Report to Congress

A Design for a Bundled End Stage Renal Disease Prospective Payment System

Michael O. Leavitt
Secretary of Health and Human Services
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I. Executive Summary

Based on CY 2006 Medicare claims data there are currently about 4,700 facilities furnishing outpatient maintenance dialysis to an estimated 315,000 Medicare dialysis patients. In 2006, total Medicare expenditures for dialysis and dialysis related drugs totaled $8.1 billion [1].

Currently, payment for outpatient maintenance dialysis services furnished to patients with end-stage renal disease (ESRD) is made on a per treatment basis known as the composite payment rate. The composite rate is a partially bundled prospective rate covering services furnished by ESRD facilities. However, ESRD facilities bill separately for certain dialysis-related services such as ESRD-related drugs and laboratory services that are outside the composite rate and payment is made under fee-for-service rules.

In 2005, the composite payment rate system accounted for approximately $4.8 billion or 60 percent of the $7.9 billion in Medicare spending for outpatient dialysis services, while the remaining 40 percent represents payment for separately billable items. The average Medicare payment per dialysis treatment in 2005 was $237.02, of which $143.20 was for composite rate services and $93.82 was for separately billable services.

The Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) have endorsed expanding the current partially bundled payment system to include separately billable services under a fully bundled ESRD PPS. CMS issued a report to Congress in 2003, summarizing the state of research at that time, concerning the feasibility of developing a bundled ESRD PPS. The research contractor, the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC), in its 2002 report clearly outlined the magnitude of the task and provided information on many of the important issues that would need to be addressed before a bundled ESRD PPS could be developed. UM-KECC also indicated that existing data are adequate for proceeding with the development of an expanded or bundled ESRD PPS [2].

The MMA required that the Secretary issue a report to Congress detailing the design and implementation of a bundled ESRD PPS for services furnished by ESRD facilities that includes to the maximum extent feasible, both composite rate and separately billable services. This report discusses the research and development of a bundled ESRD PPS based on the following features: a base per treatment rate of $234.66 (in 2006 dollars) representing combined composite rate and separately billable services; a facility-level adjustment for the wage index; and patient-level adjustments for age, gender (female), body surface area, low body mass index, duration of renal replacement therapy, and 12 comorbidities.

II. Introduction

Since August 1, 1983, Medicare has paid for certain outpatient maintenance dialysis services for end-stage renal disease (ESRD) beneficiaries under a partial prospective payment system (PPS) known as the composite payment rate. Applied on a per treatment basis, recently incorporating a limited adjustment for case-mix, and adjusting for urban/rural differences in area wage levels, the composite rate is restricted to payments for certain routinely provided drugs, laboratory tests, and supplies for dialysis-related services. It covers outpatient dialysis furnished in hospital-based and independent ESRD facilities, and is also one of two methods (Method I) under which Medicare pays for dialysis at home [3]. The other method, Method II, is also for home dialysis treatment. However, under Method II, the beneficiary works directly with a supplier to furnish the supplies and equipment needed. Approximately 3,000 ESRD beneficiaries use Method II treatment.

Based on an analysis of CMS administrative data, UM-KECC determined that in 2005, the latest year for which relatively complete data are available, the average payment under the composite rate for hospital-based and independent facilities was $146.66 and $142.77, respectively [4]. In 2005, the composite rate payment system accounted for approximately $4.8 billion or 60 percent of the $7.9 billion in Medicare spending for outpatient dialysis services. The remaining 40 percent of total spending represented payments for separately billable Part B covered injectable drugs, laboratory tests, supplies, and blood products. Outpatient payments for separately billed epoetin alpha (EPO) alone amounted to $1.9 billion in 2005, representing 62 percent of the ESRD payments not covered under the composite payment system and about 25 percent of total ESRD payments [5]. The average Medicare payment per dialysis treatment in 2005 was $237.02, of which $143.20 covered composite rate services and $93.82 was for separately billable services [6].

Critics maintain that the Medicare dialysis payment system is outdated and in need of modernization. Representing a mix of prospective payment and fee-for-service rules, the system was initially developed using Medicare cost report data for fiscal years ending in 1977, 1978, and 1979 [7]. The payment rates have never been rebased or recalibrated to reflect more recent cost data [8], and inflation updates have been made pursuant to specific statutory direction.

Certain drugs such as EPO that were not available when the composite payment system was developed, and therefore not included in the composite rate, are now widely used to treat ESRD patients [9].The system has created incentives to use profitable separately billable drugs, notably EPO [10, 11]. Another criticism of the current system is the absence of a process for updating the system, recognizing not only price changes for dialysis services, but also changes in productivity, the emergence of new technology, and changes in practice patterns.

During the last few years, policymakers and other interested parties have assessed the current system of payment for ESRD services and suggested a more fully bundled

prospective payment approach. Under a fully bundled approach, routine dialysis services currently included in the composite rate would be combined with separately billable items and services and paid a single payment rate, adjusted to reflect differences in the types of patients treated or case-mix. Such a system would be "fully prospective" in that ESRD facilities, as in any prospective payment system, would keep the difference if Medicare payments exceeded costs for the bundled composite rate and separately billable services, and would be liable for the difference if costs exceed Medicare payments.

Aside from creating a single comprehensive payment for all services included in the bundle, an expanded bundled ESRD PPS would have several objectives. These include eliminating incentives to overutilize profitable separately billable drugs, the targeting of greater payments to ESRD facilities with more costly patients, and creating incentives for efficiency. Because of the increased flexibility a bundled ESRD PPS would provide in the delivery of dialysis services, some also argue that it could increase desirable clinical outcomes, resulting in an enhanced quality of care.

The Congress has twice required studies on bundling additional services into the composite rates. In section 422(c)(1) of the Benefits Improvements and Protection Act (BIPA), Public Law (P. L.) 106-554 (Appendix 1) , Congress required the Secretary to develop and issue a report on a system that includes, to the maximum extent feasible, payment for separately billable drugs and clinical laboratory services that are routinely used in furnishing dialysis services. Section 422(b) of BIPA also required the Secretary to collect data and develop an ESRD market basket. The Secretary sent this report to Congress in May 2003.

Section 623(f) of the Medicare Modernization Act (MMA), required the Secretary to report to Congress and make recommendations on the elements and features for the design and implementation of a bundled prospective payment system for services furnished by ESRD facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests and other items that are separately billed by ESRD facilities. The MMA gave the Secretary wide discretion in recommending a bundled ESRD payment system. Section 623(f)(1) (Appendix 2), specifically required the issuance of a report to Congress by October 1, 2005 which addresses the design of the bundled ESRD PPS. This Report fulfills that statutory requirement; it is late because research in support of a bundled ESRD PPS has only recently been completed.

Section 623(e) of MMA required the Secretary to test the feasibility of using a fully case-mix adjusted bundled payment system for ESRD facilities by conducting a demonstration project (Appendix 3). While development of that demonstration is currently underway, the information in this report could be used to create a bundled payment methodology.

In addition, the MedPAC [12] and the GAO [13] have also endorsed expanding the bundle of services included in the composite rate.

III. Research to Develop a Bundled Prospective Payment System for ESRD Services

Although both the BIPA and the MMA directed the Secretary to develop a bundled ESRD PPS, the CMS began research toward that objective prior to the enactment of BIPA. In September 2000, the CMS awarded a multi-phased research contract to the UM-KECC. The first phase of that research was designed to test the feasibility of developing a bundled ESRD PPS based on currently available administrative data. The CMS requested UM-KECC to do the following:

- identify and evaluate accessible renal-related databases to determine their usefulness for the development of an expanded outpatient ESRD PPS;
- perform a case-mix literature review to determine whether prior research supported the development of a case-mix adjuster for use in a bundled ESRD PPS; and
- develop patient and facility-level analytical files for hypothesis testing, data validation, and concept modeling.

UM-KECC reported its findings to CMS in an August 2002 report, An Expanded Medicare Outpatient End Stage Renal Disease Prospective Payment System, Phase I Report [14]. That report outlined the magnitude of the task, and provided much information on many of the issues that would need to be addressed before a bundled PPS could be developed. The Phase I Report from UM-KECC, which formed the basis for the Secretary's May 2003 report to Congress, Toward a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System [15], contained three major conclusions:

1. Existing data are adequate for proceeding with the development of an expanded or bundled outpatient ESRD PPS.

2. Based on available clinical information for ESRD patients, it is feasible to further examine and possibly develop methods of case-mix adjustment in order to target greater payments to facilities treating more costly resource-intensive patients.

3. Current quality review initiatives provide a foundation for monitoring to assure quality of care for ESRD patients after implementation of a bundled ESRD PPS.

Section 623 of the MMA that was enacted in December 2003 affected the composite payment system [16]. That section of the law required revision of payments for ESRD services, effective January 1, 2005, and provided:

- an increase of 1.6 percent to the composite payment rates;
- an add-on to composite rate payments to account for the difference in payments for separately billable drugs based on a revised drug pricing methodology compared to the prior drug pricing methodology;
- a basic case-mix adjustment to a facility's otherwise applicable composite payment rate reflecting a limited number of patient characteristics;
- that total payments under the basic case-mix adjusted composite payment system be budget neutral;
- an annual update based on the projected growth in expenditures for separately billed drugs, with such update applied to the composite rate;
- authority to implement a revised wage index to adjust the composite payments for area differences in wage levels; and
- reinstatement of the ESRD exceptions process for pediatric facilities (effective October 1, 2002) [17].

The basic case-mix adjustments to the composite payment rates implemented as a result of section 1881(b)(12) of the Social Security Act, as added by Section 623(d)(1) of the MMA (Appendix 4), are important in providing a foundation for the development of the bundled ESRD PPS.

IV. The Basic Case-Mix Adjustment System

Each ESRD facility's composite rate represents a fixed payment for a bundle of services that comprise routine maintenance dialysis treatment. Services outside of this bundle, mainly injectable medications and non-routine laboratory tests, are billed separately and paid for on a fee-for-service basis. The composite rate was developed from Medicare cost report data that do not distinguish differences in resource use among patients because cost reports represent facility costs. Since it was based on Medicare cost report data, the composite rate system did not include an adjustment for case-mix from its inception on August 1, 1983 until April 1, 2005.

Patients vary in the resources required to furnish routine dialysis such as staff and equipment time. For example, all other things being equal, larger patients cost more to deliver the same dose of dialysis than do smaller patients. Also, severely debilitated or aged patients may require more staff time than do younger healthier patients. Because of the variation in resources required to furnish routine dialysis, facilities that treat a greater than average proportion of resource-intensive patients could be economically disadvantaged if they are paid a rate based on average resources. Patients costlier than average to dialyze could have faced difficulties gaining access to care because a fixed composite payment rate provided a disincentive to treat such patients. The purpose of a case-mix adjustment based on patient characteristics is to make higher payments to ESRD facilities treating more costly patients, according to objective quantifiable criteria.

Such an adjustment would reduce the disincentives to treat or provide the optimal dose of dialysis to such patients.

The costs of providing the routine dialysis services that are paid under the composite rate are reported on the Medicare cost reports for hospital-based and independent ESRD facilities (Forms CMS 2552-96 and CMS 265-94, respectively). Patient-level data on the costs of furnishing composite rate services are not collected because these costs are included as part of the composite rate and not separately billed. However, earlier UM-KECC research revealed considerable variability in costs and patient characteristics across dialysis facilities, and that several patient characteristics predicted facility costs [18].

In order to determine a basic case-mix adjustment that could be applied to each ESRD facility's composite rate, UM-KECC further examined the relationship between facility-level costs for composite rate services based on the Medicare cost reports for hospital-based and independent facilities, and the average characteristics of patients treated by the facility. The research used data from Medicare cost reports for 3,254 independent and hospital-based ESRD facilities for 2000 to 2002, patient characteristics/comorbidity data from CMS's Medical Evidence Form 2728 for 1995 through 2002, and Medicare claims for approximately 360,000 ESRD patients [19]. Based on standard techniques of multiple regression analysis and using seven facility control variables [20], UM-KECC found that age and body size had a significant relationship to composite rate costs. The body size variables were body surface area (BSA) [21] and body mass index (BMI) [22], calculated from a patient's height and weight.

A BMI less than 18.5 kg/m^2 is considered a clinical measure of being underweight and is an indicator of patients who are malnourished or suffering from comorbidities such as wasting syndrome. BSA is closely associated with the duration and intensity of dialysis required to achieve targets for dialysis adequacy. Facilities with a larger proportion of patients with a greater than average BSA, or with a BMI lower than 18.5, were found to have greater composite rate costs. The research also revealed a U-shaped relationship between age and composite rate costs, with the youngest and oldest age groups incurring greater costs for composite rate services [23].

Although several comorbidities were found to have a statistically significant relationship to composite rate costs, CMS did not adopt them to develop the basic case-mix adjustments mandated by the MMA [24]. For some comorbidities, the relationship to the composite rate costs was not stable over time and, therefore, could not be a good indicator of greater composite rate costs. Other comorbidities, such as AIDS/HIV, raised privacy concerns over their disclosure. Furthermore, establishment of the diagnostic criteria used in connection with specific comorbidities required further study.

A few findings were surprising. For example, several patient characteristics, notably diabetes (type 1 or 2) that generally are important in the etiology of ESRD, did not show statistically significant relationships to composite rate costs [25]. While the result that facilities with the greatest number of the oldest patients incurred greater costs for

composite rate services was expected, the finding that so did those facilities with a higher proportion of patients in the youngest age group (a group that excludes pediatric patients or those less than age 18), was not [26]. These relationships were further explored in a published report based on this research [23].

The outcome of UM-KECC's research [27] was a set of basic case-mix adjusters or multipliers for ESRD patients based on three variables. These variables were (1) the patient's age (five groups), (2) BSA (a patient-specific value based on incremental differences from the national patient average), and (3) BMI category (two groups; value either less than, or equal to/greater than 18.5 kg/m^2). CMS also developed a special adjuster for pediatric patients outside of UM-KECC's research methodology based on analysis of a sample of Medicare cost reports. The adjuster for each of these three variables is multiplied by the facility's composite rate to yield the "basic" case-mix adjustment for each ESRD patient according to the specified patient characteristics [28].

These adjusters were as follows:

Age Group	Composite Rate Multiplier
Pediatrics (age < 18)	1.62 *
18-44	1.223
45-59	1.055
60-69 (reference group)	1.000
70-79	1.094
80+	1.174
Body Surface Area (BSA)	
(per 0.1 m^2 change in BSA from national average of 1.84)	1.037
Low Body Mass Index	
(< 18.5kg/m^2)	1.112

* Developed by CMS. The age, BSA, and BMI multipliers do not apply under the basic case-mix adjustment for patients under age 18.

The above multipliers were derived from the coefficients from the regression model used to predict ESRD facility differences in composite rate costs. For example, the case-mix adjuster for a 47 year old person who is underweight (BMI < 18.5 kg/m^2) and has a BSA of 2.0 m^2 would be calculated as follows:

Age Factor = 1.055
BSA Factor = $1.037^{(2.0-1.84)/0.1} = 1.037^{(1.6)} = 1.060$
Low BMI Factor = 1.112
Case-Mix Adjuster = 1.055 x 1.060 x 1.112 = 1.244

The resulting case-mix adjustment factor of 1.244 for this patient would be applied to the ESRD facility's otherwise applicable composite rate [29]. A complete discussion of the regression methodology used to develop the basic case-mix adjustments is contained in the UM-KECC report to CMS [27] and the Federal Register notice implementing the adjustments beginning April 1, 2005 [28]. The approach used was similar to the methodology described on pp. 22-23 of this Report with respect to the analysis of the composite rate portion of the expanded bundle. Essentially, the regression coefficients are used to estimate the difference between a facility having 100% of patients in a risk group, and a facility having 0% of patients in a risk group. The basic case-mix regression model had an R^2 of 35.95%. A model that included control variables had an R^2 of 34.88%. Therefore, the patient characteristics contributed an additional 1.07% to the overall R^2.

This basic case-mix adjustment system was proposed and finalized in the Calendar Year (CY 2005) Physician Fee Schedule and the adjustments began on April 1, 2005. It is important to note that the basic case-mix adjustment as described only affects the composite rate. It does not reflect costs associated with separately billable services, including many drugs, laboratory tests, or services delivered by other types of providers such as inpatient hospitals and physicians. In particular, patient characteristics that affect separately billable services are not necessarily related to the cost of composite rate services used in the basic case-mix adjustment. Because of the importance of separately billable services as a measure of the dialysis resources used for each patient in the context of developing a bundled ESRD PPS (hereafter referred to as the ESRD PPS), we turn to that task in the following sections.

V. Elements of a Bundled Prospective Payment System

As with any prospective payment system, there are a number of key design features.
(1)—A prospective payment system needs to have a scope of services that are included in the bundled rate and it needs to have a unit of payment. In this report, we discuss various bundles and consider two potential units, an expansion of the current per treatment unit used (i.e., the composite rate) and a per month unit. Each unit has advantages and disadvantages.
(2)--Payment units in prospective payment systems have case-mix adjustments in order to reflect the variation of resources for different kinds of patients.
(3)--Prospective payment systems often entail some type of geographic adjustment to reflect relative differences in resource costs among geographic areas.
(4)—Prospective payment systems often have special adjustments such as for outlier cases, or special characteristics of facilities, e.g., rural location or size of facility.
(5)—Prospective payment systems often have design and implementation issues unique to the particular type of service. In the case of ESRD services, the special issues include: separation of rates or a consolidated single rate for hospital-based and independent

facilities; coverage of oral Part D versions of Part B intravenous drugs; billings for clinical laboratory services furnished by independent laboratories; payment for peritoneal dialysis; payment for Method I and Method II home dialysis patients; continuation of exceptions for pediatric facilities; payment for patient training; beneficiary coinsurance of a bundled rate; etc.

(6)—A prospective payment system involves numerous operational, administrative, and systems issues. The larger the systems changes required the more time would be needed to implement a policy. More significant systems changes would take more than 5 months. The time frames for when these systems changes can begin is after rulemaking occurs, and that can happen only after the final policy development needed for rulemaking is completed. In addition, successful implementation of a new prospective payment system requires extensive provider education.

(7)—Prospective payment systems involve setting the initial payment rates and a process for considering future changes and updates to these initial payment rates. Initial payment rates under prospective payment systems are often based on expenditures that occurred under the prior system or the expenditures that would be projected to occur in the absence of the prospective system. In the case of ESRD, questions have been raised about the excess use of EPO in recent periods and CMS has taken action by implementing its EPO monitoring policy in April 2006. Use of such expenditures in setting initial rates under a prospective system would carry forward EPO spending from the prior years. However, spending from previous years should be adjusted downward to account for the excessive use of EPO in recent periods when setting the PPS rates, either initially or as soon data are available to make such an adjustment. If data analysis supports such an adjustment to the extent behavorial changes occur in the industry in response to the EPO monitoring policy, we expect to be able to capture the effect in our analysis of the most current data. Prospective payment systems usually entail processes for consideration of updates so we discuss an ESRD market basket.

(8)—Prospective payment systems encourage providers to more efficiently furnish services. The larger the bundle, the more opportunities exist for a provider to achieve efficiency. However, a bundled prospective payment raises concerns that some providers may furnish fewer services that might be medically needed. An important feature of the bundled ESRD PPS is ensuring the quality of services furnished to beneficiaries, particularly that they receive all medically necessary services.

VI. The ESRD Services Bundle and Unit of Payment

A. Defining the Payment Bundle

As noted previously, CMS currently utilizes a partial PPS known as the composite payment rate to pay the costs of outpatient maintenance dialysis services for ESRD beneficiaries. We refer to this collection as the "ESRD bundle." In general, bundled payments for the composite rate are made to approved Medicare ESRD facilities on behalf of beneficiaries receiving dialysis in facilities or beneficiaries that have chosen Method I home dialysis [30]. The composite rate bundle includes maintenance dialysis treatments, all necessary dialysis services including routinely provided drugs, tests, equipment, supplies, and staff time. The observation and monitoring of the condition of a

patient's vascular access are included as part of the composite rate service bundle. However, outpatient procedures necessary to maintain a patient's vascular access are not. These services are separately billable. Dialysis facility providers also furnish ESRD-related injectable drugs and arrange for non-routine laboratory testing. The facilities separately bill for these items under the applicable Part B fee-for-service payment schedules. In 2005, the ESRD composite rate represented approximately 60 percent of total Medicare payments per dialysis treatment with separately billable drugs and biologicals, and laboratory tests representing the remaining 40 percent [31].

Outpatient ESRD-related healthcare services are furnished to ESRD beneficiaries by various types of outpatient providers. Bundled outpatient dialysis services of the composite rate, in combination with the separately billable injectable drugs and non-routine laboratory tests managed by dialysis facilities, capture a significant portion of the outpatient ESRD-related care. However, the full range of care furnished to ESRD patients extends beyond the purview of outpatient dialysis facilities and includes items and services furnished by physicians, vascular access clinics, and other outpatient facilities. At the present time, services furnished by these provider types are outside the scope of the ESRD composite rate bundle, and thus, not necessarily coordinated with dialysis facility providers. In addition, these services are paid under separate Medicare Part B payment methodologies.

Laboratories are paid by the dialysis facility for laboratory tests that are included in the ESRD composite rate bundle. However, laboratories bill Medicare Part B separately on a fee-for-service basis for laboratory tests that are not bundled into the composite rates paid to ESRD facilities. Such laboratory tests may include those which are determined by the physician to be needed at a greater frequency than what is built into the composite rate.

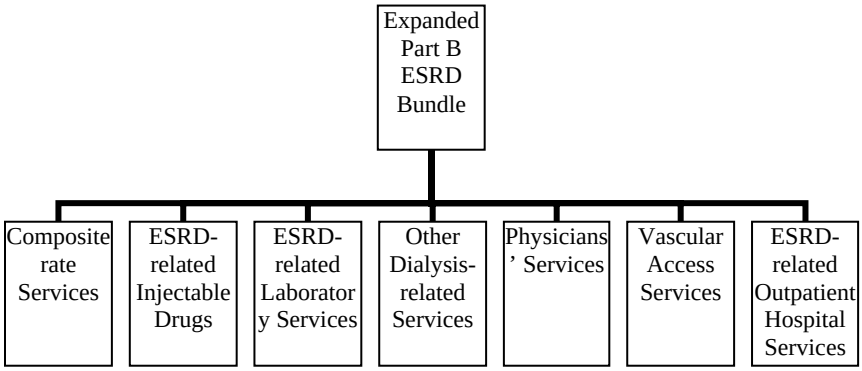
Physicians also furnish services to ESRD patients related to dialysis. Medicare pays for dialysis-related physicians' services under Medicare Part B on a capitated basis, referred to as the monthly capitation payment (MCP). The MCP is paid to a designated physician who is responsible for supervising a patient's ESRD care. MCP physicians manage patients with chronic renal failure by conducting assessments and care planning, monitoring laboratory results and the adequacy of dialysis treatment, and managing anemia and other conditions secondary to chronic renal failure. The MCP does not cover physicians' services unrelated to dialysis such as surgical services (repair of existing accesses) or interpretation of tests that have a professional component (e.g. electrocardiograms). Such services are separately billed by the physician who furnishes such services. Outpatient vascular access clinics are paid under Medicare Part B and provide access placement as well as vascular access maintenance.

CMS-sponsored research evaluated the extent to which services not currently under the purview of dialysis facilities, such as physician assessment and management, vascular access maintenance, and ESRD-related inpatient and outpatient hospitalizations, might be pooled together and paid under one comprehensive bundled PPS. Figures 1 and 2 provide two alternatives for an expanded ESRD bundle with Figure 1 representing a broader range of possible services, and Figure 2 a more targeted range of services. In an

effort to maintain consistency with the current outpatient ESRD fee-for-service based payment system, we have limited both alternatives to the inclusion of Medicare Part B services, excluding Medicare Part A ESRD-related inpatient hospitalizations.

The broader of the two alternative bundles could include: (a) composite rate services; (b) ESRD-related separately billable injectable drugs; (c) laboratory tests used in furnishing dialysis services that are currently not included in the composite rate; (d) other dialysis-related services (e.g. syringes used in the administration of ESRD-related injectable drugs); (e) MCP services; (f) outpatient vascular access maintenance; and (g) ESRD-related outpatient hospital services.

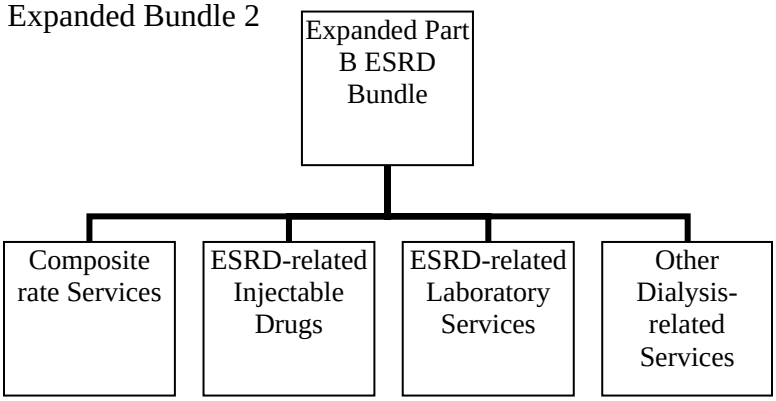
Figure 1. Expanded Bundle 1



This first approach could provide greater opportunity for efficiency and coordination of care by the ESRD facility. However, the analysis has not been conducted regarding the feasibility of including MCP services, outpatient vascular access services, or ESRD-related outpatient hospital services in an ESRD bundled payment. Since some of these services are not furnished by the ESRD facility, their inclusion in a bundled payment may present a different set of issues than the inclusion of separately billed drugs and laboratory tests. Thus, while this report discusses an expanded bundle, these services are not included as part of the bundled ESRD PPS analysis. Expanding the bundle to include these services could be considered based on further research and analysis.

An alternative version of the expanded ESRD bundle would include: (a) composite rate services; (b) ESRD-related separately billable injectable drugs; (c) laboratory tests used in furnishing dialysis services that are currently not included in the composite rate; and (d) other dialysis-related services such as supplies and blood products. Certain oral medications that substitute for injectable drugs commonly used in ESRD patients (e.g., iron and vitamin D preparations) could also be included in the bundle. Please refer to section X. B. "Potential for Duplicate Payment Under Medicare Part B and Part D" for further discussion of these drugs.

Figure 2. Expanded Bundle 2



A bundle that includes payments for services furnished by dialysis facilities would cover 96 percent of composite rate and separately billable services, with payments to independent laboratories, representative of the separately billable laboratory tests, accounting for the remaining 4 percent of the total [32].

Similar to the current ESRD composite rate bundle, payments for the expanded bundle could be made to the dialysis facility. The dialysis facility could pay independent laboratory suppliers for providing ESRD-related laboratory testing ordered by the MCP physicians. Since this approach focuses on services furnished by dialysis facilities, it would reduce administrative costs by eliminating the need for separate fee-for-service drug and laboratory claims submission, and is feasible based on UM-KECC analysis of dialysis-related Medicare claims data.

B. Unit of Payment

About 92 percent of outpatient ESRD beneficiaries requiring dialysis undergo hemodialysis (HD), furnished either in facility or at home. The most typical schedule is three sessions per week, each session averaging three to four hours. The remaining 8 percent use peritoneal dialysis (PD). PD is usually done at home, with or without machine assistance. Unlike HD, which involves the circulation of the patient's blood and filtration of toxins using an artificial kidney machine, PD removes blood toxins through the draining of the dialysate from the lining of the abdomen or peritoneum several times daily. A form of PD, nocturnal PD, can also be done with machine assistance while the patient sleeps.

ESRD facilities receive composite rate payments for PD patients equal to three times the otherwise applicable composite rate per treatment, for each week a patient is on PD. For example, a facility's payment for a patient on PD for 21 days would be equal to 21/7 x 3 or 9 times the composite rate. This payment method for PD patients has existed since the beginning of the composite payment system in 1983.

The Secretary's May 2003 report [33] pointed out that some critics have argued that the composite rate's three times weekly payment structure regardless of dialysis modality has

discouraged innovative treatment methods that could often lead to better clinical outcomes for patients and an enhanced quality of life. In recent years, ESRD facilities have relied heavily on separately billable drugs as a source of revenue growth. Some believe that this reliance on separately billable services has impeded the greater use of less costly PD and alternative treatment regimens such as nocturnal dialysis, home HD using compact portable dialysis machines, and shorter but more frequent dialysis sessions (1.5 to 2 hours).

An ESRD PPS combining composite rate and separately billable services furnished during a specified interval of time would provide the financing flexibility to use whatever forms of dialysis were in the patient's best interests. Because of Medicare's usual monthly billing cycle, an ESRD PPS based on monthly payments is a frequently mentioned approach. A unit of payment for an entire month is technically feasible. However, certain issues would need to be addressed such as hospitalization, the day of the month dialysis started, interruption of dialysis, and movement to other facilities. The alternative to a monthly unit of payment is the current system, which is per treatment.

In the next section, there is a description of the databases used in the case-mix analyses. Then the section describes the case-mix adjustments that could be used for a per treatment bundled prospective payment rate for ESRD services. After that, there is a discussion of the case-mix adjustments that could be used for a per month model. In both cases, the case-mix system is based on research from the CMS-sponsored contractor, UM-KECC.

This report highlights relevant results from UM-KECC's extensive analyses in support of the development of the case-mix adjustments for these two units of payment for the bundled ESRD PPS. The UM-KECC's complete report will be made available on the internet upon its completion.

VII. Data and Techniques Used in Analyzing Case-Mix Adjustments for Per Treatment and Per Month Units of Payment

In section IV, we pointed out the relative stability of composite rate and separately billable payments among several categories of outpatient ESRD services as reported on Medicare claims. Figures 3 and 4 reveal that for 2001 and 2005, a bundle that includes payments for services furnished by dialysis facilities would cover at least 96 percent of composite rate and separately billable services. Payments in 2005 to other providers, mainly independent laboratories for laboratory tests provided to ESRD patients, accounted for the remaining 4 percent of the total.

Figure 3: Total Medicare Allowable Payments, by Service Provider Type, 2001

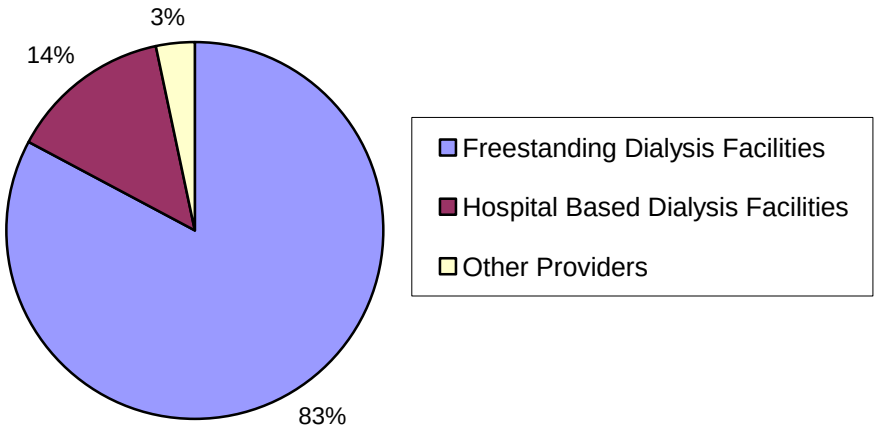
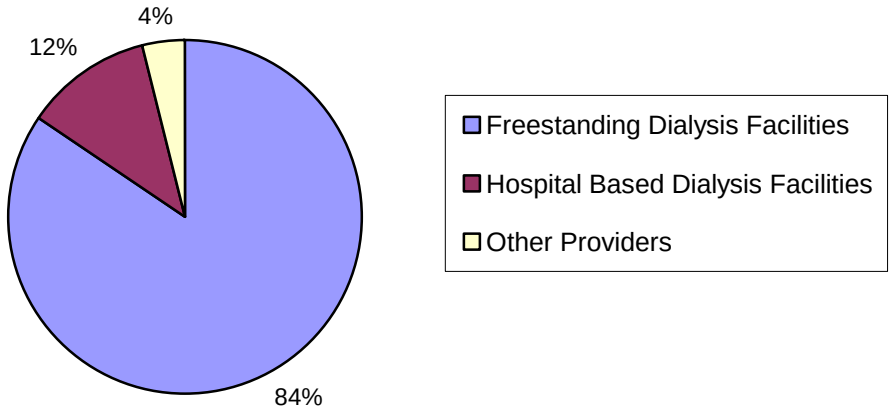


Figure 4: Total Medicare Allowable Payments, by Service Provider Type, 2005



As shown in figures 5 and 6, composite rate services and separately billable services represent 60 percent and 40 percent, of total payments.

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

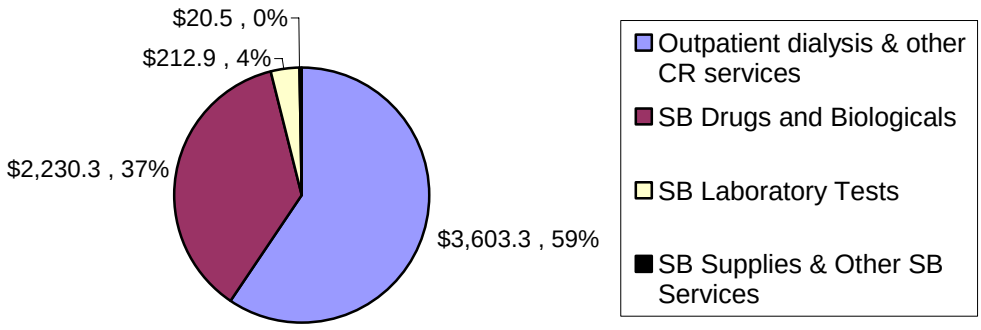
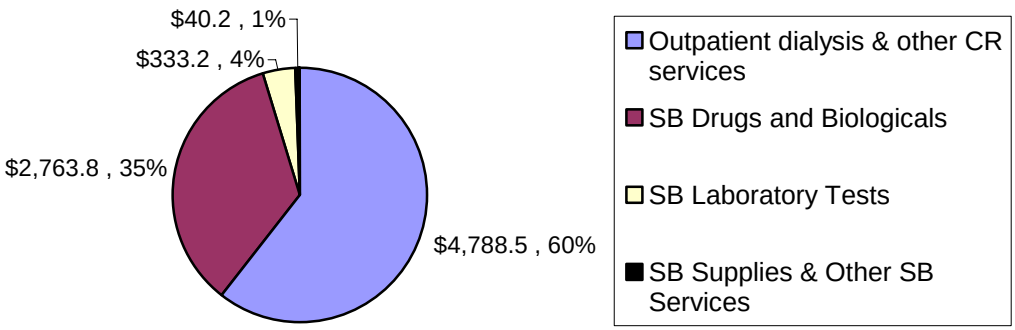


Figure 6: Total Medicare Allowable Payments (in Millions), by Type of Service, 2005



For purposes of establishing the services which comprise the bundled ESRD PPS options which are the subject of this Report, CMS has specifically defined the bundle based on the availability of cost and payment information as follows:

- Composite rate services as measured using composite rate costs as computed from the Medicare cost reports.

- Injectable drugs that are separately billed by dialysis facilities on Medicare outpatient institutional claims.
- Laboratory tests that are separately billed by dialysis facilities.
- Laboratory tests ordered by a physician who received monthly capitation payments for treating ESRD patients that are separately billed by independent laboratories on claims submitted to Medicare carriers.
- Other services separately billed by dialysis facilities that are used in conjunction with injectable medications or laboratory tests, such as blood products, syringes, and other dialysis supplies.

While cost information for composite rate services is available from the Medicare cost reports, the cost report does not contain information on the costs of the separately billable categories of services as noted above. Accordingly, the analyses reflected in this Report for separately billable services rely on separately billable payment information from Medicare claims.

A. Data Sources

The descriptive statistics, case-mix models, and other analyses presented in this Report are based primarily on CMS claims files for Medicare ESRD patients, and the Medicare cost reports for ESRD facilities. Resource utilization for separately billable services was based on patient-level Medicare outpatient claims for the years 2001 through 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 ESRD facility. The case-mix model for the bundled ESRD PPS relied on Medicare claims and cost reports for 2002 through 2004, because those years had the most complete data available.

Several data sources were used for measuring the patient and facility characteristics that were also used with 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 CMS Medical Evidence Form (CMS Form 2728), which is completed at the onset of renal replacement therapy; patient body size measures were developed from the height and weight values reported on the Form 2728; and patient comorbidities were measured using the Form 2728, supplemented with diagnoses reported on Medicare hospital inpatient, skilled nursing facility, hospital outpatient, hospice, home health agency, and physician claims. The claims diagnoses were used to identify comorbidities that were not abstracted using the Form 2728, and to capture changes in patient condition subsequent to the onset 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), the Online State Certification and Reporting System or OSCAR (hospital affiliation for satellite units), and other information obtained from CMS (identifying facilities with composite rate payment exceptions).

1. Patient Claims Data

The outpatient facility paid claims file is the primary source of information for payments facilities receive for the treatment of ESRD patients. The "type 72X" bills provided the detailed data for dialysis payments. The claims files used for the analyses in this Report are based on patients with at least one claims record for dialysis. Carrier claims and durable medical equipment claims were used to track dialysis-related payments made to other providers such as independent laboratories.

As the case-mix analyses were generated, the most complete annual data available were for CY 2004. As CY 2005 claims became available, they were included in trend analyses. The claims data counts were as follows:

Medicare Dialysis Patients, Sessions, Facilities and Claims by Calendar Year 2001 through 2005

	2001	2002	2003	2004	2005
Medicare Dialysis Patients	270,026	284,654	298,048	307,805	317,511
HD 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

2. Medicare Cost Reports

Facility-level cost and treatment data were obtained from the CMS Medicare Independent Renal Dialysis Facility Cost Report (Form CMS 265-94) and the Medicare Hospital Cost Report (Form CMS 2552-96). The number of available cost reports that contained necessary cost and treatment data for purposes of the composite rate cost analyses were as follows:

Available Cost Reports, by Facility Type, by Calendar Year 2002 through 2004

Facility Type	2002	2003	2004
Independent	3379	3663	3739
Hospital-based	430	408	387
Total	3809	4071	4126

For most facilities, a single cost report encompassed the entire calendar year. For fiscal year cost reports that spanned two calendar years, a weighted average was used based on the proportion falling within each calendar year.

3. Patient Claim and Cost Report Summary Data 2002-2004

Case-mix analyses were based on data sets that linked claims and cost report data for each year from 2002 through 2004. Claims data for patients treated in hospital satellite facilities were linked to the parent hospital using OSCAR, since cost reports are only submitted by the parent facility. The following table shows the resulting analysis files that included both claims and cost report data for measuring separately billable and composite rate resource utilization.

Medicare Dialysis Patients, Sessions, and Claims for Facilities with Cost Reports, by Calendar Year 2002 – 2004

	2002	2003	2004
Medicare Dialysis Patients	267,790	287,906	296,058
HD 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

4. Data for the Case-Mix Analyses, 2002-2004

The case-mix analyses required data for several patient and facility characteristics. After the exclusion of statistical outliers or otherwise unusable records, the table below summarizes the number of records that were used in the primary analyses for both composite rate and separately billable services:

Medicare Dialysis Patients, Sessions, and Facilities Used in the Final Analyses, by Calendar Year 2002 – 2004

	2002	2003	2004	Pooled, 2002-04
Medicare Dialysis Patients	253,149	274,010	282,049	809,208
HD 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 the pooled data from 2002 through 2004, which included a total of 809,208 Medicare ESRD patient years and 11,174 facility years. Based on the patient counts in the above tables, the case-mix analyses included 90.9 percent of patients with Medicare outpatient dialysis claims during 2002-2004. Over the three year period, the case-mix analyses included data for 416,001 Medicare ESRD patients treated in 4,112 dialysis facilities.

B. Analytical Approach

UM-KECC developed case-mix models using standard techniques of multivariate regression. In multivariate or multiple regression, a set of independent or predictor variables are tested to determine the extent to which they can predict or "explain" the variation in a related dependent or predicted variable. The unit of analysis in such models is important because the level at which resource use can be measured differs for composite rate and separately billable services. Separately billable services for individual patients can be measured using payments from Medicare claims. However, the available measure of resource use for composite rate services consists of costs from the Medicare cost reports. These costs do not distinguish patient-specific differences in resource use within facilities, because they combine treatment costs for all of the patients treated in each ESRD facility. Given this limitation in measuring resource utilization for composite rate services, UM-KECC considered two models for the estimating equations.

Under the one-equation bundled PPS model, composite rate costs and separately billable payments for all patients treated at the facility are added together. When the result is divided by the number of ESRD treatments, the predicted or dependent variable of bundled ESRD services reflects a facility-level model of combined composite rate and separately billable services. This approach has the relative simplicity of having the case-mix adjustments based on a single statistical model estimated at the facility level.

The other approach, which we refer to as the two-equation bundled PPS model, relies on two regression equations, one to predict variation in composite rate costs at the facility level, and the other to predict variation in separately billable payments at the patient level. This approach has the advantage of measuring patient-level variation in the utilization of separately billable services that is available from the Medicare claims. In addition, separate composite rate and separately billable regression equations can be readily combined into a single payment equation.

In an extensive series of analyses, UM-KECC determined that application of the one-equation bundled PPS model (i.e., a facility-level model) yielded very different regression coefficients for a number of potential case-mix adjusters compared to the two-equation bundled PPS model. These differences were attributed to the correlation between the tested case-mix variables and unobserved facility characteristics. UM-KECC concluded that a patient-level model would have the advantage of reducing potential bias related to unobserved facility characteristics, would result in more precise coefficient estimates, and yield greater stability in these estimates over time [34]. A patient-level model for the separately billable services can be combined with a facility-level model for composite rate services to yield a single payment equation. This is the approach adopted to develop the case-mix adjusters for the per treatment and per month bundled ESRD payment options described in this Report.

C. Methodology

1. Dependent Variables

The analytic approach used to develop the bundled ESRD PPS includes a facility-based regression model for composite rate services, and a patient-level regression model for separately billable services. The measures of resource use that were specified as the dependent variables in each of the two equations are defined below.

a. Average Cost Per Treatment for Composite Rate Services

Resource use for the maintenance dialysis services included in the current bundle of composite rate services was measured using the facility-level data obtained from the Medicare cost reports for independent and hospital-based ESRD facilities. The average composite rate cost per treatment at each facility was calculated by dividing the total reported allowable costs for composite rate services by the total number of dialysis treatments. For PD patients, the weeks were multiplied by 3 to obtain the number of hemodialysis equivalent treatments. The resulting composite rate cost per treatment was adjusted to eliminate the effects of varying wage levels among the areas in which ESRD facilities are located using the ESRD wage index and the labor-related share of costs from the composite rate market basket. That is, 53.711 percent of each facility's composite rate cost per treatment was divided by the wage index to control for area wage levels. A log transformation was applied to wage-adjusted composite rate costs to better satisfy the statistical assumptions of the model, and to be consistent with existing methods of adjusting payment for case-mix. As with other health care cost data, there was skewness in the cost distribution for composite rate services (i.e., when a relatively small fraction of observations account for a disproportionate fraction of costs). A logarithmic model is also consistent with the approach used under the current composite rate payment system, in that it allows the case-mix adjustments to be applied multiplicatively to the wage-adjusted payment amount. Cost per treatment values which were determined to be unusually high or low in accordance with predetermined statistical criteria (that is, statistical aberrations) were excluded from further analysis [35].

b. Average Medicare Allowable Payment (MAP) Per Treatment for Separately Billable Services

Resource use for the categories of separately billable services previously identified was measured at the patient level using the payment data on the Medicare claims for 2002-2004. This time period corresponded to the most recent three years of Medicare cost report data that were available to measure resource use for composite rate services. Medicare payments were inflated by a factor of 1.25 for services with a 20 percent patient coinsurance obligation (i.e., most injectable drugs) to yield the MAP. For services without a coinsurance requirement (i.e., laboratory tests and vaccines), the MAP was equal to the Medicare payment.

For the case-mix analyses, MAP values based on 2002-2004 claims were adjusted to approximate the relative costs for those separately billable services under the current Medicare payment system. The MAPs for the most prevalent injectable drugs were re-priced using the ratio of the Medicare payment rate in the first quarter of 2006 to the prevailing Medicare payment rate in 2002-2004. This re-pricing was done for the following injectable drugs: epoetin alfa (EPO); darbepoetin alfa (ARANESP); iron dextran; iron sucrose; sodium ferric gluconate; calcitriol; doxercalciferol; paracalcitol; levocarnitine; alteplase recombinant; and vancomycin. The resulting MAP jointly reflected the volume of services provided to each patient and the relative cost for each service based on prevailing Medicare payment.

The adjusted MAP was standardized to the number of Medicare outpatient dialysis treatments reported on the claims. This approach is consistent with the unit of payment under the current composite rate payment system. For patients who received PD during the month, the number of PD days reported on the Medicare claims was multiplied by 3/7 to yield the number of hemodialysis equivalent treatments. Monthly treatment sessions reported on the claims were capped at 20, as values in excess of this number were considered implausible. The ratio of the adjusted MAP for separately billable services divided by the total number of treatments was used to calculate the average adjusted MAP per treatment. The average MAP per treatment for EPO was limited to no more than 30,000 units, since higher doses were considered clinically suspect or inappropriate. As with the analyses of composite rate services, a logarithmic transformation was similarly applied to the values of separately billable services, with statistical outlier values excluded from further analysis [36].

2. Independent Variables

Two major types of independent or predictor variables were included in the composite rate and separately billable regression equations; case-mix payment variables and control variables. Case-mix adjustment variables were included as factors that may be used to adjust payments in either the composite rate or the separately billable equation. Control variables, which generally represented characteristics of ESRD facilities such as size, type of ownership, whether the facility was hospital-based or independent, etc., were included specifically to obtain more accurate estimates of the effect of the potential payment variables in each equation. Control variables were excluded from consideration as payment adjusters. In the absence of control variables, the relationship between the payment variables and measures of resource use may be biased.

a. Control Variables

Seven control variables were included in UM-KECC's regression analyses. They were: hospital-based versus independent; facility size (< 5,000, 5,000-10,000, and > 10,000 dialysis treatments); facility ownership (independent, large dialysis organization, regional chain, unknown); whether the facility received a composite rate payment exception between November 1993 and July 2001; percentage of patients having a urea reduction

ratio (URR) < 65 percent; rural versus urban location; and calendar year. CY 2002, 2003, and 2004 were included as a control variable in analyses that pooled three years of data.

b. Case-mix Adjustment Variables

The variables that were examined for consideration as case-mix payment adjusters included a number of variables in addition to the same patient demographic variables used in connection with the basic case-mix adjusters in the current composite rate payment system, i.e., age (six groups), BSA [21], and low BMI (values less than 18.5 kg/m^2). The additional variables for analysis included gender, the duration of renal replacement therapy, and several patient comorbidities.

Comorbidities were identified based on Form 2728 and Medicare claims data for the following conditions: specific types of heart disease (cardiac arrest, congestive heart failure, cardiac dysrhythmia, ischemic heart disease, and pericarditis), cerebrovascular disease, diabetes, peripheral vascular disease, chronic obstructive pulmonary disease, AIDS, positive HIV status (without AIDS), hepatitis B, other hepatitis, specific types of infections (septicemia, bacterial pneumonias, and other pneumonias/opportunistic infections), specific types of bleeding conditions (gastrointestinal tract bleeding and esophageal varices), specific types of anemias (acquired hemolytic anemias, hereditary hemolytic anemias, and sickle cell anemia), cancer (excluding non-melanoma skin cancers), inability to ambulate, inability to transfer, alcohol dependence, drug dependence, gastrointestinal ulcer, hyperparathyroidism, monoclonal gammopathy, myelofibrosis, and myelodysplastic syndrome. Although these comorbidities represented the available pool of conditions from the source files, the specification of comorbidities for the purpose of potential case-mix adjusters depended upon whether the conditions were relatively chronic or acute and whether certain related conditions could be combined to form a single measure.

The independent variables which we have identified were included in both the composite rate and separately billable regression equations. In defining the independent variables for each equation, however, it was necessary to link patient-level data with facility-level data. For example, measures for patient characteristics (e.g., gender) were included as potential payment variables in the facility-level composite rate equation, while measures for facility characteristics (e.g., hospital-based) were included as control variables in the patient-level equation. For the composite rate equation, case-mix measures were defined using data for all Medicare ESRD patients treated in each facility. Specifically, the percentage of a facility's patients having each patient characteristic was identified. For example, gender was measured as the percentage of patients that were female.
A 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 (with 13 treatments 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 (again, with 13 treatments). Similarly, in defining 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., percent female patients in each facility). This was the same approach used to define the case-mix measures in connection with the basic case-mix adjustments for the composite rate payment system. The resulting facility variables were included as control variables in the separately billable equation (e.g., percent of patient treatments provided in hospital-based facilities).

In the next section we describe how the initial pool of available comorbidities was reduced to yield a relatively parsimonious set of conditions for use as case-mix adjusters in the ESRD PPS.

3. Specification of Comorbidities for Case-Mix Adjustment

The selection of patient characteristics as potential case-mix adjusters from those available in Medicare's extensive databases required careful consideration. The inclusion of comorbidities in the model based on both the magnitude and statistical significance of the relationship between the comorbidity and either composite rate costs or separately billable payments was certainly a factor. Other factors were considered such as the potential for the creation of adverse incentives and administrative policy choices.

Case-mix definitions were reviewed for accuracy and the objectivity of diagnostic criteria, the relationship between the onset of the comorbidity and cost, and the simplicity of the model. In addition, clinical judgment also guided the selection of the final set of comorbidities included in the bundled ESRD payment model. A brief discussion of these considerations follows.

a. Considerations for Determining the Statistical Significance of Case-Mix Adjusters

Given the very large number of ESRD patients with Medicare claims, statistical significance is a necessary but not a sufficient condition for including a potential patient characteristic as a case-mix adjuster. Even variables with very small relationships to costs or payments are likely to be statistically significant in patient-level analyses. Such variables will add little in terms of the explanatory power of the models, and ESRD facilities caring for patients with these conditions will not receive meaningful increases in payments. Therefore, each potential case-mix adjuster was examined to ensure not only its statistical significance, but also whether its impact was economically meaningful, given the magnitude of the potential adjuster and prevalence of the comorbidity. Some variables may have a statistically significant relationship with costs and payments, but were judged not to be suitable for making payment distinctions in a bundled ESRD PPS. For example, the variables of race and ethnicity were excluded from consideration as potential payment adjusters in the model on this basis. We note that because of the demonstrated significance that race has on provider costs and drug utilization, this adjustment may warrant further consideration as we develop and implement a new ESRD PPS.

b. Potential for Adverse Incentives

Some clinical measures may be outcomes of specific dialysis-related treatment. For example, measures of hematocrit (the proportion of red blood cells in whole blood) are strongly associated with EPO and iron dosing with lower hematocrit predicting higher subsequent costs. UM-KECC determined that including a measure of the average hematocrit level for 6 to 8 months prior to the current month in the case-mix model increased the model's predictive power in terms of the proportion of variance explained (R^2) by about 5 percent. However, inclusion of such a variable would create an adverse incentive by rewarding facilities achieving lower hematocrits. Because of this adverse incentive, such measures were not considered as potential case-mix adjusters.

c. Refining the Initial Set of Patient Comorbidities

The research began with a long list of comorbidities that might be included in the bundled ESRD PPS, including the duration of renal replacement therapy. Appendix 5 lists all of the comorbidity variables that were considered, along with their data sources. Appendix 5 also notes whether the specified comorbidity was included in the final case-mix model, the basis for its inclusion/exclusion, whether it was modified or combined with other comorbid conditions, and whether the length of time from when the comorbidity first appeared had a significant effect on costs (the "look-back" period). A comprehensive discussion of UM-KECC's iterative analyses in connection with these issues will be contained in its forthcoming report. The look-back periods for chronic condition comorbidities included in the case-mix model are also noted in bold in Appendix 5.

D. Determining Potential Case-Mix Adjustments

Potential case-mix adjustments for a bundled ESRD PPS could be based on a set of patient characteristics that was refined using several criteria previously described. One of these criteria was the estimated relationship of each characteristic to composite rate costs and separately billable payments. Because separate regression equations were developed for composite rate and separately billable services, some factors might be used as payment adjusters for only one set of services.

Table 1 shows the relevant patient characteristics from which the case-mix adjusters were developed and their prevalence in the Medicare outpatient dialysis population. These patient characteristics include the basic case-mix variables (age, BSA, and low BMI), gender, duration of renal replacement therapy (RRT), and 12 refined comorbidity measures (see Appendix 5). The range of ICD-9-CM diagnostic codes corresponding to the 12 refined comorbidity measures reflected in the case-mix model are shown in Appendix 6. The complete set of ICD-9-CM codes corresponding to all diagnoses included in the case-mix comorbidities are contained in UM-KECC's forthcoming report.

Table 1. Characteristics of Medicare dialysis patients, 2002-04 (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: 2728 or claims (any)	9.2%
Cardiac arrest: 2728 or claims (any)	3.1%
Pericarditis from same month to three months ago	0.4%
HIV/AIDS: 2728 or claims (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%

In the following sections, CMS describes the relationship of these patient characteristics to both composite rate and separately billable services, and provides results regarding the precision and stability of the regression estimates that determine the payment adjustments.

1. Case-Mix Adjustment for Composite Rate Services

UM-KECC estimated the relationship between patient characteristics and composite rate costs using a facility-level regression model since patient-level data are not available. The facility-level model relates average patient characteristics to reported ESRD facility costs, using the same approach as that used to develop the basic case-mix adjustments previously described. In order to obtain case-mix adjustment factors that could be multiplied by a base payment rate, each variable was logarithmically transformed. The models were weighted by the number of dialysis treatments each facility furnished. Among the 12 refined comorbidity measures shown in Table 1, three qualified as potential payment variables in accordance with standard stepwise regression procedures, with statistical significance specified at the $p < .05$ level.

As Table 2 reveals, some of the comorbidity adjusters for CYs 2002, 2003, and 2004, tended to be somewhat unstable predictors of composite rate costs. Accordingly, the proposed payment adjusters are based on a model that uses pooled data for all three years, representing 11,174 facility-year observations during the three year period. The results are shown in Table 3.

Table 2. Yearly case-mix multipliers for composite rate services, 2002-04

	Facility-level log-linear models of average cost/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 m^2)	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: 2728 or claims	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

Table 3. Estimated case-mix multipliers for composite rate services, 2002-04 (n=11,174)

Variable	Facility-level log-linear model of average cost/session R-sq: 38.74% R-sq, control variables only: 36.97% Average $162.00/sess. Multiplier ($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: 2728 or claims (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 explanatory power (R^2) of the composite rate model that included both facility control variables and the patient characteristics shown in Table 3 was 38.74 percent. This R^2 of 38.74 is consistent with the general range of values in other Medicare case-mix adjusted PPSs. A separate model that included only the seven facility control variables previously discussed had an R^2 of 36.97 percent, while the inclusion of the Table 1 patient characteristics contributed an additional 1.77 percent. A comprehensive discussion of the development of the composite rate case-mix adjusters shown in Table 3 will be included in UM-KECC's forthcoming report.

2. Adjustment for Separately Billable Services

Because resource use for separately billable services can be measured using Medicare claims, a patient-level model was used to identify separately billable potential case-mix adjusters. UM-KECC specified a regression model, weighted by the number of dialysis treatments that 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 for CYs 2002 through 2004. Because of the large number of patient observations, the relationship between patient characteristics and payments was relatively stable during CYs 2002 through 2004, as the yearly multipliers were similar in most instances. See Table 4.

Table 4. Yearly case-mix multipliers for separately billable services, 2002-04

	Facility-level log-linear models of Medicare Allowable Payments/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: 2728 or claims (any)	1.11	<0.01	1.12	<0.01	1.14	<0.01
Cardiac arrest: 2728 or claims (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: 2728 or claims (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

In addition, most case-mix multipliers for separately billable services can be estimated relatively precisely because claims data were used that included patient specific information. The lower and upper 95 percent confidence intervals for the estimated multipliers when the data are pooled for CYs 2002 through 2004 typically reflect no more than a 3 percent difference in payments. The R^2 for a model that included both control variables and the patient characteristics in Table 5 was 8.82 percent.

Table 5. Estimated case-mix multipliers for separately billable services, 2002-04 (n=809,208)

Variable	Patient-level log-linear model of Medicare Allowable Payments/session R-sq: 8.82% R-sq, controls only: 0.84% Average $83.18/session Multiplier ($Mult_{SB}$)	p	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: 2728 or claims (any)	1.12	<.0001	(1.12, 1.13)
Cardiac arrest: 2728 or claims (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: 2728 or claims (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)

Unlike the pattern seen in the composite rate model, the control variables accounted for only 0.84 percent of the variation in separately billable payments, while the patient characteristics contributed an additional 7.98 percent to the overall R^2. All 12 comorbidity variables had a statistically significant relationship to separately billable payments. However, the magnitude of the comorbidity effects varied substantially. The largest increase was associated with gastrointestinal tract bleeding, two categories of specified infections, and pericarditis (47 percent to 88 percent higher payments). These are the acute conditions where a recent diagnosis (i.e., no more than three months ago) leads to a short-term increase and, therefore, a temporary payment adjustment. For most of the remaining comorbidities, the model estimated much smaller effects (4 percent to 16 percent for all other conditions except myelodysplastic syndrome). These are the chronic conditions for which a diagnosis leads to a long-term increase in costs and therefore, a permanent payment adjustment based on the expectation that they will tend to have a more persistent effect on separately billable costs.

A potential case-mix adjustment for a bundled ESRD PPS would combine the separate adjustments for composite rate and separately billable services (Tables 3 and 5, respectively). Section F. shows how these separate adjustments can be combined in a

single payment formula. But first, we discuss the role of the wage index and two approaches for its application in the expanded payment system.

E. Application of the Wage Index

Because of the significance of labor costs in determining the total cost of care, CMS's PPSs traditionally have used a wage index to account for differences in area wage levels. Applied to the 53.711 percent of the labor-related share of costs to develop the composite rate, the current measure is based on hospital wage and employment data for fiscal year 2003 obtained from the Medicare cost reports. In the context of a bundled ESRD PPS, there are two approaches for applying a wage index adjustment. Under the first approach (Approach 1), a base payment rate is adjusted by the applicable area wage index before applying other adjustments that reflect patient characteristics. This is the method used to adjust payments under the current composite rate payment system. Under the other approach (Approach 2), a payment model is developed that simultaneously estimates multipliers for patient characteristics and the wage index. That is, the wage index is treated as an independent variable in the regression models.

The case-mix adjustment models presented in this Report use Approach 1. The potential case-mix adjustments were based on analyses of composite rate costs that were adjusted to eliminate the effects of area wage differences on costs. This was accomplished by deflating 53.711 percent of each facility's composite rate costs by the applicable area wage index (see section VII.C.1. on Dependent Variables). No adjustment to the MAP amounts for separately billable services was made since Medicare payments for these services are not adjusted for area wage differences.

The composite rate and separately billable regression models yielded case-mix adjustments that can be applied multiplicatively to a wage index adjusted payment amount, the same approach used for the basic case-mix adjustment. A disadvantage of this approach is that it does not permit measuring the extent to which the wage index accounts for variation in resource use. Therefore, UM-KECC analyzed this question and also examined the sensitivity of the case-mix multipliers under both Approaches 1 and 2. The results of these analyses are summarized in Table 6.

Table 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 proposed case-mix adjustment.

Table 6 reveals that in the composite rate cost models, the facility control variables explained a smaller proportion of the variation in composite rate costs (36.97 percent) when these costs were not adjusted by 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 as an independent variable (Approach 2) increased the R^2 by 7.44 percent, from 34.30 percent to 41.74 percent. The R^2 of the model with facility control variables, the wage index, and case-mix was 43.41 percent.

Adding the wage index had essentially no impact on the explanatory power of the separately billable model (Table 6), since the MAP amounts for separately billable services do not reflect a wage index adjustment. Measures of the actual labor costs for separately billable services are not available. UM-KECC also found that for both the composite rate and separately billable models, the estimated case-mix coefficients were not substantially different when the wage index was added as a predictor variable. See Table 7.

In section VII. F., we explain how the separate regression adjusters for composite rate and separately billable services can be combined using a single payment formula based on each component's share of the average MAP per treatment for the period 2002-2004. These shares are 66.1% for composite rate and 33.9% for separately billable services, respectively. Therefore, under the recommended Approach 1 case-mix adjustment model, the estimated R^2 using the facility control and case-mix variables is .661 x 38.74% + .339 x 8.82% or 28.60%.

Table 7. Two approaches to adjusting analyses of composite rate costs for area wages

	Facility-level log-linear models of CR costs, 2002-04 (n=11,174)[1]			
	Wage index used to adjust labor portion of CR cost measure[2]		Wage index (WI) included as an independent variable	
Variable	Est. Multiplier	p	Est. Multiplier	p
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; Dubois formula)[4]	1.034	<.0001	1.036	<.0001
Underweight (BMI <18.5)[4]	1.07	0.3059	1.05	0.4276
Duration of RRT: <4 months	1.60	<.0001	1.63	<.0001
Alcohol/drug dependence: 2728 or claims (any)	1.12	0.0003	1.13	0.0001
Cardiac arrest: 2728 or claims (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: 2728 or claims (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).

[1]Models also include facility control variables (not shown).

[2]This model is the basis for the proposed case-mix adjustment.

The largest difference was observed for the multiplier for pediatric patients (1.48 versus 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. In a subsequent analysis to determine how well the wage index adjustment accounts for the variation in resource use in the expanded bundle of composite rate and separately billable services, UM-KECC estimated that the wage index accounts for about 4.9 percent of the total variation.

F. Potential Payment Variables

The selection of patient characteristics as case-mix adjusters was assessed using a modeling approach that relied on separate regression equations for composite rate and separately billable services. While the potential case-mix adjustments are based on

separate estimating equations (Tables 3 and 5), the equations can be combined into a single payment formula for the bundled ESRD PPS.

Table 8 demonstrates a method for combining the payment multipliers for composite rate and separately billable services.

Table 8. Proposed 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				Proposed 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	1.000	ref	1.000	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)	1.000	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
Specified infection (from 0-3 months ago)					
Septicemia	1.071	0.0052	1.701	<.0001	1.285
Bacterial pneumonia and other pneumonias/opportunistic infections	1.000	n.s.	1.469	<.0001	1.159
Gastro-intestinal 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 proposed 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 first two columns in Table 8 represent the composite rate and separately billable model results from Tables 3 and 5, respectively, carried to three significant figures. The third column of Table 8 presents a single payment multiplier for each patient characteristic based on its relationship to resource use for both composite rate and separately billable services. The payment multipliers in the third column ($Mult_{EB}$) were calculated as the weighted average of the composite rate and separately billable multipliers. The weights correspond to each component's proportion of the sum of the average composite rate costs and separately billable payments per treatment for the period 2002-2004, as shown in Table 9.

Table 9. Estimated costs for composite rate and separately billable services, 2002-04

Measure of resource use	2002 n	2002 Average $/sess.[1]	2003 n	2003 Average $/sess.[1]	2004 n	2004 Average $/sess.[1]	Pooled, 2002-04 n	Pooled, 2002-04 Average $/sess.[1]
Facility composite rate costs[2]	3,508	$162.03	3,796	$162.43	3,870	$161.55	11,174	$162.00
Patient separately billable Medicare Allowable Payments (repriced)[3]	253,149	$80.01	274,010	$81.48	282,049	$87.61	809,208	$83.18

[1]Weighted by the number of hemodialysis-equivalent dialysis sessions.

[2]Source: Medicare Cost Reports for independent and hospital-based dialysis facilities.

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

The weights were calculated using the three years of pooled data. Based on this analysis, the average cost for composite rate services per treatment was $162.00 based on the Medicare cost reports for hospital-based and independent facilities. The average MAP for separately billable services per treatment based on the Medicare claims was $83.18. The separately billable MAP amounts were updated to reflect the revised payment rates for the top 11 injectable drugs as of the first quarter of 2006. Based on the total of $245.18 per treatment, the estimated weights for composite rate and separately billable services are 0.661 ($162.00/$245.18) and 0.339 ($83.18/$245.18), respectively. The payment multipliers presented in the third column of Table 8 were calculated as $Mult_{EB} = 0.661 \times Mult_{CR} + 0.339 \times Mult_{SB}$. In this manner, the separate case-mix adjusters for composite rate and separately billable services can be combined to obtain a single set of multipliers to compute the payment rates under the bundled ESRD PPS.

Nine comorbidities were identified as potential payment adjusters for separately billable services only, as they did not have a statistically significant association with composite rate costs based on the regression results. These patient characteristic variables have a composite rate multiplier in Table 8 of 1.000. For these comorbidities, there is no payment adjuster for composite rate services. Therefore, the payment multiplier is equal to $0.661 \times 1.000 + 0.339 \times Mult_{SB}$.

The potential payment multipliers in the third column of Table 8 reflect the combined results from the two-equation case-mix model previously described in section VII.D. The pediatric multiplier of 1.091 represents a 9.1 percent increase in payments per treatment for patients under age 18 relative to the reference age group (age 60-69). The remaining age multipliers show a U-shaped effect that is a somewhat diluted version of the pattern that was observed for composite rate services, 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 percent) and 80+ (12.8 percent), and smaller adjustments for ages 45-59 (0.6 percent), and 70-79 (2.6 percent), relative to the age 60-69 reference group.

There are upward payment adjustments for females (8.8 percent), patients with a larger BSA (3.5 percent per $0.1m^2$ increase in BSA), and patients considered to be underweight (5.4 percent). Among the remaining case-mix variables, the largest payment multipliers

generally reflect temporary adjustments to the payment amount. These include upward adjustments for patients in the first 4 months of renal replacement therapy (55.1 percent), and for patients with the following comorbidities in the current month or 3 previous months: pericarditis (20.6 percent); septicemia (28.5 percent); bacterial pneumonia, other pneumonias, and opportunistic infections (15.9 percent); and gastrointestinal tract bleeding (30.0 percent). The remaining adjustments are for comorbidities that represent relatively chronic conditions. The upward payment adjustment for these comorbidities is either less than 5 percent (cardiac arrest, HIV/AIDS, hepatitis B, and cancer excluding non-melanoma skin cancer), or between 5 percent and 10 percent (hereditary hemolytic or sickle cell anemias and myelodysplastic syndrome). The payment adjustments exceed 10 percent for two chronic condition comorbidities: alcohol/drug dependence (12.2 percent) and monoclonal gammopathy (28.6 percent).

G. Determination of Per Treatment Payment Amount

The preceding section demonstrated how case-mix adjustments based on separate estimating equations for composite rate and separately billable services (i.e., the two equation model), could be combined to yield a single payment formula. The third column of Table 8 in that section contained potential case-mix adjustments. In this section, we describe how the area wage index and the case-mix adjustments could be applied to a base payment amount reflecting combined composite rate and separately billable services, resulting in a per treatment payment rate under the ESRD PPS.

1. Base Payment Amount

For the purpose of showing how the payment rates under the bundled ESRD PPS could be determined, a base payment amount is necessary. The base payment amount includes neither the wage index nor case-mix adjustments. Using 2006 dollars, the base payment amount represents an estimate of the Medicare Allowable Payment (MAP) for composite rate and separately billable services in 2006. The average MAP for composite rate services in 2006 was estimated at $151.48 [44]. The average MAP for separately billable services was calculated using Medicare claims during 2002-2004. The separately billable MAP amounts were adjusted to reflect the payment rates for the top 11 ESRD injectable drugs during the first quarter of 2006, yielding an estimate of $83.18 per treatment. Therefore, under the estimation method used by the researchers, the base payment amount for combined composite rate and separately billable services was $234.66 per treatment ($151.48 + $83.18). This is the estimate that will be used in the examples presented in section VII. I.

2. Wage Index Adjustment

The estimated base payment amount of $234.66 represents a national average, that is, a payment amount without regard to case-mix adjustments where the wage index is equal to 1.0. For geographic areas with higher or lower wage index values, the labor-related portion of the base payment amount is multiplied by the wage index corresponding to the urban/rural locale in which the ESRD facility is located. Using the bundled ESRD market

basket developed by CMS's Office of the Actuary (see section XI A. and Appendix 7), the labor-related share is 39.278 percent.

Based on a hypothetical wage index of 1.10, the labor-related portion of the base payment amount would increase by 10 percent. The wage index adjusted base rate is calculated by adding the labor-related portion (i.e., the portion multiplied by the wage index), and the non labor-related portion. In our example with an area wage index of 1.10, the wage index adjusted base payment amount would be calculated as follows:

$234.66 x 0.39278 x 1.10 + $234.66 (1- 0.39278) =
$101.3867 + $142.4902 = $243.88

3. Patient Multipliers

The case-mix multipliers shown in Table 8 can now be used to develop case-mix adjusted payment rates for individual patients, depending on the applicable number of variables involved. The product of the applicable case-mix adjustment factors represents the patient multiplier (PM). The PM is then applied to the wage index adjusted base payment amount to calculate the per treatment payment. In section VII. I., we present several comprehensive examples demonstrating several combinations of PMs, and the resulting per treatment ESRD prospective payments.

If the average PM is larger than 1.00, an adjustment would be needed to maintain budget neutrality adjustment. But before presenting our hypothetical patient examples, we first turn to the issue of outlier payments under the ESRD PPS.

H. Outlier Payments

The payment methods described in this Report are intended to target higher payments to facilities treating patients with characteristics associated with a higher cost of care. In some cases, however, patient resource requirements may result in extremely high dialysis costs that are not adequately reflected in the payment model. A payment adjustment for such atypically costly "outlier" patients can mitigate financial risk for ESRD facilities, and help protect patients whose care is more costly from discrimination. Accordingly, an outlier payment policy could be considered in connection with the ESRD PPS for those patients with higher costs.

The Medicare cost reports, the source of the data for composite rate services, do not permit the identification of high cost patients. Therefore, additional information would need to be gathered and analyzed to create an outlier payment methodology that is based on treatment costs, similar to other PPS systems.

In the absence of data to identify high-cost patients, UM-KECC analyzed definingthem as those who use markedly more separately billable services than those predicted by the case-mix adjusted per treatment payment model. To define outlier cases, UM-KECC identified patient months in which the separately billable MAP per treatment exceeded

the mean by 2 or more standard deviations, a threshold under which approximately 2.28 percent of patient months would be expected to qualify for outlier status in accordance with the normal distribution (i.e., bell shaped) curve. All outlier calculations were performed using actual dollars, not the log of dollars. Converting the separately billable MAPs for outlier patient months to an average per treatment resulted in an outlier threshold of $240 for the separately billable MAP.

For purposes of computing the estimated cost of outlier payments, we used an 80 percent marginal cost factor. An 80 percent add-on for the additional variable costs of separately billable services was determined to be reasonable, although another factor could be employed.

UM-KECC analyzed applying an outlier payment equal to 80 percent of the difference between the separately billable MAP and the threshold amount of $240. The outlier payment represents an add-on to the case-mix adjusted prospective payment that would otherwise apply based on the payment model described in sections VII. F. and G.

The UM-KECC hypothetical outlier payment adjustment worked as follows. Suppose there is a patient for whom the case-mix and wage index adjustments yield a bundled payment rate of $325 per treatment. However, this hypothetical patient incurred an average monthly separately billable MAP of $300 per treatment and composite rate costs of $150 per treatment, for a total of $450. The facility's payment would equal the sum of the ESRD PPS amount based on the payment model (i.e., $325), plus the separately billable add-on based on the separately billable MAP exceeding the outlier threshold of $240. The hypothetical outlier payment amount would be $325 + 0.8 ($300-$240) or $373 per treatment for that month.

Application of any specific outlier payment approach results in aggregate outlier payments that must be considered in establishing base payment amounts to ensure budget neutrality. Using the aforementioned outlier payment mechanism, UM-KECC calculated aggregate outlier payments, determined the increase in payments per treatment, and then estimated the degree to which the average base payment amount would need to be reduced to maintain budget neutrality. Based on this calculation, UM-KECC determined that 5.3 percent of patient months would qualify as outliers, and that a reduction of 2.5 percent to the separately billable portion of the base payment rate, or a 0.9 percent reduction to the base payment rate for the ESRD PPS, would be necessary to fund the hypothetical outlier payments. Other outlier payment approaches are possible. The outlier threshold for separately billable services could be revised based on updated billing data adjusted in other ways as well, such as by using a price index or by establishing a target percentage of outlier payments.

Analyses were performed to demonstrate the degree to which the previously described outlier payment approach reduced ESRD facility payment risk. These analyses, however, are somewhat technical and beyond the scope of this Report. To summarize, the average facility risk, as measured by standard deviation, was reduced by approximately 10 percent compared to a methodology without an outlier payment mechanism.

A description of these analyses will be included in UM-KECC's forthcoming report. That report will also contain a discussion of an alternative outlier payment approach in which only the MAP for two of the most prevalent separately billable drugs were used to identify cases qualifying for outlier status. The analysis demonstrates that an outlier mechanism could be considered a component of the bundled ESRD PPS. However, additional data and research is needed to develop an outlier payment methodology that considers all items and services provided to dialysis patients that could be included in a bundled payment and is based on costs.

I. Hypothetical Examples

In this section, we demonstrate how the potential case-mix adjustment factors presented in Table 8 could be applied for 5 hypothetical ESRD patients to yield a per treatment payment amount under the ESRD PPS. Each example uses the base payment amount of $234.66 for combined composite rate and separately billable services, and assumes an ESRD wage index value of 1.10. Therefore, our starting point in each example prior to determining the product of the case-mix adjustment factors (i.e., the patient multiplier or PM), is a wage index adjusted base rate of $243.88. This value was computed as shown in section VII.G.2. In the interests of simplicity, no budget neutrality adjustments have been included in the examples.

Example 1—Relatively healthy ESRD patient with no comorbidities

> John Smith, a 45 year old male, is 187.96 cm. (1.8796 m.) in height and weighs 95 kg. He has chronic glomerulonephritis and hypertension, underwent the creation of an AV fistula in 2000, and was diagnosed with ESRD in 2001.The patient also has secondary hyperparathyroidism.

Table 8 reveals that none of Mr. Smith's comorbidities is among those for which case-mix adjustments apply. The only pertinent factors are age, height, and weight. Using the formula for BMI [22], we see that Mr. Smith is not underweight, having a BMI of 26.89

kg/m^2, which is greater than the threshold value of 18.5, the cut-off for underweight status:

$$\begin{aligned} \text{BMI} &= \text{weight}_{kg} / \text{height}(m^2) \\ &= 95/1.8796^2 \\ &= 95/3.5329 \\ &= 26.89 \end{aligned}$$

Therefore, there is no case-mix adjustment for low BMI.

The formula for calculation of a patient's BSA [21] is:

$$\text{BSA} = 0.007184 \times \text{height}_{cm}^{.725} \times \text{weight}_{kg}^{.425}$$

Mr. Smith's BSA is computed as follows:

$$\begin{aligned} \text{BSA} &= 0.007184 \times 187.96^{.725} \times 95^{.425} \\ &= 0.007184 \times 44.5346 \times 6.9268 \\ &= 2.2161 \end{aligned}$$

However, the case-mix adjustment based on a patient's BSA under the ESRD PPS reflects slightly different values from those used in connection with the basic case-mix methodology under the composite payment system [37]. A patient with the average BSA of $1.87m^2$ would not receive any upward or downward adjustment to the case-mix adjustment based on BSA. Patients having a BSA value above the 1.87 average would receive an upward adjustment, and those below 1.87 would receive a downward adjustment. Using the Table 8 multiplier of 1.035, Mr. Smith's case-mix adjustment based on his BSA of 2.2161 is computed as follows:

$$\begin{aligned} M_{BSA} &= 1.035^{(2.2161-1.87)/0.1} \\ &= 1.035^{3.461} \\ &= 1.1264 \end{aligned}$$

Mr. Smith's PM would reflect the applicable case-mix adjustments for both age and BSA and may be expressed as:

$$\begin{aligned} \text{PM} &= M_{age} * M_{BSA} \\ &= 1.006 * 1.1264 \\ &= 1.1332 \end{aligned}$$

For this patient there would be a 0.6 percent increase to the wage-index adjusted base rate of $243.88 based on age, and a 12.64 percent increase based on BSA. These factors combine to form the PM of 1.1332. The 1.1332 PM is then multiplied by the wage-index adjusted base rate of $243.88, resulting in an ESRD PPS per treatment payment of $276.36 (1.1332 x $243.88 = $276.36).

Example 2—ESRD Patient with multiple comorbidities

> Mary Livingston, a 66 year old female, is 167.64 cm. in height and weighs 105 kg. She has diabetes mellitus, a history of chronic Hepatitis B, parathyroidism, and liver cirrhosis. She was diagnosed with ESRD in 1995, esophageal varices in 2006, and had a diagnosis of upper gastrointestinal (GI) bleeding the previous month.

We will not repeat the calculation for BMI in this example. Suffice it to say that this patient does not have a BMI less than18.5 kg/m^2, the required threshold for underweight status. Table 8 reveals that the PM in this example must be calculated to reflect the case-mix adjustments for gender, BSA, Hepatitis B, and upper GI bleeding.

Using the BSA formula [21] shown in the first example, Ms. Livingston's BSA is computed as follows:

$$\begin{aligned} BSA &= 0.007184 \times 167.64^{.725} \times 105^{.425} \\ &= 0.007184 \times 40.9896 \times 7.2278 \\ &= 2.1284 \end{aligned}$$

Based on the Table 8 multiplier of 1.035, Ms. Livingston's case-mix adjustment based on her BSA of 2.1284 would be:

$$\begin{aligned} M_{BSA} &= 1.035^{(2.1284-1.87)/0.1} \\ &= 1.035^{2.584} \\ &= 1.0930 \end{aligned}$$

Ms. Livingston's PM may be expressed as:

$$\begin{aligned} PM &= M_{gender} * M_{BSA} * M_{HepatitisB} * M_{GIBleed} \\ &= 1.088 * 1.0930 * 1.014 * 1.300 \\ &= 1.5676 \end{aligned}$$

For this patient there would be an 8.8 percent increase to the wage-index adjusted base rate of $243.88 based on gender, a 9.30 percent increase related to BSA, and a 1.4 percent increase for costs associated with treating Hepatitis B. In addition, the ESRD facility would be paid an additional 30 percent because the patient has had an upper GI bleed in the last 3 months. All of these factors combine to form the PM of 1.5676. The value of 1.5676 is then multiplied by the wage-index adjusted base rate of $243.88, resulting in an ESRD PPS per treatment payment of $382.31 (1.5676 x $243.88 = $382.31).

Example 3—Aged ESRD patient with low BMI (< 18.5kg/m^2) and history of hospitalization

Agnes Jones, an 82 year old female, is 160.02 cm. (1.6002 m.) in height and weighs 45.36 kg. She has longstanding type II diabetes mellitus and was diagnosed with ESRD in 2002. The patient has coronary artery disease and peripheral vascular disease. In January 2006 Ms. Jones began dialyzing with an upper arm AV fistula, which had been created in 2002. In March 2006, after an unsuccessful attempt to declot the AV fistula during hospitalization, Ms. Jones experienced additional bleeding complications, and has been dialyzed using a catheter ever since. Last month, the patient was again admitted to the hospital after suffering an observed cardiac arrest during outpatient dialysis. She was diagnosed with myocardial infarction, and underwent coronary artery angioplasty and coronary artery stent placement during that hospitalization. Ms. Jones was again admitted to the hospital on the 14th of the current month for congestive heart failure.

We must first use Ms. Jones' height and weight to determine if a case-mix adjustment for low BMI applies, and the magnitude of the case-mix adjustment for BSA. The patient's BMI is computed as follows:

$$\begin{aligned} \text{BMI} &= \text{weight}_{kg} / \text{height}(\text{m}^2) \\ &= 45.36/1.6002^2 \\ &= 45.36/2.5606 \\ &= 17.71 \end{aligned}$$

Ms. Jones' BMI is less than 18.5. Therefore, her PM will include a 5.4 percent case-mix adjustment for underweight status (Table 8).
The formula for calculation of a patient's BSA [21] is:

$$\text{BSA} = 0.007184 \times \text{height}_{cm}^{.725} \times \text{weight}_{kg}^{.425}$$

Ms. Jones' BSA is computed as follows:

$$\begin{aligned} \text{BSA} &= 0.007184 \times 160.02^{.725} \times 45.36^{.425} \\ &= 0.007184 \times 39.6302 \times 5.0592 \\ &= 1.4404 \end{aligned}$$

Using the Table 8 multiplier of 1.035, Ms. Jones' case-mix adjustment based on her BSA of 1.4404 is calculated as follows:

$$\begin{aligned} M_{BSA} &= 1.035^{(1.4404-1.87)/0.1} \\ &= 1.035^{(-4.296)} \\ &= 0.8626 \end{aligned}$$

Because the patient's small BSA of 1.4404 is less than the average of 1.87, Ms. Jones' case-mix adjustment of 0.8626 for BSA reflects a 13.74 percent decrease.
A review of Ms. Jones' comorbidities in conjunction with Table 8 reveals that this patient's PM must be calculated by using the case-mix adjuster for cardiac arrest. Therefore, the PM will include case-mix adjustments for age, gender, BSA, BMI, and cardiac arrest. Ms. Jones' PM may be expressed as:

$$\begin{aligned} PM &= M_{age} * M_{gender} * M_{BSA} * M_{BMI} * M_{cardiacarrest} \\ &= 1.128 * 1.088 * 0.8626 * 1.054 * 1.031 \\ &= 1.1504 \end{aligned}$$

For this patient there would be a 12.8 percent increase to the wage-index adjusted base rate of $243.88 based on age, an 8.8 percent increase related to gender, a 13.74 percent decrease for BSA, a 5.4 percent increase for costs associated with a low BMI, and a 3.1 percent increase for additional costs for treating a patient with a recent history of cardiac arrest. All of these factors combine to yield a PM of 1.1504. The 1.1504 PM is multiplied by the wage-index adjusted base rate of $243.88, resulting in an ESRD PPS per treatment payment of $280.56 (1.1504 x $243.88 = $280.56).

Example 4—Pediatric ESRD patient

> Jonathan Arnold, a 24 month old male, is 74.93 cm. in height and weighs 13 kg. He began dialysis 8 months ago due to autosomal recessive polycystic kidney disease. This pediatric patient does not have a BMI less than 18.5 kg/m^2, so no case-mix adjustment for underweight status applies.

Using the BSA formula, Jonathan's BSA is computed as follows:

$$\begin{aligned} BSA &= 0.007184 \times height_{cm}^{.725} \times weight_{kg}^{.425} \\ &= 0.007184 \times 74.93^{.725} \times 13^{.425} \\ &= 0.007184 \times 22.8626 \times 2.9746 \\ &= .4886 \end{aligned}$$

Using the Table 8 multiplier of 1.035, this pediatric patient's case-mix adjustment based on his BSA of .4886 is calculated as follows:

$$\begin{aligned} M_{BSA} &= 1.035^{(.4886-1.87)/0.1} \\ &= 1.035^{(-13.814)} \\ &= 0.6217 \end{aligned}$$

The PM for this pediatric patient must be calculated to include case-mix adjustments for age and BSA, and may be expressed as:

$$\begin{aligned} PM &= M_{age} * M_{BSA} \\ &= 1.091 * 0.6217 \\ &= 0.6783 \end{aligned}$$

For this pediatric patient there would be a 9.1 percent increase to the wage-index adjusted base rate of $243.88 based on age, but a 37.83 percent decrease because of a low BSA. Both factors combine to yield a PM of 0.6783. The 0.6783 PM is multiplied by the wage-index adjusted base rate, resulting in an ESRD PPS per treatment payment of $165.42 (0.6783 x $243.88 = $165.42).

It is important to note that pediatric dialysis patients are comparatively rare among Medicare dialysis patients, comprising about 0.2 percent of the population (Table 1). The impact of the BSA adjustment in the above example is a payment reduction of over 37 percent, compared to the age related increase of 9.1 percent. UM-KECC has performed analyses which demonstrate that the predicted separately billable MAP falls substantially short of the actual separately billable MAP for pediatric patients (i.e., those less than age 18). This occurs because the BSA multiplier of 1.035 does not accurately reflect the relationship between BSA and separately billable services for pediatric patients because of their small size and relative rarity in the Medicare dialysis population. Given the small number of pediatric patients, there is a lack of statistical robustness in the payment model with respect to those patients.

The data limitations do not permit a ready solution to this problem. We are currently examining approaches to determine if modifications to the regression based payment methodology for pediatric patients is feasible. If not, an approach could be adopted similar to that under the basic case-mix adjustment to the composite rate, in which a case-mix multiplier was derived for pediatric patients outside of the regression-based payment formula.

Each of our 4 hypothetical patient examples reflects a base payment amount of $234.66 for combined composite rate and separately billable services, and an ESRD wage index of 1.10. To demonstrate the impact of the wage index on the per treatment payment amounts, we used the same 4 examples to calculate payment amounts for ESRD facilities with wage index values ranging from .90 to 1.30. The PMs and wage-index adjusted payment amounts per treatment are shown below.

Table 10

Impact of wage adjustment on per-session payment amounts for four hypothetical examples[1]

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: Pediatric case	0.6783	$152.92	$159.17	$165.42	$171.67	$177.92

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

J. Summary of Major Features of a Bundled Per Treatment Payment System

The preceding section contained 4 hypothetical patient examples showing how the potential case-mix adjustment factors could be applied to yield per treatment payment amounts under an expanded or bundled ESRD PPS. Building upon the limited or basic case-mix adjustments mandated under the MMA, the major features of a bundled ESRD PPS could be:

- A base rate ($234.66 in 2006 dollars) representing combined composite rate and separately billable outpatient dialysis services.

- Application of the hospital wage index to the labor-related portion of the ESRD base rate. (The labor-related portion, $92.17, represents 39.278 percent of that rate, a proportion derived from relevant components of a potential bundled ESRD PPS market basket.)

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- Application of specific case-mix adjustment factors to the sum of the wage index adjusted portion of the base rate (e.g., $92.17 times the wage index value), and the non-labor component of the base rate ($142.49)). The

product of the pertinent case-mix adjustment factors is the patient multiplier (PM).

- The case-mix adjustment factors used to derive the PM reflect the variables of age, sex, BSA, low BMI, duration of renal replacement therapy (< 4 months), and 12 comorbidities. The factors, and the magnitude of the corresponding case-mix adjustments, are shown in Table 11 below.

- Outlier payments..

Table 11: Potential case-mix adjustment factors for an expanded bundle (EB) of Composite Rate (CR) and Separately Billable (SB) services

Variable	**Proposed case-mix adjustment** Mult
Age	
<18	1.091
18-44	1.209
45-59	1.006
60-69	1.000
70-79	1.026
80+	1.128
Female	1.088
Body surface area (per 0.1 m^2)	1.035
Underweight (BMI <18.5)	1.054
Duration of renal replacement therapy: <4 months	1.551
Alcohol/drug dependence (any)	1.122
Cardiac arrest: (any)	1.031
Pericarditis (from 0-3 months ago)	1.206
HIV/AIDS (any)	1.042
Hepatitis B (any)	1.014
Specified infection (from 0-3 months ago)	
Septicemia	1.285
Bacterial pneumonia and other pneumonias/opportunistic infections	1.159
Gastro-intestinal tract bleeding (from 0-3 months ago)	1.300
Hereditary hemolytic or sickle cell anemias (any)	1.053
Cancer since 1999 (any diagnosis, excluding non-melanoma skin cancer)	1.030
Myelodysplastic syndrome (any)	1.095
Monoclonal gammopathy (any)	1.286

K. Impact of an ESRD PPS

Potential changes to the ESRD payment system can be considered relative to the current payment system. The current payment system consists of the composite rate and separately billable services. The composite rate covers a specified, limited bundle of services that comprise the basic dialysis treatment. It is paid prospectively and adjusted for a limited set of facility characteristics and patient characteristics. Services outside the composite rate bundle, such as injectable medications and non-routine laboratory tests, are billed separately on a fee-for-service basis.

Potential changes could 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 they would be costlier than average to treat may face difficulties gaining access to care or obtaining optimal treatment.

UM-KECC simulated the current payment system and the modeled payment system to generate two different annual payments to each dialysis facility. Then, the researchers compared the average differences between current payments and the ESRD PPS across different types of facilities.

This analysis focuses on the difference between payments in the current system and payments under an ESRD PPS. Measures of separately billable costs were based on utilization as reported in Medicare claims from 2002 through 2004, but utilization was priced by using Medicare fees as of the first quarter of 2006.

Two estimated per-session payments were calculated for each facility-year: one under the current system and another under the modeled bundled system. For case-mix adjustments, the characteristics and comorbidities of patients were obtained from the Medical Evidence Form (Form CMS 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 independent units and $134.53 for hospital-based units. The basic case-mix adjustment was applied using multipliers for BSA, low BMI, and age. UM-KECC also used the prevailing drug add-on and budget neutrality adjustment multipliers in effect for 2006. The result is a mean adjustment multiplier for case-mix, the drug add-on, and a budget neutrality adjustment of 1.16.

The per-session payment under the modeled bundled system was calculated by bundling together the composite rate services and separately billable services. A case-mix payment adjustment multiplier was first calculated for each patient-month. This adjustment takes

into account patient case-mix including age, gender, BMI, BSA, time since the onset of ESRD, and comorbid conditions (see the earlier section on the Final Predictive Model). The mean case-mix multiplier under the system was 1.2088.

Then, a base rate was determined for the system that preserves budget neutrality with the current payment system. This is done by setting the total dollars paid to this set of facilities between 2002-2004 equal under each payment system. As described in a previous section, 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 potential case-mix adjusted payment amount was adjusted for budget neutrality by multiplying potential payments by the reciprocal of the mean case-mix multiplier under the potential system (1/1.2088 = 0.8273).

Wage adjustments were calculated slightly differently for the current and potential payments. The current payments are calculated using a blended wage adjustment for composite rate services that is based on the MSA wage adjustment and the updated CBSA wage adjustment. The potential per treatment bundled payments were calculated using the updated CBSA wage adjustment only, since the MSA wage adjustment will no longer be used following the current 4-year transition period which ends on December 31, 2009. The potential payments also used an updated labor share of 39.278 percent from the expanded bundle ESRD market basket. (More information on the labor-related share is provided in Appendix 7). After applying the current wage adjustment, the estimated average wage-adjusted MAP in the current system is $237.97/session. After applying the CBSA wage adjustment, the estimated average wage-adjusted MAP in the proposed system is $238.31/session. To keep the modeled system budget neutral with the current system, a budget neutrality adjustment of 0.9986 ($237.97/$238.31) was applied to the potential payments, setting the mean payments in the two to $237.97/session. This is used as the base rate for the analyses presented in this section.

This analysis does not include an outlier payment policy that could pay facilities for treating unusually high cost patients. 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.

To study the effect of the modeled payment system on different types of facilities, patient-month data was then 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 are compared to determine if facilities in that group get a higher or lower payment in the new system.

Urban or rural – based on whether the facility physical address in the CMS data was in a metropolitan (urban) or not (rural) or neither (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 micropolitian statistical areas were classified as rural.

Hospital-based or independent – based on CMS data.

Small, medium, or large – 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 – based on CMS data.

Census region – 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 – based on CMS data identifying facilities receiving a composite rate payment exception prior to 2005 as isolated or essential facilities, and therefore receiving a higher composite rate payment.

Isolated Essential Facility (IEF) in 2005 or non-IEF – 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 – 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) – based on CMS data showing if facilities provide PD and the extent of PD provided (less than 5 percent of patients versus 5 percent or more of patients).

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

Facility Type		Facilities			Facility Years	Average of Current Payments	Average of Proposed 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	Free standing	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 (treatments 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%
	Hospital-based	460	426	435	1,321	$245.01	$241.07	-1,6%
	LDO	2,563	2,687	2,699	7,949	$237.86	$235.74	-0.9%
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%
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 treatments from the facility cost report where available. Otherwise, source is 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 are calculated as though facilities with previous IEF status are paid at the regular rate, but facilities with current IEF are paid their special rate.

**** Excludes 93 facility-year records where information on modality is unavailable.

Table 12 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 percent, except for the small groups of Alaskan facilities (4 facilities, represented by 6 facility-years) and facilities currently receiving IEF composite rate payments (4 facilities, represented by 10 facility-years).

Urban facilities, independent 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 modeled 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 modeled ESRD PPS compared to the current system. Hospital-based facilities also receive a $3.89 lower payment under the potential system, assuming the current $4 payment differential between hospital-based and independent 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 under the modeled ESRD PPS compared to the current system.

VIII. A Per Month ESRD PPS

In section VI.B., we pointed out that an ESRD PPS combining composite rate and separately billable services furnished during a specified interval of time would offer a major advantage—the flexibility to use whatever forms of dialysis were in the patient's best interests and neutrality with respect to the mode and frequency of dialysis treatments. A monthly payment system would also comport with the method of physician payment and Medicare's usual monthly billing cycle. In this section, we describe two approaches for the development of a case-mix adjusted ESRD PPS in which payments could be made on a monthly basis.

A. Factors for Consideration of a Per Month ESRD PPS

Under a per month payment system, a standard "per patient per month" base payment amount would need to be determined. In order to use historical cost report and claims data to develop a monthly payment system, it is necessary to aggregate costs over time, and to account for time during which the patient was not at risk for incurring outpatient dialysis costs. A monthly ESRD PPS requires the calculation of a patient's "time at risk" for partial months of dialysis in order to prorate the monthly payment for patients who experience one or more events that result in less than a full month of outpatient dialysis services.

The events that might cause patients to receive less than a full month of outpatient dialysis from a facility 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 any of these events would reduce the monthly payment rate in proportion to the fraction of the month they reduce the patient's time at risk for dialysis. A patient's skipping of dialysis treatments would not be considered an event that reduces time at risk.

Table 13 shows the frequency of patient months that would be eligible for payment based on a partial monthly rate under a monthly ESRD PPS based on events that reduce time at risk, as well as months that would be eligible for the full monthly payment rate.

Table 13. 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

About 81 percent of patient months are eligible for a full month's payment. For 19 percent of patient months, the treating ESRD facility would receive a fraction of the full month payment rate in proportion to the part of the month in which the patient was at risk for outpatient dialysis. Unfortunately, the claims data do not permit the determination of which days should be considered at risk for dialysis. For example, they do not show whether a patient received outpatient dialysis on the admission date or the discharge date of a hospitalization, the most common type of event. However, there is an approach for estimating time at risk for patient months with an intervening occurrence.

Time at risk can be inferred based on the number of outpatient dialysis treatments for that month. If a patient had 9 treatments during a month in which hospitalization occurred, the time at risk could be calculated as 9(7/3) = 21 days, based on the most common outpatient dialysis regimen of 3 treatments per week. In a 30 day month, 21 days corresponds to 70 percent of the month. Therefore, the monthly payment under an ESRD PPS for this patient would be 70 percent of the otherwise applicable full monthly rate. The composite rate portion of dialysis costs based on the Medicare cost reports, as well as the separately billable component based on paid claims data, could be calculated using this time at risk technique. However, because the cost reports are annual, facility specific, and include all patients (not just Medicare patients), the total number of treatments reported would have to be transformed to an aggregate amount estimated time at risk for

a proper accrual of the measured costs. Below we describe two approaches in which the time at risk estimates could be employed to derive a monthly payment under the ESRD PPS.

1. Approach 1—Adjust Average Payment Per Treatment to Reflect a Full Month of Dialysis.

This approach would rely on the same per treatment model described in section VII.G., but would scale the per treatment payment to yield a monthly payment amount. To use the per treatment model as the basis for a payment per month for a patient with a given set of characteristics who undergoes a full month of outpatient dialysis, one would simply multiply the case-mix adjusted payment per treatment by the typical number of treatments per month. The typical number could reflect either the current average (12.8) or the current standard treatment protocol (13). A minimum number of dialysis treatments could be required as an option to ensure adequate therapy. When a patient does not receive the minimum number of treatments in months when no intervening event occurred, a reduction could be made to the monthly payment or no payment could be made at all.

Under this approach, a case-mix adjusted payment per treatment of $250.00 times the current standard treatment protocol of 13 treatments per month would result in a monthly payment amount of $3,250.00. Alternatively, using the current average of 12.8 monthly treatments would yield a monthly payment of $3,200.00. If a patient only had 9 treatments because of a hospitalization, the monthly time at risk would be 9(7/3) or 21 days. Based on a 30 day month, the monthly payment would be 21/30 or 70 percent of either $3,250.00 or $3,200.00, resulting in a partial monthly payment of $2,275.00 or $2,240.00.

2. Approach 2—Estimate Models of Payment Per Month

Under this approach, a regression model of composite rate costs and separately billable payments per month could be developed. Dialysis services 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 under Approach 1, would also apply under this method. The dependent variables in the regression models would be the actual composite rate costs and separately billable payments observed in the partial month divided by the proportion of the month at risk. This would create the cost per full month equivalent. In the analysis, each patient month would also be weighted by the proportion of the month at risk to ensure that these partial months receive weights in proportion to the actual time they represent. For example, for a patient incurring $2,100 in costs during a month in which that patient was at risk for 21 of 30 days (70 percent), the full month equivalent cost of $2,100/0.70 or $3,000 would be used, and the observation would receive a weight of 0.70 in the regression model.

3. Comparison of Per Treatment and Per Month Case-Mix Adjustments

Using Approach 2, analyses were performed to estimate the per month case-mix adjustment model. The per month model uses the same independent variables as those discussed under the per treatment methodology described in section VII. The model presented here focuses on separately billable services only, because patient-level data are not available for composite rate services. Table 14 presents a side-by-side comparison of the results for the per treatment and per month case-mix adjustment models for separately billable services.

Table 14. Per-session vs. per-month estimation models for separately billable services, 2002-04

	Per-session model: adjusted SB MAP/session[1,2] (n=809,208) R-sq: 8.82% Average $83.18/sess.		**Per-month model: adjusted SB MAP/month at risk[1,2] (n=809,210)** R-sq: 8.71% Average $1,066.50/month	
Variable	Est. Multiplier	p	Est. Multiplier	p
Age				
<18	0.45	<.0001	0.45	<.0001
18-44	1.00	0.0626	1.00	0.3101
45-59	0.99	<.0001	0.99	<.0001
60-69	1.00	ref	1.00	ref
70-79	0.96	<.0001	0.96	<.0001
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: 2728 or claims (any)	1.12	<.0001	1.11	<.0001
Cardiac arrest: 2728 or claims (any)	1.09	<.0001	1.10	<.0001
Pericarditis from same month to three months ago	1.61	<.0001	1.62	<.0001
HIV/AIDS: 2728 or claims (any)	1.13	<.0001	1.12	<.0001
Hepatitis B since 1999	1.04	<.0001	1.04	<.0001
Specified infection from same month to three months ago				
Septicemia	1.70	<.0001	1.70	<.0001
Bacterial pneumonia and other pneumonias/opportunistic infections	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

[1]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.

[2]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.

In Table 14, the separately billable per treatment case-mix multipliers are the same as shown in Table 8 with the exception of differences due to rounding. The average separately billable payment in the per month model is $1,066.50, compared to the average separately billable payment in the per treatment model of $83.18 (Table 9). Table

12 reveals that among the 22 potential case-mix adjustment variables, 12 multipliers do not change, 9 change by 0.01, and one (duration of renal replacement therapy < 4 months) changes by 0.03. Each of the control variables, which included six facility characteristic variables plus calendar year, had multipliers that changed by no more than 0.01 (not shown).

The small differences in multipliers and statistical significance likely arise from definitions used for time at risk in the per month model. Also, the cases identified as statistical outliers vary slightly between the two models. Given the very small differences in the case-mix multipliers between the per month and per treatment approaches, the decision of whether the ESRD PPS should be applied on a per treatment or per month basis will depend on other factors.

B. Areas for Further Consideration with a Monthly Unit of Payment for the ESRD PPS

A monthly ESRD PPS is technically feasible. It would yield case-mix adjusters that are virtually identical to those under the per treatment regression methodology and would offer maximum flexibility in treating outpatient dialysis patients. However, a monthly payment system raises concern that some providers may furnish fewer services than are medically necessary, or may undertake less effort in discouraging patients from skipping treatments. Operationally, this could be addressed by requiring facilities to furnish a minimum number of treatments in order to receive either the full monthly payment or any payment at all. Such a requirement would be comparable to the MCP, which requires at least four physician visits for Medicare to pay the full MCP.

A monthly ESRD PPS would be complex for months in which the patient received dialysis in multiple facilities. This could occur because of a patient switching to a different dialysis facility, or due to the need for transient dialysis treatments while the patient is away from home. An additional complicating factor where multiple facilities are involved would be the requirement to factor in the intervening events which cause the patient not to be at risk for receiving outpatient dialysis for a partial month (see Table 13). These issues would involve finding solutions to several implementation problems. For example, how would a “home” facility under a monthly ESRD PPS be determined, and who would be responsible for making the prorated monthly payment to facilities for patients in months involving an inpatient hospitalization or other intervening event, CMS or the home facility? What changes would be required on the bills to ensure an accurate calculation of time at risk for outpatient dialysis? Should a time at risk proration of a monthly payment apply to multiple facilities equally, regardless of whether the intervening event reducing the number of treatments can be attached to a single facility? These are the types of policy and operational issues that would need to be carefully considered before a monthly ESRD PPS could be implemented.

IX. Quality Monitoring

Quality monitoring and provider accountability become increasingly important as CMS moves forward in the development of a bundled ESRD payment system. These elements

are important since the incentives from any bundled prospective payment are to achieve efficiency and furnish fewer services. Several quality monitoring initiatives are already underway at CMS. These initiatives which continue to evolve and expand in a bundled ESRD PPS environment.

CMS has developed a comparative monitoring tool referred to as Dialysis Facility Compare (DFC). This tool captures administrative and quality related data submitted by dialysis facilities. It is geared towards patients and their caregivers, allowing for comparisons to be made among dialysis facilities, including facility specific information about the services and quality of care provided at dialysis facilities in any State. The key quality measures captured in this tool include a facility level measure of anemia control, adequacy of dialysis treatment, and patient survival [38].

In addition to the three facility measures contained in DFC, CMS has developed thirteen ESRD Clinical Performance Measures (CPMs) based on the National Kidney Foundation's Kidney Disease Quality Initiative Clinical Practice Guidelines. These CPMs, which are based on information contained in patients' medical records, facilitate quality monitoring of Medicare-certified dialysis facilities by capturing data surrounding hemodialysis and peritoneal dialysis adequacy, vascular access, and anemia management [39]. The CPMs are calculated and released in the Department of Health and Human Services Annual Report of the ESRD Clinical Performance Measures Project. The three facility measures reported on DFC, and the thirteen ESRD CPMs, yield sixteen overall quality measures of performance.

CPM data are currently collected on a national random sample of adult in-center hemodialysis patients, all in-center hemodialysis patients less than 18 years of age, and a national random sample of adult peritoneal dialysis patients. Data are collected annually and are currently submitted via a predominately paper based process. However, because ESRD CPMs are currently being collected on only a small random sample of five percent of adult hemodialysis and peritoneal dialysis patients nationwide, the data do not permit calculating dialysis facility-specific rates.

CPMs will continue to be updated or revised based on changes to the Clinical Practice Guidelines on which they are based. Implementation of new facility level measures will take place via a future rulemaking process which will allow for public comment. In addition, the mechanism for reporting CPMs is expected to transition from the paper based process to a fully web-based system, Consolidated Renal Operations in a Web-Enabled Network (CROWN) and referred to as CROWNWeb. CrownWeb will allow for the more timely, accurate, and efficient use of data to support administration of the ESRD program.

Finally, in an effort to promote quality of care for ESRD beneficiaries, CMS published proposed ESRD conditions for coverage on February 4, 2005 that would revise the requirements that ESRD dialysis facilities must meet to be certified under the Medicare program [40]. The revised requirements focus on the patient and the results of the care provided to the patient, establish performance expectations for facilities, encourage patients to participate in their care plan and treatment, eliminate many procedural

requirements from the current conditions for coverage, and update vital process measures as necessary to promote patient well being and continuous quality improvement. The proposed rule would require dialysis facilities to implement a quality assessment and performance improvement program and require electronic submission of CPM data on all patients. This CPM requirement would provide a timely and complete collection of CPM data via CROWNWeb and facilitate external dialysis facility performance assessment. We expect to publish the final rule at a later date.

X. Other Issues Under an ESRD Bundled PPS

A. Payment for Home Dialysis

Home dialysis is performed by an appropriately trained dialysis patient at home. Hemodialysis, Continuous Cycling Peritoneal Dialysis (CCPD), Intermittent Peritoneal Dialysis (IPD) and Continuous Ambulatory Peritoneal Dialysis (CAPD) treatment modalities may be performed at home. Medicare beneficiaries, dialyzing at home, must choose between two methods of payment (Method I or Method II). This choice is recorded on the Beneficiary Selection Form, Form CMS-382.

1. Method I - The Composite Rate

If the Medicare home dialysis patient chooses Method I (Composite Payment Rate), the dialysis facility with which the patient is associated must assume responsibility for providing all home dialysis equipment and supplies and home support services. For these services, the facility receives the same Medicare dialysis payment rate as it would receive for an in-facility patient under the composite rate system. Under this arrangement, the facility bills the Medicare Administrative Contractors (MAC) and Fiscal Intermediary (FIs), and the beneficiary is responsible for paying the Medicare Part B deductible and the 20 percent coinsurance on the Medicare rate to the facility.

2. Method II – Dealing Directly with Suppliers

In accordance with regulation section 42 CFR 414.330, a Medicare ESRD beneficiary can elect to be a Method II home patient. If a beneficiary elects Method II, the beneficiary will deal directly with a single Medicare supplier to secure the necessary supplies and equipment to dialyze at home. The selected supplier (not a dialysis facility) must accept assignment and bills the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). The beneficiary is financially responsible to the supplier for any unmet Medicare Part B deductible and for the 20 percent Medicare Part B coinsurance requirement. The amount of Medicare payment under Method II for home dialysis equipment and supplies may not exceed $1,974.25 per month for CCPD and $1,490.85 per month for all other modalities of home dialysis.

For each beneficiary it serves, the supplier is required to maintain a written agreement with a support dialysis facility to provide backup and support services. A dialysis facility that has a written agreement to supply backup and support services bills the MAC/FI for

services provided under the agreement. Under Method II, a dialysis facility may be paid up to $121.15 per month for home dialysis support services, but may not be paid for home dialysis equipment or supplies.

Under a bundled ESRD PPS, payment for all dialysis services (except physicians' services), would be included in the bundled payment to the dialysis facility. The Method II home dialysis system where the supplier of home dialysis equipment and supplies bills the DME MAC, and the dialysis facility bills for home support services, does not lend itself to an ESRD PPS payment. The Method II home dialysis approach in its present form would have to be modified or eliminated.

The supplier could still furnish, under arrangement with the support dialysis facility, home dialysis equipment and supplies to a Medicare home dialysis beneficiary. However, the supplier would have to look to the dialysis facility for payment since the ESRD PPS payment would be made to the dialysis facility by the fiscal intermediary or the Medicare Administrative Contractor (MAC). DME MACs would no longer make payment to suppliers of home dialysis equipment and supplies.

Section 1881 of the Act would need to be revised to restrict Medicare payment under the bundled ESRD PPS to be made to a renal dialysis facility for both in-facility and home dialysis services. This would reduce the administrative burden of maintaining a Method I versus Method II payment system, since all Medicare dialysis patients would be paid under the bundled ESRD PPS.

B. Potential for Duplicate Payment Under Medicare Part B and Part D

As discussed previously in this Report, drugs routinely furnished to ESRD beneficiaries are paid under the Medicare Part B benefit and are included in the current ESRD bundle. Separately billable ESRD-related injectable drugs are also paid under Medicare Part B.

However, there is a potential for certain drugs to be covered under either Part B or Part D. Specifically, in several instances coverage is available for an injectable form of a drug under Part B, and also for the oral equivalent form under Part D. For example, Vitamin D drugs such as calcitriol, doxercalciferol, and paricalcitol, and ESA drugs such as EPO, are available in the injectable form and are paid under Part B. However, oral equivalents for some of the Vitamin D drugs are currently available. In addition, oral forms of some other types of drugs (e.g., EPO) are undergoing clinical trials and may soon be readily available in the oral form. The oral forms of these ESRD-related drugs could be included as Part D drugs. However, as specified in § 1860D-2(e)(2)(B) of the Act, drugs for which payment is available under Part A or Part B are not considered Part D drugs. To the extent that payment for a drug is included in the ESRD bundled rate, but an oral form of the drug is available under Part D, ESRD facilities would have incentives to encourage patients to use the oral form of the drug rather than the injectible form of the ESRD drug. One approach to this issue would be to include payment for the ESRD drug, regardless of the form (e.g., injectable vs. oral) in the ESRD bundled rate. The ESRD PPS would be adjusted accordingly to reflect this specification. This approach would eliminate the

ambiguity providers and Part D sponsors may encounter in categorizing drugs as Part B vs. Part D, and would also guard against potential Medicare overpayments made under both the Part B and Part D benefits.

C. ESRD Exceptions

Before the enactment of BIPA, an ESRD facility could apply for and receive prospective adjustments or exceptions to its otherwise applicable composite payment rate under specified circumstances. Section 1881(b)(7) of the Act and §413.182 of Title 42 of the Regulations contain the statutory and regulatory authorities for the provision of exceptions to the composite payment rates. Although there were five exception criteria, ESRD facilities primarily filed for exceptions under the atypical service intensity (patient-mix), isolated essential facility (IEF), and self-dialysis training cost exception bases. Section 422(a)(2) of BIPA prohibited the granting of new exceptions to the composite payment rates on or after December 31, 2000, except under very limited circumstances, which expired July 1, 2001. That prohibition remains in effect, with one exception.

Section 623(b) of the MMA amended section 422(a)(2) of BIPA to afford pediatric facilities the opportunity to seek exceptions provided they did not have an exception rate in effect as of October 1, 2002. The statute defines a pediatric facility as a renal facility, 50 percent of whose patients are under age 18. Section 422(a)(2)(C) of BIPA provided that any ESRD composite rate exception in effect on December 31, 2000 would continue as long as the exception rate exceeds the applicable composite payment rate. The MMA did not revise that provision. However, in accordance with section 623(d)(1) of the MMA, the wage adjusted composite payment rates, although applied on a per treatment basis, are subject to case-mix adjustments. The patient characteristic adjusters applicable to each treatment determined the case-mix adjustment which will vary for each patient. Thus, an ESRD facility's average composite rate per treatment depended on its unique case-mix.

Since ESRD facilities can maintain their current exception rates, we expect them to compare the exception rate to the basic case-mix adjusted composite payment rate to determine the best payment rate for their facility. If the facility retains its exception rate, it would not be subject to any of the adjustments specified in section 623 of the MMA. It is likely that ESRD facilities had to determine if their exception rate per treatment exceeded its average case-mix adjusted composite payment rate per treatment.

An ESRD facility can notify its MAC/FI at any time if it wishes to give up its exception rate. Once a facility notified its MAC/FI of its election to give up its exception rate, it would lose that exception rate, regardless of basis or amount, and be subject to the basic case-mix adjusted composite payment rates beginning 30 days after the intermediary's receipt of the facility's notification letter. Facilities with exception rates are required to notify their MAC/FIs only if they wish to forego their exceptions. Many ESRD facilities that had an IEF exception found that their case-mix adjusted composite rate payments exceeded their exception rate and notified their intermediary that they wanted to give up

their exception rate. (For example, only 4 ESRD facilities have currently elected to retain their IEF exception rates – section X. F. provides a discussion on IEF providers).

Since many of the ESRD providers have already given up their exception rates in order to be paid under the current case-mix adjusted composite payment rate, retaining exception rates may not be necessary under the bundled ESRD PPS. Therefore, the authority for pediatric ESRD facilities to file for an exception and for ESRD facilities to maintain their exception rates would likely need to be reconsidered under the ESRD PPS.

D. Self Dialysis Training

Many ESRD facilities have self-dialysis training exceptions to their composite payment rates because their costs for training a patient for self-dialysis or home dialysis have exceeded what Medicare pays for these training services. Medicare covers two forms of peritoneal dialysis training. Medicare pays the ESRD facility its case-mix adjusted composite rate, plus $12 per training treatment for CAPD and $20 per training treatment for CCPD. For hemodialysis training Medicare pays the ESRD facility its case-mix adjusted composite rate plus $20 per training treatment. These payment policies have remained the same since the original composite payment rates were implemented in 1983. Because the current training payment rates have not been updated, we would need to evaluate the current cost reported by ESRD facilities to train ESRD patients for self-dialysis and home dialysis, and make appropriate changes under the ESRD PPS. The ESRD PPS could provide incentives to providers to move patients to home dialysis, even incurring the costs of training patients.

E. Other Wage Index Issues

From 1986 through 2005, the wage index used in the ESRD composite payment rates was a blend of two wage index values, one based on hospital wage data from fiscal year 1986 and the other developed from 1980 data from the Bureau of Labor Statistics (BLS). Section 1881(b)(12)(D) of the Act, as added by section 623(d) of the MMA, gave the Secretary the discretionary authority to revise the existing wage index incorporated in the ESRD composite payment rates. That provision also required that any revised wage index be phased in over a multiyear period.

CMS adopted OMB's revised geographic definitions (announced in OMB Bulletin No. 03–04, issued June 6, 2003) to determine urban and rural locales for purposes of calculating ESRD composite payment rates. In the January 1, 2006 update of the basic case-mix adjusted composite rate system, we implemented the use of OMB's revised core-based statistical area (CBSA)-based definitions for Metropolitan Statistical Areas, New England County Metropolitan Areas, and Micropolitan Statistical Areas, as the basis for revising the urban/rural locales and corresponding wage index values reflected in the composite payment rates. These definitions are the same urban and rural definitions used for the Medicare IPPS, but without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act. In conjunction with adopting OMB's geographic classifications, we replaced the weighted wage index based on a 60/40 blend

of BLS and hospital wage-index values with one developed exclusively from acute care hospital wage and employment data obtained from the Medicare hospital cost reports. We announced our intention to update the ESRD wage index annually.

In CY 2006 update, we revised the labor-related portion of the composite rate based on the ESRD composite rate market basket contained in our May 2003 report to Congress on developing a bundled outpatient ESRD payment system. Effective January 1, 2006, we began using a single labor-related share of 53.711 percent that applied to both hospital-based and independent facilities. This proportion was based on the sum of the labor-related categories of costs that comprise the ESRD composite rate market basket.

The ESRD wage index values in the historical ESRD composite payment rates reflect a floor of 0.90 and a cap of 1.30. Payments to facilities in areas where labor costs fell below 90 percent of the national average, or exceed 130 percent of that average, were not adjusted below the 90 percent or above the 130 percent level.

In the CY 2006 update, we eliminated the cap because of the effect it has had on restricting payments in high wage areas. While we stated that we would like to remove the floor as well, we were concerned that its immediate elimination could adversely affect beneficiary access to dialysis. To mitigate any potential adverse impact, we have implemented a gradual reduction in the floor to 0.85 for 2006 and 0.80 in 2007. We would need to reevaluate the continued need for the floor under the ESRD PPS.

F. Rural Areas

Some prospective payment systems provide an additional adjustment for facilities located in rural areas. In order to determine the necessity of such an adjustment under a bundled ESRD PPS, we calculated the impact of implementing a payment system based on the two-equation predictive model. We compared the difference in annual facility payments of an expanded bundle to the basic case-mix adjusted composite rate plus separately billable services. For facilities located in rural areas, this comparison showed a 0.7 percent decrease in payments (see Table 12.) Based on this analysis, we believe an adjustment for rural areas may not be warranted.

We also looked at the impact of implementing an expanded bundled ESRD PPS on ESRD facilities that had ever been granted or retained an IEF exception (see section X. C. for discussion on Composite Payment Rate Exceptions). For the 47 facilities that had ever been granted an IEF exception, we compared the difference in annual payments of an expanded bundle to the basic case-mix adjusted composite rate plus separately billable services. These 47 facilities showed a 4.3 percent increase in payments (see Table 12). Of the 47 facilities that had ever been granted an IEF exception, only 4 had elected to retain their exception. For the 4 facilities that retained an IEF exception, there was a 9.4 percent increase in payments under an expanded bundle compared to the current case-mix adjusted composite rate plus separately billable services. This analysis supports a finding that an IEF adjustment may not be warranted.

G. Hospital-based versus Independent Facilities

As of April 1, 2007, the base composite rate for hospital-based facilities is $136.68, approximately $4 more than for independent facilities. The Omnibus Budget Reconciliation Act of 1981 mandated separate rates for the two facility types. While there have been several updates to the composite rate, none have given the Secretary the authority to change the basis of dual composite rates. This approach is inconsistent with the policy among other PPSs that pay the same amount for the same service in hospital-based and independent settings.

In its June 2006 Report (and other reports), MedPAC recommended that Medicare pay the same rate for the same services across different settings. MedPAC conducted an analysis of 2003 cost report data and the 2002 DFC database. The cost report data showed that hospital-based facilities employed more nurses to deliver care while independent facilities employed more (less costly) technicians to deliver patient care. Higher cost staffing is often cited as the reason hospital-based facilities should receive a higher composite rate payment. Dialysis Facility Compare presents provider level data on quality measures -- adequacy of dialysis and anemia management. MedPAC found that while hospital-based facilities reported higher labor costs and employed more nurses, there was no difference in quality compared to independent facilities. We agree with MedPAC's recommendation and believe we must hold providers accountable to a measurable level of quality care and that the same base composite rate should apply to hospital-based and independent facilities.

XI. Updating the Bundled ESRD PPS

A. A Bundled Market Basket

Under a PPS system, base period payments are updated or inflated on either an automatic or an ad hoc basis from the historical base period used for development to the prospective payment period for which payments would apply. The most significant component of the update factor used in connection with each of the PPSs is a market basket index. There are two major components to any PPS market basket: a set of cost or expenditure weights and an appropriate price or wage variable, referred to as a price proxy, which is matched to each expenditure weight. The cost weights are derived from the Medicare cost reports for a selected base year for each type of provider (e.g., hospital, skilled nursing facility, home health agency, etc.), and the price proxies are price index levels derived from publicly available statistical series published on a consistent schedule, preferably at least on a quarterly basis. A PPS market basket is an input price index that reflects how much it would cost, at another point in time, to purchase the same mix of goods and services that was purchased in a base period. CMS's Office of the Actuary has traditionally developed the methodology for each of the market baskets for the various CMS payment systems including the weight derivation and selection of appropriate price proxies for each of the market cost categories within a given market basket. OACT contracts with Global Insight, Inc. (GII) an economic consulting firm, to forecast the individual component price proxies.

In accordance with section 422(b)(1) of BIPA, CMS developed a market basket appropriate for updating the ESRD composite payment rates. The methodology for the development of the ESRD composite rate market basket was contained in the Secretary's May 2003 report to Congress [41].

While not statutorily required for updating the composite payment rates, the ESRD composite rate market basket is nonetheless important. It is the basis for determining the labor-related share of payments which are adjusted by the ESRD urban/rural wage index. The present market basket measures composite rate input costs. It also contributes to an understanding of growth in ESRD facility costs, payments, and margins.

A market basket can be a useful starting point for determining an appropriate update mechanism. The market basket is a standardized assessment of the inputs involved with furnishing services. Thus, the market basket rate of increase is therefore a standardized measure of changes in input prices. However, any update mechanism could take a number of other factors into account, such as productivity changes, changes in efficiency, changes in real and measured case-mix, and any other variables policy officials may want to consider in determining appropriate changes to payment rates. For example, an ESRD PPS could provide incentives to achieve efficiencies that would reduce costs, e.g., a movement to subcutaneous administration of EPO. Such efficiencies could be considered in the context of a market basket update. In addition, a market basket update could be considered in the context of pay-for-performance approaches, e.g., an update could be provided based on performance on quality measures discussed below.

Using the same methodology explained in the Secretary's May 2003 Report, CMS has developed an ESRD market basket appropriate for updating the bundled ESRD PPS. That methodology, which relies on CY 2003 data as the base period, is specified in detail in Appendix 7. Appendix 7 compares the bundled ESRD market basket with the composite rate measure, identifies all data sources used, and includes a description of the cost categories, expenditure weights, and price proxies employed. Under the bundled ESRD PPS, the labor related share of payments would be reduced from 53.711 percent to 39.278 percent. (More information on the reduction in the labor-related share is provided in Appendix 7). The forecasted rate of price inflation in the bundled market basket for calendar year 2007 is 3.2 percent, compared to 3.1 percent in the composite rate market basket. These estimates are based on the 2007Q1 forecast of the ESRD bundled rate market basket by GII.

B. Discretionary Adjustment Factors

Section 422(b)(1) of BIPA noted several factors which the Secretary may consider when measuring changes in costs beyond those accounted for by the market basket:

> …the Secretary **may take into account** measures of changes in—
> (A) technology used in furnishing dialysis services;
> (B) the manner or method of furnishing dialysis services;
> (C) the amounts by which the payments…for all services billed by a facility…exceed the aggregate allowable audit costs of such services for such facility….
>
> Emphasis added.

These discretionary adjustment factors are intended to account for increases or decreases in bundled service ESRD costs other than input price changes. The Secretary's May 2003 Report offered some hypothetical examples of non-price factors, such as changes in the dosing strength of pharmaceuticals or advances in dialyzer manufacturing .

Productivity change, or change in the amount of real output per unit of input, could also be a consideration in a bundled payment system for ESRD facilities. It is important to consider and understand the concept of productivity when examining the relationship between input and output price growth. Generally speaking, if firms within a given industry are generating positive productivity gains, they are able to produce constant or increasing outputs with fewer inputs. Consequently, in competitive markets where productivity gains are achieved (and holding profit margins constant), output prices would be expected to grow less fast than input prices. Conversely, if productivity changes are negative, that is, more inputs are required to produce a constant level of outputs, the expected result would be output price growth that more significantly exceeds input price growth.

In its March 2007 report, the MedPAC stated that providers of Medicare services should be able to reduce by a modest amount each year, the quantity of inputs required to produce a unit of service while maintaining quality (unless evidence suggests that this goal is unattainable systematically across a sector for reasons outside the industry's control). To that end, MedPAC has proposed that beginning in 2008, Medicare provider payment updates should be adjusted by the 10-year moving average of the Bureau of Labor Statistics' measure of non-farm multifactor productivity. Presently that estimate is equal to 1.4 percent. CMS' Office of the Actuary is currently exploring the available literature and possible data sources, as well as seeking out industry experts, to better understand the productivity potential for various health care sectors. As such, OACT does not have a productivity adjustment as it relates to ESRD facilities.

To date, no consensus has emerged as to how to adequately measure the discretionary adjustment factors for purposes of developing an update framework. The Secretary's May 2003 Report pointed out that from 1996-2000, composite rate costs and input prices increased at similar rates, suggesting that the net effect of non-market basket factors was negligible [42]. Appendix 7, however, reveals that the rate of growth in ESRD bundled costs per treatment has consistently exceeded the bundled ESRD market basket from 1997-2004 (see Figure 3).

Though the causes and amounts of the rates of increase beyond the market basket attributable to each of the discretionary adjustment factors are unknown, the implementation of the bundled ESRD PPS will provide ESRD facilities an opportunity to respond to the system's payment incentives, and to furnish dialysis in whatever manner serves the patient's best interests. Pending the development of a methodology for measuring the discretionary adjustment factors specific to the dialysis industry, we believe that it is appropriate to base ESRD payment updates on price increases as measured by the bundled ESRD market basket, and to include adjustments for productivity and changes in the coding or classification of cases that do not reflect real changes in case mix when available. MedPAC's suggested use of the 10-year moving average of multifactor productivity in the economy as a whole appears to be a reasonable measure [43].

The table below shows the historical rates of increase in the ESRD bundled rate update factor for 2002-2006, with projections for 2007 and 2008. The first column of the table shows the unadjusted market basket. The second column shows BLS estimates of 10-year average multi-factor productivity for non-farm industries. The third column shows the ESRD update factors after the productivity adjustment.

CY	ESRD Bundled Market Basket (03=100)	Less 10-year multi-factor Productivity	Equals: ESRD market basket update factors after productivity adjustment
2002	2.7%	0.9%	1.8%
2003	3.3%	1.0%	2.3%
2004	3.4%	0.9%	2.5%
2005	3.6%	1.2%	2.4%
2006	3.9%	1.4%	2.5%
2007*	3.2%	1.5%	1.7%
2008*	2.8%	1.4%	1.4%

*Based on GII 1st quarter 2007 forecast of the ESRD market basket and GII 1st quarter forecast of the 10-year moving average of non-farm multi-factor productivity.

XII. Operational Issues for Implementation

Implementation of the bundled ESRD PPS would require a significant amount of operational change and future policy development. These include consolidated billing rules and edits; expansion of the data elements (and related codes) reported on the dialysis facility bill; a mechanism to assign a "home" facility for each patient; billing and payment during the transition period; and the effective date for implementation of the ESRD PPS. The following discussion presents each of these issues in greater detail.

A. Consolidated Billing Rules

Since the ESRD PPS payment model represents an all-inclusive payment for dialysis-related services, it is important that billing and payment for these services are made only to the dialysis facility and that duplicate payment is not made to other entities. Currently, most of the separately billable items are billed by the ESRD facility with the exception of most laboratory services and some ESRD drugs provided in a physician's office. In addition, as discussed previously, Method II home dialysis supplies and equipment are billed by a durable medical equipment (DME) supplier. While consolidated billing rules for drugs and DME supplies and equipment will be relatively straightforward, that is not the case for laboratory tests.

ESRD patients generally have many comorbid conditions and are treated by other specialists for those conditions. As such, many of the same laboratory tests ordered by a nephrologist to monitor a patient's ESRD, could also be ordered by other specialists treating the ESRD patient for other medical conditions. Therefore, it is very difficult to

differentiate between an ESRD-related test and the same test ordered for another condition. While the ideal scenario would be to require that payment for all potentially dialysis-related tests be made only to the ESRD facility, facilities may not be able to control the ordering of tests by physicians not treating the patient's renal disease. Therefore, a mechanism would need to be developed for identifying the source of a given laboratory test to allow separate payment when the test was not ordered in connection with the patient's ESRD condition.

B. Expansion of Data Elements Reported on Dialysis Facility Bill

Under the current composite rate payment system, facilities are paid a composite rate for each dialysis treatment performed. Although the composite rate includes a number of items and services beyond the dialysis treatment itself, the current billing does not provide any of the detail of the composite rate items and services provided to the patient beyond the treatment itself. Facilities bill monthly for the total number of treatments performed. As discussed earlier, this lack of data has limited our ability to predict composite rate costs at the patient-level. In order to enable refinements to the case-mix adjustments of the ESRD PPS payment model, it will be essential to obtain detailed billing information at the patient-level.

CMS is currently in the process of moving dialysis facilities to line item date of service billing. This change will provide the structure to obtain more detail on the bill and relate the items and services to a specific date during the month. In some cases, new codes would need to be developed to enable reporting of the necessary data elements. CMS expects that consultation with industry representatives would be needed to ensure that the additional reporting burden is limited to data elements that would be relevant for case-mix refinements.

C. Assignment of "Home" Facility for Each Patient

Under a monthly or any other episodic payment structure, payment for dialysis services for a given patient would be made only to one facility in any month. As a result, the need to establish a home facility for each patient becomes critical for payment purposes. The concept of a home ESRD facility is not new since the ESRD networks currently assign patients to facilities for purposes of quality improvement activities. However, since patients could potentially move between facilities during the month, rules would need to be developed to determine which facility would serve as the patient's home facility for payment purposes during the month. Then as part of the consolidated billing rules, any other facility providing dialysis services to that patient during the month would seek payment from the patient's home facility.

D. Transition Period

As with most new prospective payment systems, a transition is often provided to allow facilities to adjust to the payment system by allowing them to continue to receive a declining portion of their payment based on costs, and an increasing portion based on the

new payment system until it is fully phased in. However, since dialysis facilities are not currently paid based on costs, implementing transition payments would be more complicated. Therefore, in order to provide a transition, it would be necessary to maintain the systems capability to price each monthly ESRD bill under two payment structures: one based on the composite rate plus separately billables; and one based on the bundled ESRD PPS. As such, both payment models would need the requisite annual revisions until the old payment system is eventually phased out.

E. Effective Date

The effective date for implementation of an ESRD prospective payment system involves consideration of a number of issues. First, policy development and rulemaking would be involved. Second, systems changes are needed to ensure that accurate payments are made under the new payment system. Because the bundle would include laboratory tests that are not now processed by the dialysis facility's intermediary, the system changes that are needed to prevent duplicate payment will be extensive. All told, it is likely that 2-3 years from date of enactment would be involved in these activities.

Another issue in consideration of an effective date is the statutorily required demonstration. The process of clearing a solicitation, obtaining and reviewing applications, selecting demonstration sites, and obtaining clearance for the demonstration award typically takes a minimum of 12 months to complete. The statute requires a 3-year demonstration. The final report for the evaluation of a demonstration is typically completed 1 year after the conclusion of the demonstration. Thus, if the demonstration is to be conducted first, before implementing an ESRD prospective payment system, about 5 years would pass before the new payment system could begin to be put into place. A demonstration could shorten somewhat the time required to implement a new payment system, but such new payment system may involve operational issues that the demonstration did not deal with. Conducting a demonstration concurrently with implementation of an ESRD prospective payment system would not allow results from the demonstration to be incorporated into the design of the new system. It is unlikely that facilities would have reason to participate in a concurrent demonstration unless the terms of the demonstration were more favorable than the new system. An alternative approach to understanding the impact of an ESRD bundled payment system would be monitoring and analyzing the experience of patients and providers under the new system.

XIII. Endnotes

1. Obtained from Medicare fee-for-service claims paid and processed as of December 31, 2006.

2. Wolfe, R., Hirth, R., Wheeler, J., Tedeschi, P., Webb, R., Roys, E., Wright, G., Turenne, M., Pozniak, A., Ashby, V., Brunton, C., Reimann, S., Held, P., and Callard, S. An expanded Medicare outpatient end stage renal disease prospective payment system, Phase I report, University of Michigan, Kidney Epidemiology and Cost Center, August 2002.

3. The other method is Method II, under which home dialysis patients deal directly with a supplier of home dialysis equipment and supplies that is not a dialysis facility. See section 2740B. of CMS Pub. 15-1.

4. Table 2, Per Session Medicare Allowable Charges by Provider, 2001-2005, Options for a fully bundled ESRD PPS, UM-KECC 1/26/07 draft.

5. Table 1, Medicare Allowable Charges (in millions) by Provider, 2001-2005, Options for a fully bundled ESRD PPS, UM-KECC 1/26/07 draft

6. Table 2, UM-KECC 1/26/07 draft.

7. See May 11, 1983 Federal Register at 48 FR 21262.

8. The composite payment system was not revised to reflect changes in area wage levels until the December 8, 2003 enactment of Pub. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Revisions to the area wage index used in the system were implemented January 1, 2006, and are now made annually.

9. For example, dialysis injectable drugs such as epoetin, iron supplements, and vitamin D analogues were not available in 1983. MEDPAC Report to Congress: Medicare Payment Policy, March 2005, Washington, DC, p. 123.

10. Wish, J.B. The economic realities of erythropoiesis-stimulating agent therapy in kidney disease. Kidney International, 2006, 70, 521-525.

11. Thamer, M., Zhang, Y., Kaufman, J., Cotter, D., Dong, F., and Hernan, M. A. Dialysis facility ownership and epoetin dosing in patients receiving hemodialysis. Journal of the American Medical Association, 2007, Volume 297, Issue 15, 1667-1674.

12. MEDPAC's recommendation 8A from its March 2001 Report to Congress on Medicare Payment Policy is as follows:

> The Congress should instruct the Secretary to broaden the composite rate payment bundle to include widely used services currently excluded from it. The Secretary should continue to emphasize quality monitoring and quality improvement efforts to ensure that patients have access to high-quality dialysis care.

In its March 2005 Report, MEDPAC stated that broadening the payment bundle was a necessary component for modernizing the outpatient ESRD payment system (p. 121).

In its March 2007 Report, MEDPAC stated:

> Medicare could better achieve its objectives of providing incentives for controlling costs and promoting access to quality services if all dialysis-related services, including drugs and laboratory tests, were bundled under a single payment (p. 127).

13. GAO Report GAO-07-77, End Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility, November 2006.

14. Wolfe, R., Hirth, R., Wheeler, J., Tedeschi, P., Webb, R., Roys, E., Wright, G., Turenne, M., Pozniak, A., Ashby, V., Brunton, C., Reimann, S., Held, P., and Callard, S. An expanded Medicare outpatient end stage renal disease prospective payment system, Phase I report, University of Michigan, Kidney Epidemiology and Cost Center, August 2002.

15. Thompson, T. G., Report to Congress: toward a bundled outpatient Medicare end stage renal disease prospective payment system, Washington, DC, Department of Health and Human Services, May 2003.

16. The MMA revisions to the composite payment rates are explained in detail in the proposed and final rules published in the Federal Register dated August 5, 2004 and November 15, 2004, respectively. See 69 FR 47525 and 69 FR 66319.

17. Prior to the enactment of Pub. L. 106-554 (BIPA), ESRD facilities could receive payments in excess of their composite payment rates under specified circumstances. Section 422(a)(2) of BIPA eliminated new composite payment exceptions effective January 1, 2001. Section 623(b) of the MMA restored a limited exception for pediatric renal facilities effective October 1, 2002.

18. Hirth, R.A., Wolfe, R.A., Wheeler, J.R.C., Roys, E.C., Tedeschi, P.T., Pozniak, A.S., and Wright, G.T. Is case-mix adjustment necessary for an expanded dialysis bundle? Health Care Financing Review, 2003, 24, 77-88.

19. Hirth, R.A., Roys, E.C., Wheeler, J.R.C., Messana, J.M., Turenne, M.N., Saran, R., Pozniak, A.S., and Wolfe, R.A. Economic impact of case-mix adjusting the dialysis composite rate. Journal of the American Society of Nephrology, 2005, 16, 1172-1176.

20. ESRD facility characteristics, in addition to patient characteristics, do predict variation in facility composite rate costs. Accordingly, several were included in the regression model used to develop the basic case-mix adjusters through the use of facility control variables, so that the patient characteristic case-mix adjusters would not be distorted. The facility control variables included the wage index, facility size (based on the annual number of treatments), facility status as hospital-based or independent, percent of patients with urea reduction ratios > 65 percent, chain ownership, year of Medicare cost report, and percent of pediatric patient treatments. See Wheeler, J.R.C., et al., Understanding the basic case-mix adjustment for the composite rate, AJKD, 2006, 47, p. 670.

21. The formula for the body surface area (BSA) variable used in connection with the basic case-mix adjustment is:
BSA (m^2) = 0.007184 x height (cm.)$^{.725}$ x weight (kg.)$^{.425}$ where m^2 equals meters squared, height is in centimeters, and weight is in kilograms.
See Wang, Y., Moss, J., and Thisted, R. Predictors of body surface area. Journal of Clinical Anesthesia, 1992, 4(1), 4-10.

22. Body mass index (BMI) = weight/height$(m)^2$ where weight is in kilograms and height is in meters squared.

23. Wheeler, J.R.C., Messana, J.M., Turenne, M.N., Hirth, R.A., Pozniak, A.S., Pan, Q., Chuang, C., Slish, K., Tedeschi, P., Roys, E.C., and Wolfe, R.A. Understanding the basic case-mix adjustment for the composite rate. American Journal of Kidney Diseases, 2006, 47, p.669.

24. These comorbidities included peripheral vascular disease, positive human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) status, drug dependence, myocardial infarction, pericarditis, and multiple myeloma. See Wheeler, J.R.C., et al., Understanding the basic case-mix adjustment for the composite rate. AJKD, 2006, 47, p. 667.

25. Wheeler, J.R.C., et al., ibid.

26. Wheeler, J.R.C., et al., op.cit., pp 669-671.

27. Kidney Epidemiology and Cost Center: Methodology for developing a basic case-mix adjustment for the Medicare ESRD prospective payment system, May 19, 2004 report and April 1, 2005 addendum. Prepared under contract no. N-12004-11-504200 for the Centers for Medicare and Medicaid Services.

28. See November 15, 2004 Federal Register at 69 FR 66330.

29. For several comprehensive examples of the application of the basic case-mix adjustment, see the November 15, 2004 Federal Register at 69 FR 66333-66334.

30. Beneficiaries may choose to dialyze at home rather than in a facility. For home dialysis, a beneficiary selects one of two methods for payment and billing. Under Method I (composite rate), the facility with which the patient is associated assumes responsibility for providing all home dialysis equipment, supplies and support services. Under Method II (direct dealing) the beneficiary deals directly with a single home dialysis supplier to secure the necessary supplies and equipment to dialyze at home. See Chapter 11, Section 10 of CMS Pub. 100-02.

31. Figure 4, Total Medicare Allowable Charges (In Millions), by Type of Service, 2005, Options for fully bundled ESRD PPS, UM-KECC 1/26/07 draft.

32. Figures 1-2, Total Medicare Allowable Charges (In Millions), by Service Provider Type, 2001 and 2005Options for fully bundled ESRD PPS, UM-KECC 1/26/07 draft.

33. Thompson, T.G., op.cit., pp. 26-27.

34. Structure of the model; one equation versus two-equation modeling approach, UM-KECC 1/19/07 draft.

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

    Model structure: statistical outliers for the average cost per session, UM-KECC 1/31/07 draft, pp. 1-2.

36. The average MAP per treatment for SB 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 treatment) that represents an unusually high

level of resource use. This very high upper limit led only 8 patient observations to be excluded from the model, 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 (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 SB payments, as it was for average composite rate costs. No lower limit on SB payments was established for the purpose of identifying statistical outliers. It is plausible that a patient incurs no SB services in a particular month.

Model structure: statistical outliers for the average cost per session, UM-KECC 1/31/07 draft, pp. 3-4.

37. The BSA case-mix adjustment factor in connection with the basic case-mix adjustment was 3.7% for every $0.1m^2$ change in BSA from the national average of 1.84. The BSA case-mix adjustment factor under the bundled ESRD PPS is 3.5% for every $0.1m^2$ change in BSA from a national average of 1.87 based on updated and more complete data. All of the hypothetical patient examples reflect the revised BSA threshold of 1.87 and BSA case-mix adjustment of 3.5%.

38. Centers for Medicare and Medicaid Services. Dialysis Facility Compare web tool. Retrieved June 13, 2007.

39. Centers for Medicare and Medicaid Services. Clinical Performance Measures Project Overview. Retrieved June 13, 2007.

40. See ESRD Conditions Rule, February 4, 2005 Federal Register at 70 FR 6184.

41. Thompson, T.G., op. cit., pp. 34-59.

42. Thompson, T.G., op. cit., p. 59.

43. MedPAC: Report to the Congress, March 2007, op. cit., p 143.

44. A discussion of how the composite rate MAP for 2006 was estimated, including application of the drug add-on and budget neutrality adjustments, will be contained in UM-KECC's forthcoming report.

XIV. References

GAO Report GAO-07-77, End Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility, November 2006

Hirth, R.A., Roys, E.C., Wheeler, J.R.C., Messana, J.M., Turenne, M.N., Saran, R., Pozniak, A.S., and Wolfe, R.A. Economic impact of case-mix adjusting the dialysis composite rate. Journal of the American Society of Nephrology, 2005, 16, 1172-1176

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Kidney Epidemiology and Cost Center: Methodology for developing a basic case mix adjustment for the Medicare ESRD prospective payment system, May 19, 2004 report and April 1, 2005 addendum, Prepared under contract no. N-12004-11-504200 for the Centers for Medicare and Medicaid Services

Medicare Payment Advisory Commission (MedPAC): Report to the Congress: Medicare Payment Policy, March 2001

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Wang, Y., Moss,J., and Thisted, R., Predictors of body surface area. Journal of Clinical Anesthesia, 1992, 4(1), 4-10

Wheeler, J.R.C., Messana, J.M., Turenne, M.N., Hirth, R.A., Pozniak, A.S., Pan, Q., Chuang, C., Slish, K., Tedeschi, P., Roys, E.C., and Wolfe, R.A. Understanding the basic case-mix adjustment for the composite rate. American Journal of Kidney Diseases, 2006, 47, No. 4 April, 666-671

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Wolfe, R., Hirth, R., Wheeler, J., Tedeschi, P., Webb, R., Roys, E., Wright, G., Turenne, M., Pozniak, A., Ashby, V., Brunton, C., Reimann, S., Held, P., and Callard, S. An

expanded Medicare outpatient end stage renal disease prospective payment system, Phase I report, University of Michigan, Kidney Epidemiology and Cost Center, August 2002

Appendix 1—Section 422(c)(1) Pub. L. 106-554, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)

(c) Inclusion of Additional Services in Composite Rate

(1) Development—The Secretary of Health and Human Services shall develop a system which includes, to the maximum extent feasible, in the composite rate used for payment under section 1881(b)(7) of the Social Security Act (42 U.S.C. 1395rr(b)(7)), payment for clinical diagnostic laboratory tests and drugs (including drugs paid under section 1881(b)(11) of such Act (42 U.S.C. 1395rr(b)(11)(B)) that are routinely used in furnishing dialysis services to Medicare beneficiaries but which are currently separately billable by renal dialysis facilities.

Appendix 2—Section 623(f) of Pub. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

(f) Report on a Bundled Payment System for End Stage Renal Disease Services

(1) Report—

(A) In General.—Not later than October 1, 2005, the Secretary shall submit to Congress a report detailing the elements and features for the design and implementation of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. The report shall include a description of the methodology to be used for the establishment of payment rates, including components of the new system described in paragraph (2).
(B) The Secretary shall include in such report, recommendations on elements, features, and methodology for a bundled prospective payment system or other issues related to such system as the Secretary determines to be appropriate.

(2) Elements and Features of a Bundled Prospective Payment System—The report required under paragraph (1) shall include the following elements and features of a bundled prospective payment system:

(A) Bundle of Items and Services.—A description of the bundle of items and services to be included under the prospective payment system.

(B) Case-mix.—A description of the case-mix adjustment to account for the relative resource use of different types of patients.

(C) Wage Index.—A description of an adjustment to account for geographic differences in wages.

(D) Rural Areas.—The appropriateness of establishing a specific payment adjustment to account for additional costs incurred by rural facilities.

(E) Other Adjustments.—Such other adjustments as may be necessary to reflect the variation in costs incurred by facilities in caring for patients with end stage renal disease.

(F) Update Framework.—A methodology for appropriate updates under the prospective payment system.

(G) Additional Recommendations.—Such other matters as the Secretary determines to be appropriate.

Appendix 3—Section 623(e)(1) of Pub. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

(e) Demonstration of Bundled Case-Mix Adjusted Payment System for ESRD Services

(1) In General.—The Secretary shall establish a demonstration project of the use of a fully case-mix adjusted payment system for end stage renal disease services under section 1881 of the Social Security Act (42 U.S.C. 1395rr) for patient characteristics identified in the report under subsection (f) that bundles into such payment rates amounts for—

> (A) drugs and biologicals (including erythropoietin furnished to end stage renal disease patients under the Medicare program which are separately billed by end stage renal disease facilities (as of the date of the enactment of this Act); and
>
> (B) clinical laboratory tests related to such drugs and biologicals.

Appendix 4—Pertinent Portion of Section 623(d) of Pub. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Mandating Implementation of a Basic Case-Mix Adjustment

(d) Basic Case-Mix Adjusted Composite rate for Renal Dialysis Facility Services

(1) Section 1881(b)(42 U.S.C. 1395rr(b)) is amended by adding at the end the following new paragraphs:

> (12)(A) In lieu of payment under paragraph (7) beginning with services furnished on January 1, 2005, the Secretary shall establish a basic case-mix adjusted prospective payment system for dialysis services furnished by providers of services and renal dialysis facilities in a year to individuals in a facility and to such individuals at home. The case-mix under such system shall be for a limited number of patient characteristics.

Appendix 5 – Original and Refined Comorbidities Measures

Original Comorbid Conditions Considered for a Case-mix Model	Sources	Included in Final Models	Comments
Cardiac Arrest	2728 or claims	Yes	Explored alternative definition with AICD procedure codes but the use of AICD placement did not overlap substantially with cardiac arrest diagnosis. **Source and time frame used in model: 2728 or claims, any occurrence.**
Pericarditis	2728 or claims	Yes	See text for discussion of rationale for time frame definition (Table 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 multiple solutions for this potential problem (monitor facility for adequate dialysis provision; pay for dialysis only if patient was adequately dialyzed by URR criteria; ? others) **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: 2728 or claims, 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. Are you drug dependent if you regularly take habit-forming prescription drugs? **Source and time frame used in model: 2728 or**

			claims, 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: 2728 or claims, any occurrence.
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.
			Source and time frame used in model: 2728 or claims, any occurrence.
Gastro-Intestinal Tract Bleeding	claims	Yes	See text and Table 4 for time frame definition rationale. Including severity in the definition is one issue. Unethical practitioners could increase their use of aspirin, non-steroidal anti-inflammatory drugs or even warfarin. This is a bit 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).
			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	See text and Table 3 for time frame definition rationale and use of separate category from pneumonias. Catheters favor “sepsis”. Hypothetically, paying for blood infections is financial incentive to ignore permanent vascular access planning. See hepatitis B

			for infection control practices issue. Several QA mechanisms currently in place (particularly Fistula First at Network level) and under development which counter this misaligned incentive.
Opportunistic Infections (Pneumonias)	claims	Yes	**Source and time frame used in model: Claims, same month to 3 months ago** Combined with other Pneumonia categories. See text and Table 3 for rationale for the combination and for time frame definition rationale
Aspiration and Specified Bacterial Pneumonias	claims	Yes	**Source and time frame used in model: Claims, same month to 3 months ago** Combined with other Pneumonia categories. See text and Table 3 for rationale for the combination and for time frame definition rationale
Pneumococcal pneumonia, emphysema, lung abcess	claims	Yes	**Source and time frame used in model: Claims, same month to 3 months ago** Combined with other Pneumonia categories. See text and Table 3 for rationale for the combination and for time frame definition rationale
Monoclonal Gammopathy	claims	Yes	**Source and time frame used in model: Claims, same month to 3 months ago** Any diagnosis since 1999 Technically, fairly objective laboratory diagnosis available. This is a spectrum of diseases, ranging from clinically unimportant to clinically life-threatening (malignant form is known as multiple myeloma). The presence of a monoclonal gammopathy is a laboratory definition which encompasses this very diverse set of clinical entities. Defining severity of monoclonal gammopathy will be important issue as we move forward.
Myelodysplastic Syndrome	claims	Yes	**Source and time frame used in model: Claims, any occurrence since 1999**
Leukemia	claims	Yes	**Source and time frame used in model: Claims, any occurrence since 1999** Combined with multiple other cancer diagnoses
Hereditary Hemolytic Anemias	claims	Yes	**Source and time frame used in model: Claims, any occurrence since 1999** Combined with sickle cell anemia as both are hereditary anemias with similar impact on MAP
Sickle-Cell Anemia	claims	Yes	**Source and time frame used in model: Claims, any occurrence since 1999** 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.
Lymphoma	claims	Yes	**Source and time frame used in model: Claims, any occurrence since 1999** Combined with multiple other cancer diagnoses
Hepatitis B	claims	Yes	**Source and time frame used in model: Claims, any occurrence since 1999** Any diagnosis since 1999 Objective laboratory diagnosis is available. Need to align diagnostic criteria with historical billing code diagnostic criteria. In theory, facilities could stop vaccinating patients against hep B, resulting in more cases. Alternatively, facilities could become more lax in infection control processes. This is not likely to happen as hep B positive patients are difficult to dialyze (strict criteria from CDC for isolation), the facility surveyors could focus on infection control practices, staff are adverse to providing care to patients with potentially highly contagious severe viral illness and CMS has discussed separate payment for vaccines, which would positively incent 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.
Multiple Myeloma	claims	Yes	**Source and time frame used in model: Claims, any occurrence since 1999** Combined with multiple other cancer diagnoses
Congestive Heart Failure	2728 or claims	No	**Source and time frame used in model: Claims, any occurrence since 1999** 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 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 condition and claims comorbidity definition too vague to allow creation of 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 HTN is an outcome of dialysis treatment (related to control of volume

			overload). Use of HTN as a comorbidity in a payment model would result in misalignment between quality and payment incentives.
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.

Appendix 6 - Comorbidity ICD-9-CM Diagnostic Codes

Note: The ICD-9-CM codes that are included in each comorbidity definition may be reported either individually or as a range of codes. A separate description is provided for each individual code that is reported. For brevity, the descriptions that follow each range of codes are limited to the broadest categories within the range.

Alcohol/Drug Dependence

291-292.99
291 Alcohol-induced mental disorders
292 Drug-induced mental disorders

303-304.93
303 Alcohol dependence syndrome
304 Drug dependence

305.0-305.03
305.0 Alcohol abuse

425.5 Alcoholic cardiomyopathy

571.0-571.3
571.0 Alcoholic fatty liver
571.1 Acute alcoholic hepatitis
571.2 Alcoholic cirrhosis of liver
571.3 Alcoholic liver damage, unspecified

V11.3 Alcoholism

Cardiac Arrest

427.5 Cardiac Arrest

Pericarditis

420-420.99
420 Acute pericarditis

HIV/AIDS

042 Human immunodeficience virus with specified conditions, includes acquired immunodeficiency syndrome (AIDS)
V08 Asymptomatic human immunodeficiency virus [HIV] infection status
079.53 Human Immunodeficiency virus, type 2 [HIV-2]

795.71 Nonspecific serological evidence of human immunodeficiency virus [HIV]

Hepatitis B

070.2-070.33
070.2 Viral hepatitis B with hepatic coma
070.3 Viral hepatitis B without mention of hepatic coma

Specific Infections

Septicemia and Shock

020.2 Plague, septicemic
022.3 Anthrax septicemia
031 Diseases due to other mycobacteria
036.2 Meningococcemia

038-038.9
038 Septicemia

040.82 Toxic shock syndrome
054.5 Herpetic septicemia
771.81 Septicemia of the newborn
785.59 Other shock: endotoxic, gram-negative, hypovolemic

Bacterial Pneumonias and Opportunistic Infections and Pneumococcal pneumonias

003.22 Salmonella pneumonia
006.4 Amebic lung abcess
007.4 Cryptosporidiosis
020.3 Primary pneumonia
020.4 Secondary pneumonia
020.5 Pneumonic, unspecified
021.2 Pulmonary tularemia
022.1 Pulmonary anthrax
031.0 Diseases due to other mycobacteria, pulmonary
031.2 Diseases due to other mycobacteria, disseminated
039.1 Actinomycotic infections, pulmonary
078.5 Cytomegaloviral disease
112.4 Candidiasis of lung
112.5 Candidiasis, disseminated
112.84 Candidal esophagitis
114.0 Primary coccidioidomycosis, pulmonary

114.4 Chronic pulmonary coccidioidomycosis
114.5 Primary coccidioidomycosis, unspecified
115.05 Infection by Histoplasma capsulatum, pneumonia
115.15 Infection by Histoplasma duboisii, pneumonia
115.95 Histoplasmosis, unspecified, pneumonia
117.3 Aspergillosis
117.5 Cryptococcosis
117.7 Zygomycosis (Phycomycosis or Mucormycosis)
121.2 Paragonimiasis
122.1 Echinococcus granulosus infection of lung
130.0 Meningoencephalitis due to toxoplasmosis
130.4 Pneumonitis due to toxoplasmosis
130.8 Multisystemic disseminated toxoplasmosis
136.3 Pneumocytosis
321.0 Cryptococcal meningitis
481 Pneumococcal pneumonia (Streptococcus pneumoniae pneumonia)
482 Other bacterial pneumonias
482.0 Pneumonia due to Klebsiella pneumnoniae
482.1 Pneumonia due to Pseudomonas
482.2 Pneumonia due to Hemophilus influenzae

482.3-482.49
482.3 Pneumonia due to Streptococcus
482.4 Pneumonia due to Staphylococcus

482.8-482.89
482.8 Pneumonia due to other specified bacteria

484.1 Pneumonia in cytomegalic inclusion disease
484.6 Pneumonia in aspergillosis
484.7 Pneumonia in other systemic mycoses

507-507.8
507 Pneumonitis due to solids and liquids

510-510.9
510 Empyema

513-513.1
513 Abscess of lung and mediastinum

Gastro-Intestinal Tract Bleeding

530.21 Ulcer of esophagus with bleeding

531.0-531.01

531.0 Acute gastric ulcer with hemorrhage

531.2-531.21
531.2 Acute gastric ulcer with hemorrhage and perforation

531.4-531.41
531.4 Chronic or unspecified gastric ulcer with hemorrhage

531.6-531.61
531.6 Chronic or unspecified gastric ulcer with hemorrhage and perforation

532.0-532.01
532.0 Acute duodenal ulcer with hemorrhage

532.2-532.21
532.2 Acute duodenal ulcer with hemorrhage and perforation

532.4-532.41
532.4 Chronic or unspecified duodenal ulcer with hemorrhage

532.6-532.61
532.6 Chronic or unspecified duodenal ulcer with hemorrhage and perforation

533.0-533.01
533.0 Acute peptic ulcer with hemorrhage

533.2-533.21
533.2 Acute peptic ulcer with hemorrhage and perforation

533.4-533.41
533.4 Chronic or unspecified peptic ulcer with hemorrhage

533.6-533.61
533.6 Chronic or unspecified peptic ulcer with hemorrhage and perforation

534.0-534.01
534.0 Acute gastrojejunal ulcer with hemorrhage

534.2-534.21
534.2 Acute gastrojejunal ulcer with hemorrhage and perforation

534.4-534.41
534.4 Chronic or unspecified gastrojejunal ulcer with hemorrhage

534.6-534.61
534.6 Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation

537.83 Angiodysplasia of stomach and duodenum with hemorrhage
562.02 Diverticulosis of small intestine with hemorrhage
562.03 Diverticulitis if small intestine with hemorrhage
562.12 Diverticulosis of colon with hemorrhage
562.13 Diverticulitis if colon with hemorrhage
569.85 Angiodysplasia of intestine with hemorrhage

Hereditary Hemolytic Anemias or Sickle Cell Anemias

282-282.9
282 Hereditary hemolytic anemias

Myelodysplastic Syndrome

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

Monoclonal Gammopathy

273.1 Monoclonal paraproteinemia [includes monoclonal gammopathy]

Cancer

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

141-208.99 excluding 173-173.99
141 Malignant neoplasm of tongue
142 Malignant neoplasm of major salivary glands
143 Malignant neoplasm of gum
144 Malignant neoplasm of floor of mouth
145 Malignant neoplasm of other and unspecified parts of mouth
146 Malignant neoplasm of oropharynx
147 Malignant neoplasm of nasopharynx
148 Malignant neoplasm of hypopharynx
149 Malignant neoplasms of other and ill-defined sites within the lip, oral cavity and pharynx
150 Malignant neoplasm of the esophagus
151 Malignant neoplasm of the stomach
152 Malignant neoplasm of the small intestine including duodenum
153 Malignant neoplasm of colon
154 Malignant neoplasm of rectum, rectosigmoid junction and anus
155 Malignant neoplasm of the liver and intrahepatic bile ducts
156 Malignant neoplasm of gall bladder and extrahepatic bile ducts
157 Malignant neoplasm of pancreas

158 Malignant neoplasm of retroperitoneum and peritoneum
159 Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum
160 Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
161 Malignant neoplasm of larynx
162 Malignant neoplasm of trachea, bronchus, and lung
163 Malignant neoplasm of pleura
164 Malignant neoplasm of thymus, heart and mediastinum
165 Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs
170 Malignant neoplasm of bone and articular cartilage
171 Malignant neoplasm of connective and other soft tissue
172 Malignant melanoma of skin
174 Malignant neoplasm of female breast
175 Malignant neoplasm of male breast
176 Kaposi's sarcoma
179 Malignant neoplasm of uterus, part unspecified
180 Malignant neoplasm of cervix uteri
181 Malignant neoplasm of placenta
182 Malignant neoplasm of body of uterus
183 Malignant neoplasm of ovary and other uterine adnexa
184 Malignant neoplasm of other and unspecified female genital organs
185 Malignant neoplasm of prostate
186 Malignant neoplasm of testis
187 Malignant neoplasm of poenis and other male genital organs
188 Malignant neoplasm of bladder
189 Malignant neoplasm of kidney and other and unspecified urinary organs
190 Malignant neoplasm of eye
191 Malignant neoplasm of brain
192 Malignant neoplasm of other and unspecified parts of nervous system
193 Malignant neoplasm of thyuroid gland
194 Malignant neoplasm of other endocrine glands and related structures
195 Malignant neoplasm of other and ill-defined sites
196 Secondary and unspecified malignant neoplasm of lymph nodes
197 Secondary malignant neoplasm of respiratory and digestive systems
198 Secondary malignant neoplasm of other specified sites
199 Malignant neoplasm without specification of site
200 Lymphosarcoma and reticulosarcoma
201 Hodgkin's disease
202 Other malignant neoplasms of lymphoid and histiocytic tissue
203 Multiple myeloma and immunoproliferative neoplasms
204 Lymphoid leukemia
205 Myeloid leukemia
206 Monocytic leukemia
207 Other specified leukemia
208 Leukemia of unspecified cell type

225-225.9
225 Benign neoplasm of brain and other parts of nervous system

227.3 Benign neoplasm of pituitary gland and craniopharyngal duct (pouch)
227.4 Benign neoplasm of pineal gland
228.02 Hemangioma if intracranial structures
237.0 Neoplasm of uncertain behavior of pituitary gland and craniopharyngal duct
237.1 Neoplasm of uncertain behavior of pineal gland
237.3 Paraganglia
237.5 Neoplasm of uncertain behavior of brain and spinal cord
237.6 Neoplasm of uncertain behavior of meninges
237.7 Neurofibromatosis
237.70 Neoplasm of uncertain behavior of endocrine glands and nervous system, neurofibramatosis, unspecified
237.71 Neoplasm of uncertain behavior of endocrine glands and nervous system, neurofibramatosis, type I Von Recklinghausen's disease
237.72 Neoplasm of uncertain behavior of endocrine glands and nervous system, neurofibramatosis, type II acoustic neurofibramatosis
237.9 Neoplasm of uncertain behavior of endocrine glands and nervous system, other and unspecified
239.6 Neoplasms of unspecified nature, brain
259.2 Other endocrine disorders, carcinoid syndrome

Appendix 7 – OACT Report on the Development of a Bundled ESRD PPS Market Basket

A. Introduction Section 623(f)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required the Secretary to:

> …submit to Congress a report detailing the elements and features for the design and implementation of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. The report shall include a description of the methodology to be used for the establishment of payment rates, including the components of the new system…

CMS has developed an exploratory ESRD market basket to satisfy this requirement, which will be referred to hereafter as the "ESRD bundled rate market basket". To develop this market basket, we have built on the work previously done to develop a market basket for estimating annual cost increases in the mix of labor and non labor goods and services included in the ESRD composite rate market basket, as required by section 422(b)(1) of the Medicare, Medicaid, and SCHIP Beneficiary Improvement and Protection Act of 2000 (BIPA). The ESRD composite rate market basket was presented to Congress as part of the May 2003 Report to Congress "Toward a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System.

As mentioned previously, the bundled ESRD PPS could include items and services currently excluded from the composite rate. Specifically, a bundled system could also incorporate separately billable drugs, supplies, and laboratory services, as well as blood products, and patient training costs.

The ESRD bundled rate market basket methodology is consistent with the methodology used in the development of the hospital, skilled nursing facility, and home health agency market baskets that update the applicable prospective payments for those providers. This methodology requires the market basket to reflect how much it would cost, at another point in time, to purchase the same mix of goods and services that was purchased in a base period. To accomplish this, the ESRD bundled rate market basket is structured as a fixed-weight, Laspeyres-type price index. The effects on total expenditures resulting from changes in the quantity or mix of goods and services (intensity) purchased subsequent to the base period are by design not measured. In this manner, the index measures pure price changes only.

B. Methodology and Data Sources

The ESRD bundled rate market basket is constructed in three steps. First, a base period is selected and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories. Then, the proportion of total costs that each category represents is determined. These proportions are called cost or expenditure

weights. Each expenditure category is then matched to an appropriate price or wage variable, referred to as a price proxy. These price proxies are price index levels derived from publicly available statistical series published on a consistent schedule, preferably at least on a quarterly basis. Finally, the expenditure weight for each category is multiplied by the index level of the respective price proxy to arrive at a weighted index level for each cost category. The sum of the products (that is, the expenditure weights multiplied by the price levels) for all cost categories yields the aggregate index level of the market basket in a given year. Repeating this step for different time periods produces a series of market basket index levels over time. Dividing an index level in one period by an index level in an earlier period produces a rate of growth in the input price index over that time period.

We selected calendar year (CY) 2003 as the base year for the development of the ESRD bundled rate market basket weights. The weights for this ESRD bundled rate market basket are based off of the cost report data for independent ESRD facilities, whose cost reporting period began on or after October 1, 2002 and before October 1, 2003. Using this methodology allowed our sample to include ESRD facilities with varying cost report years, including but not limited to the federal fiscal or calendar year.

We refer to the market basket as a calendar year market basket because the base period for all price proxies and weights are set to CY2003=100. Source data included CY 2003 Medicare cost reports (Form CMS-265-94), supplemented with 2002 data from the U.S. Department of Commerce, Bureau of the Census' Business Expenditure Survey (BES). The BES data was then aged to 2003 using appropriate price proxies to estimate price growth. The price proxies used for aging of the BES data come from publicly available price indexes such as the producer price index (PPI), consumer price index (CPI), or employment cost index (ECI). All of these price proxies are published by the Bureau of Labor Statistics. CY 2003 was selected because it is the most recent year that both relatively complete Medicare cost report data and supplemental BES data is available. Analysis of Medicare cost reports for CY 1998, 1999, 2000, 2001, 2002, and 2004 showed little difference in cost weights compared to CY 2003. Medicare cost reports from hospital-based ESRD facilities were not used to construct the market basket because data from independent ESRD facilities tend to reflect the actual cost structure faced by the ESRD facility itself, and are not influenced by the allocation of overhead over the entire institution as in hospital-based facilities. This approach is consistent with our standard methodology used in the development of other market baskets, particularly those used for updating the skilled nursing facility and home health prospective payment systems (PPS). It is unlikely this is a significant limitation because we believe that the cost structure in both facilities and units would be similar.

The remainder of this appendix will explain our methodology and results of the ESRD bundled rate market basket. We first describe the cost categories and present the methodology for development of the cost category weights. We then explain the basis for the selection of each price measure used to proxy the rate of price change for each expenditure category. Finally, we present the overall bundled rate market basket and compare it to the 1997-based composite rate market basket. We include historical and projected changes of both market baskets, compare changes in the bundled market basket to the historical increases in the CPI-U, compare changes in the bundled market basket over selected time periods to changes in the cost per treatment, and define the bundled rate labor-related share.

C. Cost Category Weights

Using Worksheets A, A2, and B from the CY 2003 Medicare cost reports, we first computed cost shares for nine major expenditure categories: Wages and Salaries, Employee Benefits for direct patient care, Pharmaceuticals, Supplies, Laboratory Services, Biological products, Administrative and General, Housekeeping and Operations, and Capital-Related costs. Edits were applied to include only cost reports where total costs were greater than zero. In order to reduce potential distortions from outliers in the calculation of the cost weights for the major expenditure categories, cost values for each category less than the 5th percentile or greater than the 95th percentile were excluded from the computations. The resulting data set included information from approximately 3,362 independent ESRD facilities' cost reports from an available pool of 3,737 cost reports. Expenditures for the nine cost categories as a proportion of total expenditures are shown in Table 1. These categories account for 100 percent of total expenses under a potential bundled rate.

Table 1.—Initial 2003-Based End-Stage Renal Disease Potential Bundled Rate Major Cost Categories and Weights Determined from the Medicare Cost Reports

Expense Category	CY 2003-Based Weights
Wages and Salaries	27.787%
Benefits for Direct Patient Care	4.892%
Pharmaceuticals	30.153%
Blood products	0.087%
Supplies	9.986%
Laboratory Services	0.287%
Housekeeping and Operations	2.951%
Administrative and General	14.087%
Capital-Related Costs	9.769%
Total	100.000%

Note: Totals may not sum to 100 due to rounding

We supplemented the expenditure categories developed from the Medicare cost reports with available BES data. The BES was used because the cost reports do not collect detailed information on items such as benefits for all employees, professional fees,

and utilities--categories that we chose to break out separately to more accurately reflect changes in ESRD facility costs. We describe below how the initially computed categories and weights were modified to yield revised bundled rate market basket expenditure categories and weights presented in this appendix.

Wages and Salaries

The initially computed weight for wages and salaries for direct patient care was derived from Worksheet B of the Medicare cost report. However, because Worksheet B only includes direct patient care salaries, it was necessary to devise a methodology to include all salaries, not just direct patient care salaries, in order to calculate the appropriate market basket weight. This was accomplished by first computing from the trial balance of the cost report (Worksheet A) the ratio of salaries to total costs in each cost center. We applied these ratios to the costs reported on Worksheet B for the corresponding cost centers to obtain the total wages and salaries for each bundled rate cost center. These salaries were then summed and added to the direct patient care salary. To avoid double counting, the weight for each cost category was reduced to exclude the estimated share of non-direct patient care salaries. When divided by total bundled rate costs, the result is a cost weight for total salaries, not just direct patient care salaries. This increased the expenditure weight from 22.267 percent for direct patient care salaries to 27.787 percent for total salaries, as shown in Table 1. After including expenditures for all employee benefits, professional fees and utilities from BES data, the weight for wages and salaries was 26.806 percent.

Benefits

The benefits weight was derived from the 2002 BES aged forward to 2003 using the benefits ECI for health service workers, since a benefit share for *all* employees is not available from the ESRD Medicare cost reports. The cost reports only reflect benefits for direct patient care. We applied the benefits proportion of wages and salaries from the BES to the salary amount calculated from the cost reports as described above. This resulted in a benefit weight that was 1.782 percentage points larger (6.502 vs.4.719) than the benefits for direct patient care calculated directly from the cost reports. To avoid double counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.782 percentage points for benefits from pharmaceuticals, biological products, administrative and general, supplies, laboratory services, housekeeping and operations, and the capital components. This calculation reapportions the benefits expense for each of these categories using a method similar to the method used for distributing non-direct patient care salaries as described above. While this method does not explicitly apportion the benefit share based on benefit data, it does approximate the proportion of each cost center’s costs that are benefits using available salary expenditure data.

Professional Fees

A separate weight for professional fees was developed using the 2002 BES. We inflated the 2002 BES professional expenditures to 2003 dollars using the employment cost index for private service occupations wages and salaries. Professional fees include accounting, bookkeeping, legal expenses, transportation and warehousing services, printing services, management, consulting, administrative, and professional fees. Similar to the methodology used for computing benefits, we first calculated the ratio of BES professional fees to total BES wages and salaries. We applied this ratio to the total wages and salaries share calculated from the cost reports to estimate the proportion of ESRD facility professional fees. The resulting weight was 1.478 percent. To avoid double counting, this proportion was deducted from the calculated weight for the Administrative and Other (A&O) expenditure category, where these fees would have been reported on the Medicare cost reports.

Utilities

We developed a weight for utility expenses using information from the 2002 BES, as utilities are not separately identified on the Medicare cost report. We aged the 2002 utility expenditures to 2003 using various relevant PPI and CPI series. We disaggregated the utilities category to reflect three subcategories: electricity, fuel (natural gas), and water and sewerage. We computed the ratio of each BES category to the total BES wages and salaries category. We applied each ratio to the total wages and salaries share calculated from the cost reports to estimate the ESRD facility weight for each utility expenditure category. These amounts were then deducted from the share of the combined Operation & Maintenance of Plant and Housekeeping cost category, where the expenses would have been reported on the Medicare cost report. The resulting electricity, natural gas, and water and sewerage bundled rate market basket weights were 0.552, 0.089, and 0.429 percent, respectively, yielding a combined utilities weight of 1.070 percent.

Pharmaceuticals

The bundled rate market basket includes expenditures for all drugs, including separately billable drugs. We were able to calculate an expenditure weight for pharmaceuticals directly from the Drugs cost center on Worksheet B plus the expenditures of EPO which are reported on worksheet A2 of the Medicare cost reports. Since this weight should represent the expenditures on drugs only, we exclude an estimate of the expenditures for syringes used to administer the EPO injections. The Medicare payment rate of $10 per 1,000 units of EPO (used to pay EPO until 2005) included a $0.50 fee per administration for syringes. We estimated administration by assuming that 90 percent of patients receive EPO injections and that there is one $0.50 syringe for each administration. We then add the expenditures for syringes to the supplies cost category. We also exclude vaccine expenditures from the drug cost category. Vaccine expenditures which are mandated as separately reimbursable were excluded from the total drug expenditures. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines, described in subparagraph (A) or (B) of section 1861(s)(10) of the Act, be

paid based on 95 percent of average wholesale price (AWP) of the drug. Since these drugs are excluded from other prospective payment systems, we excluded them in a potential ESRD bundled market basket as well. We estimated expenditures for these three vaccines are approximately 1 percent of the total Medicare allowable payments for separately billable drugs. Also, to avoid double counting, the weight for this category was reduced to exclude the estimated share of non-direct patient care salaries and benefits associated with the Drugs and Epoetin cost centers from Worksheet A. This resulted in a market basket weight for pharmaceuticals of 28.820 percent. EPO expenditures accounted for 21.595 percentage points of the drug weight, while all other drugs accounted for the remaining 7.225 percentage points of the drug weight.

Blood Products

We calculated the weight for blood products in the bundled rate market basket using the separately billable expenditure amounts for the whole blood and packed red blood cells cost center on Worksheet A of the Medicare cost report. We then added the expenditures for Administrative and Other (A&O) for whole blood and packed red blood cells from Worksheet B to the net expenses from worksheet A to arrive at a total expenditure amount for blood products. This total was divided by total expenses to derive a weight for the blood products component in the bundled rate market basket. Similar to other expenditure category adjustments, we reduced the computed weight to exclude salaries and benefits associated with the blood cost centers using Worksheet A. The adjusted blood products market basket weight was 0.079 percent.

Supplies

We calculated the weight for supplies included in the bundled rate using the reimbursable and separately billable expenditure amounts for the Supplies cost center on Worksheet B of the Medicare cost report. Supplies that are separately billable are reported as a separate line item on the cost reports and were also included. We also added expenses for syringes associated with the administration of EPO to this cost category and removed it from the EPO drug expenditures. The Medicare payment rate of $10 per 1,000 units of EPO (used to pay EPO until 2005) included a $0.50 fee per administration for syringes. We estimated administration by assuming that 90 percent of patients receive EPO injections and that there is one $0.50 syringe for each administration. This total was divided by total expenses to derive a weight for the supplies component in the bundled rate market basket. The computed weight for this category was reduced by the non-direct patient care salaries and benefits associated with the Supplies cost center using Worksheet A. The resulting market basket weight for supplies was 9.825 percent.

Laboratory Services

We calculated the weight for laboratory fees included in the bundled rate using the reimbursable and separately billable expenditure amounts for the Laboratory cost center on Worksheet B of the Medicare cost report. Laboratories that are separately billable are

reported as a separate line item on the cost reports and were also included. The cost report expenditures do not include laboratories paid for under the Medicare fee schedule, only facility-furnished laboratory tests. Since a large majority of laboratory tests are paid though the fee schedule, we inflated the laboratory fees. The inflation factor was computed from the ratio of ESRD facility Medicare laboratory payment data to the other facility Medicare laboratory payment data. For 2003, we increased the laboratory expenditure data by a factor of 13.987. The weight for this category was similarly reduced by the non-direct patient care salaries and benefits associated with the Laboratory cost center using Worksheet A. The resulting market basket weight for laboratory services was 3.868 percent.

Telephone

Because telephone service expenses are not separately identified on the Medicare cost report, we developed a weight using the 2002 BES. We inflated the 2002 BES telephone expenditures to 2003 dollars using the CPI for telephone services. We computed the ratio of BES telephone expenses to total BES wages and salaries. We then applied this ratio to the total wages and salaries share calculated from the cost reports to estimate the proportion of ESRD facility costs accounted for by telephone expense. To avoid double counting, this proportion was then deducted from the weight for the Administrative and Other expenditure category, where these expenses would have been reported on the Medicare cost reports. The resulting market basket weight for telephone services was 0.430 percent.

Housekeeping and Operations

We developed a market basket weight for this category using data from Worksheet A of the cost reports. Worksheet B combines the Capital-Related costs for buildings and fixtures with the Operation and Maintenance of Plant (Operations) and Housekeeping cost centers, so we were unable to calculate a weight directly from Worksheet B. We separated these expenses from capital-related costs because we reasoned that housekeeping and operations expenditures, such as janitorial and building services costs, were largely service-related and would be more appropriately proxied by a service-related price index. To avoid double counting, we subtracted from the housekeeping and operations weight the utilities proportion described above, as well as the non-direct patient care salaries and benefits share associated with the Operations and Housekeeping cost centers from Worksheet A. The resulting market basket weight for housekeeping and operations was 1.621 percent.

Administrative and Other (A&O)

We computed the proportion of total A&O expenditures using the A&O cost center data from Worksheet B of the Medicare cost reports minus the A&O expenditures related to the biological products. Additionally, this proportion was adjusted to exclude the expense shares for professional fees and telephone services. This adjustment reduced the weight for A&O from 13.590 percent to 11.682 percent. Examples of A&O costs include

expenses for data processing, malpractice, laundry, medical records, and other general administrative services. Similar to other expenditure category adjustments, we reduced the computed weight to exclude salaries and benefits associated with the A&O cost center using Worksheet A. The adjusted Administrative and Other expenses market basket weight was 10.713 percent.

Capital

We developed a market basket weight for the capital category using data from Worksheet B of the cost reports. Capital-related costs include depreciation and lease expense for buildings, fixtures, and movable equipment, property taxes, insurance, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. Because housekeeping and operations costs are included in the Worksheet B cost center for buildings and fixtures capital related expense, we excluded these costs and developed a separate expenditure category as noted above. Similar to the methodology used for other market basket cost categories with a salaries component, we computed a share for non-direct patient care salaries and benefits associated with the Capital-related machinery cost center. We used Worksheet B to develop two capital-related cost categories, one for buildings and fixtures, and one for machinery. We reasoned that although ESRD facilities lease much of their fixed and movable equipment, they tend to purchase their dialysis machines. Because leased capital and purchased capital could have very different changes in costs, we felt that separate price proxies would be more appropriate to track price changes for the different capital-related categories over time. The resulting market basket weights for capital-related costs for buildings and equipment and capital-related machinery were 6.243 and 2.546 percent, respectively. The table also lists the expenditure categories in the 97-based composite market basket. The main differences between the composite and bundled weights are reflected in those cost categories whose expenditures were separately billable, such as drugs, supplies, and laboratories.

Table 2 lists all of the expenditure categories in a potential ESRD bundled rate market basket (ESRDB) and their corresponding CY 2003 cost weights and proxies, as developed in accordance with the methodology described above.

Table 2.— ESRD Bundled Rate Market Basket (ESRDB) and ESRD Composite rate Market Basket (ESRDC) Cost Categories, Weights, and Price Proxies

Cost Category	Price/Wage Variable	ESRDB CY2003 Weights (Percent)	ESRDC CY1997 Weights (Percent)
Total Compensation			
Wages and Salaries	ECI- Health Care and Social Assistance (Civilian)	26.806	38.808
Employee Benefits	ECI- Benefits Health Care and Social Assistance (Civilian)	6.502	8.580
Professional Fees	ECI- Compensation Service Occupations (Priv.)	1.478	0.903
Utilities			
Electricity	PPI - Commercial Electric Power	0.552	0.818
Natural Gas	PPI - Commercial Natural Gas	0.089	0.113
Water and Sewerage	CPI - Water & Sewage	0.429	0.593
All Other			
Pharmaceuticals	PPI - Prescription Drugs	28.820	0.967
Blood Products	PPI – Blood and Hepatitis Vaccine	0.079	0.000
Supplies	PPI- medical, surgical, and personal aid devices	9.825	17.748
Laboratories	PPI- Medical Laboratories	3.868	0.433
Telephone	CPI - Telephone Services	0.430	0.875
Housekeeping and Operations	PPI-Building, cleaning, and maintenance	1.621	1.247
Administrative and Other Costs	PPI – Finished goods less food and energy	10.713	14.886
Capital Costs			
Capital Related-Building and Equipment	CPI-Residential Rent	6.243	9.071
Capital Related-Machinery	PPI-Electrical Machinery and Equipment	2.546	4.957

E. Price Proxies

Once we determined CY 2003 ESRD bundled rate market basket expenditure categories and weights, appropriate wage and price series or proxies were selected to measure the rate of price change for each category. All of the proxies are based on U.S. Department of Labor, Bureau of Labor Statistics (BLS) data, and are grouped into one of the following three BLS categories:

Producer Price Indexes (PPIs)—PPIs measure changes in the prices producers receive for their output. PPIs are the preferable price proxies for goods and services that ESRD facilities purchase as inputs in producing dialysis services, since these facilities

generally make purchases in the wholesale market. The PPIs use measure price change at the final stage of production.

Consumer Price Indexes (CPIs)—CPIs measure changes in the prices of final goods and services purchased by the typical consumer. Because these indexes may not reflect the prices faced by a producer, CPIs were used only if an appropriate PPI was not available, or if the expenditure more closely resembled a retail rather than wholesale purchase. For example, the CPI was used for telephone services as a proxy for the telephone cost category because there is no corresponding PPI, and based on reasoning that commercial and residential rates change similarly.

Employment Cost Indexes (ECIs)—ECIs measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. They are fixed weight indexes that strictly measure changes in wages and benefits per hour, and are not affected by shifts in employment mix.

Wages and Salaries

The *ECI (wages and salaries) for health care and social assistance workers (civilian)* was used as the measure of price growth for wages and salaries in the ESRD bundled rate market baskets. ESRD facilities compete with hospitals and other health care entities for a limited number of registered nurses (RNs) and other licensed staff. RNs, licensed practical nurses (LPNs), dietitians, social workers, and physicians represent approximately 40 percent of the ESRD facility occupational mix. According to cost report data, registered nurses account for about 25 percent of the occupational mix and technicians now make up a third of the occupational mix. According to the National Kidney Foundation, "the Patient Care Technician (PCT) is the primary direct care giver for patients undergoing dialysis treatments. They work closely with, and under the direct supervision of, registered nurses as an important member of the patient care team. Through primarily on the job training, a PCT must learn and understand the scientific principles of dialysis, the process of the dialysis treatment, and how to respond to the physical and emotional needs of people undergoing dialysis treatments." Therefore, a price proxy that more fully reflects these types of occupations would be preferred to one that reflects just economy-wide wages. We feel the ECI for health service workers reflects both the types of occupations employed by ESRD facilities, and the competitive nature of the dialysis and health services labor markets.

We researched the possibility of using occupation-specific wage proxies with the occupational distribution for ESRD facilities. However, detailed occupation-specific wage proxies, such as for RNs or technicians are not available through the two major wage surveys produced and published regularly by BLS (Average Hourly Earnings and the Employment Cost Index). Only surveys that are available annually and are not intended for time-series use have this information. We also researched aggregating ESRD occupations into general occupational groupings, such as professional and technical, and matching them with available aggregate occupational price proxies. Our analysis of the ESRD occupational weights from the Medicare cost reports suggested that a significant portion of ESRD occupations (about 80 percent) fall into the health care practitioner or support occupations. There are currently four ECI series published by the BLS for the health care sector: Health care and social assistance, Hospitals, Nursing and

residential care facilities, and Nursing care facilities. Based on the available data sources, we believe that the ECI for health care and social assistance workers would be the best available option to capture the wage pressures faced by ESRD facilities. It also best captures the wage pressures of health occupations caused by the tight labor market for specific occupations facing shortages (such as nurses) and the strong demand for health care services over the past few years. Based on this, we believe the ECI for health care and social assistance is the most appropriate price proxy for wages and salaries in the ESRD bundled rate market basket.

Benefits

We use the *ECI for employee benefits for health care and social assistance workers (civilian)* as the proxy for Employee Benefits. We selected the ECI for health service workers because it most accurately represents the labor conditions associated with ESRD facilities' employee benefit costs, similar to our finding for wages and salaries.

Professional Fees

We use the *ECI for wages and salaries of service occupations (private)* as the proxy for professional fees. This ECI was selected because it includes occupations such as lawyers, accountants, and bookkeepers that are represented in this cost category. We also considered using the ECI for wages and salaries of professional, scientific, and technical workers (private); however, we felt the occupational mix of the ECI for service occupations better represented the occupational mix in this category for ESRD facilities. Table 4 displays the average increases in wages and salaries for the two series we considered.

Table 3. Employment Cost Index Comparison of Wages and Salaries of service occupations and professional, scientific and technical workers, annual percent changes, 2001-2005

	2001	2002	2003	2004	2005	Average
ECI - Service occupations	3.4	2.9	2.3	2.0	2.2	2.6
ECI - Professional, Scientific, & Technical	3.3	1.5	2.0	3.8	1.7	2.5

Utilities

We use the *PPIs for commercial electric power* and *commercial natural gas* as the proxies for the electricity and natural gas cost centers, respectively. We use the *CPI for water and sewage* as the price proxy for the water and sewerage cost center. These are the same proxies used for these cost components in the market baskets for hospitals and skilled nursing facilities produced by CMS.

Capital-Related – Building and Equipment

We use the *CPI for residential rent* as the price proxy for the building, fixtures, and moveable equipment cost category. As described earlier, this cost category includes building and fixtures, leased buildings, fixed equipment, and moveable equipment. Because machine equipment, particularly dialysis machines, is reflected in a separate cost category, the bulk of the expenditures captured here are for building and fixed equipment. Thus, it would be preferable to have a proxy that captures the price change associated with this type of capital expense. While there can often be significant differences in the price levels for residential and commercial rent, the CPI for residential rent likely approximates the change in the underlying costs associated with ESRD facilities' capital costs such as depreciation, interest, taxes, and other capital costs. Given the lack of an ESRD-specific proxy for capital costs or an appropriate commercial rent proxy, we reason the CPI for residential rent will adequately proxy the change in capital costs facing ESRD facilities.

Capital-Related – Machinery

We use the *PPI for Electrical Machinery and Equipment* as the price proxy for the machine equipment cost category. This PPI includes dialysis machines, which appear to be a significant component of machine equipment costs reported by ESRD facilities. We evaluated two additional detailed PPIs as potential price proxies for this category*: X-ray and electromedical equipment* and *miscellaneous electrical machinery and equipment.* While both of these detailed indexes contain dialysis machines, they are less reliably published (more likely to have series breaks or be terminated) and more volatile than the *PPI for electrical machinery and equipment.* Over time, however, the *PPI for electrical machinery and equipment* has moved similarly to these more detailed indexes. Based on this analysis we believe that the *PPI for electrical machinery and equipment* is the most appropriate proxy for this cost category.

Pharmaceuticals

ESRD facilities use a variety of drugs during dialysis treatment with Epoetin alpha (EPO) – currently a separately billable drug – accounting for the majority of ESRD facility drug expenses. CMS pays for erythropoietic agents to treat chronic anemia in ESRD patients. At present, Epogen and Aranesp (both manufactured by a single supplier) are the only erythropoietic drugs available to treat anemia in ESRD patients. Medicare is the dominant purchaser of EPO since it is mainly used to treat kidney dialysis patients.

For the bundled rate market basket, we have considered using the *PPI for prescription drugs* as the price proxy for the pharmaceuticals category. This is the same proxy used for pharmaceuticals in other CMS market baskets and reflects the price change associated with the average mix of pharmaceuticals used economy-wide. This price series was considered to proxy the cost category for pharmaceuticals for a variety of reasons. First, it is a publicly available, regularly-published price index. Second, although not ESRD-specific, we anticipate the price change associated with the assortment of drugs

administered in ESRD facilities (including EPO) would be similar to the average prescription drug price change across the entire economy.

Although we believe that the PPI for prescription drugs is the best available price proxy for drugs in ESRD facilities, as Medicare is the dominant payer for these drugs, we are mindful that the selection of any price proxy will likely influence the overall market price for these drugs. Due to the unique circumstances associated with EPO (and the changes in ESRD prescription drug utilization that may occur as a result of including separately billable drugs in the ESRD bundled rate market basket), unless an alternative were used to reflect changes in pricing of ESRD drugs, one approach would be to rebase the bundled rate periodically. A rebasing could occur, for example, to adjust downward the market basket for the reported excessive use of EPO in recent periods if data showed this to be the case.

Blood Products

We use the *PPI for blood and derivatives, human use* as the price proxy for the blood products category. The only other option available to proxy this cost category was the higher level *PPI for biological products which* includes more detailed PPIs for blood, vaccines, other biologics, biologics for veterinary use, primary products, and secondary products. Since we only include the costs for blood and exclude other biological products like vaccines, we feel the most appropriate index to use is the *PPI for blood products, human use*.

Supplies

We use the change in the commodity-based, *PPI for medical, surgical, and personal aid devices* as a proxy for changes in ESRD supply prices. Many of the supplies used in dialysis are included in this PPI, such as dialyzers, catheters, I.V. equipment, syringes, and other general medical supplies used in dialysis treatment.

Laboratories

We use the *PPI for medical laboratories* as the price proxy for the ESRD laboratories cost category. Most of the laboratory tests used in dialysis are blood chemistry tests (a covered component of the medical laboratories PPI). Additionally, some ESRD facilities are using diagnostic imaging services to monitor patient site access, and the points where waste exchange takes place (also a covered component of the medical laboratories PPI).

Telephone

We use the *CPI for telephone services* as the price proxy for the telephone cost category. Although businesses often pay substantially different rates for telephone services than do individuals, the lack of a PPI for telephone services necessitates the use of the CPI. The price levels for telephone services faced by business and individuals are expected to vary; however, we would expect the change in price over time to be similar, as they reflect

similar underlying cost pressures. Furthermore, this index is used as the price proxy for telephone services in other market baskets produced by CMS.

Housekeeping and Operations

We use the *PPI for Building Cleaning and Maintenance Services* as the price proxy for the building services and operations cost category. This PPI includes housekeeping, janitorial, and maintenance (excluding repairs) services, and is representative of the types of costs included in this cost category.

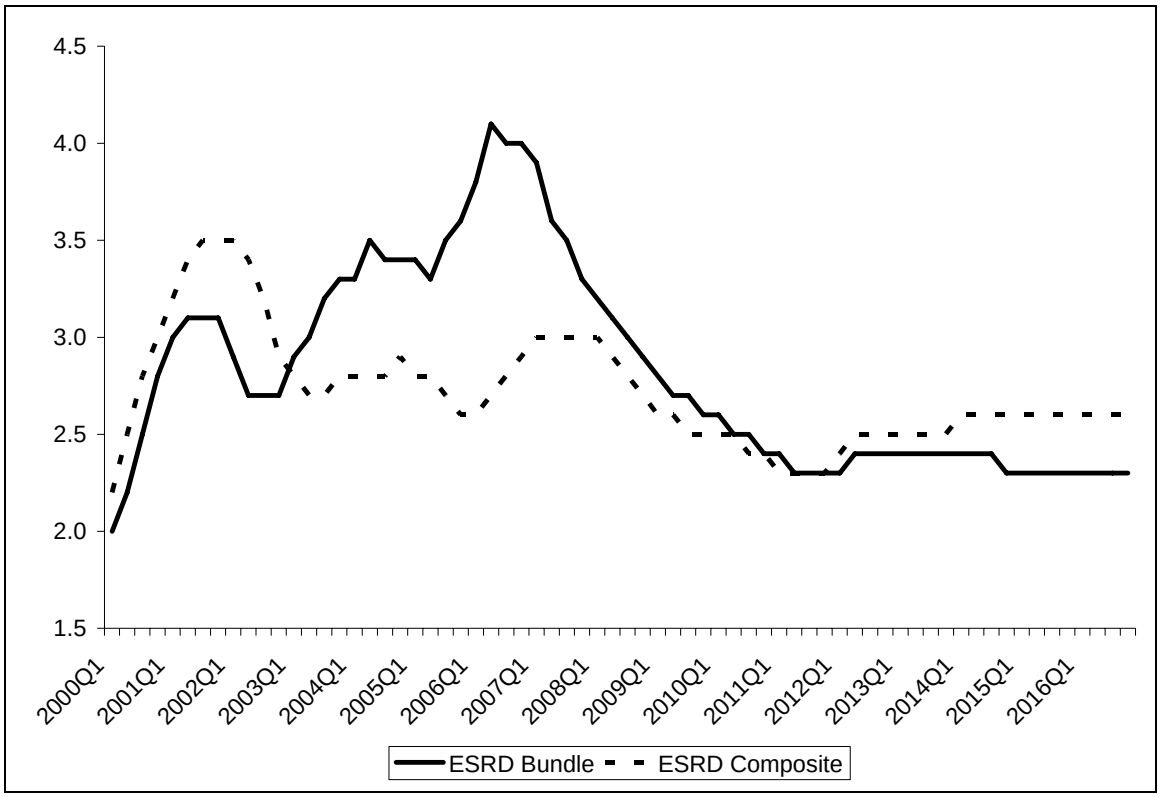
Administrative and Other

We use the *PPI for Finished Goods Less Food and Energy* as the price proxy for the administrative and other cost category. This category includes costs such as data processing, purchasing, taxes, home office costs, and malpractice costs. The costs represented in this category are diverse and are primarily associated with the purchase of services. These costs are best represented by a general measure of inflation such as the *PPI less food and energy*. Food and energy are excluded from the index to remove the volatility associated with both indexes, which would not be appropriate for a general measure of inflation. Additionally, energy prices are already captured in the utility price proxies.

E. ESRD Bundled Rate Market Basket Increases

The ESRD bundled rate market baskets reflect the combination of the weights and proxies discussed above. Figure 1 below compares the four quarter moving average percent change for the ESRD bundled rate market basket (ESRDB) and the ESRD composite rate market basket from the previous Report to Congress (ESRDC) for 2000-2016. Over the historical period (2000:1 through 2006:2) the ESRDB market basket average increase was 3.1 percent while the ESRDC market basket average increase was 2.9 percent.

Figure 1. --ESRD Bundled Rate Market Basket and the ESRD Composite rate Market Basket; 4-Quarter Moving Average Percent Changes



Source: 2006 3rd Quarter Forecast from Global Insights/DRI-WEFA

Table 4: Comparison of the 2003-Based ESRD Bundled Rate Market basket and the 1997-based ESRD Composite rate Market Basket, Percent Change, 2005-2016

CY beginning Jan. 1st	ESRDB	ESRDC
Historical CY2005	3.6	2.6
CY2006	4.0	2.9
CY2007	3.3	3.0
CY2008	2.9	2.7
CY2009	2.6	2.5
CY2010	2.4	2.4
CY2011	2.3	2.3
CY2012	2.4	2.5
CY2013	2.4	2.5
CY2014	2.3	2.6
CY2015	2.3	2.6
CY2016	2.3	2.6

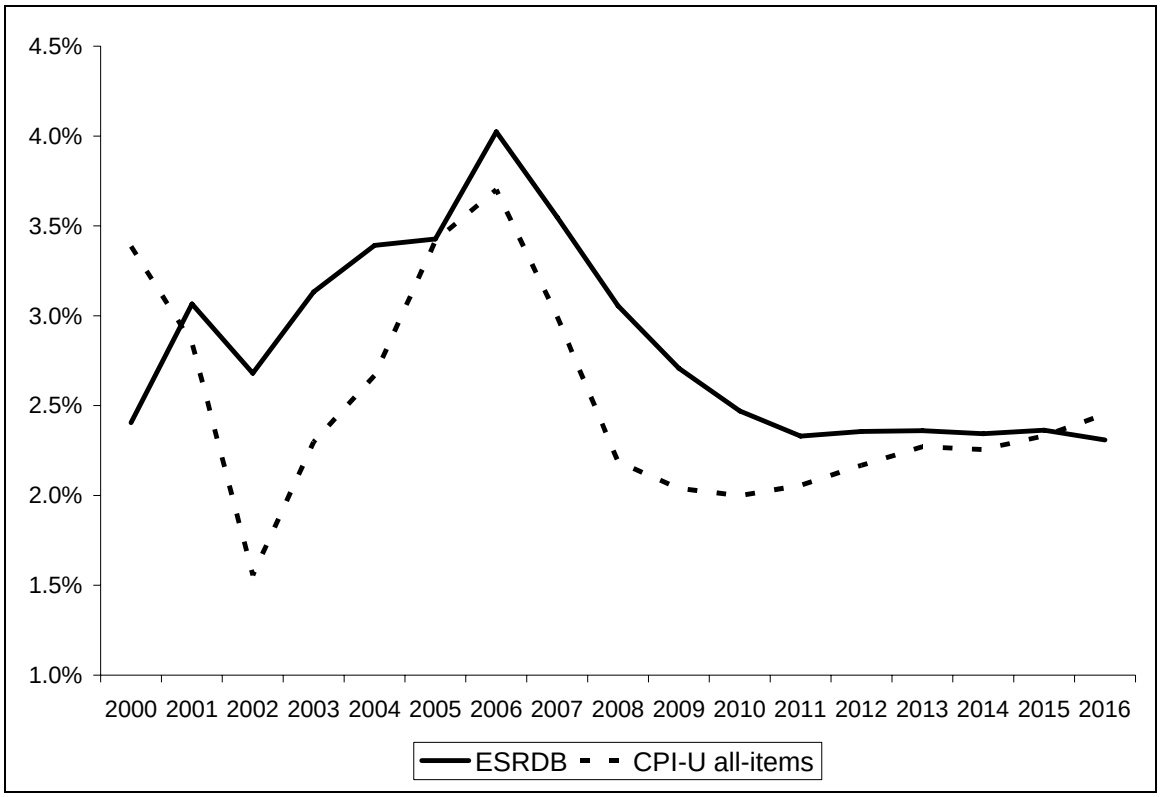
Source: 2006 3rd Quarter Forecast from Global Insights/DRI-WEFA

Table 4 shows that the forecasted rate of growth for CY 2005 through CY 2016 for the ESRD bundled rate and ESRD composite rate market baskets. The changes in the ESRDB market basket are higher than the ESRDC market basket from 2003 through

2010 mainly because the forecasted price for pharmaceuticals is projected to grow at a faster rate than most of the other market basket components until around 2011. After 2011, the trend reverses and the compensation categories are forecasted to grow at a slightly faster rate than the pharmaceutical components. The reason the two series converge in the later years of the forecast is mainly due to the leveling off of pharmaceutical prices to a rate that is slightly slower than the inflation in wages and benefits. These two cost components; compensation and pharmaceuticals, account for approximately 62 percent of the bundled market basket weight and 48 percent of the composite market basket weight.

Figure 2 below shows the historical and projected increases in the ESRDB market basket for 2000-2016 compared to the BLS CPI-U All Items for the same period.

Figure 2. --ESRD Bundled Rate Market Basket and the Consumer Price Index-All Urban Consumers (CPI-U; Annual Percent Changes (CY 2000-2016)



Source: 2006 3rd Quarter Forecast from Global Insights/DRI-WEFA

Over the historical period (2000-2005), the ESRDB market basket average increase was 3.0 percent while the CPI-U average increase was 2.7 percent. The forecasted ESRDB market basket increases follow a similar trend to the forecasted CPI increases yet are increasing approximately 0.3 percent faster than the CPI-U All Items.

The variation in the CPI-U in 2002 is due to low inflation for apparel and transportation service. Similarly in 2005 – 2006 periods the relatively high inflation is due to transportation service prices, particularly with respect to the volatility of motor fuel prices. This volatility is not observed in the either ESRD market basket because there is not a significant cost for motor fuels.

Table 5: CY 2007 Forecasted Annual Percent Changes for All Cost Categories in the Proposed 2003-Based ESRD Bundled Market Basket

Cost Categories	Price Proxy	Weight ESRDB	CY2007 Percent Change ESRDB
Total		100.00	3.3
Compensation		33.308	3.5
Wages and Salaries	ECI- Health Care and Social Assistance (Civilian)	26.806	3.4
Employee Benefits	ECI- Benefits Health Care and Social Assistance (Civilian)	6.502	3.7
Professional Fees	ECI- Compensation Service Occupations (Private)	1.478	3.0
Utilities		1.070	6.5
Electricity	PPI - Commercial Electric Power	0.552	4.4
Natural Gas	PPI - Commercial Natural Gas	0.089	23.9
Water and Sewerage	CPI – Water & Sewage	0.429	4.7
All Other		55.356	3.3
Pharmaceuticals	PPI - Prescription Drugs	28.820	4.0
Blood Products	PPI – Blood and derivatives, human use	0.079	9.4
Supplies	PPI- medical, surgical, and personal aid devices	9.825	2.3
Laboratories	PPI- Medical Laboratories	3.868	1.6
Telephone	CPI - Telephone Services	0.430	1.3
Housekeeping and Operations	PPI-Building, cleaning, and maintenance	1.621	1.7
Administrative and Other Costs	PPI – Finished goods less food and energy	10.713	2.7
Capital Costs		8.789	2.6
Capital Related-Building and Equipment	CPI-Residential Rent	6.243	3.4
Capital Related-Machinery	PPI-Electrical Machinery and Equipment	2.546	0.2

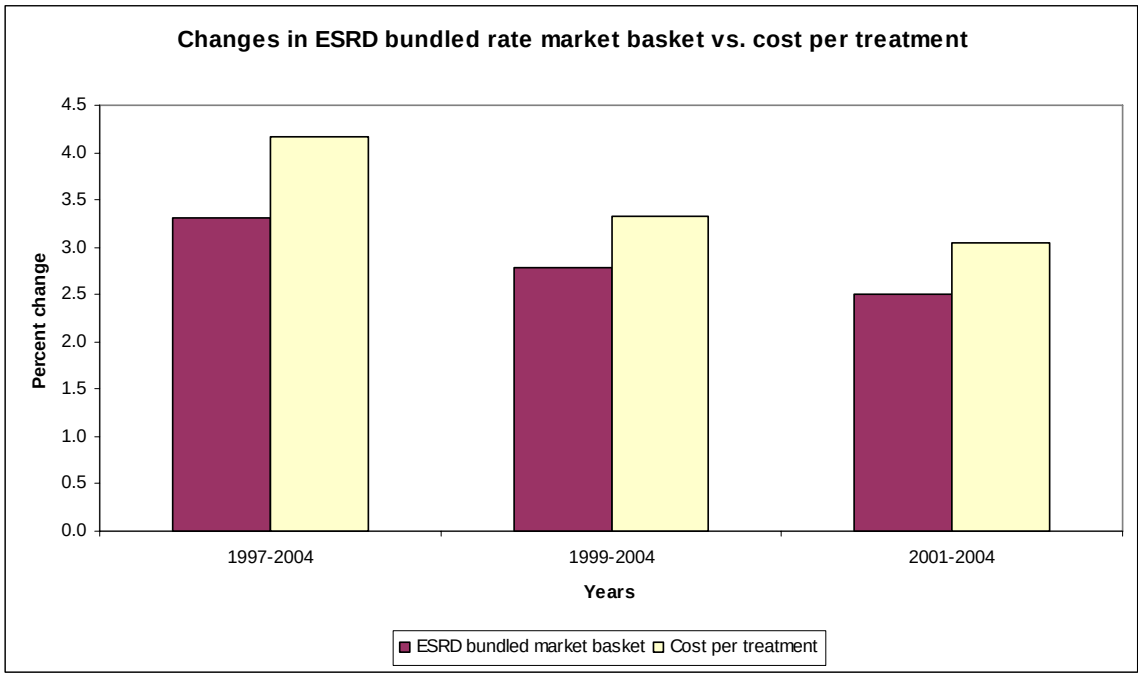
Source: Global Insights, Inc, 3rd Qtr, 2006;

Table 5 lists the ESRDB cost category weights and the CY07 price proxy growth associated with each of the cost categories. Natural gas and blood product prices have grown the fastest over the year; however, since the weight for both of these cost categories is relatively low the effect on the aggregate index is not large. Pharmaceutical and wages and salary prices are forecasted to rise 4.0 and 3.4 percent respectively in CY2007. The two cost categories are the primary drivers of overall input cost pressures for ESRD providers.

F. Cost Per Treatment Analysis/Non-Market Basket Factors

In addition to comparing the change in the ESRDB market basket to the change in the CPI-U, we have performed a preliminary comparison of the change in the ESRDB market basket to the change in the ESRD bundled rate cost per treatment. The chart below shows average annual percent changes in these two measures over recent periods.

Figure 3. – Changes in the ESRDB Market Basket and Changes in Cost per Treatment, Selected Time Periods



The chart demonstrates that during the past ten years, cost per treatment for services included in the ESRD bundled rate has consistently grown faster than the ESRDB market basket. This indicates that non-market factors (such as changes in intensity and productivity improvements) may need to be taken into account when determining an update factor for ESRD bundled rate services.

It is important to consider and understand the concept of productivity when examining the relationship between input and output price growth. Generally speaking, if firms within a given industry are generating positive productivity gains, they are able to produce constant or increasing outputs with fewer inputs. Consequently, in competitive markets where productivity gains are achieved (and holding profit margins constant), output prices would be expected to grow less fast than input prices. Conversely, if productivity changes are negative, that is, more inputs are required to produce a constant level of outputs, the expected result would be output price growth that more significantly exceeds input price growth.

In their March, 2007 report, the Medicare Payment Advisory Commission (MedPAC) stated that providers of Medicare services should be able to, by a modest amount each year, reduce the quantity of inputs required to produce a unit of service while maintaining quality (unless evidence suggests that this goal is unattainable systematically across a sector for reasons outside the industry's control). To that end, MedPAC has proposed that beginning in 2008, Medicare provider payment updates should be adjusted by the 10-year moving average of the Bureau of Labor Statistics' measure of non-farm business sector multifactor productivity. Presently, that estimate is equal to 1.3 percent.

G. ESRD Labor-Related Share

The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share is typically the sum of wages and salaries, fringe benefits, professional fees, labor-intensive services, and a portion of the capital share from an appropriate market basket.

We used the 2003-based ESRD bundled rate market basket costs to determine the labor-related share for ESRD facilities under a bundled system. Under the bundled rate market basket (ESRDB), the labor-related share for ESRD facilities is 39.278, and under the composite rate market basket (ESRDC), the labor-related share is 53.711, as shown in Table 4 below. These figures represent the sum of wages and salaries, employee benefits, professional fees, housekeeping and operations, and 46 percent of the weight for capital-related building and equipment expenses (the portion of capital that we have determined to be influenced by local labor markets). The drop in the labor-related share is primarily a function of the inclusion of nonlabor-related cost categories, such as prescription drugs, into the market basket.

Table 6 – ESRD Bundled Rate Market Baskets Labor-Related Share

Cost Category	2003-based ESRD Bundled Rate Labor Share (Percent)	1997-based ESRDC Rate Labor Share (Percent)
Wages and salaries	26.806%	38.808%
Employee benefits	6.502%	8.580%
Professional fees	1.478%	0.903%
Housekeeping and operations	1.621%	1.247%
SUBTOTAL	36.406	49.538
Labor-related share of capital-related building & equipment	2.872	4.173
TOTAL	39.278	53.711

The labor-related share for capital-related expenses (46 percent of ESRD facilities' adjusted capital-related building and equipment expenses) reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local area wages. Capital-related expenses are affected in some proportion by local area labor costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local area wage costs, such as interest rates. Thus, it is appropriate that capital-related expenses would vary less with local wages than would operating expenses for ESRD facilities. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

H. Conclusions

As directed by section 623(f) of the MMA, we have constructed a potential ESRD bundled rate market basket that includes all separately billable drugs (except vaccines), laboratory tests, and supplies. The all-inclusive market basket has the benefit of encompassing all Medicare-allowable ESRD services into a single PPS system that can be updated on an annual basis. We have compared the ESRD bundled rate market basket with the 1997-based ESRD composite rate market basket.

It is important to note the relative disadvantage of the bundled rate market basket. Most importantly, the all-inclusive market basket could be subject to criticism regarding the use of an aggregate pharmaceutical index to proxy changes in a drug provided by a monopoly supplier.

We hope this report provides information for Congress as it continues to discuss more efficient methods for payment to ESRD facilities.