

This compares with an average payment multiplier of 1.287 for adult patients based on CY 2007 claims. These average payment multipliers reflect both the case-mix and low volume adjustments.

The multipliers in Table 33 do not include the proposed adjustment for low-volume ESRD facilities described in section VIII.C.2. of this proposed rule. In CY 2007, approximately 24 percent of pediatric outpatient Medicare dialysis treatments were provided in facilities with less than 3,000 total treatments. This figure compares to 2.3 percent of Medicare dialysis treatments among adult patients. In addition, approximately 12.6 percent of Medicare treatments for pediatric patients were furnished in facilities with less than 3,000 treatments during each year from CY 2004 through 2006, and which neither opened nor closed during CY 2006. The comparable figure for adult patients was 0.6 percent. Therefore, pediatric patients would be much more likely to be eligible for the low-volume facility adjustment of 20.2 percent, which we have proposed, as described in section VIII.C.2. of this proposed rule.

## **X. Other Proposed Adjustments**

### **A. Outlier Policy**

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS 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. The outlier payment policy would be designed to protect an ESRD facility from significant financial losses due to unusually high costs. Any outlier payment due would be added to the per-treatment, patient and facility-level adjusted ESRD PPS payment amount.

Generally, outlier payment mechanisms in Medicare prospective payment systems are based on a provider's cost for care compared to projected payments under the PPS. When a provider's cost exceeds a threshold amount (the projected payment plus a fixed dollar loss amount), Medicare pays a percentage of the difference (the loss sharing percentage) as an outlier payment. We propose that the ESRD outlier policy parallel the outlier policies adopted under other Medicare PPSs.

Specifically, as discussed in more detail below, we would compare an ESRD facility's predicted Medicare Allowable Payment (MAP) amount per treatment for outlier services to the facility's imputed MAP amount per treatment for outlier services to determine whether the ESRD facility

would be eligible for additional payment under the proposed outlier policy. We propose to limit the outlier services to those items and services that currently are separately billable under Part B and renal dialysis service drugs proposed for inclusion under the ESRD PPS that currently are separately billable under Part D.

An ESRD facility would be eligible for an outlier payment when its imputed MAP amount per treatment for the outlier services exceeds the outlier threshold, or the facility's predicted MAP amount per treatment for the outlier services plus the fixed dollar loss amount. We propose that the outlier payment would be equal to 80 percent of the amount by which the facility's imputed costs exceeds the outlier threshold.

The current basic case-mix adjusted composite payment system does not provide for outlier payments. However, in the 2008 Report to Congress entitled "A Design for a Bundled End Stage Renal Disease Prospective Payment System", we discussed outlier payments as a way of mitigating risk incurred by ESRD facilities in providing treatment to patients with characteristics associated with higher costs. The 2008 report described a hypothetical outlier policy that would target higher payments to facilities for patients who encountered higher than average

monthly Medicare Allowable Payments (MAPs) for items and services that currently are separately billable under Part B. Specifically, the report proposed setting the hypothetical outlier payment amount at 80 percent of the difference between the separately billable MAP and a threshold amount. The report proposed that the threshold amount be based on the average separately billable MAP amount per treatment plus 2 or more standard deviations. ESRD facilities meeting this criterion were assumed to receive an outlier payment equal to a percentage of the difference between the separately billable MAP amount and the threshold amount.

To maintain budget neutrality, the 2008 report proposed that the portion of the base rate attributable to items and services that currently are separately billable under Part B be reduced by 2.5 percent to fund projected outlier payments. This percentage would have qualified approximately 5 percent of total patient months as outliers. A copy of the 2008 report is available at: <http://www.cms.hhs.gov/ESRDGeneralInformation/Downloads/ESRDReportToCongress.pdf>.

#### 1. Eligibility for Outlier Payment

We are proposing that an ESRD facility would be eligible for an additional payment under the ESRD PPS where the

facility's imputed, average per treatment costs for ESRD outlier services furnished to a beneficiary exceed the predicted per treatment MAP amount for outlier services plus the fixed dollar loss amount, as indicated in proposed §413.237(b). We propose to base eligibility for outlier payments on ESRD outlier services, that is, only those items and services that are separately billable under Medicare Part B with regard to the current basic case-mix adjusted composite payment system and renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D, rather than all items and services comprising the bundled payment under the proposed ESRD PPS.

The comprehensive listing of our outlier policy definitions are set forth in §413.237 of this proposed rule.

a. ESRD Outlier Services

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 that any unusual variation in the cost of the renal dialysis services comprising the base rate under the proposed ESRD PPS is likely to be due to variation in the items and services that currently are separately billable under Part B and those renal dialysis service drugs currently covered under Part D. Therefore, including these items and services that are either currently separately billable under Part B or covered under Part D under the proposed ESRD PPS creates new financial risk for ESRD facilities. In addition, significant variations in these services may impair access to appropriate care, as an ESRD facility may have a disincentive to provide adequate treatment to those ESRD patients likely to have significantly higher than average costs. We believe these concerns could be addressed by an outlier policy.

As set forth in proposed §413.237(a), we are proposing to base eligibility for outlier payments under the ESRD PPS on a comparison of the predicted MAP amounts and imputed MAP amounts for (1) items and services that currently are separately billable under Medicare Part B, including ESRD-related drugs, ESRD-related laboratory tests, and ESRD-related services; and (2) renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D. From this

point forward, we refer to these services as the "ESRD outlier services."

As described further in section XIV, of this proposed rule, we are considering the extent to which the 50 percent rule that pertains to the Automated Multi-Channel Chemistry (AMCC) separately billable laboratory tests under the basic case mix adjusted composite payment system should continue to apply in the context of the proposed ESRD PPS.

Section 1881(b)(14) prohibits the unbundling of services, including laboratory services. Thus, under the proposed ESRD PPS, Medicare would not make separate payment for laboratory tests, rendering the 50 percent rule irrelevant for payment purposes. The 50 percent rule's relevance would be limited to its use in determining eligibility for outlier payment.

As described above, we are proposing to define outlier services as items and services that currently are separately billable under Medicare Part B, including ESRD-related drugs, ESRD-related laboratory tests, and ESRD-related services; and (2) renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Medicare Part D. Under this proposal, to ensure that the AMCC tests qualify as separately billable under the basic case mix adjusted

composite payment system, and thus, qualify as outlier services, it would be necessary for ESRD facilities to continue applying the 50 percent rule under the proposed ESRD PPS. Conversely, excluding AAMC tests to which the 50 percent rule apply from the definition of outlier services would negate the need to apply the 50 percent rule under the proposed ESRD PPS.

We believe that the overall impact of excluding the AMCC tests to which the 50 percent rule applies from the definition of outlier services would be small. As shown in table 8, laboratory tests comprise 3.45 percent of the total MAP amount which is the basis of the ESRD PPS base rate. The subset of laboratory tests associated with the AMCC tests to which the 50 percent rule applies under the basic case mix adjusted composite payment system comprises an even smaller proportion of the overall base rate. As a result, we are considering excluding AAMC tests to which the 50 percent rule apply from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS. We request public comments on whether or not to include the the AMCC tests to which the 50 percent rule applies within the definition of outlier services and retain the 50 percent rule under the proposed ESRD PPS. We also invite comment on our proposal

to limit the ESRD outlier services to items and services currently separately billable under Part B and those renal dialysis service drugs currently covered under Part D.

We note that if we also were to base eligibility for outlier payments on variation in the cost of all items and services included in the ESRD PPS bundle, including those services included in the bundle under the current ESRD basic case-mix adjusted composite payment amount (hereinafter the "composite rate items and services"), this may require an expansion in the data that we currently collect from ESRD facilities, which would increase ESRD facilities' reporting burden. Specifically, if we were to base eligibility for outlier payments on variation in the cost of all items and services included in the ESRD PPS bundle, we would need to compare a more comprehensive predicted MAP amount for a treatment to the ESRD facility's more comprehensive imputed MAP amount for the treatment. However, composite rate items and services, and the ESRD facilities' costs associated with providing these items and services, are not listed individually on the claims. As a result, it would not be possible to compare an imputed MAP amount for the more comprehensive definition of outlier services, that is, all items and services included in the

ESRD PPS bundle, to the predicted MAP amount for these items and services.

To correct this deficiency, we could collect patient-level data reflecting the cost of the composite rate items and services. Under this approach, we believe that it would be necessary to revise the ESRD facility claim form. For example, ESRD facilities would need to report by line item all composite rate services and the associated charges of each of those services. However, we are not proposing revisions to the ESRD facility claim.

We believe that under a bundled payment system, in the future we may be able to simulate ESRD facility costs for outlier services using charges on the claims and applying the cost-to-charge ratios calculated using the cost reports. However, this data would only become available after the 2011 cost reports had been settled.

b. Predicted ESRD Outlier Services MAP Amounts

Predicted outlier services MAP amounts for a patient would be determined by multiplying the adjusted average outlier services MAP amount, described further below, by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers used in the regression analysis to compute the payment adjustments.

As described previously in section VIII. of this proposed rule, the predicted separately billable MAP amounts are based on the patient-level regression model for separately billable services. Thus, it is possible to predict patient-specific separately billable MAP amounts for these services by multiplying the average separately billable MAP amounts by the separately billable case-mix adjusters. However, although in this proposed rule we have included the cost of the Part D drugs in the base rate, the Part D drugs have not been incorporated into the separately billable services regression model that generates case-mix payment adjusters. Therefore, we are unable to predict payment for renal dialysis service drugs proposed for inclusion in the ESRD PPS that are currently covered under Medicare Part D. As a result, the predicted MAP amounts are understated. Nonetheless, within this proposed rule, our references to predicted outlier services MAP amounts assume the inclusion of these additional drugs to demonstrate the way in which the outlier policy would apply when these additional drugs are incorporated into the regression model for purposes of the final rule. For the final rule we intend to incorporate these drugs into the regression analysis to derive a comprehensive predicted MAP amount for all proposed ESRD outlier services, including

(1) the items and services that currently are separately billable under Medicare Part B and (2) renal dialysis service drugs proposed for inclusion in the ESRD PPS that currently are covered under Medicare Part D.

Specifically, for the final rule, the separately billable case-mix adjusters could either be updated to reflect Part D drugs, assigning appropriate weights to the separately billable and Part D portions of the outlier services case-mix adjusters, or distinct payment multipliers for the Part D drugs could be developed.

Please refer to Table 34 below for the list of case-mix adjustment multipliers for outlier services for adult patients.

**Table 34**

**Payment multipliers for an expanded bundle of services, ages 18 and older, 2004-06**

Variable	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment <sup>3,4</sup>
	Composite rate services <sup>1</sup>	Outlier services <sup>2</sup>	
	PmtMult <sub>CR</sub>	PmtMult <sub>SB</sub>	
<b>Adjustments for dialysis patient characteristics</b>			
Age			
18-44	1.280	1.018	1.194
45-59	1.000	1.000	1.000
60-69	1.014	1.006	1.012
70-79	1.105	0.960	1.057
80+	1.150	0.923	1.076
Female	1.124	1.149	1.132
Body surface area (BSA, per 0.1 m <sup>2</sup> ; mean BSA=1.87)	1.035	1.033	1.034
Underweight (BMI <18.5)	1.000 <sup>^</sup>	1.060	1.020
Time since onset of renal dialysis: <4 months	1.508	1.401	1.473
Alcohol/drug dependence (claims since 2000 or 2728)	1.155	1.139	1.150

Cardiac arrest (claims since 2000 or 2728)	1.000^	1.098	1.032
Pericarditis from same month to three months ago	1.000^	1.595	1.195
HIV/AIDS (claims since 2000 or 2728)	1.363	1.220	1.316
Hepatitis B (claims since 2000)	1.115	1.035	1.089
Specified infection from same month to 3 months ago			
Septicemia	1.000^	1.715	1.234
Bacterial pneumonia and other pneumonias/opportunistic infections	1.256	1.412	1.307
Gastro-intestinal tract bleeding from same month to 3 months ago	1.000^	1.965	1.316
	1.248	1.179	1.226
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.143	1.097	1.128
Cancer (claims since 2000; excludes non-melanoma skin cancer)			
Myelodysplastic syndrome (claims since 2000)	1.000^	1.257	1.084
Monoclonal gammopathy (claims since 2000)	1.000^	1.063	1.021
<b>Low volume facility adjustment</b> Facility size < 3,000 treatments during each year from 2004-06	1.383	0.940	1.202

<sup>A</sup>A multiplier 1.000 was used for factors that lacked statistical significance in models of resource use or lacked stability over time in the estimated multipliers.

<sup>1</sup>The CR payment multipliers (PmtMult<sub>CR</sub>) are based on a facility level log-linear regression model of the average composite rate cost/session for 2004-06 (n=11,814 facility years). This model also included facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) and the percent of pediatric patients as additional covariates (R-sq=46.0%).

<sup>2</sup>Although we refer to outlier services, these multipliers are limited to the inclusion of items and services that currently are separately billable under Medicare Part B and do not reflect renal dialysis service drugs proposed for inclusion in the ESRD PPS that are currently covered under Medicare Part D. Based on a patient level log-linear regression model of separately billable Medicare Allowable Payments/session for 2004-06 (n=890,776 patient years) that included facility characteristics (an indicator of low volume facilities as a potential payment variable as well as control variables for other facility size categories, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%) as additional covariates (R-sq=8.7%).

<sup>3</sup>The combined payment multipliers for patient characteristics were calculated as  $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$ , where PmtMult<sub>CR</sub> is the estimated multiplier from a facility level model of composite rate costs and PmtMult<sub>SB</sub> is the estimated multiplier from a patient level model of separately billable costs. Based on total estimated costs of \$169.67 per session for composite rate services, \$82.45 per session for separately billable services, and \$252.12 per session for an expanded bundle (\$169.67+\$82.45), the relative weights are Weight<sub>CR</sub>=0.673 for composite rate services (\$169.67/\$252.12) and Weight<sub>SB</sub>=0.327 for separately billable services (\$82.45/\$252.12).

<sup>4</sup>To determine the incremental payment for low volume facilities, the low volume facility payment multiplier was calculated relative to all other facilities combined. The estimated low volume coefficients from the regression models (which correspond to the CR and SB multipliers of 1.383 and 0.940, respectively, in the table above) were first divided by the weighted average of the other facility size coefficients in the models. A similar weighting procedure to that described above for the other payment multipliers was then used in calculating the resulting low volume adjustment of 1.202. The same payment adjustment is being used for both adult and pediatric patients in a low volume facility.

Please refer to Table 35 below for the list of case-mix adjustment multipliers for outlier services for pediatric patients.

**Table 35**

**Calculating combined payment multipliers for pediatric patients based on adjustments for age, modality, and comorbidity**

Cell	Patient characteristics			Modeled outlier services <sup>2</sup> multiplier	Payment multipliers		
	Age	Modality	Comorbidities <sup>1</sup>		Outlier Services <sup>2</sup> payment multiplier (PmtMult <sub>SB</sub> )	CR payment multiplier (PmtMult <sub>CR</sub> )	Expanded bundle payment multiplier (PmtMult <sub>EB</sub> )
1	<13	PD	None	1.000	0.149	1.199	0.963
2	<13	PD	1 or more	1.485	0.221	1.199	0.980
3	<13	Hemo	None	3.861	0.576	1.199	1.059
4	<13	Hemo	1 or more	5.647	0.842	1.199	1.119
5	13-17	PD	None	1.508	0.225	1.199	0.980
6	13-17	PD	1 or more	2.244	0.335	1.199	1.005
7	13-17	Hemo	None	5.831	0.869	1.199	1.125
8	13-17	Hemo	1 or more	8.534	1.272	1.199	1.215

<sup>1</sup>The comorbidity adjustment is based on the presence of HIV/AIDS (2728 or claims since 2000), septicemia within 3 months, diabetes (2728 or claims since 2000), and cardiac arrest (2728 or claims since 2000).

<sup>2</sup>Although we refer to outlier services, these multipliers are limited to the inclusion of items and services that currently are separately billable under Medicare Part B and do not reflect renal dialysis service drugs proposed for inclusion in the ESRD PPS that are currently covered under Medicare Part D.

To generate the adjusted average outlier services MAP amount that is multiplied by the product of the patient-specific outlier services case-mix adjusters, we begin with the average outlier services MAP amount per treatment. The average outlier services MAP amount per treatment is based on payment amounts reported on 2007 claims and adjusted to reflect projected prices for 2011. As discussed above, payments for Part D drugs are not included. The average MAP amount per treatment for outlier services is then

adjusted by the case-mix and wage adjustment standardization factor, a MIPPA reduction of .98, and the outlier policy of .99 resulting in the adjusted average outlier services MAP amount by which the product of the patient-specific outlier services case-mix adjusters are multiplied.

The proposed adjusted average outlier services MAP amount is \$64.54. As illustrated in the hypothetical examples in section X.A.3, the adjusted average outlier services MAP amount, would be multiplied by the product of the patient-specific outlier services payment multipliers to yield the predicted outlier services MAP amount.

As described further in section X.A.1.d., the fixed dollar loss amount would be added to this amount.

<b>Table 36 Adjusted Average Outlier Services MAP Amount</b>		
Average outlier services MAP amount per treatment <sup>1</sup>	\$84.99	
Adjustments		
Standardization for case mix and wage adjustments <sup>2</sup>	0.7827	
MIPPA reduction	0.98	
Outlier policy	0.99	
Adjusted average outlier services MAP amount <sup>3</sup>	\$64.54	
	<b>Patient age</b>	
	<b>&lt; 18</b>	<b>18 and older</b>
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold <sup>4</sup>	\$174.31	\$134.96

<sup>1</sup>Excludes patients for whom not all case mix measures were available to calculate projected payments under an expanded bundle.

<sup>2</sup>Applied to the average outlier MAP per treatment.

<sup>3</sup>Because Part D drugs are not yet reflected in the outlier services payment multipliers, this number is understated. This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP for each patient.

<sup>4</sup>The fixed dollar loss amounts were calculated using 2007 data to yield total outlier payments that represent 1% of total projected payments for an expanded ESRD PPS. These amounts correspond to 1.963 times the standard deviation of the prediction error for ages <18 and 1.952 times the standard deviation of the prediction error for ages 18 and older.

### c. Estimating the Imputed ESRD Outlier Services MAP

#### Amounts

As discussed above, we propose to base eligibility for outlier payments on a comparison of an ESRD facility's predicted Medicare Allowable Payment (MAP) amount per treatment for the ESRD outlier services to the facility's imputed MAP amount per treatment for the ESRD outlier services. We discuss above our proposed methodology for determining the predicted outlier services MAP amounts for a patient. In estimating a provider's imputed costs, under some Medicare PPSs, such as the Hospital Inpatient Prospective Payment System, we estimate a provider's costs by applying a provider-specific cost-to-charge ratio to the covered charges for the treatment. The cost-to-charge ratio is based in part on the provider's cost report. Under other Medicare PPSs, we estimate a provider's costs

using available data. For example, under the Prospective Payment System for Home Health Agencies we impute the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines (42 CFR §484.240(d)). For the reasons discussed below, we are proposing to estimate an ESRD facility's imputed costs for the ESRD outlier services based on available data rather than a provider-specific cost-to-charge ratio.

Although ESRD facilities currently identify costs associated with certain ESRD outlier services such as EPO and vaccines, our analysis revealed that other ESRD-related drugs and biologicals appear to be under-reported or not reported. For this reason, we do not believe that a cost-to-charge ratio that would be based on such reported information would accurately reflect an ESRD facility's cost for drugs. We therefore are proposing to estimate a provider's costs based on available data, rather than applying a cost-to-charge ratio to facility charges to impute their cost.

As described in greater detail below, the imputed separately billable MAP amounts would be based on pricing mechanisms currently in place for these services. Whereas,

in the case of Part D drugs proposed for inclusion in the ESRD PPS, we have not proposed a preferred pricing mechanism for the imputed MAP amounts but rather, solicit comments on several approaches for imputing these drug prices.

i. Data Used to Estimate Imputed ESRD Outlier Services MAP Amounts

With respect to estimating the imputed MAP amounts of ESRD outlier services that are separately billable under Part B, we propose to use Average Sales Prices (ASP) data for the Part B ESRD-related drugs (which is updated quarterly) and annual laboratory fee schedules for the previously separately billable laboratory tests. We propose to use various pricing mechanisms for the other separately billable ESRD-related services. Specifically, for medical/surgical supplies used to administer separately billable drugs, we propose to estimate MAP amounts based on the predetermined fees that apply to these items under the current base case-mix adjusted composite payment system. For example, we pay \$0.50 for each syringe identified on an ESRD facility's claims form. For other medical/surgical supplies such as IV sets and gloves, the claims processing manual currently allows Medicare contractors to elect among various options to price these supplies, such as the Drug

Topics Red Book, Med-Span, or First Data Bank (CMS Pub 100-04, Chapter 8, Section 60.2.1). We propose that the FI/MAC would continue to use the pricing mechanisms that are currently in place for items and services that currently are separately billable under Part B to estimate costs for these other medical/surgical supplies.

Finally, payment for blood, supplies used to administer blood, and blood processing fees furnished by hospital-based ESRD facilities under the current basic case-mix adjusted composite payment system is based on a reasonable cost basis. Payment for blood, supplies used to administer the blood, and blood processing fees, on behalf of patients in independent ESRD facilities currently is made at the lower of the actual charge on the bill or a reasonable charge that the MAC/FI determines. We are proposing to estimate hospital-based and independent ESRD facilities' costs for blood, supplies used to administer blood, and blood processing fees using the pricing mechanisms that are currently in place for items and services that currently are separately billable under Part B. We are not in this proposed rule, specifying the mechanism by which we propose to estimate the imputed MAP amounts for drugs formerly covered under Medicare Part D but that would become renal dialysis service drugs when the

ESRD PPS would be implemented in 2011. Rather, we request public comment on the following potential approaches for estimating the imputed MAP amounts of these drugs and on alternative approaches.

Approach 1:

First, although we believe ASP pricing data for renal dialysis service drugs currently covered under Part D would facilitate the computation of the estimated costs of these drugs, we do not collect ASP pricing information under section 1927 of the Act for these drugs. We request public comment on whether manufacturers would be willing to submit ASP pricing data for renal dialysis service drugs currently covered under Part D on a voluntary basis.

Approach 2:

An alternate approach for estimating the imputed MAP amounts of renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D would be to use data retrieved from the online Medicare Prescription Drug Plan Finder. (This online tool, available at [medicare.gov](http://medicare.gov) provides the prices that are charged by each Part D plan's network pharmacy.) For example, the Part D drug prices for each drug designated as a Part B renal dialysis service could be estimated based on a national average price charged by all Part D plans and

their network pharmacies. We believe that establishing a single national average price for each drug designated as a Part B renal dialysis service would be consistent with the approach for Part B drugs in which we use national ASP pricing.

These national average prices could be updated on an ongoing basis using data on the Medicare Prescription Drug Plan Finder. Similar to the way in which we update Part B ASP pricing, national average Medicare Prescription Drug Plan Finder prices could be updated on a quarterly basis. The prices reflected in the Medicare Prescription Drug Plan Finder are reflective of the prices that are negotiated by larger buying groups. As a result, our primary concern with this pricing approach is that such prices may fail to reflect the drug prices that smaller facilities may pay in acquiring these drugs and could therefore disadvantage these facilities.

Approach 3:

An alternative approach for estimating the imputed MAP amounts of renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D would be to use Wholesale Acquisition Cost (WAC). Because WAC is the manufacturer's list price to wholesalers, we believe that it is more reflective of the

price paid by the end user than the Average Wholesale Price. In addition, as set forth in CMS Pub 100-04, Chapter 17, Section 20.1.3, payment allowance limits for drugs and biological that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. As a result, we believe that this pricing mechanism would be consistent with pricing that currently occurs for drugs that are separately billable under Part B.

Approach 4:

Another alternative option for estimating the imputed MAP amounts of the renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle but currently covered under Part D would be to use the national average prescription drug event (PDE) data that is submitted for each Part D claim. To correct for the lag time for receipt of complete PDE data by CMS, we would update the most recent PDE data by the CPI update for drugs.

Approach 5:

A final approach for estimating the imputed MAP amounts for renal dialysis service drugs currently covered under Part D would be to require ESRD facilities to list on their claims forms their costs for the renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D. The facility cost that would be reported on the claim would need to be the amount after accounting for manufacturer rebates, discounts, and other price concessions. Under this approach, payment would be based on an ESRD facility's cost as identified on the claim. As indicated previously, while it may be possible to use cost-to-charge ratios on the cost report to simulate cost in the future, that information would not be available when the ESRD PPS would begin in 2011.

We believe that most, if not all, of the renal dialysis service drugs proposed for inclusion in the ESRD PPS but currently covered under Part D have clinical treatment indications beyond ESRD, such as for the treatment of bone disease in advanced chronic kidney disease patients. These drugs therefore will continue to be covered under Part D for these other indications. Consequently, Part D pricing information would continue to be available for these drugs and could be used in the

computation of outlier eligibility and payment under the approaches #2, and #4 discussed above.

We request public comment on the potential approaches set forth above for estimating the imputed MAP amounts of renal dialysis service drugs proposed for inclusion in the ESRD PPS bundle that currently are covered under Part D. We are also interested in any other potential data sources for estimating the imputed MAP amount of those ESRD-related drugs currently paid under Part D.

ii. Determining Imputed Per Treatment ESRD Outlier Services MAP Amount

ESRD facilities currently submit claims on a monthly basis that identify line item dates of service. For purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient. Specifically, we are proposing that the ESRD facility would identify by line item on the monthly claim, all ESRD outlier services furnished to the patient. We would then estimate the imputed MAP amount for these services applying one of the proposed methodologies discussed above in section X. A. 1. c. i. The imputed outlier services MAP amounts for each of these services would be aggregated and then divided by the

corresponding number of treatments identified on the claim to yield the imputed outlier services MAP amount per treatment. An ESRD facility would be eligible for an outlier payment if the imputed average outlier services MAP amount per treatment exceeds the sum of the predicted, outlier services MAP amount per treatment and the fixed dollar loss amount, as described below.

d. Outlier Percentage and Fixed Dollar Loss Amounts

As discussed in section VII.D.a, we are proposing that payments under section 1881(b)(14)(D)(ii) of the Act for outlier cases be applied in a budget neutral manner. Therefore, 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 the percentage of total ESRD PPS payments that are intended for payment of outlier cases, as defined in proposed §413.220(b)(4).

Using an outlier loss sharing percentage of 80 percent (which is discussed in the following section), we considered various percentages from 1 percent to 3 percent of aggregate payments and the fixed dollar loss amount that is computed from these two factors. (As discussed below, we are proposing separate fixed dollar loss amounts for the pediatric and adult populations.) The appropriate outlier

amount was determined by comparing the predicted outlier services MAP amount (which, for the reasons explained previously was limited to items and services that were separately billable under Medicare Part B), for the treatment plus the fixed dollar loss amount to the imputed per treatment ESRD outlier services MAP amount. For example, using an outlier percentage of 1 percent, if the total outlier payment amount for all providers was determined to be higher or lower than 1 percent of the total payments under the proposed ESRD PPS, then the fixed dollar loss amount was adjusted accordingly. This was done in an iterative fashion until the fixed dollar amount produced total outlier payment amounts for all ESRD facilities equal to 1 percent of total payments. We applied a similar process to identify the fixed dollar loss amount associated with other outlier percentages.

We analyzed outlier percentages from 1 to 3 percent of total ESRD PPS payments and the corresponding fixed dollar loss amounts and percentage of patient months qualifying for outlier payments, which are presented in Table 37.

	<b>1%</b>	<b>1.5%</b>	<b>2%</b>	<b>2.5%</b>	<b>3%</b>
Age 18 and Older: Patient Months Qualifying for Outlier Payment	5.3%	7.3%	9.3%	11.5%	13.8%
Age < 18: Patient Months Qualifying for Outlier Payment	2.6%	3.8%	5.7%	7.6%	10.7%
Age 18 and Older: Fixed Dollar Loss Amount	\$134.96	\$109.24	\$89.88	\$74.32	\$61.67
Age < 18: Fixed Dollar Loss Amount	\$174.31	\$124.32	\$90.04	\$65.62	\$47.70

Based on consideration of the various outlier percentages, we are proposing that the outlier percentage would be 1 percent of total ESRD PPS payments. We believe an outlier percentage of 1 percent strikes an appropriate balance between our objectives of paying an adequate amount for the most costly patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. In addition, this outlier percentage is consistent with other Medicare PPSs, such as the 1 percent policy paid under the Outpatient PPS.

The fixed dollar loss amounts that would be added to the predicted, outlier services MAP amounts would differ for adult and pediatric patients due to differences in the usage of separately billable services among adult and pediatric patients, especially drugs. As a result, we are proposing separate fixed dollar loss amounts, defined in

proposed §413.237(a)(4-5) of \$134.96 for adult patients and \$174.31 for pediatric patients.

## 2.Outlier Payments

The loss sharing percentage is the percentage of costs exceeding the fixed dollar loss amount that is paid by Medicare. We considered various loss sharing percentages for the proposed ESRD PPS outlier policy. We are proposing an 80 percent loss sharing percentage because this percentage is consistent with certain other Medicare payment systems, including the Inpatient Rehabilitation Facility and Home Health PPSs, and, more importantly, is consistent with the amount Medicare pays, in general, for Part B services.

In addition, while for the reasons stated above we believe it is important to ensure that we pay ESRD facilities an outlier payment that is an adequate amount for treatments involving high costs, at the same time we want to preserve the efficiency incentives inherent under a prospective payment system. We believe an 80 percent loss sharing percentage strikes a reasonable balance between these policy objectives. In particular, we note that to the extent the cost to ESRD facilities of the inputs required to deliver additional services beyond the outlier threshold (the sum of the predicted outlier services MAP

amount plus the fixed dollar loss amount) is greater than the 80 percent loss sharing ratio, there would be less incentive to increase utilization of outlier services inappropriately to receive outlier payments.

We propose to implement an annual monitoring process that would identify patterns of increased utilization of outlier services and any associated outlier payments across ESRD facilities. For example, we would be most interested in identifying ESRD facilities that receive significant outlier payments. We believe that this monitoring effort would prevent potential abuse and provide us with an outlet for addressing abuse.

For treatments eligible for outlier payments, we are proposing that the per treatment outlier payment equal 80 percent (the loss sharing percentage) of the imputed average ESRD outlier service MAP amounts in excess of the sum of the predicted, outlier services MAP amount per treatment and the fixed dollar loss amount, as specified in proposed §413.237(c). For treatments eligible for the outlier payment, the outlier payment would be added to each ESRD PPS per treatment payment amount.

### 3. Hypothetical Outlier Payment Examples

Please refer to the hypothetical outlier examples for both adult and pediatric patients set forth below for an illustration of (1) the way in which predicted and imputed ESRD outlier services MAP amounts are calculated and compared in determining eligibility for outlier payment, and (2) the way in which outlier payments would be calculated.

Hypothetical Example- Adult Patient:

Martha, a 66 year old female who is 167.64 cm. tall, weighs 105 kg. and has three co-morbid conditions; HIV/AIDS, septicemia and hereditary hemolytic or sickle cell anemia. As described in hypothetical example number 4 within section XI. of this proposed rule, a patient of this weight and height is not below the threshold for underweight status and thus would not qualify for a low BMI adjustment.

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

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

Martha's BSA is calculated as:

$$\text{BSA}_{\text{Martha}} = 0.00718 * 167.64^{.725} * 105^{.425}$$

$$= 0.007184 * 40.9896 * 7.2278$$

$$= 2.1284$$

As identified in table 29, the separately billable multiplier for BSA would be 1.033. Martha's case-mix adjustment based on her BSA of 2.1284 would be:

$$= 1.033^{(2.1284-1.87/0.1)} = 1.088$$

$$= 1.033^{2.584}$$

$$= 1.088$$

Step 1: Determine the predicted, ESRD outlier services MAP amount.

The product of the patient-level outlier services case-mix adjusters as identified in table 34:= 66 year old:

1.006, female: 1.149, BSA: 1.088, HIV/AIDS: 1.220, septicemia: 1.715, and hereditary hemolytic or sickle cell anemias: 1.179

$$= 1.006 * 1.149 * 1.088 * 1.220 * 1.715 * 1.179$$

$$= \mathbf{3.10231}$$

The adjusted, average, ESRD outlier services MAP amount = \$64.54

The adjusted, average ESRD outlier services MAP amount \* product of the outlier services case-mix adjusters:

$$= \$64.54 * 3.10231$$

$$= \mathbf{\$200.22}$$

Step 2: Determine the imputed average, per treatment, ESRD outlier services MAP amount.

The imputed monthly ESRD outlier services amount = \$4000

The corresponding total number of treatments = 10

$$\begin{aligned} &\text{The imputed, average, per treatment, outlier services} \\ &\text{MAP amount} = \\ &= \$4000/10 \\ &= \mathbf{\$400} \end{aligned}$$

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

$$\begin{aligned} &\text{The fixed dollar loss amount} = \$134.96 \\ &\text{The predicted, ESRD outlier services MAP amount} = \\ &\$200.22 \\ &= \$200.22 + \$134.96 \\ &= \mathbf{\$335.18} \end{aligned}$$

Step 4: Calculate outlier payment.

$$\begin{aligned} &\text{Outlier payment} = \text{imputed average, per treatment,} \\ &\text{outlier services MAP amount} - (\text{predicted, ESRD outlier} \\ &\text{services MAP amount plus the fixed dollar loss amount}) * \\ &\text{loss sharing percentage:} \\ &= (\$400 - \$335.18) * .80 \\ &= \$64.82 * .80 \\ &= \mathbf{\$51.22} \end{aligned}$$

Hypothetical Example- Pediatric Patient:

John, a 13 year old hemodialysis pediatric patient with 1 or more co-morbidities.

Step 1: Determine the predicted, ESRD outlier services MAP amount.

As identified in table 35, the patient-level ESRD outlier services case-mix adjuster:

=13 year old hemodialysis patient with 1 or more co-morbidities

= **1.272**

The adjusted, average, ESRD outlier services MAP amount = \$64.54

The adjusted, average, ESRD outlier services MAP amount \* the

product of the outlier services case-mix adjusters:

= \$64.54 \* 1.272

= **\$80.09**

Step 2: Determine the imputed, average, per treatment, ESRD outlier services MAP amount.

The imputed monthly ESRD outlier services amount = \$4000

The corresponding total number of treatments = 10

The imputed, average, per treatment, outlier services MAP amount =

= \$4000/10

= **\$400**

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount.

The fixed dollar loss amount = \$174.31

The predicted, ESRD outlier services MAP amount =  
\$80.09

= \$80.09 + \$174.31

= **\$254.40**

Step 4: Calculate outlier payment.

Outlier payment = imputed, average, per treatment, outlier services MAP amount - (predicted, ESRD outlier services MAP amount plus the fixed dollar loss amount) \* loss sharing percentage:

= (\$400 - \$254.40) \* .80

= \$145.60 \* .80

= **\$116.48**

The outlier payment amount would be added to the ESRD PPS payment amount, per treatment. For a detailed description of calculating the ESRD PPS payment amount per treatment, please refer to the hypothetical examples in section XI. of this proposed rule.

#### 4. Application of Outlier Policy During the Transition and in Relation to the ESA Monitoring Policy

As discussed in section XIII. A. of this proposed rule, section 1881(b)(14)(E)(i) of the Act requires the

Secretary to provide a four-year transition from the current basic case-mix adjusted composite payment system to the ESRD PPS for renal dialysis services furnished beginning January 1, 2011. Under the transition, ESRD facilities would receive a blended rate based in part on the payment rates under the current basic case-mix adjusted composite rate payment system and in part on the payment rates under the ESRD PPS. Section 1881(b)(14)(E)(ii) of the Act permits ESRD facilities to make a one-time election to be excluded from the transition from the current case-mix adjusted composite payment system to the ESRD PPS. Those ESRD providers and facilities that elect to be excluded from the transition would receive 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 rate.

As indicated above, the current ESRD basic case-mix adjusted composite payment system does not provide for outlier payments. Rather, the proposed outlier payment policy would be limited to the proposed ESRD PPS. We therefore propose that for those ESRD facilities that do not elect to be excluded from the 4-year transition, outlier payments would be limited to the portion of the

blended rate based on the payment rates under the proposed ESRD PPS.

Nothing within this proposed outlier payment policy would replace the claims monitoring implications related to the utilization of separately billable erythropoiesis-stimulating agents (ESAs) including currently available epoetin alfa (EPOGEN<sup>®</sup>, or EPO), darbepoetin alfa (ARANESP<sup>®</sup>) or any ESAs that may be developed in the future and used by beneficiaries receiving renal dialysis services. As we discuss in section XIV.B of this proposed rule, we are evaluating the extent to which we could continue to apply the ESA Monitoring Policy under the proposed ESRD PPS. We are also considering ways in which outlier payments would be computed under the proposed ESRD PPS. We believe that any dosing reductions associated with the application of the ESA Monitoring Policy would be factored in prior to determining eligibility for outlier payment.

We expect that ESRD facilities would exercise prudent clinical judgment in prescribing ESAs for patients who are resistant to these drugs, so as not to over-prescribe with the intent of capitalizing on outlier payments. However, we request public comments that would outline additional safeguards to protect against overuse of ESAs among the ESA-resistant patient population.

**XI. Comprehensive Payment Model Examples**

In section VIII., we demonstrated how the case-mix adjustments based on separate estimating equations for CR and SB services (that is, the two equation model), were combined to obtain a single payment formula under the proposed ESRD PPS. Table 29 in that section contained the proposed case-mix adjustments applicable to adult patients. In section IX, we presented our proposed pediatric payment model under the ESRD PPS. Table 33 in that section contained the pediatric classification categories and corresponding case-mix adjusters which we propose to apply to pediatric ESRD patients. In this section, we explain how the area wage index and the case-mix adjustments would be applied to the proposed base rate described in section VII. reflecting combined CR and SB services, resulting in a patient-specific per treatment payment amount under the proposed ESRD PPS, as set forth in proposed §413.215. We demonstrate how the proposed case-mix adjustments presented in Tables 29 and 33 would be applied for 7 hypothetical ESRD patients to obtain the per treatment payment amounts under the ESRD PPS. The product of the applicable case-mix adjustment factors is the patient multiplier or PM. The ESRD PPS case-mix adjusters are shown in Table 29 for adult patients and Table 33 for pediatric patients. Each example