

of total estimated payments that would have been made under the current basic case-mix adjusted payment system) to the total estimated payments under the transition, or 3.0 percent. For 2011, application of this factor would result in a 3.0 percent reduction in all payments to ESRD facilities. We propose to apply this adjustment to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS. We propose to calculate similar factors for CYs 2012 and 2013 that would allow a blended payment system to be budget neutral to a fully implemented 100 percent ESRD PPS.

We invite comments on the calculation and application of the proposed two part transition budget neutrality adjustment factor.

## **VIII. Cost Regression Used to Develop Proposed Payment Adjustment Factors**

### **A. Proposed Regression Analysis**

#### **1. Dependent Variables**

The proposed two-equation regression approach used to develop the proposed ESRD PPS includes a facility-based regression model for composite rate service, 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 explained below.

a. Average Cost per Treatment for Composite Rate Services

We measured resource use for the maintenance dialysis services included in the current bundle of composite rate services using ESRD facility data obtained from the Medicare cost reports for hospital-based ESRD providers and independent ESRD facilities. The average composite rate cost per treatment for each ESRD facility was calculated by dividing the total reported allowable costs for composite rate services for CYs 2004, 2005, and 2006 (Worksheet B, column 11, rows 7-16 on CMS 265-94; Worksheet I-2, column 11, rows 2-11 on CMS 2552-96) by the total number of dialysis treatments and Worksheet C, column 1, rows 1-10 on CMS 265-94; Worksheet I-4, column 1, rows 1-10 on CMS 2552-96). Continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) patient weeks were multiplied by 3 to obtain the number of hemodialysis equivalent treatments. We point out that our computation of the total composite rate costs included in this per treatment calculation includes costs incurred for training expenses, as well as all costs incurred by ESRD facilities for home dialysis patients. 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 CY 2009 ESRD wage index and the estimated labor-related share of costs from the composite rate market basket. The description of that labor-related share was contained in the Secretary's 2008 Report to Congress. That is, 53.711 percent of each ESRD facility's composite rate cost per treatment was divided by the ESRD wage index to control for area wage differences. No floor or ceiling was imposed on the wage index values used to deflate the composite rate costs per treatment. We applied a natural log transformation to the wage-deflated composite rate costs per treatment to better satisfy the statistical assumptions of the regression model, and to be consistent with existing methods of adjusting for case-mix, in which a multiplicative payment adjuster is applied for each case-mix variable. As with other health care cost data, there was skewness in the cost distribution for composite rate services in which a relatively small fraction of observations account for a disproportionate fraction of costs. Cost per treatment values which were determined to be unusually high or low in accordance with predetermined statistical criteria were excluded from further analysis. (For an explanation of the statistical methodology used to identify outlier composite rate costs

per treatment, see pp 45-48 of UM-KECC's February 2008 report.)

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

Resource use for separately billable dialysis related services was measured at the patient level using the payment data on the Medicare claims for CYs 2004-2006. This time period corresponded to the most recent 3 years of Medicare cost report data that were available to measure resource use for composite rate services. Measures of resource use included the following separately billable services: injectable drugs billed by ESRD facilities , including ESAs; oral forms of ESAs and other oral drugs used to treat ESRD payable under Medicare part D; laboratory services provided to ESRD patients, billed by freestanding laboratory suppliers and ordered by physicians who receive monthly capitation payments for treating ESRD patients, or billed by ESRD facilities ; other services billed by ESRD facilities , including support services for Method II home patients; medical equipment and supplies for Method II home patients billed by durable medical equipment suppliers.

We obtained Medicare claims data for separately billable services for CYs 2004-2006 for patient months in

which outpatient dialysis was provided and Medicare was the primary payer. For oral drugs (formerly) covered under Medicare part D, we used CY 2007 claims data for ESRD beneficiaries with Medicare part D coverage. Measures of resource use were based on MAPs, which were calculated using the payment data on the claims. Currently, the only payment data available for Part D claims are for CYs 2006 and 2007. However, these data were not available in sufficient time to be included in the development of the proposed separately billable case-mix adjusters, given the lead time necessary for the preparation of the proposed rule. We expect that additional Part D claims data will be available for the preparation of the final rule.

Therefore, we intend to include appropriate available payment data from Part D claims for CYs 2006 through 2008 in our development of the regression based case-mix adjusters for the overall payment model, and will address their inclusion in the final rule. Payments for Part D drugs were included in the proposed ESRD base rate, which relied on claims for CY 2007. See section VII.A.7.

Medicare payments were inflated by a factor of 1.25 for services that have a 20 percent patient coinsurance (for example, most injectable drugs) to yield the MAP. For laboratory tests that have no patient coinsurance

obligation, the Medicare payment is identical to the MAP. As required under section 1881(b)(14)(B) of the Act, as added by section 153(b)(1) of MIPPA, vaccines are excluded from the ESRD PPS and therefore, were excluded from the computation of separately billable drugs. The MAP amounts do not include the annual part B payment deductible, which may apply to separately billable services because we were unable to determine whether the deductible amount was incurred in connection with another part B service. We point out that the part B payment deductible can apply in connection with any part B service, not just outpatient dialysis related services.

For the case-mix analyses, MAP values based on CY 2004 through 2006 claims were adjusted to approximate drug payments for the current year. In CY 2007 the top 11 separately billed Part B drugs accounted for approximately 99.8 percent of drug expenditures for Medicare ESRD beneficiaries. We repriced the MAPs for these drugs in 2004, 2005, and 2006 by using a ratio. That ratio was obtained by dividing the Medicare payment rate in the first quarter of 2008 by the Medicare payment rate in 2004, 2005, and 2006. This repricing was done for the following injectable drugs: epoetin alfa, darbepoetin alfa (ARANESP®), iron dextran, iron sucrose, sodium ferric

gluconate, calcitriol, doxercalciferol, paracalcitol, levocarnitine, alteplase recombinant, and vancomycin. (Although iron dextran was among the top 11 drugs in CYs 2004-2006, it was superseded by daptomycin in CY 2007.) The resulting MAP closely reflects the current prices based on Medicare reimbursement rates. The ratios used to adjust the MAPs for the 11 specified injectable drugs are shown in Table 11.

**Table 11**  
**Payment ratios used to reprice Medicare Allowable Payments (MAP) for 11 separately billable injectable drugs**

Injectable drug	Ratios by year/quarter					
	2004	2005	2006, Quarter 1	2006, Quarter 2	2006, Quarter 3	2006, Quarter 4
Epoetin alfa	0.8963	0.9183	0.9366	0.9603	0.9456	0.9489
Darbepoetin alfa	0.6101	**	0.9675	0.9535	0.9557	0.9669
Iron dextran*	0.6488	1.0622	1.0333	1.0242	1.0545	1.0489
Iron sucrose	0.5530	0.9865	1.0224	1.0111	0.9973	1.0055
Sodium ferric gluconate complex	0.5934	0.9794	0.9902	0.9589	1.0208	1.0073
Calcitriol	0.2406	0.3458	0.4709	0.7186	0.6548	0.6324
Doxercalciferol	0.4367	0.9238	0.8946	0.7584	0.7604	0.8355
Paricalcitol	0.7135	0.9508	0.9984	1.0018	0.9982	0.9976
Levocarnitine	0.1677	0.4208	0.5633	0.7135	0.5782	0.5484
Alteplase, recombinant	0.9366	1.0829	1.0944	1.0969	1.0853	1.0717
Vancomycin HCl	0.4909	1.1581	1.1064	1.0655	1.0674	1.0314

\*Starting in 2006, the repricing ratio for this drug was determined using the average payment rate for the two forms of iron dextran that could be billed.

\*\*Due to quarterly price changes for darbepoetin alfa during 2005, a different repricing ratio was used for each quarter: 0.8160, 0.8970, 0.9454, and 0.9602 for Quarters 1, 2, 3, and 4 of 2005, respectively.

The adjusted MAP values were standardized to reflect the number of Medicare outpatient dialysis treatments reported on the claims. This approach is consistent with the unit of payment under the current composite payment system. For patients who received PD during the month, the number of PD days reported on the claims was multiplied by 3/7 to obtain the number of HD-equivalent treatments. For example, 7 PD days were converted to 3 treatments since hemodialysis is typically performed 3 times per week. Monthly treatments reported on the claims were capped at 20 treatments in excess of this number were considered implausible. 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. The ratio of the adjusted MAP values for separately billable services divided by the total number of treatments was used to calculate the average adjusted MAP per treatment. As with the analysis of composite rate services, we applied a natural log transformation to the values of the separately billable MAPs per treatment, with statistical outlier values excluded from further analysis employing the same criteria used to identify aberrant composite rate costs.

## 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 payment 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 represent characteristics of ESRD facilities such as size, type of ownership, facility type (whether hospital-based or independent), etc., were specifically included to obtain more accurate estimates of the payment impact of the potential payment variables in each equation. Control variables were excluded from consideration as actual payment adjusters because they represent facility characteristics rather than patient characteristics. In the absence of using control variables in each regression equation, the relationship between the payment variables and measures of resource use may be biased.

a. Control Variables

Seven control variables were included in the regression analysis. They were: (1) renal dialysis facility type (hospital-based versus independent facility); (2) facility size (<3,000 for less than three years, 3,000 to 5,000, 5,000-10,000, and > 10,000 dialysis treatments);

(3) type of ownership (independent, large dialysis organization, regional chain, unknown);

(4) whether the ESRD facility received a composite rate payment exception between November 1993 and July 2001;

(5) adequacy of dialysis, based on the percentage of patients having a urea reduction ratio (URR) < 65 percent;

(6) rural versus urban location; and (7) calendar year. Calendar years 2004, 2005, and 2006 were included as a control variable in analyses that pooled three years of data.

b. Proposed Case-Mix Adjustment Variables

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix, but gives the Secretary broad discretion with regard to the selection of patient-specific measures which would comprise the case-mix adjusters. As part of our case-mix analysis, we identified the same patient demographic variables used in connection with the basic case-mix adjusters under the current composite payment system: age (five groups, excluding patients less than age 18), BSA, and low BMI (values less than 18.5 kg/m<sup>2</sup>). BSA was calculated as a function of height (H, in centimeters) and weight (W, in kilograms) using the following formula:

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

BMI values below  $18.5 \text{ kg/m}^2$  were used to identify patients who were underweight. BSA and low BMI are currently used as part of the basic case-mix adjustment for the composite payment system.

The same set of independent variables was included in both the composite rate and separately billable regression equations. To define the independent variables for each equation, however, it was necessary to link patient and facility-level data. For example, measures for patient characteristics (for example, female gender) were included as potential payment variables in the facility level composite rate equation, while measures for facility characteristics (for example, hospital-based or independent facility) were included as control variables in the patient level separately billable equation. For the composite rate equation, we defined case-mix measures using data for all Medicare dialysis patients treated in each facility. Specifically, we determined the percentage of a facility's patients having each patient characteristic. For example, patient's sex was measured as the percentage of patients that were female. For the equation of the separately billable MAPs, we defined measures for facility characteristics using data for all facilities that treated each Medicare dialysis patient.

These patient and facility control variables were weighted 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 treatments. For example, in defining facility-level case-mix measures, the characteristics of patients who were treated at the dialysis facility for twelve full months (for example, with 13 treatments each month), were given twelve times as much weight as the characteristics of patients who were treated at the facility for only one month (for example, with 13 treatments). Similarly, to define patient-level measures for the 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 (for example, percent female and average BSA among patients in each facility). This was the same approach used to define the basic case-mix measures under the composite payment system. The resulting facility variables were included as control variables in the separately billable equation (for example, percent of a patient's treatment furnished in a hospital-based

facility). In the sections that follow, we describe how we considered and evaluated independent variables for use as potential case-mix adjusters in the proposed ESRD PPS to determine their relationship to composite rate costs and separately billable payments.

## B. Proposed Patient-Level Adjustments

The following are the patient level adjustments we considered for the proposed ESRD PPS. The patient level adjustments that we are proposing are set forth at proposed §413.235.

### 1. Patient Age

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's age. Consequently, we analyzed age as part of the regression analysis and found that age is a strong predictor of variation in payments for ESRD patients. In addition, age is an objective measure and data on age are readily available.

As discussed previously in section I.B.3., the basic case-mix adjusted composite payment system currently in effect includes payment adjustments for age. As shown in Table 12 below, there are five age groupings and payment adjustment factors that describe the distribution of the patient population: