$

$$\begin{aligned} PM &= 1.006 * 1.035\text{^}((BSA - 1.87)/0.1) \\ &= 1.006 * 1.035\text{^}((2.2161 - 1.87)/0.1) \\ &= 1.006 * 1.035\text{^}(3.461) \\ &= 1.006 * 1.1264 \\ &= 1.1332 \end{aligned}$$

For this patient there is a 0.6% increase to the wage-adjusted base rate based on age because the age category coefficient for a 45 year old is 1.006. There is also a multiplicative adjustment of 12.64% due to the patient's BSA.[6] These case-mix multipliers combine to form the PM of 1.1332.

The 1.1332 PM is then applied to the hypothetical wage-adjusted base rate of $243.88 resulting in a per-session payment of $276.36 (1.1332 x $243.88).

[5] BSA is calculated using the DuBois formula (27): BSA = 0.007184 * (height in cm^0.725) * (weight in kilograms^0.425).
[6] This multiplier was derived by raising the BSA multiplier of 1.035 to the power of the difference between the patient's BSA and the average BSA of 1.87, scaled to reflect increments of 0.1 m²; that is, there is a 1.035 multiplier for every 0.1m² above the average BSA and a 1/1.035 multiplier for every 0.1m² below the average BSA.

B. MULTIPLE COMORBIDITIES

A 66 year old female (height: 167.64 cm, weight: 105 kg) with diabetes mellitus, a history of chronic Hepatitis B, parathyroidism, and liver cirrhosis. The patient was diagnosed with ESRD in 1995 and esophageal varices in 2006 and had a diagnosis of upper gastrointestinal (GI) bleeding the previous month.

The patient-specific multiplier (PM) for this example must be calculated by adjusting to account for gender, BSA, Hepatitis B, and upper GI bleeding.

$$PM = M_{gender} * M_{BSA} * M_{Hepatitis\ B} * M_{GI\ bleed}$$

$$\begin{aligned} PM &= 1.088 * 1.035^{((BSA - 1.87)/0.1)} * 1.014 * 1.300 \\ &= 1.088 * 1.035^{((2.1284 - 1.87)/0.1)} * 1.014 * 1.300 \\ &= 1.088 * 1.035^{(2.584)} * 1.014 * 1.300 \\ &= 1.088 * 1.0930 * 1.014 * 1.300 \\ &= 1.5676 \end{aligned}$$

The patient receives an 8.8% increase in payment related to gender, a 9.30% increase related to BSA, and a 1.4% increase for costs associated with treating Hepatitis B. Furthermore, the patient multiplier reflects a 30.0% increase because the patient has had an upper gastrointestinal bleed in the last three months. The 1.5676 PM is then applied to the wage adjusted base rate of $243.88 for a per session payment of $382.31 (1.5676 x $243.88).

C. ELDERLY, LOW BMI (<18.5 KG/M²), AND HOSPITALIZATION

An 82 year old female (height: 160.02 cm, weight: 45.36 kg) with longstanding type II diabetes mellitus was diagnosed with ESRD in 2002. The patient has known coronary artery disease and peripheral vascular disease. She began 2006 dialyzing via an upper arm AV fistula (created in 2002).

In March, 2006, after an attempted declot of the AV fistula (which was unsuccessful), the patient experienced additional bleeding complications and has been dialyzed via a catheter since. Patient was again admitted to hospital in the prior month after suffering a witnessed cardiac arrest during dialysis. She was diagnosed with myocardial infarction and underwent coronary artery angioplasty and coronary artery stent placement during that hospitalization. She was again admitted to the hospital on the 14th of the current month for congestive heart failure.

The current patient-specific multiplier (PM) for this example adjusts for age, gender, BSA, BMI, and cardiac arrest.

$$PM = M_{age} * M_{gender} * M_{BSA} * M_{BMI} * M_{Cardiac\ Arrest}$$

$$\begin{aligned} PM &= 1.128 * 1.088 * 1.035^{((BSA - 1.87)/0.1)} * 1.054 * 1.031 \\ &= 1.128 * 1.088 * 1.035^{((1.4404 - 1.87)/0.1)} * 1.054 * 1.031 \\ &= 1.128 * 1.088 * 1.035^{(-4.296)} * 1.054 * 1.031 \\ &= 1.128 * 1.088 * 0.8626 * 1.054 * 1.031 \\ &= 1.1504 \end{aligned}$$

The patient receives a 12.8% increase related to age, an 8.8% increase related to gender, a 13.74% decrease related to a small BSA, a 5.4% increase for costs associated with a low BMI, and a 3.1% increase for the additional costs associated with treating a patient with a recent history of cardiac

arrest. The 1.1504 PM is then applied to a wage-adjusted base rate of $243.88 for a per session payment of $280.56 (1.1504 x $243.88).

D. OUTLIER PAYMENTS

A 59 year old female (height: 162.56 cm, weight: 81 kg) diagnosed with ESRD and lymphoma in 2002. The patient receives 120,000 units of EPO per week due to bone marrow hyporesponsiveness. She has received blood transfusions every other month (2 units).

The patient-specific multiplier (PM) for this example adjusts for age, gender, BSA, and cancer.

$$PM = M_{age} * M_{gender} * M_{BSA} * M_{cancer}$$

$$\begin{aligned} PM &= 1.006 * 1.0858 * 1.035^{((BSA - 1.87)/0.1)} * 1.03 \\ &= 1.006 * 1.0858 * 1.035^{((1.8640 - 1.87)/0.1)} * 1.03 \\ &= 1.006 * 1.0858 * 1.035^{(-0.06)} * 1.03 \\ &= 1.006 * 1.088 * 0.9979 * 1.03 \\ &= 1.1250 \end{aligned}$$

This patient receives a 0.6% increase due to age, an 8.8% increase for gender, a 0.21% decrease for a low BSA, and a 3.0% increase related to the lymphoma. The 1.1250 PM is then applied to a wage adjusted base rate of $243.88 for a per session payment of $274.37 (1.1250 x $243.88).

The dialysis provider has submitted separately billable utilization data, documenting the extensive separately billable resources used in treatment of this patient. Medicare has applied predetermined payment rates and found the allowable separately billable payment for this patient to be $400 per session. Using a Medicare determined global threshold of $240 per session, there is a total of $160 per session in cost that is eligible for reimbursement at 80% for a total additional payment of $128 per session.

Medicare determined SB costs	$400
Medicare global outlier threshold	-$240
Eligible costs for reimbursement	$160
Reimbursement percentage	x 80%
Total outlier payment	$128

The total per session payment to the facility would then be $402.37 ($274.37 for the case-mix and wage adjusted rate + $128 outlier payment).

E. YOUNG PEDIATRIC PATIENT

A 24 month old male (height: 74.93 cm, weight: 13 kg) who began renal replacement therapy 8 months ago.

Pediatric dialysis is extraordinarily rare, and its cost is not well projected by our case-mix coefficients. The downward BSA adjustments outweigh any payment increases related to those less than 18 years of age. This is primarily due to the small number of pediatric cases in the dialysis population and their very small size.

The patient-specific multiplier (PM) for this example is adjusted for age, and BSA.

$$PM = M_{age} * M_{BSA}$$

$$\begin{aligned} PM &= 1.091 * 1.035\text{^}((BSA - 1.87)/0.1) \\ &= 1.091 * 1.035\text{^}((0.4886 - 1.87)/0.1) \\ &= 1.091 * 1.035\text{^}(-13.814) \\ &= 1.091 * 0.6217 \\ &= 0.6783 \end{aligned}$$

This patient receives a 9.1% increase due to age but a 37.83% decrease for a low BSA. The 0.6783 PM is then applied to a wage adjusted base rate of $243.88 for a per session payment of $165.42 (0.6784 x $243.88).

We have conducted additional analyses that demonstrate predicted SB MAP fall substantially short of actual SB MAP for all pediatric patients (less than 18 years of age). We believe the problem is specifically related to the body size adjustment and derives from the fact that our analyses are based on very few pediatric patients. The estimated BSA multiplier (1.034) therefore does not accurately reflect the relationship between BSA and SB costs of small patients. Another potential source of the problem is that pediatric patients may not be fully and accurately identified with available data. Therefore, the model presented in this report should not be applied to pediatric patients.

F. EXAMPLES AT DIFFERENT FACILITIES

The five hypothetical examples presented above applied the same wage adjustment (1.10) to the estimated base rate. To illustrate the effect of the wage adjustment on the payment amount, we used the same five examples to calculate payment amounts for facilities having other wage indices. The resulting case-mix and wage-adjusted payment amounts are presented in Table 11-1.

Table 11-1
Impact of wage adjustment on per-session payment amounts for five hypothetical examples*

Hypothetical example	Patient multiplier	Area wage index				
		0.9	1.0	1.1	1.2	1.3
One: Relatively healthy, no comorbidities	1.1332	$255.47	$265.92	$276.36	$286.80	$297.25
Two: Multiple comorbidities	1.5676	$353.40	$367.85	$382.31	$396.74	$411.20
Three: Elderly, low BMI, and hospitalization	1.1504	$259.35	$269.95	$280.56	$291.15	$301.76
Four: Outlier payments**	1.1250	$381.62	$391.99	$402.37	$412.26	$423.10
Five: Pediatric case	0.6783	$152.92	$159.17	$165.42	$171.67	$177.92

*An estimated base rate of $234.66 was used. No budget neutrality adjustments were applied.

**Includes the outlier payment of $128/session.

XII. IMPACT ANALYSIS

A. INTRODUCTION

Legislated changes to the ESRD payment system must be studied relative to the current payment system. As described in Chapter V of this report, the current payment system consists of composite rate and separately billable services. The composite rate covers a specified, limited bundle of services that comprise the basic dialysis session. It is paid prospectively and adjusted for a limited set of facility characteristics (local health care worker wages and hospital-based status) and patient characteristics (age, body surface area, and low body mass index). Services outside the composite rate bundle, such as injectable medications and non-routine laboratory tests, are billed separately on a fee-for-service basis.

The changes would expand the composite rate bundle to include many separately billable services, increase the prospective payment to cover these services, and implement several new payment adjustments to the expanded bundle. Payment adjustments are necessary because the cost to deliver both composite rate and separately billable services varies from one patient to another. Without appropriate payment adjustments, patients with characteristics that indicate that they would be costlier than average to treat may face difficulties gaining access to care or obtaining optimal treatment.

For the impact analyses presented here, we simulated dialysis facility payments under both current and modeled payment systems to generate two different annual payments to each U.S. dialysis facility for 2002-2004. The analysis was done at the facility level due to the unavailability of a measure of composite rate costs at the patient level. First, we examined the variation of measured costs, current payments, and modeled payments across facilities. Second, we compared the average differences between current payments and modeled payments across different types of facilities. The analyses presented in this section assume no change in resource utilization by dialysis facilities and other providers. The actual financial impact of the payment system described in this report might vary from these analyses if providers change patterns of resource utilization in response to the new payment system.

B. METHODS

Our analysis focused on the difference between payments in the current system and payments under the model system. We also compared payments under these two systems to estimates of facility costs. We combined facility level costs of composite rate services, as reported in the Medicare Independent Renal Dialysis Facility Cost Reports (Form CMS 265-94) and the Medicare Hospital Cost Reports (Form CMS 2552-96), and aggregated patient level costs of separately billable services to the facility level. Measures of separately billable costs were based on utilization as reported in Medicare claims from 2002-2004, but utilization was priced by using Medicare fees that prevailed in the first quarter of 2006. Therefore, separately billable cost measures were based on recent Medicare payment rates that reflect studies of acquisition costs for key injectable medications. Using these data, we calculated the per session cost for each facility year. by adding the average Medicare Allowable Payment (MAP) per session for separately billable services from the Medicare claims (mean $82.79) to the average cost per session for composite rate services from the facility's Cost Reports (mean $162.00).

We also calculated two estimated per session payments for each facility year: one under the current system and another under the model system. For case mix adjustments, the characteristics and comorbidities of patients were obtained from the Medical Evidence Form (CMS Form 2728) and Medicare claims.

The per session payment under the current system was calculated by adding each patient's monthly separately billable per session costs (mean $82.79) to the estimated composite rate payment used in 2006. The 2006 base rate for composite rate payments, before wage adjustment, was $130.40 per dialysis session for freestanding units and $134.53 for hospital-based units. The basic case-mix adjustment was applied using multipliers for BSA, low BMI, and age. We also used the prevailing drug add-on and budget neutrality adjustment multipliers for 2006 (22). The result is a mean adjustment multiplier for case-mix, drug add-on, and budget neutrality of 1.16.

The per session payment under the model system was calculated differently. In this system, the composite rate services and separately billable services are bundled together. Therefore, a case-mix payment adjustment multiplier was first calculated for each patient month. This adjustment accounted for patient case-mix including age, sex, BMI, BSA, time since start of ESRD, and comorbid conditions (see the combined case-mix adjustment model presented in Chapter IX, Section C). The mean case-mix multiplier under the model system was 1.2088.

Then, we defined a base rate for this system that preserved budget neutrality with the current payment system. This was done by setting the total dollars paid to this set of facilities between 2002-2004 equal under each payment system. As described in Chapter X, the mean Medicare Allowable Payment under the current system was estimated to be $234.66 per dialysis session in 2006 prior to applying the wage adjustment. The modeled case-mix adjusted payment amount was adjusted for budget neutrality by multiplying modeled payments by the reciprocal of the mean case-mix multiplier under the model system (1 / 1.2088 = 0.8273).

Wage adjustments were calculated slightly differently for the current and modeled payments. The current composite rate service payment adjustment was based on a blended MSA wage adjustment and the updated CBSA wage adjustment. Modeled payments were calculated using only the updated CBSA wage adjustment. At the end of the current 4 year transition period (ending December 31, 2009) the MSA wage adjustment will no longer be used. The modeled payments also include an updated labor share of 39.278% for the expanded bundle ESRD market basket from the CMS Office of the Actuary. After applying the current wage adjustment, the estimated average wage-adjusted MAP in the current system was $237.97 per session. After applying the CBSA wage adjustment, the estimated average wage-adjusted MAP in the model system was $238.31/session. To keep the model system budget neutral with the current system, a budget neutrality adjustment of 0.9986 ($237.97/$238.31) was applied to the modeled payments, setting the mean payments in the two systems to $237.97. This value was used as the base rate for the analyses presented in this section.

The small number of facilities for which we could not determine the wage index did not receive a wage adjustment. While it is important to note the slightly different methods for wage adjustment between the current and model systems, other versions of this analysis (not shown here) which used different wage adjustment methods and unadjusted methods showed little difference in the results presented below.

This analysis did not include an outlier payment policy that reimburses facilities for treating unusually high cost patients (see Section X, Determination of per Session Payment Amount).

All data sources cover the time period from 2002 through 2004. The final data set included 4,007 facilities in 2002, 4,152 facilities in 2003, and 4,323 facilities in 2004 for 12,482 total facility-years.

C. EFFECT ON FACILITY TYPES

To study the effect of the new payment system on different types of facilities, patient month data was aggregated to the facility year level. Each facility year was assigned to one group in each of the following classifications, and the mean payments in each group were compared to determine if facilities in that group would receive higher or lower payment in the new system.

- *Urban or rural* – Designation is based on whether the facility's physical address in the CMS data was in a metropolitan statistical area (urban) or not (rural) according to the Core Based Statistical Areas announced in June 2003 by the U.S. Office of Management and Budget. Note that facilities in micropolitan statistical areas were classified as rural.

- *Hospital-based or freestanding* – Designation based on CMS data.

- *Small, medium, or large* – Designation based on the number of dialysis sessions provided per year according to CMS data.

- *Independent, regional chain, large dialysis organization (LDO), hospital based, or unknown ownership* – Designation based on CMS data.

- *Census region* – Assignment based on the physical address in CMS data, stratified by state into nine regions identified by the U.S. Census Bureau.

- *Isolated Essential Facility prior to 2005 (IEF) or non-IEF* – Assignment based on CMS data identifying facilities receiving a composite rate payment exception prior to 2005 as isolated essential facilities, and therefore receiving a higher composite rate payment. Includes facilities that were designated as IEF in 2005 (see next definition).

- *Isolated Essential Facility (IEF) in 2005 or non-IEF* – Assignment based on CMS data currently identifying IEFs that retained their composite rate payment exceptions following the implementation of the basic case-mix adjustment.

- *Alaska, Hawaii, or other* – Designation based on the physical address in CMS data. The 48 contiguous states and the District of Columbia are included in the other category.

- *Provides peritoneal dialysis (PD)* – Designation based on CMS data showing if facilities provide PD and the extent of PD provided (less than 5% of patients versus 5% or more of patients).

D. RESULTS

Table 12-1 shows descriptive statistics for measured costs, current payments, and modeled payments. Figure 12-1 shows the percent of sessions by dollars per session, while Figure 12-2 shows the distributions of costs, current payments, and modeled payments as box plots.

The variation in payments was much lower than the variation in measured costs in both the current and model payment systems. In the current payment system, composite rate services are already bundled, and variation in the composite payment rate across facilities is substantially lower than variation in reported costs. The variation in the modeled payments is even lower than the variation in the current payments. Most of the difference in variation is explained by expansion of the bundle to include services previously separately billed by facilities. These comparisons reflect differences among measured costs, current payments, and modeled payments, not the fit of the statistical models (see the previous section on the Final Payment System for more on statistical model fit).

It is interesting to note the difference in how payments are distributed around the mean of $237.97 in the current system and in the model system. In the current system, 54.6% of facility-years had a per session payment under the mean, compared to 56.0% in the model payment system. This shift is also seen in the reduction of the 99th percentile per session payment of $296.30 under the current system to $280.03 under the model system, while the change in 1st percentile payments is smaller ($191.82 under the current system compared to $209.40 under the model system). Overall, 54.3% of facility years have an increased per session payment in the model system when compared to the current system.

Table 12-2 and Figure 12-3 show the average change in the per session payments to different types of dialysis facilities. The overall average change is constrained to be zero. Both systems use the same number of facilities, the same number of dialysis sessions, and the same total dollars. Each facility type has an average payment difference of less than 6%, except for the small groups of Alaskan facilities (4 facilities represented by 6 facility-years) and of facilities currently receiving an IEF composite rate payment (4 facilities, represented by 10 facility-years).

Urban facilities, freestanding facilities, facilities with less than 5,000 sessions per year, facilities owned independently, facilities owned by a regional chain, facilities with unknown ownership, facilities designated as IEFs, and facilities that provide a large amount of PD tend to have higher payments in the model system than in the current system. On the other hand, rural facilities, facilities with at least 5,000 sessions per year, facilities owned by a LDO, facilities not on the IEF lists, and facilities that provide little or no PD tend to have lower payments in the model system than in the current system. Hospital based facilities also receive a $3.89 lower payment under the model system, assuming the current $4 payment differential between hospital based and freestanding facilities built into the composite rate system does not continue.

Facilities in the East North Central, East South Central, South Atlantic, and West South Central census regions tend to have lower payments in the model system when compared to the current system.

Table 12-1
Measured costs, current payments, and modeled payments per dialysis session, 2002-2004

	N	1st Percentile	Median	Mean	99th Percentile
Measured Costs	11,863	$169.12	$236.78	$257.83	$470.13
Current Payments	12,482	$191.82	$237.04	$237.97	$296.30
Modeled Payments	12,482	$209.40	$236.04	$237.97	$280.03

Statistical outliers excluded during model estimation were included in this analysis. See Chapter VII, Section C, Statistical Outliers for the Average Cost per Session.
Measured costs not available for 619 facility-years.
Weighted by number of dialysis sessions.

Figure 12-1
Frequency distributions of measured costs, current payments, and modeled payments per dialysis session, 2002-2004

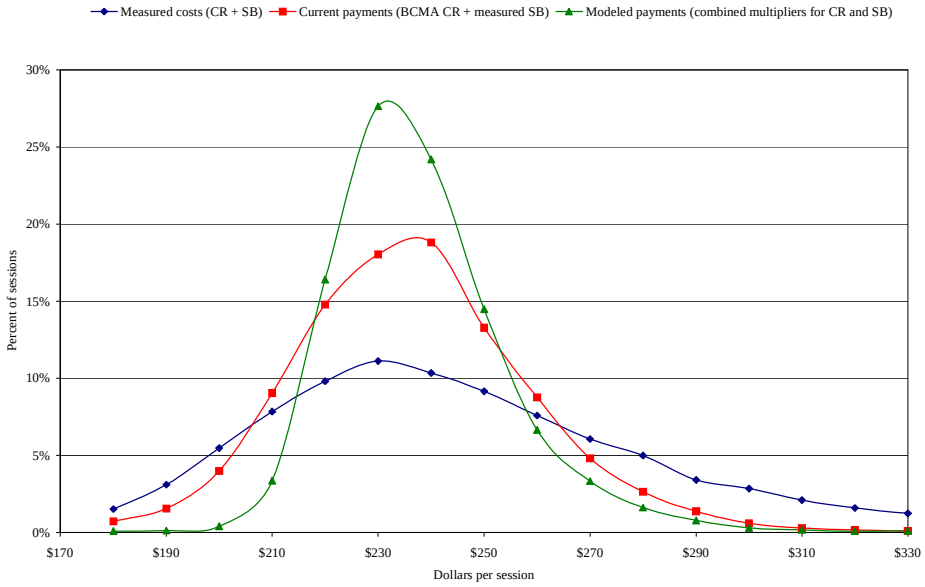


Figure 12-2
Box plots of measured costs, current payments, and modeled payments per dialysis session, 2002-2004

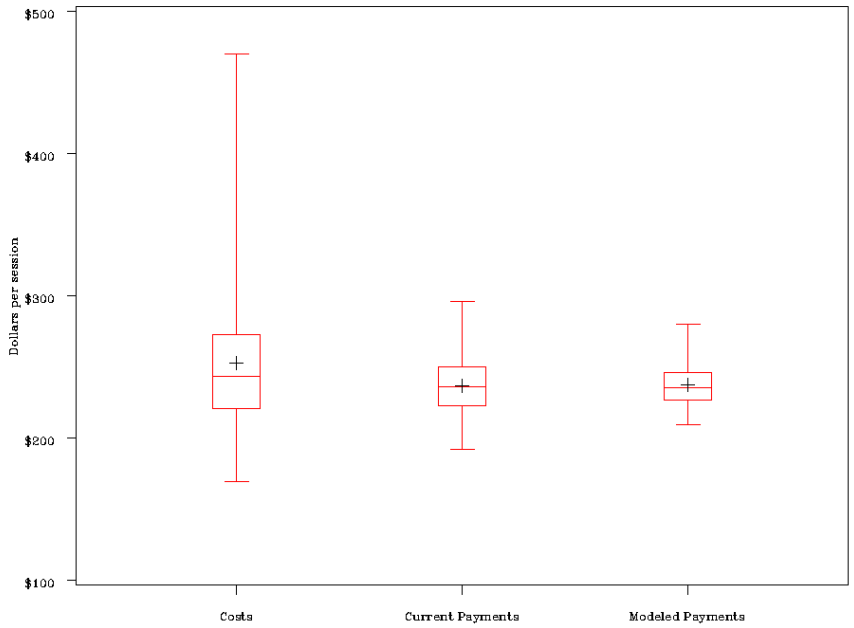
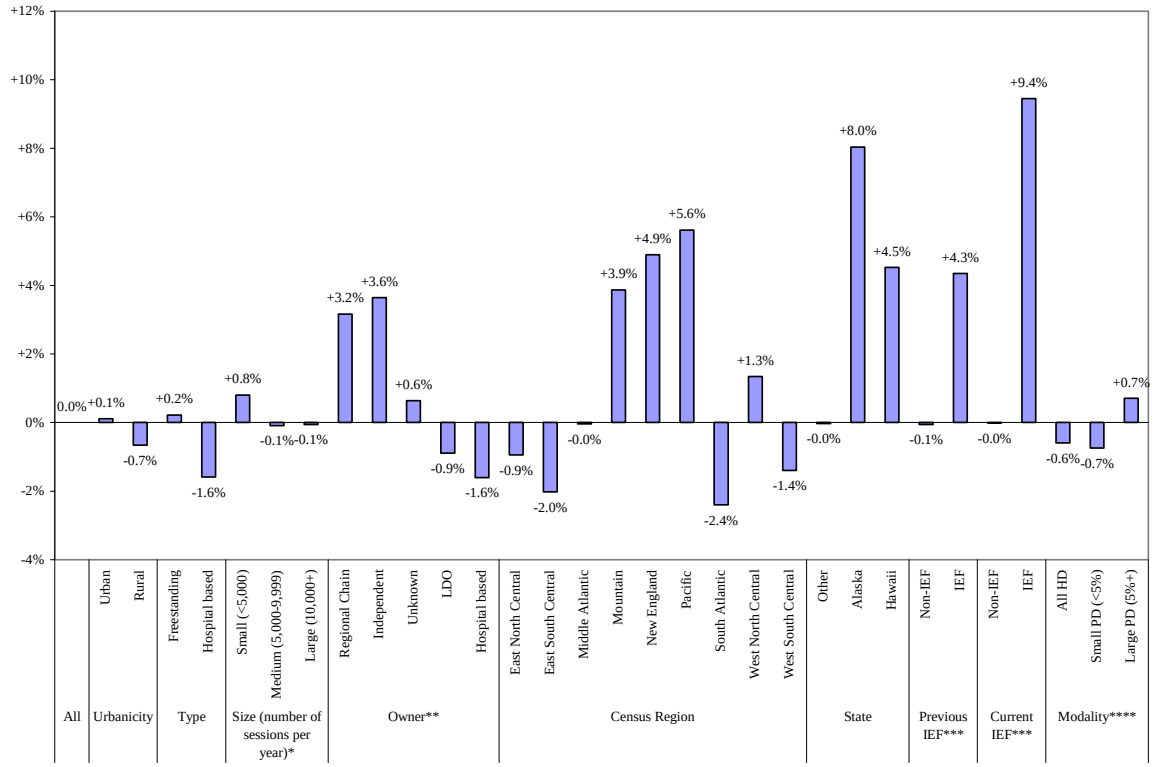


Table 12-2
Changes in average payments at different types of facilities, 2002-2004

Facility Type		Facilities			Facility Years	Average of Current Payments	Average of Modeled Payments	Percent Change
		2002	2003	2004				
All		4,007	4,152	4,323	12,482	$237.97	$237.97	0.0%
Urbanicity	Urban	3,162	3,276	3,420	9,858	$239.72	$239.99	+0.1%
	Rural	845	876	903	2,624	$228.09	$226.58	-0.7%
Type	Freestanding	3,527	3,707	3,870	11,104	$237.08	$237.60	+0.2%
	Hospital based	480	445	453	1,378	$244.62	$240.73	-1.6%
Size (sessions per year)*	Small (<5,000)	1,044	1,031	1,086	3,161	$233.58	$235.46	+0.8%
	Medium (5,000 - 9,999)	1,272	1,351	1,366	3,989	$235.23	$235.02	-0.1%
	Large (10,000+)	1,691	1,770	1,871	5,332	$239.45	$239.31	-0.1%
Owner**	Regional Chain	244	270	270	784	$234.31	$241.72	+3.2%
	Independent	599	671	680	1,950	$234.89	$243.44	+3.6%
	Unknown	141	98	239	478	$237.17	$238.68	+0.6%
	LDO	2,563	2,687	2,699	7,949	$237.86	$235.74	-0.9%
	Hospital based	460	426	435	1,321	$245.01	$241.07	-1.6%
Census Region	East North Central	571	620	649	1,840	$241.62	$239.33	-0.9%
	East South Central	337	353	363	1,053	$233.65	$228.93	-2.0%
	Middle Atlantic	494	491	513	1,498	$250.47	$250.37	-0.0%
	Mountain	213	220	234	667	$222.03	$230.62	+3.9%
	New England	130	131	135	396	$237.23	$248.84	+4.9%
	Pacific	437	463	484	1,384	$237.11	$250.42	+5.6%
	South Atlantic	990	1,012	1,038	3,040	$238.93	$233.19	-2.4%
	West North Central	282	291	305	878	$229.68	$232.77	+1.3%
	West South Central	553	571	602	1,726	$231.69	$228.46	-1.4%
State	Other	3,997	4,142	4,310	12,449	$238.03	$237.96	-0.0%
	Alaska	1	1	4	6	$239.04	$258.25	+8.0%
	Hawaii	9	9	9	27	$226.36	$236.60	+4.5%
Prior IEF***	non-IEF	3,960	4,106	4,276	12,342	$238.17	$238.03	-0.1%
	IEF	47	46	47	140	$224.03	$233.77	+4.3%
Current IEF***	non-IEF	4,004	4,149	4,319	12,472	$238.00	$237.98	-0.0%
	IEF	3	3	4	10	$207.97	$227.62	+9.4%
Modality**	All HD	2,188	2,184	2,301	6,673	$238.61	$237.19	-0.6%
	Small PD (<5%)	448	462	434	1,344	$242.71	$240.90	-0.7%
	Large PD (5%+)	1,336	1,477	1,559	4,372	$236.33	$238.00	+0.7%

* Number of sessions from the facility cost report where available. Otherwise, source was annual facility survey (432 facility-year records) or sum of sessions from claims (106 facility-year records).
** Of the 1,378 facility-year records reporting hospital based status, 57 also indicated form of ownership (e.g., LDO or regional chain). Those 57 records were included with the reported ownership categories. The remaining 1,321 facility-year records for hospital based units without ownership information are presented as a separate category.
*** Current payments were calculated as though facilities with previous IEF status were paid at the regular rate, but facilities with current IEF were paid their special rate.
**** Excludes 93 facility-year records where information on modality is unavailable.

Figure 12-3
Average change in payments to facilities per dialysis session, 2002-2004



* Number of sessions from the facility cost report where available. Otherwise, source was annual facility survey (432 facility-year records) or sum of sessions from claims (106 facility-year records).
** Of the 1,378 facility-year records reporting hospital based status, 57 also indicated form of ownership (e.g., LDO or regional chain). Those 57 records were included with the reported ownership categories. The remaining 1,321 facility-year records for hospital based units without ownership information are presented as a separate category.
*** Isolated essential facilities: the previous IEF category includes facilities that recently gave up their special payment rate and facilities continuing to receive a special payment rate. The current IEF category includes only facilities that continue to be paid their special rate. The current IEF category is a subset of the previous IEF category.
**** Excludes 93 facility-year records where information on modality was unavailable.

XIII. IMPLEMENTATION ISSUES

Various specific operational issues will need to be resolved before implementing an expanded prospective payment system. A number of the important issues are discussed below.

A. REPORTING REQUIREMENTS, BILLING, AND CONTRACTING

1. Billing for sessions or months

If a per session payment approach is adopted, dialysis facilities will be required to bill Medicare for services provided on a per session basis. A monthly bill similar to that currently in place, wherein the facility reports the number of sessions provided to the patient, should be sufficient. Patients receiving outpatient dialysis sessions at more than one facility in the month do not pose any particular problems here, as all facilities can be paid for the number of sessions they provide, subject to limitations that may be set on the total number of billable sessions per unit of time. A per session payment also preserves facilities' incentives to encourage patient compliance with the prescribed number of dialysis sessions. These incentives may even be strengthened under an expanded bundle because a skipped session also results in losing the capitation payment for drugs and labs; in the current system, the facility can make up for lost drug and lab billings by providing "make up" services at the next session. In addition, a per session payment allows Medicare to capture mid-month changes that may occur in payment adjusters (age, comorbidities, facility, etc.).

If a per month payment approach is adopted, it is likely that one facility will be designated the primary dialysis provider and will receive the payment for the entire month. The primary dialysis provider will bill Medicare for all covered services provided. For the roughly 80 percent of patient months where there is no event reducing the time at-risk for outpatient dialysis, and where the patient receives dialysis sessions from only one facility, the primary dialysis provider is clearly established and will be paid the full monthly capitation. (See Chapter V, Section C, for data on events reducing time at-risk.)

For months where an event occurs that reduces the time at risk, the primary dialysis provider will be responsible for reporting both the events and the dates of these events on the patient bill. The primary dialysis provider will be paid the monthly capitation, adjusted downward for the percentage of time not at-risk. (See Chapter V, Section C, for a method to prorate payment according to time at-risk.) Medicare may want to consider requiring a minimum number of sessions for the facility to receive a full monthly capitation payment in order to guard against disincentives to discourage patients from skipping sessions when payment is based only upon time at risk.

In situations where the patient is treated at more than one outpatient dialysis facility, the primary provider will receive the monthly capitation payment (full or prorated) and other facilities will be required to bill the primary dialysis provider for services provided. Although cooperation between dialysis facilities commonly occurs, billing by secondary dialysis facilities of primary facilities will require additional mechanisms to capture payments and any potential changes in payment adjusters.

To avoid the complications associated with designating a primary facility that receives the entire monthly payment for a patient, Medicare could allow each facility that provides care for a patient to bill for that patient. However, the fiscal intermediaries processing the claims would need to match

dialysis claims for the same patient to detect and resolve any overlaps in reported service dates. Based on our analysis of Medicare claims, such overlaps of service dates occur. Further, facilities billing through different fiscal intermediaries would require the fiscal intermediaries to coordinate for proper billing. Payments would then be adjusted for time at-risk. This adjusted per month payment has the benefit of avoiding potential complications between facilities but still has the drawback of not capturing changes in comorbidity payment adjusters that occur at the same facility during the month.

2. Payments to other (non-dialysis) providers

Some services included in the payment bundle may not be provided by dialysis facilities. Specifically, laboratory services provided by 12,000+ independent laboratories are likely to be included in the payment bundle. As a result, the dialysis facility will be paid for these services, either on a per-session or a per-month basis. Independent laboratories will be required to bill the primary dialysis facilities for these services. Dialysis facilities already have contractual or other relationships with laboratories for services currently included in the Composite Rate. (See Chapter V, Section B, for a definition of dialysis related labs.)

3. Reporting patient characteristics

Implementation of the payment models described in this report, whether on a per-session or a per-month basis, requires that dialysis facilities report additional patient characteristics on the Medicare bill. Using the model that served as the basis for many of the analyses presented here, facilities will have to report patient comorbidities and measures of health status. The list of comorbidities and measures of health status will depend on the final payment model selected for implementation. In terms of frequency of reporting, we recommend the approach adopted for the BCMA for composite rate payment that requires the facilities to report patient height and weight. Because payments are increased for patients with specified comorbidities, facilities have an incentive to report as many comorbidities as can be justified. Detailed rules will be required to increase the likelihood of consistent reporting of comorbidities across facilities.

4. Reporting resource utilization

Information on the use of diagnostic and therapeutic services currently paid for as separately billable services is necessary for determination of potential outlier payments, quality assurance measures, updates of the case-mix adjustment model, and possibly pay-for-performance initiatives. Therefore, dialysis facilities will be required to report on patient bills the use of these services. Tying the reporting of diagnostic and therapeutic services to forms of payment aligns incentives that will increase their likelihood of being reported.

B. MANAGING INCENTIVES

1. Increased reporting of patient comorbidities

As noted above, facilities will have an incentive to report all comorbidities that can be justified on the patient bill. CMS should monitor the frequency of comorbidities reported and audit as appropriate. In addition, budget neutrality requires that payments be calibrated for any increase in comorbidity reporting that occurs in response to the bundled payment system. The data found in Table 9-1 (frequencies of comorbidities for 2002-2004) were used to estimate the case-mix multipliers described earlier in this report and can serve as a baseline for CMS in monitoring changes. Moving

forward, CMS must ensure that comorbidity definitions and reporting instructions are as unambiguous as possible.

2. Reductions in services per session

As is the case with any bundled service, there is an incentive to reduce the services provided per session in an effort to improve profit margins. This reduction has the potential to be both appropriate and inappropriate depending on the impact the reduction has on the patient. Careful development of quality assurance and pay-for-performance measures is necessary to identify and prevent instances of inappropriate reductions in resource utilization.

3. Reductions in sessions per month

If a per month payment system is adopted, there may be an incentive to reduce the number of sessions provided in a month. Specifically, in situations where there is a cost to the dialysis facility of providing a service but no additional revenue, there is the potential for inappropriate reductions in sessions. To mitigate this potential risk, appropriate quality assurance and pay-for-performance mechanisms will be required under a per month payment system.

C. QUALITY ASSURANCE

As discussed above, the determination of the components of the bundle may have implications for patient outcomes, as do the method and validity of case-mix adjustment. Some intermediate outcomes (e.g., achieved hematocrit) attributed to dialysis facilities may be influenced by other healthcare providers (12,38). In addition, caution must be used in defining appropriate targets for quality assurance purposes, as illustrated by the recent controversy over anemia management in dialysis (15,16, 39, 40, 41). Whatever the design decisions regarding bundle components and case-mix adjustment, there will remain a need to monitor the performance of providers to ensure patient quality. Some specific quality measures are discussed in the following section.

D. PAY-FOR-PERFORMANCE

Performance based contracting is a rapidly emerging trend in health care payment policy. Under so-called pay-for-performance (P4P) systems, payers acting on behalf of patients, employers, and/or society are linking a portion of provider payments to performance on specified measures of quality. The assumption is that incentive payments will stimulate increases in quality related effort on the part of providers, leading to improved health outcomes for patients. CMS has recently established an administrative policy to promote the use of incentive payments for improved performance in all Medicare programs.

1. P4P criteria

With respect to ESRD or dialysis sessions, work on the ESRD Disease Management Demonstration has proposed several clinical indicators as criteria for a P4P system. Payment is based on meeting national performance targets for each of the measures, and improving upon each facility's performance. The set of specific measures to be adopted is still undetermined. Listed below are several measures under consideration. Some items on this list were developed by Arbor Research

Collaborative for Health, an entity collaborating with UM-KECC. Some of the measures may be relevant for either quality monitoring or P4P, or both.

- Adequacy of Hemodialysis
  Percentage of patients with spKt/V $\geq$ 1.2

- Anemia Management
  Percentage of patients with Hgb $\geq$ 11 g/dl

- Serum Calcium
  Percent of patients with serum calcium < 10 mg/dl

- Serum Phosphorous
  Percent of patients with serum phosphorous < 6 mg/dl

- Vascular Access
  Percent of patients with catheters (not counting catheters used while a fistula or graft is maturing) < 10%
  Percent of patients with AV fistula in use > 40 - 60% (varies by year)

Another potential set of P4P criteria are the Clinical Performance Measures (CPMs) developed and now monitored by CMS. A recent paper by Parfrey (34) related the research by Rocco et al. (35) on the relationship between CPMs and patient outcomes to other research on the efficacy of CPMs. Rocco et al. looked at four CPMs: hemoglobin value of 11 g/dL (110 g/L) or greater; serum albumin value of 4 g/dL (40 g/L) or greater or 3.7 g/dL (37 g/L) or greater (bromcresol green and bromcresol purple laboratory methods, respectively); use of a fistula for vascular access; and measured single-pool Kt/V urea value of 1.2 or greater. These investigators report that large percentages of dialysis patients do not meet performance targets; only seven percent of patients met all four targets. Therefore, there exists opportunity for improvement, perhaps motivated by P4P. Rocco et al. (35) find that meeting both individual targets and the full set of targets was associated with reduced mortality and hospitalization. Parfrey (34) puts these results into context, noting that of the four measures, only the Kt/V criterion is supported by randomized controlled trial evidence of improved health outcomes. However, Parfrey argues that because hemoglobin value of 11 or greater is associated with higher quality of life and because fistulas likely lead to better vascular access outcomes than grafts, these criteria also have merit. He concludes that "quality assurance initiatives to achieve these targets can be supported." Because serum albumin is not readily amenable to intervention, Parfrey argues it is not a good candidate criterion for P4P.

This recent work and other research support the feasibility of a P4P system to stimulate improvements in dialysis care. There appear to be measures of clinical care that are associated with improved patient outcomes and failure to achieve potential targets on some of these measures.

2. P4P design considerations

The design of P4P systems is currently the subject of experimentation for the full range of health care services. As noted above, the ESRD Disease Management Demonstration rewards dialysis providers based on both improvements over time in the quality criteria and performance compared to national benchmarks, which are set to rise over time. There are two aspects of this design that are consistent with results of prior P4P evaluations by members of our research team and others.

First, rewarding both improvement and performance in comparison to a standard serves to motivate relatively low-performing providers as well as to support continued excellence in relatively high-performing providers (36). Further, continuous improvement in quality is encouraged through increases in established thresholds (37).

Second, rewards are designed to be paid to dialysis facilities, rather than to dialysis physicians. This aspect is consistent with our research, which has shown that there is greater variation across dialysis facilities in performance than there is across dialysis physicians (38,42). Hence, dialysis facilities appear to have more opportunity to reduce variability and achieve performance targets than do dialysis physicians. In addition, dialysis facilities are likely to have a greater ability to establish processes necessary to achieve performance targets (36). Indeed, large dialysis organizations may be especially able to bring resources and care systems to bear to achieve improvements in care quality. Therefore, a prerequisite to successful P4P implementation identified in prior research, namely, an organized provider system with sufficient financial and managerial resources, appears to be in place.

Finally, the ESRD Disease Management Demonstration reward system is based on withheld payment of five percent of Medicare payments to dialysis facilities. In the context of inpatient hospital care, this level of reward by a large payer has been shown to be sufficient to support quality improvement (37,43).

E. PERIODIC PAYMENT SYSTEM UPDATES

CMS should plan for periodic updates of the payment amounts and case-mix adjustment models. Over time, changes can occur in clinical practice (in part due to the change in incentives under bundling, and in part due to new knowledge and treatment options), input prices, the prevalence and/or reporting of comorbidities, and the relationships between comorbidities and costs. Therefore, CMS should ensure that sufficient data are available to re-estimate the parameters and relationships in this report in order to ensure that the payment system remains up-to-date and continues to ensure access to high quality dialysis related services.

XIV. CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH

A. CONCLUSIONS

The primary objective of this report was to analyze options to establish an expanded prospective payment system for outpatient dialysis services. One overall conclusion is that a reasonable expanded bundle definition can be developed using available data. Available CMS data allow the definition of a set of services associated with dialysis care which could be included in an expanded, prospectively paid bundle of services. Although some additional coordination between dialysis units and other providers (e.g., independent laboratories) would undoubtedly be required, for the most important separately billable services (e.g., injectable medications for anemia management), billings from providers other than the dialysis unit are rare. This research also identified a variety of patient

characteristics that could be appropriate to adjust payments to account for variations across patients in the cost of delivering dialysis related care. These patient characteristics were derived primarily from the Medical Evidence Form (CMS Form 2728) and Medicare claims, and were used to develop case-mix adjustment models that explained up to 34% percent of the variation in measured costs.

The implementation of a bundled payment system will reduce the variation in payments across both patients and facilities. Hence there will be a substantial number of facilities that will experience a material reduction in their revenues and a substantial number of facilities that will experience a material increase in their revenues, absent changes in practice patterns in response to the implementation of an expanded bundle.

A more broadly bundled payment system will provide strong financial incentives to reduce utilization of injectable medications and other services that are separately billable in the current system. To the extent that some of the current high utilization results from inefficient care management, a bundled payment system can produce social benefit, and the real financial risk to facilities would be less than would be implied by the projected changes in revenues. However, to the extent that some of the current high utilization reflects true differences in the need for care not accounted for by the case-mix adjustment model and any additional outlier payments, a bundled payment system may result in an inappropriate restriction of indicated care. Because of incentives to reduce use of separately billable services, increased monitoring and quality assurance systems will be necessary. Dialysis services appear to be amenable to the implementation of a pay-for-performance system because quality measures are available, providing opportunities to maintain high levels of performance and even make further improvements. An expanded bundle will also increase the predictability of Medicare expenditures and provide a mechanism for the introduction of new technologies (e.g., bundling anemia management rather than specific billable medications used to treat anemia).

The variation in observed costs not predicted by the case-mix model is substantial. To the extent that some facilities cannot respond appropriately to the incentives in the bundled system to reduce costs without compromising patient outcomes, these facilities may face material financial risk. Therefore, developing an outlier payment system is advisable. Due to data limitations, it is currently not possible to design an outlier payment system that uses patient-level cost data for all services in an expanded bundle. However, available patient-level data could be used to establish outlier payments for separately billable services, which are being added to the existing composite rate bundle and would account for the increased financial risk to facilities under a more broadly bundled payment system.

A number of other implementation challenges remain. One challenge involves developing payment policies for pediatric patients. Due to the relative paucity of data on pediatric patients in the analyses, the model does not reliably estimate costs for pediatric patients. The model systematically underpredicts separately billable costs incurred by pediatric patients. Another key challenge involves the selection and measurement of comorbidities as payment adjusters. The model building process followed in this research was guided by several desired criteria, including model parsimony and the likelihood that diagnoses could be measured objectively and did not vary "too much" in severity. The ultimate effectiveness of the case-mix adjustment model will depend not only on its explanatory power, but also on the ability to write regulations that provide clear instructions to facilities on how to define and report comorbidities. If the comorbidities reported under a prospective payment system are inconsistent with the diagnoses that were found in the historical billing data, in terms of either prevalence or severity, the case-mix adjustment system will have to be re-calibrated.

Finally, several requirements on dialysis facilities should be recognized as a new payment system is implemented. Facilities will be required to report more clinical information relating to the case-mix measures used in the payment model. While the payment will be prospective, facilities should also be

required to continue to report data regarding service utilization to allow future updates to the case-mix adjusted payment system. Relationships with clinical laboratories and other providers may need to be expanded to manage the "consolidated billing" process under which dialysis facilities become the only providers that can be paid for services specified as part of the expanded bundle.

B. RECOMMENDATIONS FOR FUTURE RESEARCH

As noted above, the implementation of a system of case-mix adjusted payments for an expanded bundle of dialysis services changes substantially the incentives facing dialysis providers and likely imposes a new set of information management requirements on providers, fiscal intermediaries, and CMS. To monitor responses to the new incentives and to enable updating of system parameters based on these responses and new data, it will be very important to extend a program of evaluation and research into the post-implementation period. Below is a description of several research and evaluation questions that merit consideration. The set is meant to be illustrative of the range of issues that could be investigated. It is by no means exhaustive.

To support the research and evaluation described here, it is essential to ensure collection of data on utilization of all services provided to ESRD patients, as well as of patient characteristics that are part of the payment model. In addition, patient characteristics that are not part of the case-mix adjustment payment model will be important to support studies informing model revision. Finally, facility Cost Reports remain a necessary source of data going forward.

A key operational question is the extent to which comorbidity data reported in the prospective payment system are consistent with the historical claims data used in estimating the payment multipliers in this report. It will be important to update the model to reflect data under the prospective payment system.

Development of a payment model for pediatric patients requires additional research. One step toward creating a more predictive model of actual costs for pediatric patients would be to utilize newly available measures of current height and weight, as opposed to those reported on CMS Form 2728. Differences between these two sources of anthropometric data may be particularly important for children who are actively growing. A second step could be to estimate models limited to pediatric patients using most recent Medicare claims data.

Perhaps the most important questions to answer regarding the new payment system concern effects on quality, cost (as determined by changes in clinical practice), and access.

Regarding quality, a natural line of research is to compare performance on patient outcome measures such as urea reduction and hematocrit before and after altering the incentive system, controlling for patient characteristics. This work could be extended to identifying performance differences across types of providers and types of patients in the new payment system.

Comparing clinical practice and resulting cost of dialysis care before and after altering the incentive system is an equally important step. Clinical practice measures meriting scrutiny include route of EPO administration, use of iron, frequency of dialysis, and utilization of home dialysis modalities. Again, identifying differences across provider types and patient types will add to our understanding of incentive effects.

In terms of access, as noted throughout this report, one of the main objectives of adjusting payments for patient condition is to help ensure access to care for especially ill and therefore costly patients.

Hence, a key component of the evaluation of the new system will be to determine its effects on access to dialysis services. The concept of access is difficult to make operational; often what is done is to draw inferences about access based on patterns of utilization. Hence, a first step is to determine if changes in patterns of dialysis services use for specific types of patients occur. Patients of particular interest are those with historically higher use of separately billable services than would be predicted by the payment model. For example, patient travel patterns, before and after implementation, could be examined to determine if vulnerable patients have difficulty finding convenient local care. Additionally, the ESRD Networks and patient advocacy organizations could expand tracking of complaints regarding access to care. As above, identifying differences across types of facilities in utilization patterns post-PPS will be important.

As the new payment system may alter patterns of dialysis service utilization and clinical practice, more data will become available to support research relating outcomes performance to changes in utilization and clinical practice. This research will enhance understanding of processes of care leading to improved patient outcomes.

The incentives under the new PPS might alter patterns of care for other providers and services. In particular, rates of hospitalization, use of hospital outpatient services including emergency services, and even use of primary care services may be affected. Research is necessary to document these effects and their implications for overall Medicare expenditures.

The new PPS might alter the organization of dialysis and related services. Dialysis facilities might see advantage in integrating vertically with clinical laboratories, hospitals, physicians, and other providers. Or, the new system might present increased advantage to horizontal integration of an already highly concentrated industry. Since these potential organizational changes have implications for cost, quality, and access, a research effort aimed at measuring and understanding these changes is in order.

Another key factor that may interact with an expanded bundle to further influence patterns of care is the Medicare Part D prescription drug benefit. Increased insurance coverage for outpatient prescriptions may encourage the substitution away from the injectable forms covered in the expanded bundle. This is possible for iron, and particularly likely for Vitamin D, given that each major formulation is now available in oral form. Patients on home therapies may be particularly vulnerable to such substitution. Substitution should be monitored both to determine updates to the payment rate for the expanded bundle, and to ensure that patient financial burdens, and subsequent therapeutic non-compliance, are not excessive.

Finally, answers to the questions posed above, while important on their own, are essential to refinement of the new payment system in the future. Potential refinements include: (1) further expansion of the bundle to include other outpatient services, such as vascular access, and inpatient services; and (2) alignment of incentives for physicians and facilities. Evaluation of these and other potential refinements requires an ongoing program of evaluation and research.

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Appendix A:
Data Sources

February 2008

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Data Sources

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Introduction

This document summarizes the data and sources of data used by the University of Michigan, Kidney Epidemiology and Cost Center (UM-KECC) to prepare the attached report to CMS End Stage Renal Disease Payment System: Results of Research on Case Mix Adjustment for An Expanded Bundle. Accomplishing this objective requires a careful analysis of the workings and shortcomings of the existing payment system, an analysis of how well existing data are able to inform decisions about the costs incurred by an efficient provider delivering high quality services, and analyses of the relationships between dialysis modality, case mix, and costs. These analyses will be required to devise a system that ensures access to quality care for more complex patients and ensures equitable reimbursement to those facilities who serve them. Broadening the bundle of services included in the composite rate can simplify the billing process and can remove incentives for excessive use of separately billable services. However, broadening the bundle necessitates increased attention to quality assurance measures to ensure that an expanded PPS does not result in an inappropriate reduction in the use of some services that were formerly billed separately (e.g. EPO). Further, case mix adjustments may have to be developed.

Data Sources

We divided the prospective payment system data sources into three groups. The first group consists of primary, recurring, government data sources used to identify ESRD patients and to provide demographics for them. The second group consists of primary, recurring, government data sources that provide information on the care and treatment of dialysis patients. Both of these sources collect data about entire populations rather than about samples. The third group consists of primary, recurring, government data sources used to identify and characterize dialysis facilities.

Databases

For this project, the following group 1 databases are used. From the Centers for Medicare and Medicaid Services (CMS) Renal Management Information System (REMIS), formerly the ESRD Program Medical Management and Information System (PMMIS) and the Renal Beneficiary and Utilization System (REBUS), UM-KECC uses the Patient Master File (IDEN) and the Medical Evidence (ME) databases as the starting point for finding patients who are eligible for Medicare ESRD coverage. We add patients to this database and refine the placement of patients into facilities using the CMS Enrollment Data Base (EDB) and the Standard Management Information System (SIMS) database, which is managed by the ESRD Networks. We obtain information about transplants from the CMS Inpatient SAF and directly from the Organ Procurement Transplant Network (OPTN) through the Scientific Registry of Transplant Recipients (SRTR). The SIMS data and the SRTR data are not used for this project except to establish transplant dates for censoring dialysis months. Using these databases, UM-KECC creates a finder file containing all known cross-referenced Medicare IDs for these patients. This file is used for searching other CMS group 1 and 2 databases for additional information about these patients. We obtain information about death dates

from the Renal Management Information System (REMIS) Death Notification database as well as from the Social Security System Death Master File. We obtain claim information by using this finder file to subset the CMS Institutional Standard Analytic Files (SAFs) for inpatient hospital, outpatient hospital (dialysis facilities are a subset), Skilled Nursing Facility, Home Health Agency and Hospice claims. We also obtain carrier claims and Durable Medical Equipment (DME) claims from the National Claims History Files at CMS. We subset the Outpatient claims into dialysis facilities and other facilities by the presence of a dialysis revenue center. Generally we further subset the dialysis facility claims for analysis using only TYPE_OF_BILL = '72' claims. We obtain group 3 data such as the hospital and dialysis facility Cost Reports (CMS Public Use Files) from CMS. We use the CMS Annual Facility Survey (AFS) and the CMS Online Survey Certification and Reporting (OSCAR) database to better identify facilities and to add facility information to our database.

1. ESRD Program Medical Management and Information System (PMMIS)
2. Renal Beneficiary and Utilization System (REBUS)
3. Renal Management Information System (REMIS)

The REMIS Patient Master File (IDEN) contains basic patient identification, demographics and eligibility data. It contains a Health Information Claim Account Number (HICAN) number and a list of Social Security Numbers, to which the Beneficiary Identity Code (BIC) can be added to form additional HICAN numbers that have been used to identify the patient over time. UM-KECC uses this list together with a similar list obtained from the EDB to assign a KECC Identification Number, KECC_ID. We build a cross reference table associating all of the patient's HICAN numbers with this KECC_ID.

The REMIS Medical Evidence contains data elements concerning dialysis, transplant, and self-care training collected from the CMS Form 2728 ESRD Medical Evidence Report form. A beneficiary may have one medical evidence record for each period of ESRD entitlement. A CMS-2728 is completed by the provider within 45 days of when the patient has been determined to have ESRD and is signed by the physician after a patient's regularly scheduled course of therapy begins (generally the first dialysis session).

The REMIS Death Notification contains information commonly captured on form CMS-2746. The information contained includes the date of death, the primary and secondary causes of death, the current ESRD provider, whether dialysis was discontinued and why, if the patient had received a transplant and the date of transplantation, and if the patient died with a functioning kidney.

4. CMS Enrollment Database (EDB)

The Medicare Enrollment database is a relational database the contains demographic information as well as Part A and Part B entitlement history periods with the reason for entitlement coded (up to 6 Part A periods and up to 10 Part B), HMO status data(up to 50 periods of coverage), a history of residences(up to 50 periods), a list of other Healthcare Identification Codes that have identified that patient(up to 10), a history of ESRD coverage(up to 5 periods), and a history of primary payers(up to 20 periods of time when Medicare is the secondary payer).

For this project the EDB contributes to the development of finder files for getting other CMS data like the SAFs. We also use the primary payer history and the HMO history to exclude bills received in periods when the patient has HMO coverage or when Medicare is a secondary payer.

5. CMS Standard Analytic Files (SAFs)

UM-KECC predominantly uses the outpatient SAF as dialysis facilities are contained in that SAF with TYPE_OF_BILL = '72'. We use the entire outpatient SAF as well as the inpatient, the skilled nursing facility, the home health agency and the hospice SAFs to search for comorbidities. The SAFS are usually transported to researchers with a header portion of the record which contains patient demographics, total charges and payments for the entire claim, and physician information among other fields. The SAFs also contain a series of trailer records among which are diagnostic trailers, procedure trailers, claim related value trailers, claim occurrence trailers and the revenue center trailers. There are several other types of trailers but the above are those useful for KECC research.

The SAFs are a set of paid claims files containing information on facility charges and payments for services, the attending and operating physician, the provider, some patient demographic information, International Classification of Diseases, version 9 Clinical Modification(ICD-9-CM) diagnoses and procedures and Current Procedural Terminology (CPT-4) and HCFA Common Procedure Coding System (HCPCS) procedures. Charges and payments are reported at the revenue center level where they can be directly connected to the revenue center HCPCS, which describes the services performed for the patient, since July 2000.

6. CMS Carrier Claims

The CMS carrier claims are generated by physicians, laboratories, radiology centers, and other suppliers. For this project UM-KECC uses these claims to identify comorbidities and laboratory charges.

The carrier claims are a set of paid claims files containing information on physician or supplier charges and payments, the attending and referring physician, the supplier, and some patient demographic information. They consist of a header portion with several trailers. There is a diagnostic trailer and a line item trailer. The line item trailer is analogous to the revenue center trailers in the SAFs.

7. CMS Hospital and Freestanding Dialysis Facility Cost Reports

The Medicare Cost Reports are a nearly universal provider level database. All renal facilities that are certified by Medicare (freestanding or hospital based) are required to submit annually a detailed cost report containing a breakdown of costs. The Medicare Cost Reports for freestanding and hospital based renal facilities have been collected for many years. Currently available on the CMS website are databases for the years 1994-2005. There is one observation per facility per quarter and there were more than 4,000 facilities reporting cost information in the last available cost report.

There are two separate databases for Medicare Cost Reports, one for hospital based facilities and one for freestanding facilities. In both databases, however, total costs, FTE costs, erythropoietin (EPO) costs, other separately billable costs, and other institutional costs can be determined. These databases could be useful for providing overall cost values. The hospital based facilities cost reports do not complete the ESRD portion of the cost reports with any great regularity, however.

Two forms are used for the collection of Medicare Cost Reports. The independent renal facility (freestanding) form is CMS 265-94 and the Hospital based renal facility form is CMS 2552-96 from which the renal minimum data set is generated from Worksheets S-2 and S-5 and Worksheets I 1-5. These data collection forms are included in Appendix 1. The data for hospital based facilities and for freestanding facilities are generated in the facilities and forwarded directly to CMS.

These files are public use files and are available on the CMS website for downloading.

CMS Annual Facility Survey

The CMS Annual Facility Survey (AFS) is a near universe of facility level data collected annually from freestanding and hospital related dialysis facilities. The CMS Annual Facility Survey has been collected since 1980. With the addition of non-Medicare certified Veteran's Administration Facilities in 1992, the survey is completed by more than 99% of existing dialysis facilities.

The provider address is part of the survey and the data fields: city, SSA county code, Federal Information Processing Standard (FIPS) county code, and zip code are useful for determining urbanicity as part of potential price adjusters. The survey also provides counts by modality of treatment (hemodialysis, peritoneal dialysis) at the beginning and end of the survey period which can be used to validate counts determined from claims data. Similarly, data fields describe organs harvested, organs obtained, organs transplanted, and patients transplanted all of which may be relevant to cost determination. The survey contains the field, total stations, which can be utilized to determine cost effectiveness.

The AFS is collected on the form CMS 2744 which can be found in the Appendix. The data are collected by the CMS ESRD Networks and forwarded to CMS.

The AFS is a public use file available for downloading on the CMS website: www.cms.hhs.gov.

CMS Online Survey, Certification, and Reporting (OSCAR) Database

The OSCAR database is a collection of data on facilities including a facility master list. OSCAR is used to store the surveys conducted by state surveyors. These data are useful for checking the reliability of overlapping items on the Medicare Cost Reports and CMS and CDC facility surveys, and as a source of information on quality deficiencies identified by state surveyors. This can be useful in the ongoing monitoring of care under the revised PPS. The primary weaknesses are that facilities are not surveyed every year and that although the data elements are uniform nationally, the survey process varies by state.

Social Security Administration Death Master File

The Social Security System Death Master File contains information on all persons reported to the Social Security System as being deceased.

The SSA Death Master File is used by leading government, financial, investigative, credit reporting organization, medical research and other industries to verify identity as well as to prevent fraud and comply with the USA Patriot Act. To assist in this effort, NTIS and SSA are working together to offer the SSA Death Master File more frequently, with fewer delays, and in different formats.

The Death Master File (DMF) from the Social Security Administration (SSA) contains over 65 million records of deaths that have been reported to SSA. This file includes the following information on each decedent, if the data are available to the SSA: SSN, name, date of birth, date of death, state or country of residence (2/88 and prior), ZIP code of last residence, and ZIP code of lump sum payment. The SSA does not have a death record for all persons; therefore, SSA does not guarantee the veracity of the file. Thus, the absence of a particular person is not proof this person is alive.

UM-KECC uses the SSN, the name, and the date of birth to link this file with our other databases and to link with our KECC_ID.

Appendix B:
Comorbidity ICD-9-CM Diagnostic Codes

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Appendix B:
Comorbidity ICD-9-CM Diagnostic Codes

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Alcohol/Drug Dependence

291 Alcoholic psychoses
2910 Alcoholic psychoses, alcohol withdrawal delirium
2911 Alcoholic psychoses, alcohol amnestic syndrome
2912 Alcoholic psychoses, other alcohol dementia
2913 Alcoholic psychoses, alcohol withdrawal hallucinosis
2914 Alcoholic psychoses, idiosyncratic alcohol intoxication
2915 Alcoholic psychoses, alcoholic jealousy
2918 Alcoholic psychoses, other specified alcohol psychoses
29181 Alcoholic psychoses, other specified alcohol psychoses, alcohol withdrawal
29189 Alcoholic psychoses, other specified alcohol psychoses, other
2919 Alcoholic psychoses, unspecified alcoholic psychoses
292 Drug psychoses
2920 Drug withdrawal syndrome
2921 Paranoid and/or hallucinatory states induced by drugs
29211 Paranoid and/or hallucinatory states induced by drugs, drug-induced organic delusional syndrome
29212 Paranoid and/or hallucinatory states induced by drugs, drug-induced hallucinosis
2922 Pathological drug intxication
2928 Other specified drug-induced mental disorders
29281 Other specified drug-induced mental disorders, drug-induced delirium
29282 Other specified drug-induced mental disorders, drug-induced dementia
29283 Other specified drug-induced mental disorders, drug-induced amnestic syndrome
29284 Other specified drug-induced mental disorders, drug-induced organic affective syndrome
29289 Other specified drug-induced mental disorders, other
2929 Unspecified drug-induced mental disorder
303 Alcohol dependence syndrome
3030 Alcohol dependence syndrome, acute alcoholic intoxication
30300 Alcohol dependence syndrome, acute alcoholic intoxication, unspecified
30301 Alcohol dependence syndrome, acute alcoholic intoxication, continuous
30302 Alcohol dependence syndrome, acute alcoholic intoxication, episodic
30303 Alcohol dependence syndrome, acute alcoholic intoxication, in remission
3039 Alcohol dependence syndrome, other and unspecified alcohol dependence
30390 Alcohol dependence syndrome, other and unspecified alcohol dependence, unspecified
30391 Alcohol dependence syndrome, other and unspecified alcohol dependence, continuous
30392 Alcohol dependence syndrome, other and unspecified alcohol dependence, episodic
30393 Alcohol dependence syndrome, other and unspecified alcohol dependence, in remission
304 Drug dependence
3040 Drug dependence, opioid type dependence
30400 Drug dependence, opioid type dependence, unspecified
30401 Drug dependence, opioid type dependence, continuous
30402 Drug dependence, opioid type dependence, episodic
30403 Drug dependence, opioid type dependence, in remission
3041 Drug dependence, barbiturate and similarly acting sedative or hypnotic dependence

30410 Drug dependence, barbiturate and similarly acting sedative or hypnotic dependence, unspecified
30411 Drug dependence, barbiturate and similarly acting sedative or hypnotic dependence, continuous
30412 Drug dependence, barbiturate and similarly acting sedative or hypnotic dependence, episodic
30413 Drug dependence, barbiturate and similarly acting sedative or hypnotic dependence, in remission
3042 Drug dependence, cocaine dependence
30420 Drug dependence, cocaine dependence, unspecified
30421 Drug dependence, cocaine dependence, continuous
30422 Drug dependence, cocaine dependence, episodic
30423 Drug dependence, cocaine dependence, in remission
3043 Drug dependence, Cannabis dependence
30430 Drug dependence, Cannabis dependence, unspecified
30431 Drug dependence, Cannabis dependence, continuous
30432 Drug dependence, Cannabis dependence, episodic
30433 Drug dependence, Cannabis dependence, in remission
3044 Drug dependence, amphetamine and other psychostimulant dependence
30440 Drug dependence, amphetamine and other psychostimulant dependence, unspecified
30441 Drug dependence, amphetamine and other psychostimulant dependence, continuous
30442 Drug dependence, amphetamine and other psychostimulant dependence, episodic
30443 Drug dependence, amphetamine and other psychostimulant dependence, in remission
3045 Drug dependence, hallucinogen dependence
30450 Drug dependence, hallucinogen dependence, unspecified
30451 Drug dependence, hallucinogen dependence, continuous
30452 Drug dependence, hallucinogen dependence, episodic
30453 Drug dependence, hallucinogen dependence, in remission
3046 Drug dependence, other specified drug dependence
30460 Drug dependence, other specified drug dependence, unspecified
30461 Drug dependence, other specified drug dependence, continuous
30462 Drug dependence, other specified drug dependence, episodic
30463 Drug dependence, other specified drug dependence, in remission
3047 Drug dependence, combinations of opioid type drug with any other
30470 Drug dependence, combinations of opioid type drug with any other, unspecified
30471 Drug dependence, combinations of opioid type drug with any other, continuous
30472 Drug dependence, combinations of opioid type drug with any other, episodic
30473 Drug dependence, combinations of opioid type drug with any other, in remission
3048 Drug dependence, combinations of drug dependence excluding opioid type drug
30480 Drug dependence, combinations of drug dependence excluding opioid type drug, unspecified
30481 Drug dependence, combinations of drug dependence excluding opioid type drug, continuous
30482 Drug dependence, combinations of drug dependence excluding opioid type drug, episodic
30483 Drug dependence, combinations of drug dependence excluding opioid type drug, in remission
3049 Drug dependence, unspecified drug dependence
30490 Drug dependence, unspecified drug dependence, unspecified
30491 Drug dependence, unspecified drug dependence, continuous
30492 Drug dependence, unspecified drug dependence, episodic
30493 Drug dependence, unspecified drug dependence, in remission
3050 Nondependent abuse of drugs, alcohol abuse
30500 Nondependent abuse of drugs, alcohol abuse, unspecified
30501 Nondependent abuse of drugs, alcohol abuse, continuous
30502 Nondependent abuse of drugs, alcohol abuse, episodic
30503 Nondependent abuse of drugs, alcohol abuse, in remission
4255 Alcoholic cardiomyopathy
5710 Alcoholic fatty liver
5711 Acute alcoholic hepatitis
5712 Alcoholic cirrhosis of liver
5713 Alcoholic liver damage, unspecified
V113 Personal history of mental disorder, alcoholism

Cardiac Arrest

4275 Cardiac Arrest

Pericarditis

420 Acute pericarditis
4200 Acute pericarditis in diseases classified elsewhere
4209 Other and unspecified pericarditis
42090 Other and unspecified pericarditis, acute pericarditis, unspecified
42091 Other and unspecified pericarditis, acute idiopathic paricarditis
42099 Other and unspecified pericarditis, other

HIV/AIDS

042 Human immunodeficience virus with specified conditions, includes acquired immunodeficiency syndrome (AIDS)
V08 Asymptotic human immunodeficiency virus [HIV] infection status
07953 Human Immunodeficiency virus, type 2 [HIV-2]
79571 Nonspecific serological evidence of human immunodeficiency virus [HIV]

Hepatitis B

0702 Viral hepatitis B with hepatic coma
07020 Viral hepatitis B with hepatic coma, acute or unspecified, without mention of hepatitis delta
07021 Viral hepatitis B with hepatic coma, acute or unspecified, with hepatitis delta
07022 Viral hepatitis B with hepatic coma, chronic, without mention of hepatitis delta
07023 Viral hepatitis B with hepatic coma, chronic, with hepatitis delta
0703 Viral hepatitis B without mention of hepatic coma
07030 Viral hepatitis B without mention of hepatic coma, acute or unspecified, without mention of hepatitis delta
07031 Viral hepatitis B without mention of hepatic coma, acute or unspecified, with hepatitis delta
07032 Viral hepatitis B without mention of hepatic coma, chronic, without mention of hepatitis delta
07033 Viral hepatitis B without mention of hepatic coma, chronic, with hepatitis delta

Specific Infections

Septicemia and Shock

0202 Plague, septicemic
0223 Anthrax septicemia

031 Diseases due to other mycobacteria
0362 Meningococcemia
038 Septicemia
0380 Septicemia, streptococcal
0381 Septicemia, staphylococcal
03810 Septicemia, staphylococcal, unspecified
03811 Septicemia, staphylococcal, Staphylocaccal aureus
03819 Septicemia, staphylococcal, other
0382 Septicemia, Pneumococcal septicemia
0383 Septicemia, due to anaerobes
0384 Septicemia, due to other gram-negative organisms
03840 Septicemia, due to other gram-negative organisms, unspecified
03841 Septicemia, due to other gram-negative organisms, Hemophilus influenzae
03842 Septicemia, due to other gram-negative organisms, Escherichia coli
03843 Septicemia, due to other gram-negative organisms, pseudomonas
03844 Septicemia, due to other gram-negative organisms, serratia
03849 Septicemia, due to other gram-negative organisms, other
0388 Septicemia, other specified
0389 Septicemia, unspecified
04082 Toxic shock syndrome
0545 Herpetic septicemia
77181 Septicemia of the newborn
78559 Other shock: endotoxic, gram-negative, hypovolemic

Bacterial Pneumonias and Opportunistic Infections and Pneumococcal pneumonias

482 Other bacterial pneumonias
4820 Pneumonia due to Klebsiella pneumnoniae
4821 Pneumonia due to Pseudomonas
4824 Pneumonia due to Staphylococcus
48240 Pneumonia due to Staphylococcus, unspecified
48241 Pneumonia due to Staphylococcus aureus
48249 Pneumonia due to other Staphylococcus pneumonia
4828 Pneumonia due to other specified bacteria
48281 Pneumonia due to Anaerobes
48282 Pneumonia due to Escherichia coli (E. coli)
48283 Pneumonia due to other gram-negative bacteria
48284 Legionnaires' disease
48289 Pneumonia due to other specified bacteria
507 Pneumonitis due to solids and liquids
5070 Pneumonitis due to inhalation of food or vomitus
5071 Pneumonitis due to inhalation of oils and essences
5078 Pneumonitis due to other solids and liquids
0074 Cryptosporidiosis
0310 Diseases due to other mycobacteria, pulmonary
0312 Diseases due to other mycobacteria, disseminated
0785 Cytomegaloviral disease
1124 Candidiasis of lung
1125 Candidiasis, disseminated
11284 Candidal esophagitis
1173 Aspergillosis
1175 Cryptococcosis

1177 Zygomycosis (Phycomycosis or Mucormycosis)
1300 Meningoencephalitis due to toxoplasmosis
1308 Multisystemic disseminated toxoplasmosis
1363 Pneumocytosis
3210 Cryptococcal meningitis
4841 Pneumonia in cytomegalic inclusion disease
00322 Salmonella pneumonia
0064 Amebic lung abcess
0203 Primary pneumonia
0204 Secondary pneumonia
0205 Pneumonic, unspecified
0212 Pulmonary tularemia
0221 Pulmonary anthrax
0391 Actinomycotic infections, pulmonary
1140 Primary coccidioidomycosis, pulmonary
1144 Chronic pulmonary coccidioidomycosis
1145 Primary coccidioidomycosis, unspecified
11505 Infection by Histoplasma capsulatum, pneumonia
11515 Infection by Histoplasma duboisii, pneumonia
11595 Histoplasmosis, unspecified, pneumonia
1212 Paragonimiasis
1221 Echinococcus granulosus infection of lung
1304 Pneumonitis due to toxoplasmosis
481 Pneumococcal pneumonia (Streptococcus pneumoniae pneumonia)
4822 Pneumonia due to Hemophilus influenzae
4823 Pneumonia due to Streptococcus
48230 Pneumonia due to Streptococcus, unspecified
48231 Pneumonia due to Streptococcus, Group A
48232 Pneumonia due to Streptococcus, Group B
48239 Pneumonia due to Streptococcus, other Streptococcus
4846 Pneumonia in aspergillosis
4847 Pneumonia in other systemic mycoses
510 Empyema
5100 Empyema, with fistula
5109 Empyema. without mention of fistula
513 Abscess of lung and mediastinum
5130 Abscess of lung
5131 Abscess of mediastinum

Gastro-Intestinal Tract Bleeding

53021 Ulcer of esophagus with bleeding
5310 acute gastric ulcer with hemorrhage
53100 acute gastric ulcer with hemorrhage without mention of obstruction
53101 acute gastric ulcer with hemorrhage with obstruction
5312 acute gastric ulcer with hemorrhage and perforation
53121 acute gastric ulcer with hemorrhage and perforation without mention of obstruction
53120 acute gastric ulcer with hemorrhage and perforation with obstruction
5314 chronic or unspecified gastric ulcer with hemorrhage
53140 chronic or unspecified gastric ulcer with hemorrhage without mention of obstruction
53141 chronic or unspecified gastric ulcer with hemorrhage with obstruction
5316 chronic or unspecified gastric ulcer with hemorrhage and perforation

53160 chronic or unspecified gastric ulcer with hemorrhage and perforation without mention of obstruction
53161 chronic or unspecified gastric ulcer with hemorrhage and perforation with obstruction
5320 acute duodenal ulcer with hemorrhage
53200 acute duodenal ulcer with hemorrhage without mention of obstruction
53201 acute duodenal ulcer with hemorrhage with obstruction
5322 acute duodenal ulcer with hemorrhage and perforation
53221 acute duodenal ulcer with hemorrhage and perforation without mention of obstruction
53220 acute duodenal ulcer with hemorrhage and perforation with obstruction
5324 chronic or unspecified duodenal ulcer with hemorrhage
53240 chronic or unspecified duodenal ulcer with hemorrhage without mention of obstruction
53241 chronic or unspecified duodenal ulcer with hemorrhage with obstruction
5326 chronic or unspecified duodenal ulcer with hemorrhage and perforation
53260 chronic or unspecified duodenal ulcer with hemorrhage and perforation without mention of obstruction
53261 chronic or unspecified duodenal ulcer with hemorrhage and perforation with obstruction
5330 acute peptic ulcer with hemorrhage
53300 acute peptic ulcer with hemorrhage without mention of obstruction
53301 acute peptic ulcer with hemorrhage with obstruction
5332 acute peptic ulcer with hemorrhage and perforation
53321 acute peptic ulcer with hemorrhage and perforation without mention of obstruction
53320 acute peptic ulcer with hemorrhage and perforation with obstruction
5334 chronic or unspecified peptic ulcer with hemorrhage
53340 chronic or unspecified peptic ulcer with hemorrhage without mention of obstruction
53341 chronic or unspecified peptic ulcer with hemorrhage with obstruction
5336 chronic or unspecified peptic ulcer with hemorrhage and perforation
53360 chronic or unspecified peptic ulcer with hemorrhage and perforation without mention of obstruction
53361 chronic or unspecified peptic ulcer with hemorrhage and perforation with obstruction
5340 acute gastrojejunal ulcer with hemorrhage
53400 acute gastrojejunal ulcer with hemorrhage without mention of obstruction
53401 acute gastrojejunal ulcer with hemorrhage with obstruction
5342 acute gastrojejunal ulcer with hemorrhage and perforation
53421 acute gastrojejunal ulcer with hemorrhage and perforation without mention of obstruction
53420 acute gastrojejunal ulcer with hemorrhage and perforation with obstruction
5344 chronic or unspecified gastrojejunal ulcer with hemorrhage
53440 chronic or unspecified gastrojejunal ulcer with hemorrhage without mention of obstruction
53441 chronic or unspecified gastrojejunal ulcer with hemorrhage with obstruction
5346 chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation
53460 chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation without mention of obstruction
53461 chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation with obstruction
53783 angiodysplasia of stomach and duodenum with hemorrhage
56202 diverticulosis of small intestine with hemorrhage
56203 diverticulitis if small intestine with hemorrhage
56212 diverticulosis of colon with hemorrhage
56213 DIVERTICULITIS IF COLON WITH HEMORRHAGE
56985 Angiodysplasia of intestine with hemorrhage

Hereditary Hemollytic Anemias or Sickle Cell Anemias

282 Hereditary hemolytic anemias
2820 Hereditary spherocytosis
2821 Hereditary elliptocytosis

2822 Anemias due to disorders of glutathione metabolism
2823 Other hemolytic anemias due to enzyme deficiency
2824 Thalassemias
28241 Sickle-cell thalassemia without crisis
28242 Sickle-cell thalassemia with crisis
28249 Other thalassemias
2825 Sickle-cell trait
2827 Other hemoglobinopathies
2828 Other specified hereditary hemolytic anemias
2829 Hereditary hemolytic anemia, unspecified
2826 Sickle-cell disease
28260 Sickle-cell disease, unspecified
28261 Sickle-cell disease, Hb-SS disease without crisis
28262 Sickle-cell disease, Hb-SS disease with crisis
28263 Sickle-cell disease, Sickle-cell/Hb-C disease without crisis
28264 Sickle-cell disease, Sickle-cell/Hb-C disease with crisis
28268 Sickle-cell disease, Other sickle-cell disease without crisis
28269 Sickle-cell disease, Other sickle-cell disease with crisis

Myelodysplastic Syndrome

2387 Neoplasms of other lymphatic and hematopoietic tissues [includes myelodysplastic syndrome]

Monoclonal Gammopathy

2731 Monoclonal paraproteinemia [includes monoclonal gammopathy]

Cancer (excludes non-melanoma skin cancer includes some benign neoplasms of the central nervous system)

141 Malignant neoplasm of tongue
1410 Malignant neoplasm of tongue, base
1411 Malignant neoplasm of tongue, dorsal surface
1412 Malignant neoplasm of tongue, tip and lateral border
1413 Malignant neoplasm of tongue, ventral surface
1414 Malignant neoplasm of tongue, anterior two-thirds, part unspecified
1415 Malignant neoplasm of tongue, junctional zone
1416 Malignant neoplasm of tongue, lingual tonsil
1418 Malignant neoplasm of tongue, other sites
1419 Malignant neoplasm of tongue, unspecified
142 Malignant neoplasm of major salivary glands
1420 Malignant neoplasm of major salivary glands, parotid
1421 Malignant neoplasm of major salivary glands, submandibular
1422 Malignant neoplasm of major salivary glands, sublingual
1428 Malignant neoplasm of major salivary glands, other
1429 Malignant neoplasm of major salivary glands, unspecified
143 Malignant neoplasm of gum

1430 Malignant neoplasm of gum, upper
1431 Malignant neoplasm of gum, lower
1438 Malignant neoplasm of gum, other sites
1439 Malignant neoplasm of gum, unspecified
144 Malignant neoplasm of floor of mouth
1440 Malignant neoplasm of floor of mouth, anterior portion
1441 Malignant neoplasm of floor of mouth, lateral portion
1448 Malignant neoplasm of floor of mouth, other sites
1449 Malignant neoplasm of floor of mouth, part unspecified
145 Malignant neoplasm of other and unspecified parts of mouth
1450 Malignant neoplasm of other and unspecified parts of mouth, cheek mucosa
1451 Malignant neoplasm of other and unspecified parts of mouth, vestibule
1452 Malignant neoplasm of other and unspecified parts of mouth, hard palate
1453 Malignant neoplasm of other and unspecified parts of mouth, soft palate
1454 Malignant neoplasm of other and unspecified parts of mouth, uvula
1455 Malignant neoplasm of other and unspecified parts of mouth, palate, unspecified
1456 Malignant neoplasm of other and unspecified parts of mouth, retromolar area
1458 Malignant neoplasm of other and unspecified parts of mouthother specified parts
1459 Malignant neoplasm of other and unspecified parts of mouth, unspecified
146 Malignant neoplasm of oropharynx
1460 Malignant neoplasm of oropharynx, tonsil
1461 Malignant neoplasm of oropharynx, tonsillar fossa
1462 Malignant neoplasm of oropharynx, tonsillar pillars
1463 Malignant neoplasm of oropharynx, vallecula
1464 Malignant neoplasm of oropharynx, anterior aspect of epiglottis
1465 Malignant neoplasm of oropharynx, junctional region
1466 Malignant neoplasm of oropharynx, lateral wall
1467 Malignant neoplasm of oropharynx, posterior wall
1468 Malignant neoplasm of oropharynx, other specified sites
1469 Malignant neoplasm of oropharynx.unspecified
147 Malignant neoplasm of nasopharynx
1470 Malignant neoplasm of nasopharynx, superior wall
1471 Malignant neoplasm of nasopharynx, posterior wall
1472 Malignant neoplasm of nasopharynx, lateral wall
1473 Malignant neoplasm of nasopharynx, anterior wall
1478 Malignant neoplasm of nasopharynx, other specified sites
1479 Malignant neoplasm of nasopharynx, unspecified
148 Malignant neoplasm of hypopharynx
1480 Malignant neoplasm of hypopharynx, postcricoid regiion
1481 Malignant neoplasm of hypopharynx, pyriform sinus
1482 Malignant neoplasm of hypopharynx, aryepiglottic fold, hypopharyngeal aspect
1483 Malignant neoplasm of hypopharynx, posterior hypopharyngeal wall
1488 Malignant neoplasm of hypopharynx, other specified sites
1489 Malignant neoplasm of hypopharynx, unspecified
149 Malignant neoplasms of other and ill-defined sites within the lip, oral cavity and pharynx
1490 Malignant neoplasms of other and ill-defined sites within the lip, oral cavity and pharynx, pharynx unspecified
1491 Malignant neoplasms of other and ill-defined sites within the lip, oral cavity and pharynx, Waldeyer's ring
1498 Malignant neoplasms of other and ill-defined sites within the lip, oral cavity and pharynx, other
1499 Malignant neoplasms of other and ill-defined sites within the lip, oral cavity and pharynx, ill-defined
150 Malignant neoplasm of the esophagus
1500 Malignant neoplasm of the cervical esophagus
1501 Malignant neoplasm of the thoracic esophagus
1502 Malignant neoplasm of the abdominal esophagus
1503 Malignant neoplasm of the upper third of the esophagus

1504 Malignant neoplasm of the middle third of the esophagus
1505 Malignant neoplasm of the lower third of the esophagus
1508 Malignant neoplasm of the esophagus, other specified part
1509 Malignant neoplasm of the esophagus unspecified
151 Malignant neoplasm of the stomach
1510 Malignant neoplasm of the stomach, cardia
1511 Malignant neoplasm of the stomach, pylorus
1512 Malignant neoplasm of the stomach, pyloric antrum
1513 Malignant neoplasm of the stomach, fundus of stomach
1514 Malignant neoplasm of the stomach, body of stomach
1515 Malignant neoplasm of the stomach, lesser curvature, unspecified
1516 Malignant neoplasm of the stomach, greater curvature, unspecified
1518 Malignant neoplasm of the stomach, other specified site
1519 Malignant neoplasm of the stomach, unspecified
152 Malignant neoplasm of the small intestine including duodenum
1520 Malignant neoplasm of the small intestine including duodenum, duodenum
1521 Malignant neoplasm of the small intestine including duodenum, jejunum
1522 Malignant neoplasm of the small intestine including duodenum, ileum
1523 Malignant neoplasm of the small intestine including duodenum, Meckel's diverticulum
1528 Malignant neoplasm of the small intestine including duodenum, other specified site
1529 Malignant neoplasm of the small intestine including duodenum, unspecified
153 Malignant neoplasm of colon
1530 Malignant neoplasm of colon, hepatic flexure
1531 Malignant neoplasm of colon, transverse colon
1532 Malignant neoplasm of colon, descending colon
1533 Malignant neoplasm of colon, sigmoid colon
1534 Malignant neoplasm of colon, cecum
1535 Malignant neoplasm of colon, appendix
1536 Malignant neoplasm of colon, ascending colon
1537 Malignant neoplasm of colon, splenic flexure
1538 Malignant neoplasm of colon, other specified sites
1539 Malignant neoplasm of colon, unspecified
154 Malignant neoplasm of rectum, rectosigmoid junction and anus
1540 Malignant neoplasm of rectum, rectosigmoid junction and anus, rectosigmoid junction
1541 Malignant neoplasm of rectum, rectosigmoid junction and anus, rectum
1542 Malignant neoplasm of rectum, rectosigmoid junction and anus, anal canal
1543 Malignant neoplasm of rectum, rectosigmoid junction and anus, anus, unspecified
1548 Malignant neoplasm of rectum, rectosigmoid junction and anus, other
155 Malignant neoplasm of the liver and intrahepatic bile ducts
1550 Malignant neoplasm of the liver and intrahepatic bile ducts, liver, primary
1551 Malignant neoplasm of the liver and intrahepatic bile ducts, intrahepatic bile ducts
1552 Malignant neoplasm of the liver and interhepatic bile ducts, liver, not specified as primary or secondary
156 Malignant neoplasm of gall bladder and extrahepatic bile ducts
1560 Malignant neoplasm of gall bladder and extrahepatic bile ducts, gallbladder
1561 Malignant neoplasm of gall bladder and extrahepatic bile ducts, extrahepatic bile ducts
1562 Malignant neoplasm of gall bladder and extrahepatic bile ducts, ampulla of Vater
1568 Malignant neoplasm of gall bladder and extrahepatic bile ducts, other specified sites
1569 Malignant neoplasm of gall bladder and extrahepatic bile ducts, biliary tract, part unspecified
157 Malignant neoplasm of pancreas
1570 Malignant neoplasm of pancreas, head
1571 Malignant neoplasm of pancreas, body
1572 Malignant neoplasm of pancreas, tail
1573 Malignant neoplasm of pancreas, pancreatic duct
1574 Malignant neoplasm of pancreas, islets of Langerhans
1578 Malignant neoplasm of pancreas, other specified site

1579 Malignant neoplasm of pancreas, part unspecified
158 Malignant neoplasm of retroperitoneum and peritoneum
1580 Malignant neoplasm of retroperitoneum and peritoneum, retroperitoneum
1588 Malignant neoplasm of retroperitoneum and peritoneum, specified part of peritoneum
1589 Malignant neoplasm of retroperitoneum and peritoneum, unspecified
159 Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum
1590 Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum, intestinal tract, unspecified
1591 Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum, spleen, NEC
1598 Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum, other sites
1599 Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum, ill-defined
160 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
1600 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, nasal cavities
1601 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, auditory tube, middle ear, and mastoid air cells
1602 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, maxillary sinus
1603 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, aethmoidal sinus
1604 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, frontal sinus
1605 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, sphenoidal sinus
1608 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, other
1609 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses, accessory sinus, unspecified
161 Malignant neoplasm of larynx
1610 Malignant neoplasm of larynx, glottis
1611 Malignant neoplasm of larynx, supraglottis
1612 Malignant neoplasm of larynx, subglottis
1613 Malignant neoplasm of larynx, laryngeal cartilages
1618 Malignant neoplasm of larynx, other specified sites
1619 Malignant neoplasm of larynx, unspecified
162 Malignant neoplasm of trachea, bronchus, and lung
1620 Malignant neoplasm of trachea, bronchus, and lung, trachea
1622 Malignant neoplasm of trachea, bronchus, and lung, main bronchus
1623 Malignant neoplasm of trachea, bronchus, and lung, upper lobe, bronchus or lung
1624 Malignant neoplasm of trachea, bronchus, and lung, middle lobe, bronchus or lung
1625 Malignant neoplasm of trachea, bronchus, and lung, lower lobe, bronchus or lung
1628 Malignant neoplasm of trachea, bronchus, and lung, other specified parts
1629 Malignant neoplasm of trachea, bronchus, and lung, unspecified
163 Malignant neoplasm of pleura
1630 Malignant neoplasm of pleura, parietal pleura
1631 Malignant neoplasm of pleura, visceral pleura
1638 Malignant neoplasm of pleura, other specified sites
1639 Malignant neoplasm of pleura, unspecified
164 Malignant neoplasm of thymus, heart and mediastinum
1640 Malignant neoplasm of thymus, heart and mediastinum, thymus
1641 Malignant neoplasm of thymus, heart and mediastinum, heart
1642 Malignant neoplasm of thymus, heart and mediastinum, anterior mediastinum
1643 Malignant neoplasm of thymus, heart and mediastinum, posterior mediastinum
1648 Malignant neoplasm of thymus, heart and mediastinum, other
1649 Malignant neoplasm of thymus, heart and mediastinum, part unspecified
165 Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs
1650 Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs, upper respiratory trace, part unspecified

1658 Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs, other
1659 Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs, ill-defined sites
170 Malignant neoplasm of bone and articular cartilage
1700 Malignant neoplasm of bone and articular cartilage, bones of skull and face, except mandible
1701 Malignant neoplasm of bone and articular cartilage, mandible
1702 Malignant neoplasm of bone and articular cartilage, vertebral column, excluding sacrum and coccyx
1703 Malignant neoplasm of bone and articular cartilage, ribs, sternum, and clavicle
1704 Malignant neoplasm of bone and articular cartilage, scapula and long bones of upper limb
1705 Malignant neoplasm of bone and articular cartilage, short bones of upper limb
1706 Malignant neoplasm of bone and articular cartilage, pelvic bones, sacrum, and coccyx
1707 Malignant neoplasm of bone and articular cartilage, long bones of lower limb
1708 Malignant neoplasm of bone and articular cartilage, short bones of lower limb
1709 Malignant neoplasm of bone and articular cartilage, site unspecified
171 Malignant neoplasm of connective and other soft tissue
1710 Malignant neoplasm of connective and other soft tissue, head, face, and neck
1712 Malignant neoplasm of connective and other soft tissue, upper limb, including shoulder
1713 Malignant neoplasm of connective and other soft tissue, lower limb, including hip
1714 Malignant neoplasm of connective and other soft tissue, thorax
1715 Malignant neoplasm of connective and other soft tissue, abdomen
1716 Malignant neoplasm of connective and other soft tissue, pelvis
1717 Malignant neoplasm of connective and other soft tissue, trunk, unspecified
1718 Malignant neoplasm of connective and other soft tissue, other specified sites
1719 Malignant neoplasm of connective and other soft tissue, site unspecified
172 Malignant melanoma of skin
1720 Malignant melanoma of skin, lip
1721 Malignant melanoma of skin, eyelid including canthus
1722 Malignant melanoma of skin, ear and auditory canal
1723 Malignant melanoma of skin, other and unspecified parts of face
1724 Malignant melanoma of skin, scalp and neck
1725 Malignant melanoma of skin, trunk, except scrotum
1726 Malignant melanoma of skin, upper limb, including shoulder
1727 Malignant melanoma of skin, lower limb, including hip
1728 Malignant melanoma of skin, other specified sites of skin
1729 Malignant melanoma of skin, site unspecified
174 Malignant neoplasm of female breast
1740 Malignant neoplasm of female breast, nipple and areola
1741 Malignant neoplasm of female breast, central portion
1742 Malignant neoplasm of female breast, upper-inner quadrant
1743 Malignant neoplasm of female breast, lower-inner quadrant
1744 Malignant neoplasm of female breast, upper-outer quadrant
1745 Malignant neoplasm of female breast, lower-outer quadrant
1746 Malignant neoplasm of female breast, axillary tail
1748 Malignant neoplasm of female breast, other specified sites
1749 Malignant neoplasm of female breast, unspecified
175 Malignant neoplasm of male breast
1750 Malignant neoplasm of male breast, nipple and areola
1759 Malignant neoplasm of male breast, other and unspecified sites
176 Kaposi's sarcoma
1760 Kaposi's sarcoma, skin
1761 Kaposi's sarcoma, soft tissue
1762 Kaposi's sarcoma, palate
1763 Kaposi's sarcoma, gastrointestinal sites
1764 Kaposi's sarcoma, lung
1765 Kaposi's sarcoma, lymph nodes

1768 Kaposi's sarcoma, other specified sites
1769 Kaposi's sarcoma, unspecified
179 Malignant neoplasm of uterus, part unspecified
180 Malignant neoplasm of cervix uteri
1800 Malignant neoplasm of cervix uteri,endocervix
1801 Malignant neoplasm of cervix uteri, exocervix
1808 Malignant neoplasm of cervix uteri, other specified sites
1809 Malignant neoplasm of cervix uteri, unspecified
181 Malignant neoplasm of placenta
182 Malignant neoplasm of body of uterus
1820 Malignant neoplasm of body of uterus, corpus uteri, except isthmus
1821 Malignant neoplasm of body of uterus, isthmus
1828 Malignant neoplasm of body of uterus, other specified sites
183 Malignant neoplasm of ovary and other uterine adnexa
1830 Malignant neoplasm of ovary and other uterine adnexa, ovary
1832 Malignant neoplasm of ovary and other uterine adnexa, Fallopian tube
1833 Malignant neoplasm of ovary and other uterine adnexa, broad ligament
1834 Malignant neoplasm of ovary and other uterine adnexa, parametrium
1835 Malignant neoplasm of ovary and other uterine adnexa, round ligament
1838 Malignant neoplasm of ovary and other uterine adnexa, other specified sites
1839 Malignant neoplasm of ovary and other uterine adnexa, unspecified
184 Malignant neoplasm of other and unspecified female genital organs
1840 Malignant neoplasm of other and unspecified female genital organs, vagina
1841 Malignant neoplasm of other and unspecified female genital organs, labia majora
1842 Malignant neoplasm of other and unspecified female genital organs, labia minora
1843 Malignant neoplasm of other and unspecified female genital organs, clitoris
1844 Malignant neoplasm of other and unspecified female genital organs, vulva, unspecified
1848 Malignant neoplasm of other and unspecified female genital organs, other specified sites
1849 Malignant neoplasm of other and unspecified female genital organs, unspecified
185 Malignant neoplasm of prostate
186 Malignant neoplasm of testis
1860 Malignant neoplasm of testis, undescended testis
1869 Malignant neoplasm of testis, other and unspecified testis
187 Malignant neoplasm of poenis and other male genital organs
1871 Malignant neoplasm of poenis and other male genital organs, prepuce
1872 Malignant neoplasm of poenis and other male genital organs, glans penis
1873 Malignant neoplasm of poenis and other male genital organs, body of penis
1874 Malignant neoplasm of poenis and other male genital organs, penis, part unspecified
1875 Malignant neoplasm of poenis and other male genital organs, epididymis
1876 Malignant neoplasm of poenis and other male genital organs, spermatic cord
1877 Malignant neoplasm of poenis and other male genital organs, scrotum
1878 Malignant neoplasm of poenis and other male genital organs, other specified sites
1879 Malignant neoplasm of poenis and other male genital organs, unspecified
188 Malignant neoplasm of bladder
1880 Malignant neoplasm of bladder, trigone of urinary bladder
1881 Malignant neoplasm of bladder, dome of urinary bladder
1882 Malignant neoplasm of bladder, lateral wall of urinary bladder
1883 Malignant neoplasm of bladder, anterior wall of urinary bladder
1884 Malignant neoplasm of bladder, posterior wall of urinary bladder
1885 Malignant neoplasm of bladder, bladder neck
1886 Malignant neoplasm of bladder, ureteric orifice
1887 Malignant neoplasm of bladder, urachus
1888 Malignant neoplasm of bladder, other specified sites
1889 Malignant neoplasm of bladder, unspecified
189 Malignant neoplasm of kidney and other and unspecified urinary organs
1890 Malignant neoplasm of kidney and other and unspecified urinary organs, kidney, except pelvis

1891 Malignant neoplasm of kidney and other and unspecified urinary organs, renal pelvis
1892 Malignant neoplasm of kidney and other and unspecified urinary organs, ureter
1893 Malignant neoplasm of kidney and other and unspecified urinary organs, urethra
1894 Malignant neoplasm of kidney and other and unspecified urinary organs, paraurethral glands
1898 Malignant neoplasm of kidney and other and unspecified urinary organs, other specifeid sites
1899 Malignant neoplasm of kidney and other and unspecified urinary organs, unspecified
190 Malignant neoplasm of eye
1900 Malignant neoplasm of eye, eyeball, except conjunctive, corneam retina and shoroid
1901 Malignant neoplasm of eye, orbit
1902 Malignant neoplasm of eye, lacrimal gland
1903 Malignant neoplasm of eye, conjunctiva
1904 Malignant neoplasm of eye, cornea
1905 Malignant neoplasm of eye, retina
1906 Malignant neoplasm of eye, choroid
1907 Malignant neoplasm of eye, lacrimal duct
1908 Malignant neoplasm of eye, other specifeid sites
1909 Malignant neoplasm of eye, unspecified
191 Malignant neoplasm of brain
1910 Malignant neoplasm of brain, cerebrum, except lobes and ventricles
1911 Malignant neoplasm of brain, frontal lobe
1912 Malignant neoplasm of brain, temporal lobe
1913 Malignant neoplasm of brain, parietal lobe
1914 Malignant neoplasm of brain, occipital lobe
1915 Malignant neoplasm of brain, ventricles
1916 Malignant neoplasm of brain , cerebellum NOS
1917 Malignant neoplasm of brain, brain stem
1918 Malignant neoplasm of brain, other parts
1919 Malignant neoplasm of brain, unspecified
192 Malignant neoplasm of other and unspecified parts of nervous system
1920 Malignant neoplasm of other and unspecified parts of nervous system, cranial nerves
1921 Malignant neoplasm of other and unspecified parts of nervous system, cerebral meninges
1922 Malignant neoplasm of other and unspecified parts of nervous system, spinal cord
1923 Malignant neoplasm of other and unspecified parts of nervous system, spinal meninges
1928 Malignant neoplasm of other and unspecified parts of nervous system, other specified sites
1929 Malignant neoplasm of other and unspecified parts of nervous system, part unspecified
193 Malignant neoplasm of thyuroid gland
194 Malignant neoplasm of other endocrine glands and related structures
1940 Malignant neoplasm of other endocrine glands and related structures
1941 Malignant neoplasm of other endocrine glands and related structures, adrenal gland
1943 Malignant neoplasm of other endocrine glands and related structures, adrenal gland
1944 Malignant neoplasm of other endocrine glands and related structures, pineal gland
1945 Malignant neoplasm of other endocrine glands and related structures, carotid body
1946 Malignant neoplasm of other endocrine glands and related structures, aortic body and other paraganglia
1948 Malignant neoplasm of other endocrine glands and related structures, other
1949 Malignant neoplasm of other endocrine glands and related structures, unspecified
195 Malignant neoplasm of other and ill-defined sites
1950 Malignant neoplasm of other and ill-defined sites, head, face and neck
1951 Malignant neoplasm of other and ill-defined sites, thorax
1952 Malignant neoplasm of other and ill-defined sites, abdomen
1953 Malignant neoplasm of other and ill-defined sites, pelvis
1954 Malignant neoplasm of other and ill-defined sites, upper limb
1955 Malignant neoplasm of other and ill-defined sites, lower limb
1958 Malignant neoplasm of other and ill-defined sites, other specified sites
196 Secondary and unspecified malignant neoplasm of lymph nodes
1960 Secondary and unspecified malignant neoplasm of lymph nodes, head, face, and neck

1961 Secondary and unspecified malignant neoplasm of lymph nodes, intrathoracic
1962 Secondary and unspecified malignant neoplasm of lymph nodes, intra-abdominal
1963 Secondary and unspecified malignant neoplasm of lymph nodes, axilla and upper limb
1965 Secondary and unspecified malignant neoplasm of lymph nodes, inguinal region and lower limb
1966 Secondary and unspecified malignant neoplasm of lymph nodes, intrapelvic
1968 Secondary and unspecified malignant neoplasm of lymph nodes, multiple sites
1969 Secondary and unspecified malignant neoplasm of lymph nodes, site unspecified
197 Secondary malignant neoplasm of respiratory and digestive systems
1970 Secondary malignant neoplasm of respiratory and digestive systems, lung
1971 Secondary malignant neoplasm of respiratory and digestive systems, mediastinum
1972 Secondary malignant neoplasm of respiratory and digestive systems, pleura
1973 Secondary malignant neoplasm of respiratory and digestive systems, other respiratory organs
1974 Secondary malignant neoplasm of respiratory and digestive systems, small intestine, including duodenum
1975 Secondary malignant neoplasm of respiratory and digestive systems, large intestine and rectum
1976 Secondary malignant neoplasm of respiratory and digestive systems, retroperitoneum and peritoneum
1977 Secondary malignant neoplasm of respiratory and digestive systems, liver, specified as secondary
1978 Secondary malignant neoplasm of respiratory and digestive systems, other digestive organs and spleen
198 Secondary malignant neoplasm of other specified sites
1980 Secondary malignant neoplasm of other specified sites, kidney
1981 Secondary malignant neoplasm of other specified sites, other urinary organs
1982 Secondary malignant neoplasm of other specified sites, skin
1983 Secondary malignant neoplasm of other specified sites, brain and spinal cord
1984 Secondary malignant neoplasm of other specified sites, other parts of nervous system
1985 Secondary malignant neoplasm of other specified sites, bone and bone marrow
1986 Secondary malignant neoplasm of other specified sites, ovary
1987 Secondary malignant neoplasm of other specified sites, adrenal gland
1988 Secondary malignant neoplasm of other specified sites, other specified sites
19881 Secondary malignant neoplasm of other specified sites, other specified sites, breast
19882 Secondary malignant neoplasm of other specified sites, other specified sites, genital organs
19889 Secondary malignant neoplasm of other specified sites, other specified sites, other
199 Malignant neoplasm without specification of site
1990 Malignant neoplasm without specification of site, disseminated
1991 Malignant neoplasm without specification of site, disseminated
200 Lymphosarcoma and reticulosarcoma
2000 Lymphosarcoma and reticulosarcoma, reticulosarcoma
20000 Lymphosarcoma and reticulosarcoma, reticulosarcoma, unspecified site, extranodal and solid organ sites
20001 Lymphosarcoma and reticulosarcoma, reticulosarcoma, lymph nodes of head, face, and neck
20002 Lymphosarcoma and reticulosarcoma, reticulosarcoma, intrathoracic lymph nodes
20003 Lymphosarcoma and reticulosarcoma, reticulosarcoma, intra-abdominal lymph nodes
20004 Lymphosarcoma and reticulosarcoma, reticulosarcoma, lymph nodes of axilla and upper limb
20005 Lymphosarcoma and reticulosarcoma, reticulosarcoma, lymph nodes of inguinal region and lower limb
20006 Lymphosarcoma and reticulosarcoma, reticulosarcoma, intrapelvic lymph nodes
20007 Lymphosarcoma and reticulosarcoma, reticulosarcoma, spleen
20008 Lymphosarcoma and reticulosarcoma, reticulosarcoma, lymph nodes of multiple sites
2001 Lymphosarcoma and reticulosarcoma, Lymphosarcoma
20010 Lymphosarcoma and reticulosarcoma, Lymphosarcoma, unspecified site, extranodal and solid organ sites
20011 Lymphosarcoma and reticulosarcoma, Lymphosarcoma, lymph nodes of head, face, and neck
20012 Lymphosarcoma and reticulosarcoma, Lymphosarcoma, intrathoracic lymph nodes
20013 Lymphosarcoma and reticulosarcoma, Lymphosarcoma, intra-abdominal lymph nodes
20014 Lymphosarcoma and reticulosarcoma, Lymphosarcoma, lymph nodes of axilla and upper limb

20015 Lymphosarcoma and reticulosarcoma, Lymphosarcoma, lymph nodes of inguinal region and lower limb
20016 Lymphosarcoma and reticulosarcoma, Lymphosarcoma, intrapelvic lymph nodes
20017 Lymphosarcoma and reticulosarcoma, Lymphosarcoma, spleen
20018 Lymphosarcoma and reticulosarcoma, Lymphosarcoma, lymph nodes of multiple sites
2002 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma
20020 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma, unspecified site, extranodal and solid organ sites
20021 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma, lymph nodes of head, face, and neck
20022 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma, intrathoracic lymph nodes
20023 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma, intra-abdominal lymph nodes
20024 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma, lymph nodes of axilla and upper limb
20025 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma, lymph nodes of inguinal region and lower limb
20026 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma, intrapelvic lymph nodes
20027 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma, spleen
20028 Lymphosarcoma and reticulosarcoma, Burkitt's tumor or lymphoma, lymph nodes of multiple sites
2008 Lymphosarcoma and reticulosarcoma, other named variants
20080 Lymphosarcoma and reticulosarcoma, other named variants, unspecified site, extranodal and solid organ sites
20081 Lymphosarcoma and reticulosarcoma, other named variants, lymph nodes of head, face, and neck
20082 Lymphosarcoma and reticulosarcoma, other named variants, intrathoracic lymph nodes
20083 Lymphosarcoma and reticulosarcoma, other named variants, intra-abdominal lymph nodes
20084 Lymphosarcoma and reticulosarcoma, other named variants, lymph nodes of axilla and upper limb
20085 Lymphosarcoma and reticulosarcoma, other named variants, lymph nodes of inguinal region and lower limb
20086 Lymphosarcoma and reticulosarcoma, other named variants, intrapelvic lymph nodes
20087 Lymphosarcoma and reticulosarcoma, other named variants, spleen
20088 Lymphosarcoma and reticulosarcoma, other named variants, lymph nodes of multiple sites
201 Hodgkin's disease
2010 Hodgkin's disease, Hodgkin's paragranuloma
20100 Hodgkin's disease, Hodgkin's paragranuloma, unspecified site, extranodal and solid organ site
20101 Hodgkin's disease, Hodgkin's paragranuloma, lymph nodes of head, face, and neck
20102 Hodgkin's disease, Hodgkin's paragranuloma, intrathoracic lymph nodes
20103 Hodgkin's disease, Hodgkin's paragranuloma, intra-abdominal lymph nodes
20104 Hodgkin's disease, Hodgkin's paragranuloma, lymph nodes of axilla and upper limb
20105 Hodgkin's disease, Hodgkin's paragranuloma, lymph nodes of inguinal region and lower limb
20106 Hodgkin's disease, Hodgkin's paragranuloma, intrapelvic lymph nodes
20107 Hodgkin's disease, Hodgkin's paragranuloma, spleen
20108 Hodgkin's disease, Hodgkin's paragranuloma, lymph nodes of multiple sites
2011 Hodgkin's disease, Hodgkin's granuloma
20110 Hodgkin's disease, Hodgkin's granuloma, unspecified site, extranodal and solid organ site
20111 Hodgkin's disease, Hodgkin's granuloma, lymph nodes of head, face, and neck
20112 Hodgkin's disease, Hodgkin's granuloma, intrathoracic lymph nodes
20113 Hodgkin's disease, Hodgkin's granuloma, intra-abdominal lymph nodes
20114 Hodgkin's disease, Hodgkin's granuloma, lymph nodes of axilla and upper limb
20115 Hodgkin's disease, Hodgkin's granuloma, lymph nodes of inguinal region and lower limb
20116 Hodgkin's disease, Hodgkin's granuloma, intrapelvic lymph nodes
20117 Hodgkin's disease, Hodgkin's granuloma, spleen
20118 Hodgkin's disease, Hodgkin's granuloma, lymph nodes of multiple sites
2012 Hodgkin's disease, Hodgkin's sarcoma
20120 Hodgkin's disease, Hodgkin's sarcoma, unspecified site, extranodal and solid organ site
20121 Hodgkin's disease, Hodgkin's sarcoma, lymph nodes of head, face, and neck
20122 Hodgkin's disease, Hodgkin's sarcoma, intrathoracic lymph nodes

20123 Hodgkin's disease, Hodgkin's sarcoma, intra-abdominal lymph nodes
20124 Hodgkin's disease, Hodgkin's sarcoma, lymph nodes of axilla and upper limb
20125 Hodgkin's disease, Hodgkin's sarcoma, lymph nodes of inguinal region and lower limb
20126 Hodgkin's disease, Hodgkin's sarcoma, intrapelvic lymph nodes
20127 Hodgkin's disease, Hodgkin's sarcoma, spleen
20128 Hodgkin's disease, Hodgkin's sarcoma, lymph nodes of multiple sites
2014 Hodgkin's disease, Lymphocytic-histiocytic predominance
20140 Hodgkin's disease, Lymphocytic-histiocytic predominance, unspecified site, extranodal and solid organ site
20141 Hodgkin's disease, Lymphocytic-histiocytic predominance, lymph nodes of head, face, and neck
20142 Hodgkin's disease, Lymphocytic-histiocytic predominance, intrathoracic lymph nodes
20143 Hodgkin's disease, Lymphocytic-histiocytic predominance, intra-abdominal lymph nodes
20144 Hodgkin's disease, Lymphocytic-histiocytic predominance, lymph nodes of axilla and upper limb
20145 Hodgkin's disease, Lymphocytic-histiocytic predominance, lymph nodes of inguinal region and lower limb
20146 Hodgkin's disease, Lymphocytic-histiocytic predominance, intrapelvic lymph nodes
20147 Hodgkin's disease, Lymphocytic-histiocytic predominance, spleen
20148 Hodgkin's disease, Lymphocytic-histiocytic predominance, lymph nodes of multiple sites
2015 Hodgkin's disease, Nodular sclerosis
20150 Hodgkin's disease, Nodular sclerosis, unspecified site, extranodal and solid organ site
20151 Hodgkin's disease, Nodular sclerosis, lymph nodes of head, face, and neck
20152 Hodgkin's disease, Nodular sclerosis, intrathoracic lymph nodes
20153 Hodgkin's disease, Nodular sclerosis, intra-abdominal lymph nodes
20154 Hodgkin's disease, Nodular sclerosis, lymph nodes of axilla and upper limb
20155 Hodgkin's disease, Nodular sclerosis, lymph nodes of inguinal region and lower limb
20156 Hodgkin's disease, Nodular sclerosis, intrapelvic lymph nodes
20157 Hodgkin's disease, Nodular sclerosis, spleen
20158 Hodgkin's disease, Nodular sclerosis, lymph nodes of multiple sites
2016 Hodgkin's disease, Mixed cellularity
20160 Hodgkin's disease, Mixed cellularity, unspecified site, extranodal and solid organ site
20161 Hodgkin's disease, Mixed cellularity, lymph nodes of head, face, and neck
20162 Hodgkin's disease, Mixed cellularity, intrathoracic lymph nodes
20163 Hodgkin's disease, Mixed cellularity, intra-abdominal lymph nodes
20164 Hodgkin's disease, Mixed cellularity, lymph nodes of axilla and upper limb 20165 Hodgkin's disease, Mixed cellularity, lymph nodes of inguinal region and lower limb
20166 Hodgkin's disease, Mixed cellularity, intrapelvic lymph nodes
20167 Hodgkin's disease, Mixed cellularity, spleen
20168 Hodgkin's disease, Mixed cellularity, lymph nodes of multiple sites
2017 Hodgkin's disease, Lymphocytic depletion
20170 Hodgkin's disease, Lymphocytic depletion, unspecified site, extranodal and solid organ site
20171 Hodgkin's disease, Lymphocytic depletion, lymph nodes of head, face, and neck
20172 Hodgkin's disease, Lymphocytic depletion, intrathoracic lymph nodes
20173 Hodgkin's disease, Lymphocytic depletion, intra-abdominal lymph nodes
20174 Hodgkin's disease, Lymphocytic depletion, lymph nodes of axilla and upper limb
20175 Hodgkin's disease, Lymphocytic depletion, lymph nodes of inguinal region and lower limb
20176 Hodgkin's disease, Lymphocytic depletion, intrapelvic lymph nodes
20177 Hodgkin's disease, Lymphocytic depletion, spleen
20178 Hodgkin's disease, Lymphocytic depletion, lymph nodes of multiple sites
2019 Hodgkin's disease, unspecified
20190 Hodgkin's disease, unspecified, unspecified site, extranodal and solid organ sites
20191 Hodgkin's disease, unspecified, lymph nodes of head, face, and neck
20192 Hodgkin's disease, unspecified, intrathoracic lymph nodes
20193 Hodgkin's disease, unspecified, intra-abdominal lymph nodes
20194 Hodgkin's disease, unspecified, lymph nodes of axilla and upper limb
20195 Hodgkin's disease, unspecified, lymph nodes of inguinal region and lower limb
20196 Hodgkin's disease, unspecified, intrapelvic lymph nodes

20197 Hodgkin's disease, unspecified, spleen
20198 Hodgkin's disease, unspecified, lymph nodes of multiple sites
202 Other malignant neoplasms of lymphoid and histiocytic tissue
2020 Nodular lymphoma
20200 Nodular lymphoma, unspecified site, extranodal and solid organ sites
20201 Nodular lymphoma, lymph nodes of head, face, and neck
20202 Nodular lymphoma, intrathoracic lymph nodes
20203 Nodular lymphoma, intra-abdominal lymph nodes
20204 Nodular lymphoma, lymph nodes of axilla and upper limb
20205 Nodular lymphoma, lymph nodes of inguinal region and lower limb
20206 Nodular lymphoma, intrapelvic lymph nodes
20207 Nodular lymphoma, spleen
20208 Nodular lymphoma, lymph nodes of multiple sites
2021 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides
20210 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides, extranodal and solid organ site
20211 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides, lymph nodes of head, face, and neck
20212 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides, intrathoracic lymph nodes
20213 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides, intra-abdominal lymph nodes
20214 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides, lymph nodes of axilla and upper limb
20215 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides, lymph nodes of inguinal region and lower limb
20216 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides, intrapelvic lymph nodes
20217 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides, spleen
20218 Other malignant neoplasms of lymphoid and histiocytic tissue, Mycosis fungoides, lymph nodes of multiple sites
2022 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease
20220 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease, extranodal and solid organ site
20221 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease, lymph nodes of head, face, and neck
20222 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease, intrathoracic lymph nodes
20223 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease, intra-abdominal lymph nodes
20224 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease, lymph nodes of axilla and upper limb
20225 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease, lymph nodes of inguinal region and lower limb
20226 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease, intrapelvic lymph nodes
20227 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease, spleen
20228 Other malignant neoplasms of lymphoid and histiocytic tissue, Sezary's disease, lymph nodes of multiple sites
2023 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis
20230 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis, extranodal and solid organ site
20231 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis, lymph nodes of head, face, and neck
20232 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis, intrathoracic lymph nodes

20233 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis, intra-abdominal lymph nodes
20234 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis, lymph nodes of axilla and upper limb
20235 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis, lymph nodes of inguinal region and lower limb
20236 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis, intrapelvic lymph nodes
20237 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis, spleen
20238 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant histiocytosis, lymph nodes of multiple sites
2024 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis
20240 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis, extranodal and solid organ site
20241 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis, lymph nodes of head, face, and neck
20242 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis, intrathoracic lymph nodes
20243 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis, intra-abdominal lymph nodes histiocytosis
20244 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis, lymph nodes of axilla and upper limb
20245 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis, lymph nodes of inguinal region and lower limb
20246 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis, intrapelvic lymph nodes
20247 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis, spleen
20248 Other malignant neoplasms of lymphoid and histiocytic tissue, leukemic reticuloendotheliosis, lymph nodes of multiple sites
2025 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease
20250 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease, extranodal and solid organ site
20251 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease, lymph nodes of head, face, and neck
20252 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease, intrathoracic lymph nodes
20253 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease, intra-abdominal lymph nodes histiocytosis
20254 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease, lymph nodes of axilla and upper limb
20255 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease, lymph nodes of inguinal region and lower limb
20256 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease, intrapelvic lymph nodes
20257 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease, spleen
20258 Other malignant neoplasms of lymphoid and histiocytic tissue, Letterer-Siwe disease, lymph nodes of multiple sites
2026 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors
20260 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors, extranodal and solid organ site
20261 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors, lymph nodes of head, face, and neck
20262 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors, intrathoracic lymph nodes

20263 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors, intra-abdominal lymph nodes histiocytosis
20264 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors, lymph nodes of axilla and upper limb
20265 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors, lymph nodes of inguinal region and lower limb
20266 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors, intrapelvic lymph nodes
20267 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors, spleen
20268 Other malignant neoplasms of lymphoid and histiocytic tissue, malignant mast cell tumors, lymph nodes of multiple sites
2028 Other lymphomas
20280 Other lymphomas, unspecified site, extranodal and solid organ sites
20281 Other lymphomas, lymph nodes of head, face, and neck
20282 Other lymphomas, intrathoracic lymph nodes
20283 Other lymphomas, intra-abdominal lymph nodes
20284 Other lymphomas, lymph nodes of axilla and upper limb
20285 Other lymphomas, lymph nodes of inguinal region and lower limb
20286 Other lymphomas, intrapelvic lymph nodes
20287 Other lymphomas, spleen
20288 Other lymphomas, lymph nodes of multiple sites
2029 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified
20290 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified, extranodal and solid organ site
20291 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified, lymph nodes of head, face, and neck
20292 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified, intrathoracic lymph nodes
20293 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified, intra-abdominal lymph nodes histiocytosis
20294 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified, lymph nodes of axilla and upper limb
20295 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified, lymph nodes of inguinal region and lower limb
20296 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified, intrapelvic lymph nodes
20297 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified, spleen
20298 Other malignant neoplasms of lymphoid and histiocytic tissue, other and unspecified, lymph nodes of multiple sites
203 Multiple myeloma and immunoproliferative neoplasms
2030 Multiple myeloma
20300 Multiple myeloma without mention of remission
20301 Multiple myeloma in remission
2031 Plasma cell leukemia
20310 Plasma cell leukemia without mention of remission
20311 Plasma cell leukemia in remission
2038 Other immunoproliferative neoplasms
20380 Other immunoproliferative neoplasms without mention of remission
20381 Other immunoproliferative neoplasms in remission
204 Lymphoid leukemia
2040 Lymphoid leukemia, acute
20400 Lymphoid leukemia, acute without mention of remission
20401 Lymphoid leukemia, acute in remission
2041 Lymphoid leukemia, chronic
20410 Lymphoid leukemia, chronic without mention of remission
20411 Lymphoid leukemia, chronic in remission

2042 Lymphoid leukemia, subacute
20420 Lymphoid leukemia, subacute without mention of remission
20421 Lymphoid leukemia, subacute in remission
2048 Lymphoid leukemia, other
20480 Lymphoid leukemia, other without mention of remission
20481 Lymphoid leukemia, other in remission
2049 Lymphoid leukemia, unspecified
20490 Lymphoid leukemia, unspecified without mention of remission
20491 Lymphoid leukemia, unspecified in remission
205 Myeloid leukemia
2050 Myeloid leukemia, acute
20500 Myeloid leukemia, acute without mention of remission
20501 Myeloid leukemia, acute in remission
2051 Myeloid leukemia, chronic
20510 Myeloid leukemia, chronic without mention of remission
20511 Myeloid leukemia, chronic in remission
2052 Myeloid leukemia, subacute
20520 Myeloid leukemia, subacute without mention of remission
20521 Myeloid leukemia, subacute in remission
2053 Myeloid leukemia, myeloid sarcoma
20530 Myeloid leukemia, myeloid sarcoma without mention of remission
20531 Myeloid leukemia, myeloid sarcoma in remission
2058 Myeloid leukemia, other
20580 Myeloid leukemia, other without mention of remission
20581 Myeloid leukemia, other in remission
2059 Myeloid leukemia, unspecified
20590 Myeloid leukemia, unspecified without mention of remission
20591 Myeloid leukemia, unspecified in remission
206 Monocytic leukemia
2060 Monocytic leukemia, acute
20600 Monocytic leukemia, acute without mention of remission
20601 Monocytic leukemia, acute in remission
2061 Monocytic leukemia, chronic
20610 Monocytic leukemia, chronic without mention of remission
20611 Monocytic leukemia, chronic in remission
2062 Monocytic leukemia, subacute
20620 Monocytic leukemia, subacute without mention of remission
20621 Monocytic leukemia, subacute in remission
2068 Monocytic leukemia, other
20680 Monocytic leukemia, other without mention of remission
20681 Monocytic leukemia, other in remission
2069 Monocytic leukemia, unspecified
20690 Monocytic leukemia, unspecified without mention of remission
20691 Monocytic leukemia, unspecified in remission
207 Other specified leukemia
2070 Other specified leukemia, Acute erythremia and erythroleukemia
20700 Other specified leukemia, Acute erythremia and erythroleukemia without mention of remission
20701 Other specified leukemia, Acute erythremia and erythroleukemia in remission
2071 Other specified leukemia, Chronic erythremia
20710 Other specified leukemia, Chronic erythremia without mention of remission
20711 Other specified leukemia, Chronic erythremia in remission
2072 Other specified leukemia, Megakaryocytic leukemia
20720 Other specified leukemia, Megakaryocytic leukemia without mention of remission
20721 Other specified leukemia, Megakaryocytic leukemia in remission
2078 Other specified leukemia, Other
20780 Other specified leukemia, Other without mention of remission

20781 Other specified leukemia, Other in remission
208 Leukemia of unspecified cell type
2080 Leukemia of unspecified cell type, acute
20800 Leukemia of unspecified cell type, acute without mention of remission
20801 Leukemia of unspecified cell type, acute in remission
2081 Leukemia of unspecified cell type, chronic
20810 Leukemia of unspecified cell type, chronic without mention of remission
20811 Leukemia of unspecified cell type, chronic in remission
2082 Leukemia of unspecified cell type, subacute
20820 Leukemia of unspecified cell type, subacute without mention of remission
20821 Leukemia of unspecified cell type, subacute in remission
2088 Leukemia of unspecified cell type, other
20880 Leukemia of unspecified cell type, other without mention of remission
20881 Leukemia of unspecified cell type, other in remission
2089 Leukemia of unspecified cell type, unspecified
20890 Leukemia of unspecified cell type, unspecified without mention of remission
20891 Leukemia of unspecified cell type, unspecified in remission
225 Benign neoplasm of brain and other parts of nervous system
2250 Benign neoplasm of brain and other parts of nervous system, brain
2251 Benign neoplasm of brain and other parts of nervous system, cranial nerves
2252 Benign neoplasm of brain and other parts of nervous system, cerebral meninges
2253 Benign neoplasm of brain and other parts of nervous system, spinal cord
2254 Benign neoplasm of brain and other parts of nervous system, spinal meninges
2258 Benign neoplasm of brain and other parts of nervous system, other specified sites
2259 Benign neoplasm of brain and other parts of nervous system, unspecified
2273 Benign neoplasm of pituitary gland and craniopharyngal duct (pouch)
2274 Benign neoplasm of pineal gland
22802 Hemangioma if intracranial structures
2370 Neoplasm of uncertain behavior of pituitary gland and craniopharyngal duct
2371 Neoplasm of uncertain behavior of pineal gland
2373 Paraganglia
2375 Neoplasm of uncertain behavior of brain and spinal cord
2376 Neoplasm of uncertain behavior of meninges
2377 Neurofibromatosis
23770 Neoplasm of uncertain behavior of endocrine glands and nervous system, neurofibramatosis, unspecified
23771 Neoplasm of uncertain behavior of endocrine glands and nervous system, neurofibramatosis, type I Von Recklinghausen's disease
23772 Neoplasm of uncertain behavior of endocrine glands and nervous system, neurofibramatosis, type II acoustic neurofibramatosis
2379 Neoplasm of uncertain behavior of endocrine glands and nervous system, other and unspecified
2396 Neoplasms of unspecified nature, brain
2592 Other endocrine disorders, carcinoid syndrome

Appendix C:
Technical Appendix

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A Two-Level Model to Explain the Differences between the Regression Coefficients of Certain Patients' Characteristics on Patient Level and those on Facility level

The differences between regression coefficients of certain patient characteristics can be explained by a two-level model. The two levels refer to patient level and facility level. For example, we would like to use regression analysis methods to explain the relationship between factor A and the outcome measure B. Now suppose we have another possible confounding factor C. If the values of C do not vary from patient to patient, then C will not be called a confounder. Either including C or excluding C at both patient level and facility level will give the same result in terms of the relationship between factor A and outcome measure B.

But if there is a strong association between C and A, then C will become a confounder. C is also a confounder if there is association between C and B. If we exclude this factor C, we will not have the same interpretation of the relationship between factor A and B. The reason is that there are some effects on B that won't be explained by A alone.

Hypothetically speaking, we want to conduct weighted linear regression analysis at both the patient level and the facility level to understand the relationship between a certain disease (factor A) and medical costs (outcome measure B). Without adjusting for a confounding factor (confounder C), we found that having this disease will induce a 100 dollar increase in medical cost. After including confounder C in the model, we found that having this disease will induce only 70 dollar increase in medical cost. The 30 dollar difference is explained by confounder C since people with this confounder are more likely to have this type of disease.

If we don't include confounding factor C in the model, there will be bias. The extent of bias is associated with the strength of the correlation between confounder and covariate, the strength of the relationship between confounder and outcome measure and the facility level covariate variation. So to correctly model the relationship between the outcome measure and covariate factor, we should take confounding effects into consideration. If the confounder is a facility level variable, its effects on the estimated relationship between Factor B and Outcome A can be mitigated by estimating the regression model at the patient level (which makes use of variation among patients within a facility), and can be further mitigated by including facility intercepts in the model.