

February 2008 report, End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle (see pp. 38-44 and Technical Appendix C).

II. Development of ESRD PPS Base Rate

The patient-specific case-mix adjustments developed from the two-equation regression model for composite rate and separately billable services, which we have described in section VIII. of this proposed rule, would be applied to a base payment rate per treatment ("base rate"). The base rate would also be adjusted to reflect ESRD facility differences in area wage levels using a proposed wage index as described in section VIII.C. In this section, we describe the calculation of the proposed ESRD base rate, as set forth in proposed §413.220, and the computation of the reduction factors used to adjust the base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act. The base rate presented in this proposed rule, and defined in proposed §413.171, was calculated entirely from CY 2007 Medicare claims data. The proposed base rate, which represents the average Medicare allowable payment (MAP) for composite rate and separately billable services, was developed from CY 2007 claims data. We used claims data for CY 2007 in connection with the

preparation of this proposed rule because such data were the latest available. We expect to have claims data for CY 2008 and partial claims information for CY 2009 in connection with our preparation of the final rule.

Comparing per treatment payment amounts developed from available claims data for CYs 2007, 2008, and 2009 would permit a determination as to which year resulted in the "lowest per patient utilization" of dialysis services as required in accordance with section 1881(b)(14)(A)(ii) of the Act. The components of the proposed base rate based on CY 2007 claims data and the methodology used to project the base rate to CY 2011 (the first year of the ESRD PPS), are described below.

A. Calculation of the CY 2007 Unadjusted Rate Per Treatment

Sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act, as added by MIPPA, specify the renal dialysis services, and other items and services, which must be included in the payment bundle of the ESRD PPS. Table 8 shows the payments for the various components which comprise the renal dialysis services which we propose to include in our development of the base rate using available CY 2007 claims data, in accordance with our interpretation of the statute. We first describe each of the components

of the ESRD PPS payment bundle included in the CY 2007 unadjusted rate per treatment. Thereafter, we describe the adjustments used to calculate the ESRD PPS base rate from the CY 2007 unadjusted rate per treatment.

Table 8
Medicare Allowable Payments (MAP) for composite rate and separately billable services, 2007

Description	Actual MAP for 2007, as reported on claims ¹
Total Medicare Allowable Payments by service category	
Outpatient dialysis and other composite rate services[^]	\$5,705,412,338
Dialysis support services[^]	\$1,447,484
Part B drugs and biologicals[^]	
Epogen*	\$1,846,771,009
Darbepoetin	\$167,776,951
Vitamin D	\$402,447,416
Calcitriol	\$3,116,590
Doxercalciferol	\$76,770,839
Paricalcitol	\$322,559,988
Iron	\$234,031,283
Iron Sucrose	\$165,992,904
NA Ferric Gluconate	\$68,038,379
Levocarnitine	\$5,025,914
Alteplase	\$26,682,197
Vancomycin	\$3,578,996
Daptomycin	\$1,234,405
Other injectables	\$7,467,546
Laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating ESRD patients^{**}	\$319,165,724
DME supplies and equipment	
DME supplies	\$15,039,695
DME equipment	\$3,358,535
Supplies and other services billed by dialysis facilities[^]	\$44,864,130
Part D drugs	\$455,683,740
Total Medicare Allowable Payments for Composite Rate (CR) and Separately Billable (SB) Services	\$9,239,987,362
Total Medicare Hemodialysis-equivalent sessions^{***}	36,523,791
Average Medicare Allowable Payment per Session for CR and SB services	\$252.99

¹Based on payment amounts reported on Medicare claims for 2007. Excludes facilities without a valid county code for determining the CBSA wage index and patients with an unknown birthdate.

[^]Billed by dialysis facilities.

*Monthly payments for EPO were capped to reflect no more than 30,000 units per session.

**Includes lab tests billed by dialysis facilities on outpatient institutional claims and lab tests ordered by physicians receiving monthly capitation payment (MCP) amounts and billed on carrier claims. Labs ordered by physicians receiving MCP amounts were determined using a list of MCP physicians from 2006. The estimates for total lab payments will be updated when the list of MCP physicians for 2007 is available.

***Hemodialysis-equivalent sessions were capped at 20 per patient per month and include both sessions reported on dialysis facility claims and an estimate for Method II patients. The estimated sessions for Method II patients were based on the average number of sessions per month reported for Method I peritoneal dialysis patients (12.5 in 2007).

1. Composite rate services

The first component of the ESRD PPS payment bundle shown in Table 8 is "Outpatient dialysis and other composite rate services". This line item refers to total CY 2007 payments for composite rate services as obtained from ESRD facility claims (bill type 72X claims). This total includes all composite rate payments to ESRD facilities, including exception payments made in accordance with §413.182 through §413.186. Claims from ESRD facilities that did not have a valid county code, such that the relevant CBSA-based wage index (see section VIII.C.) could not be determined, were excluded. In addition, claims for patients with a missing birth date, which is necessary in order to calculate the basic case-mix

adjustment under the composite payment system, were also excluded.

2. Dialysis support services

We computed a total amount for the next component of the ESRD PPS payment bundle shown in Table 8, "Dialysis support services". This total represents total payments for support services furnished to Method II home dialysis patients, and reported under subcategory 5 of revenue codes 082X through 085X on the type 72X claims.

3. Part B Drugs and Biologicals

The next component of the ESRD PPS bundle shown in Table 8 is "Part B drugs and biologicals". We found that total payments for the top 11 Part B drugs and biologicals reported on the type 72X claims, accounted for 99.7 percent of total spending for Part B drugs. Monthly payments for Epogen were capped to reflect no more than 30,000 units per treatment, as amounts in excess of this value were considered clinically implausible.

4. Laboratory tests

Another component of the ESRD PPS bundle shown in Table 8 is "Laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating ESRD patients". Payments for laboratory tests represent the total amount paid to

dialysis facilities for outpatient laboratory tests billed on the type 72X claims, as well as payments for laboratory tests ordered by physicians receiving MCP amounts and billed on carrier claims. We identified laboratory tests ordered by physicians receiving MCP using the list of physicians for CY 2006, which was the latest available list at the time of this proposed rule. The estimates for total laboratory payments will be updated using the list of CY 2007 MCP physicians in connection with the publication of the final rule.

5. DME supplies and equipment

"DME supplies and equipment" is another component of the ESRD PPS payment bundle. Payments for these items and services were obtained from the CMS 1500 claims for Method II home patients.

6. Supplies and other services billed by dialysis facilities

This category of the ESRD PPS payment bundle primarily includes payments for syringes used in the administration of intravenous drugs during the provision of outpatient dialysis. These supplies and services were billed by the dialysis facilities on the type 72X claims.

7. Former Part D drugs

This amount represents total payments on behalf of the ESRD beneficiaries with Part D coverage in CY 2007 for Part D drugs and biologicals which we consider furnished for the treatment of ESRD. These drugs and biologicals, which are identified by class below, were obtained from CY 2007 Part D claims submitted on behalf of the Medicare ESRD beneficiaries with valid type 72X claims in CY 2007 with Part D coverage, using the NDC codes for the following drugs and biologicals:

Vitamin D Analogues

**Calcitriol
Paracalcitol
Doxercalciferol**

Calcimimetic

Cinacalcet hydrochloride

Oral phosphate binder

**Lanthanum carbonate
Calcium acetate
Sevelamer hydrochloride
Sevelamer carbonate**

The NDC codes used to identify the above drugs and biologicals are shown in the Appendix in Table C.

The number of Medicare ESRD beneficiaries for which valid type 72X claims were filed in CY 2007, number of ESRD beneficiaries with Part D drug coverage, and number of beneficiaries with Part D claims for the specified drugs

and biologicals noted above, are shown in Table 9. CY 2006 data are also shown in Table 9 for comparison purposes.

Table 9
Medicare Dialysis Patients with Payments for Part D Drugs, 2006 and 2007

	2006		2007	
	Patients	%	Patients	%
ESRD patients with Medicare payments on outpatient dialysis facility claims *	324,836		328,841	
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs	207,035	63.74%	219,451	66.73%
ESRD patients with Medicare payments on outpatient dialysis facility claims and any payment for Part D drugs included in the ESRD PPS **	159,570	49.12%	175,132	53.26%

*Includes 'type 72X' outpatient institutional claims.

**Includes Vitamin D Analogs (Calcitriol, Paracalcitol, and Doxercalciferol), Calcimimetics (Cinacalcet Hydrochloride), and Oral Phosphate Binders (Lanthanum Carbonate, Calcium Acetate, Sevelamer Hydrochloride, and Sevelamer Carbonate).

The payment total for former Part D drugs includes payments by Medicare prescription drug plans, and all payments made by or on behalf of ESRD beneficiaries for the specified drugs. As noted in Table 9, the payment total for former Part D drugs only includes data for the 66.73 percent of ESRD beneficiaries who were enrolled in Part D. As a result, we do not have patient-specific information on the cost of drugs (part D equivalent drugs) for the remaining third of ESRD beneficiaries who do not have Part D coverage. To the extent these beneficiaries have drug coverage through their employer or other insurance, we do not have access to specific usage or payment information

for these medications. Nonetheless, when the ESRD PPS is implemented January 1, 2011, former Part D drugs would become renal dialysis services in accordance with section 1881(b)(14)(ii)(B) of the Act. As such, ESRD facilities would be responsible for providing ESRD-related oral drugs formerly covered under Part D to their patients.

We are considering use of a proxy to capture the costs associated with ESRD-related drugs for those patients without Part D coverage. One possible approach would be for us to include payments under the Retiree Drug Subsidy (RDS) program which is described below. We believe that as the RDS payments could be made for ESRD-related drugs under title XVIII of the Act, use of RDS data would be consistent with section 1881(b)(14)(A)(ii) which requires that in implementing the ESRD PPS, the Secretary must ensure that the estimated total amount of payments *under* this title for 2011 for renal dialysis services equals 98 percent of the estimated total amount of payments that would have been made under this title if the ESRD PPS were not implemented.

The RDS program was enacted in December 2003 by section 101 of the MMA. The program, which was effective January 1, 2006, was designed to support existing retiree benefit arrangements by providing subsidy payments to plan sponsors (that is, employers and unions). Subsidy payments

to qualifying drug plan sponsors (for example, employers, unions) equal 28 percent of each qualifying retiree's allowable costs for prescription drugs otherwise covered by Medicare Part D, that are attributable to such drug costs between an applicable cost threshold and cost limit. For plan years ending in 2007, the applicable cost threshold is \$265 and the cost limit is \$5350.

Based on CMS' Office of the Actuary's most recent CY 2007, we provided subsidy payments totaling \$3.8 billion on behalf of 7.0 million beneficiaries. Plans submit aggregate qualifying cost data and a list of eligible beneficiaries. We could determine the number of ESRD qualifying covered retirees under the RDS as a percentage of all qualifying covered retirees under RDS. We could further estimate the ESRD-related percentage of the \$3.8 billion in subsidy payments and add this amount to the estimated aggregate payments in 2007. We note that since we do not receive patient-specific information on drug usage under the RDS program, it would not be possible to capture the effect of these drugs on the patient and facility-level adjustment factors. We refer readers to 42 CFR §423.880 through §423.894 for more information on the RDS provisions. We invite public comment on this approach

and other possible approaches to enable us to capture drug payment information for all Medicare ESRD patients.

8. Total MAP

The total MAP amount represents the total payments made in CY 2007 for the composite rate and separately billable categories described above (that is, the sum of the payments for the items and services described in 1.through 7.) We propose to use the total MAP amount as the ESRD PPS base rate amount.

9. Total Medicare hemodialysis-equivalent sessions

In order to calculate the proposed ESRD PPS base rate per treatment, it was necessary to divide the total MAP amount described above by the number of Medicare HD-equivalent sessions. The number of Medicare HD-equivalent sessions represents the total Medicare treatments for outpatient dialysis as reported on the type 72X claims submitted by dialysis facilities. PD patient weeks were converted to HD-equivalent sessions. For this purpose one week of PD was considered equivalent to three HD treatments. Accordingly, a patient on PD for 21 days would have $(21/7) \times 3$ or 9 HD-equivalent sessions. In determining the total number of Medicare treatments, the number of HD-equivalent sessions were capped at 20 per patient per month. We propose to use the total number of

CY 2007 Medicare HD-equivalent dialysis sessions, 36,523,791, to calculate the ESRD PPS base rate.

10. Average MAP per treatment

We divided the total MAP in item 8, \$9,239,987,362, by the total Medicare hemodialysis-equivalent sessions in item 9, 36,523,791, to yield an unadjusted rate per treatment for renal dialysis services in CY 2007. This unadjusted rate per treatment is \$252.99. We propose to update this per treatment amount to reflect CY 2011 prices, and to standardize it to eliminate the effects of the case-mix and wage index adjustments in order to ensure duplicate payments do not occur under the ESRD PPS through the subsequent introduction of these variables in the payment formula. We also propose to further reduce the projected CY 2011 payment rate for estimated outlier payments, and the budget neutrality offset as set forth in sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. This is the proposed amount per treatment that would be multiplied under the ESRD PPS to reflect patient-specific differences in case-mix, and other adjustments as set forth in section 1881(b)(14)(D) of the Act. We refer to this projected CY 2011 payment rate, after application of the standardization, outlier, and budget neutrality offsets, as the ESRD PPS base rate. The

proposed definition of the base rate is set forth in proposed §413.171. Our proposed methodology for calculating the base rate to reflect the standardization, outlier, and budget neutrality reductions is explained in the sections that follow.

B. Determining the Update Factors for the Budget-Neutrality Calculation

In order to estimate payments under the current payment system for each facility in CY 2011, the first year of the ESRD PPS, the components of the CY 2007 unadjusted per treatment rate were updated to reflect estimated 2011 prices, using the methodology as described in greater detail below. It is necessary to estimate 2011 payments under the current ESRD payment system (including all separately billable items) for each facility in order to meet the statutory budget-neutrality requirement for the ESRD PPS. Section 1881(b)(14)(A)(ii) of the Act requires that the ESRD PPS payment system be 98 percent budget neutral in 2011. In other words, the estimated total amount of payments under the ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented.

Therefore, we must first estimate what ESRD facilities would have been paid under the current system in CY 2011, by updating the 2007 payments to reflect 2011 prices. We then divide the total estimated CY 2011 payments by the number of CY 2007 treatments to determine the CY 2011 average payment per treatment. We do not make adjustments for future changes in treatments as this would require us to make assumptions about patient specific characteristics. If we were to project CY 2011 treatments we would increase the current basic case-mix adjusted composite payments by the same amount. This would in effect have no impact on the calculation of the per treatment amount. This CY 2011 unadjusted per treatment payment amount becomes the basis for meeting the budget neutrality requirement. Below we describe the update factors used to estimate CY 2011 payments for each component.

1. Composite rate services.

In order to update the basic case-mix adjusted composite payments to 2011, we began with the CY 2009 base composite rate (\$133.81) and the CY 2009 drug add-on percentage of 15.2 percent. In accordance with section 153(a) of MIPPA and 1881(b)(14) of the Act, we updated the composite rate by 1.0 percent for CY 2010 and by the estimated ESRD bundled market basket percentage increase

minus 1 percentage point (1.5 percent) for CY 2011 resulting in a 2011 composite rate of \$137.18. A full description of the ESRD bundled (ESRDB) market basket is presented in section XII. of this proposed rule. We are proposing to use this base composite rate for CY 2011, which includes ESRD bundled market basket minus 1 percentage point, to update the CY 2010 composite rate for purposes of establishing the ESRD PPS base rate, given that we interpret section 1881(b)(14)(F)(ii) to require us to update the composite rate portion of the blend by the market basket percentage minus 1.0 percentage point in all years of the transition (which includes CY 2011). Therefore, using the market basket in this way would be a consistent approach. As described in section XII. of this preamble, we are proposing a market basket increase of 2.5 percent for CY 2011. Therefore, we are proposing a 1.5 percent update to the composite rate for CY 2011, resulting in a CY 2011 composite rate of \$137.18 ($\$135.15 * 1.015$). We note that the drug add-on percentage is reduced from 15.2 to 14.8 as a result of the increases to the composite rate in CYs 2010 and 2011. Since the drug add-on is calculated as percentage of the base composite rate, the drug add-on percentage decreases with increases in the composite rate. The CY 2009 Physician Fee Schedule final

rule provides details on why increases to the base composite rate require decreases to the drug add-on percentage to ensure that the total drug add-on dollar amount remains the same (73 FR 69755). We intend to update the drug add-on, if necessary, for the ESRD PPS final rule.

We used the applicable facility-level and patient-level basic case-mix adjustments from the CY 2007 claims to re-compute payment using the applicable basic case-mix adjustments applied to a 100 percent CBSA wage-adjusted composite rate using the most recently available ESRD wage index, which is the CY 2009 final rule ESRD wage index with a 0.60 floor. We did this to use the most recent wage indexes available in estimating 2011 payments. The other components of the bundle, which are discussed below do not have payments which are computed with wage indexes. We used a 0.60 floor because we anticipate that floor will be in effect in CY 2011. We have been reducing the wage index floor by .05 every year and we expect to continue this policy. (More information on CBSAs and the wage index floor is presented in section VIII.C.1 of this proposed rule).

In addition, payment rates to facilities that have chosen to retain their exceptions under the basic case-mix composite payment system are not updated because, once

approved, the exception amounts were fixed payment amounts, and hence the 2007 amounts represent the 2011 amounts. See the CY 2005 PFS final rule for a discussion regarding the application of statutory increases to exception amounts (69 FR 66332).

2. Self-Dialysis support services for Method II patients.

The allowance per month under Method II for home dialysis support services may not exceed \$121.15 per month for all forms of dialysis. Since home dialysis support services for Method II patients are subject to a monthly capitation payment that is not increased, the CY 2007 amounts represent the CY 2011 amounts.

3. Part B Drugs and biologicals.

Under the current system, payments for ESRD drugs and biologicals under Part B are paid on average sales price plus 6 percent (ASP+6 percent) methodology. We reviewed ASP prices for four quarters of 2006, 2007, 2008 and two quarters of 2009 for the top eleven separately billable drugs. Given the variability shown in the prices over the last several years and the lack of a clear pattern, we propose to use the 2009 prices as proxy for 2011 values. At the time of the final rule, we will reevaluate this decision based on additional quarters of ASP drug pricing data. Thus, we used the growth from the average of the

quarters for 2007 to the average of the two available quarters of 2009. For other ESRD-related Part B drugs, we used a weighted average of the top eleven Part B drugs to update those drug prices to 2011. Since the top eleven drugs represent 99.7 percent of total separately billable Part B drug payments, we believe that the overall weighted average was representative for the remaining 0.3 percent. See Table 10 for the growth factor that was applied to the 2007 drug payment levels.

Table 10

Drugs and biologicals	Price Updates
EPO	1.7%
Paricalcitol	-2.8%
Sodium_ferric_glut	-0.5%
Iron_sucrose	4.8%
Levocarnitine	-19.0%
Doxercalciferol	17.8%
Calcitriol	-14.1%
Vancomycin	-11.1%
Alteplase	2.3%
Aranesp	-8.2%
Daptomycin	13.9%
Other injectables	1.1%

4. Laboratory tests.

We updated payments for laboratory tests paid through the laboratory fee schedule to 2011 using projected CPI-U increases and any legislative adjustments that would be applied to this fee schedule. This is the statutory update

required for lab services. This amount totaled a growth of 5.1 percent from 2007 to 2011.

5. DME supplies and equipment.

Since payments for supplies and equipments for Method II patients are subject to a monthly capitation payment that has not increased, the CY 2007 amount represents the 2011 amounts.

6. Supplies and other services.

This category primarily includes the \$0.50 administration fee for separately billable Part B drugs. Since this fee has not increased, there was no price update.

7. Former Part D drugs.

Former Part D drugs were updated by the growth rates for overall prescription drug prices that were used in the National Health Expenditure Projections. See

[http://www.cms.hhs.gov/NationalHealthExpendData/03 National HealthAccountsProjected.asp#TopOfPage](http://www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp#TopOfPage)

for further reference on the National Health Expenditure Projections. Since we do not currently have enough data to establish a trend for Part D prices and since we use this price growth in the overall Part D projections, we believe it is an adequate proxy. This amount totaled a growth of 12.2 percent from 2007 to 2011.

Once we determined updated CY 2011 payments for each component of the items and services discussed above, we added the components together to determine each ESRD facility's total payments under the current payment system in CY 2011. These estimated total 2011 MAPs divided by the total 2007 Medicare HD-equivalent sessions yield the unadjusted per treatment base rate for renal dialysis services in CY 2011 of \$261.58.

We used \$261.58 as the starting point for further adjustments in determining the proposed ESRD PPS per treatment base rate. The 2011 unadjusted average payment per treatment of \$261.58 was then used in the payment model to estimate total payments under the proposed ESRD PPS in CY 2011. These CY 2011 ESRD PPS estimated payments were based on treatment data from the CY 2007 claims file.

C. Standardization Adjustment

CY 2011 payments under the proposed ESRD PPS were initially estimated without a budget-neutrality adjustment, using the unadjusted CY 2011 average payment per treatment amount of \$261.58. We calculated the PPS payments using treatment counts from the 2007 claims file. The wage index and all applicable proposed patient-level and facility-level adjustments were applied to the unadjusted CY 2011 average payment per treatment to determine the estimated

payment amount under the proposed ESRD PPS for each treatment and ESRD facility. We note that to simulate payments, we used the latest available final CY 2009 ESRD wage indexes, with no floor. While we anticipate a 0.60 floor for the ESRD wage index for the current basic case-mix composite payment system, we are proposing to eliminate the wage index floor for the ESRD wage index to be used for the proposed ESRD PPS in CY 2011 (see section VIII.C.1 for a detailed discussion of the ESRD wage index).

Next, we standardized the ESRD PPS payments in order to account for the overall positive effects of the proposed ESRD PPS case-mix patient and facility adjustment factors and wage indexes. We must standardize payments in order to ensure that total projected PPS payments are equal to the payments under the current basic case-mix adjusted composite payment system. In order to standardize the ESRD PPS payments, we compared the proposed ESRD PPS amounts calculated from the treatment counts in the 2007 claims file to the current system payments from the 2007 Medicare claims file updated to 2011 (as explained in greater detail in section VII.B. above). A standardization factor was calculated by dividing total estimated payments in 2011 under the current payment system by estimated payments

under the proposed ESRD PPS in 2011. The standardization factor was calculated to be 0.7827, or a reduction of 21.73 percent. As a result, the CY 2011 unadjusted per treatment base rate of \$261.58 was reduced by 21.73 percent to \$204.74.

We are proposing that the base rate per treatment be further modified by the adjustments described below.

D. Calculation of the Budget-Neutrality Adjustments

a. Outlier Adjustment

Section 1881(b)(14)(D)(ii) of the Act provides that the ESRD PPS shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis-stimulating agents necessary for anemia management. We believe the payment adjustment under section 1881(b)(14)(D)(ii) of the Act for outlier cases should be applied in a budget neutral manner, as doing so will ensure that estimated total payments under the proposed ESRD PPS equals 98 percent of the estimated total amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented.

To ensure that the proposed outlier policy under the ESRD PPS is budget neutral, we propose to reduce the base

rate by the proposed outlier percentage, or 1 percent. Specifically, we propose to reduce the base rate from \$204.74 to \$202.69. We did this to account for the 1 percent of aggregate ESRD PPS payments estimated to be made as outlier payments. We then re-estimated the prospective payment amounts with the new reduced base rate of \$202.69, allowing 1 percent of payments to be outliers. The appropriate outlier payment amount for each treatment was determined as described in greater detail in section X.A.2 of this proposed rule. The outlier amount was computed for all treatments, and the total outlier payment, across all treatments amount was added to the prospective payment amount for all treatments.

In summary, we are proposing an outlier percentage of 1 percent; therefore, the proposed base rate per treatment must include a reduction of 1 percent. Thus the proposed standardized base rate of \$204.74 was reduced by 1 percent to yield a proposed base rate of \$202.69.

b. 98 percent Budget Neutrality adjustment

Section 1881(b)(14)(A)(ii) of the Act requires that the proposed ESRD PPS payment system be 98 percent budget neutral. In other words, the estimated total amount of payments under the ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total

amount of payments for renal dialysis services that would have been made with respect to services in 2011 if the ESRD PPS had not been implemented. Therefore, we reduced the 2011 standardized base rate per treatment, which was already adjusted for 1 percent outlier payments, by an additional two percent, from \$202.69, to yield a proposed base rate of \$198.64.

To summarize, the proposed base rate per treatment with an outlier adjustment and budget neutrality was calculated to be \$198.64. This amount includes a 21.73-percent reduction from \$261.58 to account for standardization to the projected CY 2011 current system payment per treatment, a 1-percent reduction to account for proposed outlier payments, and a 2-percent reduction for the required 98-percent budget neutrality. The outlier policy we are proposing is set forth at proposed §413.237.

E. Calculation of Transition Budget-Neutrality Adjustment

Section 1881 (b) (14) (E) (i) of the Act requires the Secretary to provide "a four-year phase-in" of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, with payments under the ESRD PPS "fully implemented for renal dialysis services furnished on or after January 1, 2014." Although the statute uses the term "phase-in", for purposes of the proposed ESRD PPS, we

will use the term "transition" to be consistent with other Medicare payment systems.

Section 1881(b)(14)(E)(ii) of the Act permits ESRD facilities to make a one-time election to be excluded from the transition. An ESRD facility that elects to be excluded from the transition receives payments for renal dialysis services provided on or after January 1, 2011 based on 100 percent of the payment rate under the ESRD PPS, rather than a blended payment based in part on the payment rate with regard to the current basic case-mix adjusted composite payment system and in part on the payment rate under the ESRD PPS. The implementation of the transition is discussed in section XIII.A of this proposed rule. The transition period policy is set forth in proposed §413.239.

Section 1881(b)(14)(E)(iii) of the Act also requires that we make an adjustment to payments for renal dialysis services provided by ESRD facilities during the transition so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. The transition budget neutrality adjustment would be comprised of two parts. First, we would make a payment adjustment

under the basic case-mix adjusted composite payment system portion of the blended rate during the transition, in addition to computing a factor that would make the estimated total amount of payments under the ESRD PPS including payments under the transition equal the estimated total amount of payments that would otherwise occur without such a transition. We describe each part in detail in the paragraphs that follow.

First, to ensure that estimated total payments during the transition equal the estimated total amount of payments that would otherwise occur without such a transition, in addition to accounting for payments for composite rate services and items and services that are separately billable under Part B, it is necessary to reflect payments for ESRD-related Part D drugs that are currently separately payable under Title XVIII. Specifically, as we discussed in section III. of this proposed rule, section 1881(b)(14)(B) of the Act defines renal dialysis services to include, among other things, certain drugs and biologicals, including drugs and biologicals that were separately payable under Parts B and D. Under the current ESRD basic case-mix adjusted composite payment system, ESRD facilities generally do not furnish oral drugs and biologicals to their ESRD patients. ESRD patients

currently acquire these drugs and biologicals either through Medicare Part D, private insurance, or independently.

As described in section III. of this proposed rule, we are proposing to include renal dialysis service drugs formerly covered under Part D under the proposed ESRD PPS. As a result, we are further proposing that ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement.

As further discussed in section VII. of this proposed rule, the cost of the drugs and biologicals currently separately payable under Part D that we propose to be designated as Part B renal dialysis services for purposes of the proposed ESRD PPS, would be reflected in the ESRD PPS portion of the blended payment. That is, once the ESRD PPS is implemented on January 1, 2011, ESRD-related Part D drugs would become Part B renal dialysis service drugs and would no longer be separately covered under Part D. This is due to section 1881(b)(14)(A)(1) of the Act, which specifies that after January 1, 2011, a single payment is made under title XVIII for renal dialysis services furnished by ESRD facilities in lieu of any other payment

for such services, as well as the new statutory definition under section 1881(b)(14)(B) of the Act. In addition, we note that ESRD-related Part D drugs are not part of the basic case-mix adjusted composite payment system or otherwise covered under Part B (in contrast to other separately billable ESRD-related items and services). As a result, ESRD facilities that elect to go through the transition would have no mechanism by which to receive payment for former Part D drugs with regard to the basic case-mix adjusted composite payment system portion of the payment blend (though such services would be captured with regard to the portion of the blended payment for the ESRD PPS). Because ESRD-related Part D drug payments would not be included in the portion of the blend based on the basic case-mix adjusted composite payment system, payments to ESRD facilities that elect to go through the transition may be understated during the transition.

Additionally, as required by section 1881(b)(14)(A)(ii) of the Act and described in section VII.D.b of this preamble, the estimated total amount of payments under the proposed ESRD PPS in 2011, including any payment adjustments, must equal 98 percent of the estimated total amount of payments for renal dialysis services under

title XVIII that would have been made with respect to services in 2011 if the ESRD PPS system had not been implemented. As we noted, Part D drugs are not part of the basic case-mix adjusted composite payment system or otherwise covered under part B as separately billable ESRD-related items or services. However, because the payments for the ESRD-related Part D drugs proposed for inclusion in the ESRD PPS were made under title XVIII, we are required to include such items in the 98 percent budget neutrality adjustment.

Thus, to be consistent with the 98 percent budget neutrality requirement and to make estimated payments during the transition equal payments without the transition, we propose to provide a \$14.00 per treatment adjustment to the portion of the blend with regard to the basic case-mix adjusted composite payment system. This amount is based on the 2011 per treatment ESRD-related Part D drug payments included in the proposed ESRD PPS base rate. We first computed the 2007 per Part D payment per treatment described in section VII.A. We then updated this amount to 2011 by applying the 12.2 percent update factor described in section VII.B.

We further propose that the \$14 per treatment adjustment that would be made to the portion of the blend

with regard to the basic case-mix adjusted composite payment system would be made without regard to basic case-mix adjustments or wage index adjustments. This is because ESRD-related Part D drugs were not included in the development of the adjustments for the basic case-mix adjusted composite payment system.

We considered an alternative approach for meeting the statutory transition budget neutrality adjustment. Under this approach, we would exclude estimated payments for ESRD-related Part D drugs from the estimated 2011 payments related to the basic case-mix adjusted composite payment system. That is to say, we would not pay ESRD facilities for the ESRD-related Part D drug payment with regard to the basic case-mix adjusted composite payment system portion of the blended payment during the transition, and therefore, we estimate that ESRD facilities may receive smaller blended payment amounts during the transition. Excluding ESRD-related Part D drugs from the basic case-mix adjusted composite payment portion of the blended payment would likely lower blended payments under the transition and, as a result, we estimate that many more facilities would elect to be paid 100 percent of the ESRD PPS rather than electing to go through the transition. These facilities would have to give up their option to go through the transition in

order to receive 100 percent ESRD PPS payments for ESRD-related Part D drugs. The transition provides a more gradual change to ESRD PPS for those facilities that would receive lower payments under the proposed ESRD PPS. We believe it is more equitable to provide a \$14 per treatment adjustment the portion of the blend related to the basic case-mix adjusted composite payment system. In addition, we believe that the transition budget neutrality adjustment should not change facilities' incentives with respect to whether or not to opt out of the transition. This approach would change the incentives because excluding ESRD-related Part D drugs from portion of the blended payment related to the basic case-mix adjusted composite payment system might lower blended payments under the transition, thereby increasing the incentive to elect to be paid under 100 percent ESRD PPS. This approach also would skew the impact analysis because it compares payment amount related to the basic case-mix adjusted composite payment system without Part D payments, while payments under the proposed ESRD PPS include payments for Part D drugs. For the impact analysis to accurately represent payments that are included in the proposed ESRD PPS and be consistent with the 98 percent budget neutrality requirement, we believe we need to include payments for ESRD-related Part D drugs in our

estimate of what ESRD facilities would be paid in 2011 for both the basic case-mix adjusted composite payment system and the proposed ESRD PPS, had an ESRD PPS not been implemented. For these reasons we rejected this alternative.

Accordingly, in order to make ESRD PPS budget neutral during the transition with respect to ESRD-related Part D drugs, we propose to make a \$14 per treatment adjustment to the portion of the blend related to the basic case-mix adjusted composite rate payment system.

The second part of the transition budget neutrality adjustment addresses the overall effect of the ESRD facilities' decision whether to be paid under the transition versus being paid under the ESRD PPS. In the absence of such an adjustment, total payments would be higher under the transition payment system (blended payment amount) than under a 100 percent fully implemented PPS payment system, as we presume that each provider would likely choose the option that is most beneficial to them. In other words, we believe ESRD facilities that estimate that their aggregate payments will be higher under the transition than under the ESRD PPS likely will elect to be paid under the transition. This in turn would increase the total payments paid by CMS, with total payments then likely

to exceed the 98 percent budget neutrality target amount, as discussed in section VII.D.b of this proposed rule. We interpret this provision as requiring, during the first 3 years of the transition, a budget neutrality adjustment applied to all payments to ESRD facilities (both those paid under the transition and those electing to be paid under the ESRD PPS) to offset the additional payments to those ESRD facilities that elect to be paid a blended payment under the transition rather than to be paid based on 100 percent of the payment amount under the proposed ESRD PPS. Thus, we are proposing to create a transition budget neutrality adjustment factor to be applied to all payments to ESRD facilities during the transition. This transition budget neutrality adjustment factor is intended to make the estimated total payments under the transition equal our estimate of total payments under the ESRD PPS were there no transition.

One alternative we considered was applying the budget neutrality adjustment factor to the 2011 ESRD PPS base rate only. However, we believe this approach would unfairly penalize those facilities that opt to be paid based on 100 percent of the payment amount under the ESRD PPS, as it would lower all of their payments. Those facilities that

are paid on a blended payment methodology would only have 25 percent of their payment lowered in CY 2011, as only 25 percent of the blended payment is based on the payment amount under the proposed ESRD PPS. Thus, in effect, this approach would result in those facilities electing to be paid based on 100 percent of the payment rate under the ESRD PPS subsidizing those electing to be paid under the transition. In addition, we believe that the transition budget neutrality adjustment should not change facilities' incentives with respect to whether or not to opt out of the transition. This alternative would change the incentives by lowering payments under the ESRD PPS by a larger percentage than the blended payments under the transition, thereby increasing the incentive to elect to be paid under the transition. For these reasons we rejected this alternative.

Another alternative we considered was applying the adjustment only to the blended payments for facilities that elect to be paid under the transition. However, we believe that this approach would unfairly penalize those ESRD facilities that choose to be paid under the transition, as it would lower their payments but would not lower the payments to those facilities that elect to be paid based on 100 percent of the payment rate under the ESRD PPS.

Similar to the alternative in the previous paragraph, this alternative would also affect ESRD facilities' incentives with respect to whether or not to opt out of the transition, and thus we also rejected this alternative.

We therefore propose to apply the transition budget neutrality adjustment factor to all ESRD payments, including the component of the blended rates based on the current basic case-mix adjusted composite payment system. We propose this approach, because we believe that it would not unfairly penalize one group, it would evenly distribute the effect of the transition budget neutrality adjustment, and it would not change ESRD facilities' incentives with respect to whether to opt out of the transition.

In calculating the transition budget neutrality adjustment factor, we propose to first determine the estimated increase in payments under the transition and then determine an offset factor. In order to do this, we must first make assumptions on which facilities would choose to opt out of the transition and be paid based on 100 percent of the payment rate under the ESRD PPS in 2011. In order to estimate which ESRD facilities will and will not elect to opt out of the transition, we are proposing to estimate aggregate payments for each ESRD facility under both the current basic case-mix adjusted composite payment

system, including payments for separately billable services, and the proposed ESRD PPS (based on 100 percent of the payment amount under the ESRD PPS). We are assuming that facilities that would receive higher aggregate payments under the proposed ESRD PPS would elect to be paid based on 100 percent of the payment rates under the ESRD PPS. Conversely, ESRD facilities that would receive higher aggregate payments under the current basic case-mix adjusted composite payment system would elect to be paid the blended rate under the transition.

Based on this approach, we estimate that 36 percent of ESRD facilities will choose to be excluded from the transition and that 64 percent of ESRD facilities will choose to be paid the blended rate under the transition. Consequently, we estimate that during the first year of the transition, total payments to all ESRD facilities would exceed the estimated payments under the ESRD PPS in the absence of the transition. Thus, in order to maintain the 98 percent budget neutrality required by section 1881(b)(14)(E)(iii) of the Act during the initial year of the transition period, we are proposing to reduce all payments to ESRD facilities in CY 2011 by a factor that is equal to 1 minus the ratio of the estimated payments under the ESRD PPS were there no transition (that is, 98 percent

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