IX. Pediatric Patients

Section 1881(b)(14)(D)(iv)(I) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the discretionary authority to develop pediatric payment adjustments in connection with the ESRD PPS. Below we discuss the current system with regard to ESRD facilities that furnish renal dialysis services to pediatric patients, as well as our proposed methodology for developing a pediatric payment adjustment under the proposed ESRD PPS.

A. Current System

The current basic case-mix adjusted composite payment system uses a set of case-mix adjusters or multipliers based on three variables -- age, BSA, and low BMI. Employing the same 2000 to 2002 data and regression methodology used to derive the basic case-mix adjusters, we attempted, when implementing the current payment system, to develop case-mix adjusters for outpatient ESRD patients under age 18. However, we found that for the approximately 600 Medicare pediatric patients for whom claims were available from 2000 through 2002, the results were highly variable and statistically unstable, and therefore, inappropriate for the development of case-mix adjusters in accordance with the same methodology otherwise applicable to adult Medicare ESRD patients (see 69 FR 66326-27

published November 15, 2004). Section 623(b)(1)(D) of the MMA amended section 422(a)(2) of BIPA to provide that beginning October 1, 2002, ESRD facilities in which at least 50 percent of patients are under age 18, are considered ESRD pediatric facilities, and are eligible for a pediatric exception to the composite payment rate. However, due to the relative costliness of pediatric ESRD patients, we believed that it was appropriate to develop a temporary methodology applicable to ESRD facilities, which furnish outpatient dialysis to pediatric patients, regardless of whether the facility met the definition of a pediatric facility. Our intent was to rely on a temporary methodology pending the completion of research, which could yield empirically based case-mix adjusters under a bundled ESRD PPS.

In the CY 2005 PFS final rule with comment period, published on November 15, 2004 (69 FR 66327), implementing the basic case-mix adjustment to the composite payment system we described the methodology used to develop a 62 percent pediatric increase (that is, an adjustment factor of 1.62) automatically applied to the composite payment rate per treatment for any facility furnishing outpatient dialysis services to pediatric patients. That factor was based on the average amount of the atypical

services exceptions granted for 20 ESRD facilities, each of which sought and received an exception for the atypical costs incurred for the treatment of outpatient pediatric patients, compared to the average unadjusted composite payment rate (that is, the payment without regard to exception amounts) for these same 20 facilities. We explained that application of the pediatric adjustment factor of 1.62 in lieu of an explicit pediatric case-mix adjustment was temporary, and would be eliminated once an appropriate methodology, preferably one applicable to both pediatric and adult Medicare patients, could be developed.

The Secretary's 2008 Report presented a design for a case-mix adjusted ESRD PPS, which included not only composite rate services but also separately billable dialysis services, weighted in accordance with the two-equation model described in section VIII. of this notice of proposed rulemaking.

In applying the case-mix adjustment factors resulting from the two-equation regression model described in the Secretary's 2008 Report to pediatric patients, we noted the following:

> [P]ediatric dialysis patients are comparatively rare among Medicare dialysis patients, comprising about 0.2 percent of the population. The impact of the BSA adjustment in the above example is a payment reduction of over 37 percent, compared to the age related

> increase of 9.1 percent. UM-KECC has performed analyses which demonstrate that the predicted separately billable MAP falls substantially short of the actual separately billable MAP for pediatric patients (that is, those less than age 18). This occurs because the BSA multiplier of 1.035 does not accurately reflect the relationship between BSA and separately billable services for pediatric patients because of their small size and relative rarity in the Medicare dialysis population. Given the small number of pediatric patients, there is a lack of statistical robustness in the payment model with respect to those patients. The data limitations do not permit a ready solution to this problem. We are currently examining approaches to determine if modifications to the regression based payment methodology for pediatric patients is feasible.
>
> See Secretary's February 2008 Report to Congress, pp. 47-48.

Based on UM-KECC research subsequent to the issuance of the Secretary's 2008 Report, we believe that a separate regression based case-mix model is feasible for pediatric patients using a limited number of variables. In the following sections, we describe the payment model used to develop the payment adjusters which we are proposing to apply for Medicare pediatric ESRD patients.

B. Selection of a Pediatric Composite Rate Payment Adjustment

One approach to developing a payment adjustment is to use the results of an updated composite rate cost model.

Such a model could employ one or several age categories for pediatric patients. Table 31 presents a model of composite rate costs for the purpose of demonstrating a method for arriving at a pediatric composite rate multiplier, with a single pediatric age category. This model was estimated using Medicare cost report, claims, and other data for CYs 2004-2006. The model uses ESRD facility data on composite rate costs and average patient characteristics. Because pediatric patients comprise such a low percentage of the total patient load of most facilities, the measures of many patient characteristics at the facility level (that is, the average patient characteristics at the facility) are dominated by the characteristics of adult patients. Therefore, while average patient characteristics are shown in Table 31 in the model, they are only used as control variables. That is, while statistically significant payment adjusters may be shown in Table 31 for patient characteristic variables, there is no actual associated payment adjustment that would apply to composite rate services for pediatric patients. For example, the pediatric composite rate cost model assumes no payment adjustment for body size (BSA or low BMI), gender, duration of renal replacement therapy, or co-morbidities. The key coefficient is the one for the age less than 18 variable.

The estimated regression-based multiplier of 1.199 reflects an increase in the composite rate portion of the base payment rate of 19.9 percent for patients less than 18, relative to patients age 45-59. The model shown in Table 31 with a single pediatric age category is the model we are proposing to use to adjust the composite rate portion of the proposed ESRD for pediatric patients.

Table 31
Payment multipliers from a facility level model of composite rate costs

Variable*	Composite rate services (n=11,814 facility years; R-sq=46.0%)	
	$Mult_{CR}$	p-value
Adjustments for dialysis patient characteristics		
Age		
<18	1.199	<0.001
18-44	1.280	<0.001
45-59	1.000	ref
60-69	1.014	0.665
70-79	1.105	<0.001
80+	1.150	<0.001
Female	1.124	<0.001
Body surface area (BSA, per 0.1 m^2; mean BSA=1.87)	1.035	<0.001
Underweight (BMI <18.5)	1.000^	--
Time since onset of renal dialysis: <4 months	1.508	<0.001
Alcohol/drug dependence (claims since 2000 or 2728)	1.155	<0.001
Cardiac Arrest (claims since 2000 or 2728)	1.000^	--
Pericarditis from same month to three months ago	1.000^	--
HIV/AIDS (claims since 2000 or 2728)	1.363	<0.001
Hepatitis B (claims since 2000)	1.115	<0.001
Specified infection from same month to three months ago		
Septicemia	1.000^	--
Bacterial pneumonia and other pneumonias/opportunistic infections	1.256	0.021
Gastro-intestinal tract bleeding from same month to three months ago	1.000^	--
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.248	<0.001
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.143	<0.001
Myelodysplastic Syndrome (claims since 2000)	1.000^	--
Monoclonal Gammopathy between (claims since 2000)	1.000^	--

Low volume facility adjustment Facility size < 3,000 treatments during each year from 2004-06	1.383	<0.001

*Both the composite rate and separately billable models included the following facility control variables: facility size categories other than the low volume category, urban/rural location, calendar year, facility ownership type, composite rate payment exception, and % of patients in the facility with URR<65%.

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

The type of cost model shown in Table 31 could also employ multiple pediatric age categories. However, because of the small number of patients in each pediatric age category, the payment adjusters, based on the coefficients of the age variables, are unstable. Therefore, with respect to a payment adjustment applicable to composite rate services for pediatric patients, we believe that a single age category is most appropriate. Although the proposed payment adjuster of 1.199 for the composite rate portion of the ESRD PPS for pediatric patients is substantially less than the current adjustment of 1.62, we point out that this is an empirically developed measure derived from data for all Medicare outpatient ESRD pediatric patients treated by ESRD facilities. The 1.62 value was developed from only those facilities that sought and obtained an exception to their otherwise applicable composite payment rates.

C. Selection of a Pediatric Separately Billable Payment Adjustment

Although the number of pediatric patients is small, we believe that it is feasible to estimate a payment model for separately billable services furnished to pediatric patients. However, the small sample size limits statistical power and results in a more limited set of potential payment adjusters. Unlike the adult separately billable payment model, which includes multipliers for particular patient co-morbidities, age, body size, and other variables, we evaluated pediatric separately billable payment models based on categories defined by patient characteristics including age, the presence of co-morbidities, and dialysis modality. This model structure is feasible because of the relatively small number of characteristics generating adjustments.

We considered several factors in developing the payment model for separately billable services: the number and definition of the age categories; the number and set of co-morbidities; the reflection of modality as a payment variable; and the potential inclusion of other patient characteristics, such as gender, onset of renal dialysis, and history of transplantation. We developed several exploratory models for separately billable services furnished to pediatric patients in order to develop the model proposed in this notice.

All of the analyses were performed using log-linear regression models of the average separately billable MAP per treatment during the year as the dependent variable. The data were pooled over the 3-year period CY 2004-2006, resulting in up to three yearly observations for each pediatric patient. The potential payment multipliers that were estimated by the model often required a statistical "smearing" adjustment to limit retransformation bias.

Under statistical "smearing", a correction factor is applied to the predictions from a model that is estimated on the logarithmic scale (for example, the log of the average MAP per treatment). In the context of examining healthcare cost data that are not normally distributed, retransformation bias may occur when converting predicted values that are made on the log scale (that is, log dollars) back to the original scale (that is, dollars), yielding biased estimates of the mean cost in dollars. In order to make valid inferences about the relationships between patient characteristics and the MAPs (that is, in dollars), it is essential that retransformation bias be limited as much as possible. Because the difference between the measured MAP and predicted MAP for each observation (that is, the residuals) did not vary in the desired random pattern, indicating correlation between the

variance of the residuals and some of the patient characteristics in each model (statistically known as "heteroscedasticity"), separate smearing factors were applied by patient subgroup. The smearing adjustments were based on the average retransformed residual for each patient category. For further information on the use of statistical smearing, retransformation, and heteroscedasticity, see Duan, N., Smearing estimate: a nonparametric retransformation method, Journal of the American Statistical Association, 78, 1983, pp. 605-610, and Manning, W. G., The logged dependent variable, heteroscedasticity, and the retransformation problem, Journal of Health Economics, 17, 1998, pp. 283-295.

We examined numerous separately billable payment models to determine the most appropriate age categories (defined by two age groups), and the selection of co-morbidity categories, defined as two groups (no co-morbidities, and the presence of one or more of the co-morbidities listed in the footnotes to Table 32). Individual co-morbidities that were considered for inclusion in the co-morbidity categories were each identified as statistically significant predictors of separately billable MAP per treatment based on a stepwise regression model. Some of the more important factors which

we considered before arriving at the pediatric payment model we are proposing in this notice of proposed rulemaking are discussed below. Because our consideration of each of these factors resulted in the pediatric payment adjustments we are proposing in this rule, we invite comment on their use.

(1) Use of two age categories <13, and 13-17.

Because of the small number of pediatric patients, we limited the number of age groups to two. Because the data revealed a natural break relating to increased body size and greater utilization of resources corresponding with the onset of adolescence, we defined the pediatric age categories as less than 13, and age 13-17.

(2) Omission of hyperparathyroidism as a co-morbidity

Hyperparathyroidism had a relatively low reported incidence in the claims data. However, hyperparathyroidism clinically is a frequently encountered condition in pediatric dialysis patients. This co-morbidity has a relatively high potential for overreporting compared to other co-morbidities. Because hyperparathyroidism was associated with a relatively small payment increase, omitting this diagnosis from the list of co-morbidities generating a payment adjustment increases the potential payment multipliers for other co-morbidities. However,

given the widespread occurrence of hyperparathyroidism in the pediatric dialysis patient population, we believe its omission results in minimal distortion in the adjusters for most payment categories. We invite comment on our proposal to omit hyperparathyroidism as a co-morbidity in our proposed pediatric payment model.

(3) Capping separately billable MAP per treatment at $289.00 per treatment for all pediatric patients.

The cap of $289.00 was based on a standard outer fence method for identifying statistically aberrant values.(For a further explanation on the application of this method, see p. 46 of UM-KECC's February 2008 report, "End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle" and footnote 35 of the Secretary's February 2008 Report to Congress, both cited previously in this proposed rule. The outer fence was defined as the 75th percentile of the separately billable MAP per treatment, plus three times the interquartile range, which is the 75th percentile minus the 25th percentile.) Capping the separately billable MAP does not lead to substantially different payment multipliers. The standard deviation of the prediction error falls substantially for some of the payment groups, especially those that were quite large. Some of this reduction may be

due to the elimination of erroneous data through the capping mechanism. In any case, the fact that the case-mix payment adjusters did not materially change regardless of the application of the standard outer fence method for eliminating aberrant values suggests that the predicted payments are not biased through the inclusion of valid or invalid values.

(4) Adjustment for dialysis modality.

Our analysis revealed that the main problem with a separately billable payment model that does not recognize modality is that it results in an underpayment for HD and an overpayment for PD. For models that did not pay differentially by modality, the average prediction errors were all positive for PD and negative for HD. The errors in both directions were large relative to the predicted means. By contrast, the prediction errors in models that distinguish payment by modality were much smaller and did not consistently favor PD over HD. Hence, payment by modality reduces the difference between actual and predicted payments. In doing so, it reduces the incentive to steer patients to a particular modality based purely on

the payment implications. It also substantially improves the predictive power of the payment models.

However, payment by modality introduces an inconsistency with how modality is treated currently under the basic case-mix adjusted composite payment system, and with how we are proposing to treat it for adults under the proposed ESRD PPS. There are a small number of payment groups with relatively large differences between actual and predicted payments even when the models adjust for modality. Paying by modality for pediatric patients is also inconsistent with the payment goal of encouraging home dialysis. However, we note that partly because of the popularity of PD among pediatric patients, it may not be necessary to encourage home therapies for this population. In addition, paying by modality doubles the number of payment categories from four to eight, increasing administrative complexity. We are specifically soliciting comments on our proposal to use modality as a payment variable in our pediatric payment model.

(5) Exclusion of other patient characteristic variables. Among the other patient characteristics that were considered as potential payment adjusters for separately billable pediatric services, gender, and onset of dialysis (that is, the start of dialysis within 4 months of the

current treatment), were not identified as statistically significant predictors of MAP using CY 2004-2006 data. Based on models that included adjustments for age, dialysis modality, and number of co-morbidities, history of transplantation was associated with a higher separately billable MAP per treatment. However, the inclusion of an additional adjustment for history of transplantation did not substantially improve the explanatory power of the model, or substantially reduce the prediction errors for most patient subgroups. In addition, its inclusion would double the number of payment categories in the model from 8 to 16, six of which had very small numbers of patients (less than 50 patients).

Given the results of the analyses described, we are proposing a pediatric payment adjustment for separately billable services that uses two age categories (<age 13, age 13-17), two co-morbidity categories (none, and one or more co-morbidities from among the following diagnoses: HIV/AIDS, septicemia, cardiac arrest, and diabetes), and dialysis modality (HD or PD), as the bases for classifying pediatric patients into one of eight groups. The specified co-morbidities were the only statistically significant predictors of SB MAP resulting from the application of the stepwise regression. Using data available for CY 2004-

2006, we present the results in Table 32. Similar to the adult ESRD PPS payment model, the proposed pediatric separately billable payment model reflects the repricing of the top 11 Part B separately billable drugs to the payment rates used in the first quarter of 2008. The ratios used to adjust the MAPs for the 11 specified injectable drugs are identical to those used to reprice the drugs for the adult separately billable MAPs shown in Table 11.

Table 32
Measured and predicted separately billable Medicare Allowable Payments (MAP) for pediatric patients, 2004-2006

Preliminary **Predicted MAP based on age, modality, and comorbidity groups**

	Patient characteristics					Modeled separately billable (SB) multiplier[3]	Separately billable MAP per session			
									Prediction error	
Cell	Age	Modality	Comorbidities[1]	Patients[2]	Patient-facility months		Actual mean	Predicted mean[4]	Mean	SD
1	<13	PD	None	333	3,376	1.000	$12.28	$12.06	-$0.22	$21.39
2	<13	PD	1 or more	68	310	1.485	$10.14	$17.90	$7.76	$17.35
3	<13	Hemo	None	267	1,757	3.861	$51.82	$46.55	-$5.27	$52.81
4	<13	Hemo	1 or more	120	751	5.647	$83.35	$68.08	-$15.27	$67.89
5	13-17	PD	None	296	2,598	1.508	$19.70	$18.18	-$1.52	$37.12
6	13-17	PD	1 or more	66	456	2.244	$33.49	$27.06	-$6.43	$54.88
7	13-17	Hemo	None	656	5,765	5.831	$70.95	$70.30	-$0.65	$62.28
8	13-17	Hemo	1 or more	255	2,002	8.534	$87.61	$102.89	$15.28	$64.08

[1]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).

[2]Note that individual patients can appear in more than one cell during 2004-06.

[3]Based on a pediatric patient level regression model of SB MAP/session for 2004-06 (n=2,375 pediatric patient years) that included age (<13 vs. 13-17), modality (PD vs. HD), and comorbidity (none vs. 1 or more) as covariates (R-sq=32.8%). Subgroup-specific smearing adjustments were applied to the model estimates.

[4]Predicted SB MAP per session are based on a log-linear regression model that included the patient characteristics in this table, subgroup-specific smearing adjustments, and a budget neutrality adjustment.

For purposes of the payment adjustments, the relevant column is labeled "Modeled separately billable (SB) multiplier". These values reflect the relative costliness

of separately billable services for each of the eight pediatric patient groups, with the reference category (under 13, PD, no co-morbidities) having a multiplier set to 1.00. We invite comment on our proposed use of these variables to construct the proposed pediatric ESRD payment model.

D. A Combined Composite Rate and Separately Billable Payment Model for Pediatric Patients

Similar to the payment model for adult patients described in section X of this proposed rule, a payment model for pediatric patients can be constructed from cost/payment models of composite rate and separately billable services. A composite rate cost model can be estimated to generate a payment adjuster or multiplier for patients in a pediatric age group or groups. Because this kind of composite rate cost model is based on ESRD facility data, and there are very few pediatric patients, estimating additional pediatric co-morbidity multipliers is not feasible. However, a separately billable cost model can be estimated that would generate payment adjustments for particular patient characteristics. While the results from the composite rate and separately billable cost models can be combined into a single payment model following the same approach used in connection with the two equation adult

payment methodology, the payment model for adult patients cannot be applied to pediatric patients without modification.

The results presented in Tables 31 and 32 can be used to develop a payment model for ESRD pediatric patients (age < 18). The method which we propose combines results from a facility-level model for CR services (Table 31) and a pediatric patient-level model for SB services (Table 32). The outcome is a single set of payment multipliers that can be used to determine the case-mix adjusted payment rate for individual pediatric patients.

The process of combining the CR and SB adjustments required decisions about the following issues:

1. How to apply the modeled SB multipliers, which are based on a separate payment model for pediatric patients, to the SB portion of the overall base rate, which applies to both adult and pediatric patients as described in section VII.

2. The relative weighting of CR and SB services for pediatric patients.

For each of the 8 pediatric classification categories in Table 32, the modeled SB multipliers are expressed relative to a reference category of pediatric patients (age < 13, PD, no co-morbidities). To obtain payment

multipliers that can be applied to an overall base rate, the modeled SB multipliers need to be expressed relative to the estimated SB portion of the overall base rate for all patients. This can be accomplished by adjusting the modeled SB payment multipliers by the ratio of the actual SB MAP for the pediatric reference category ($12.28 per treatment for patients < age 13, PD, no co-morbidities) to the actual SB MAP among patients of all ages ($82.38 per treatment). These SB MAP values were computed from claims for CYs 2004 through 2006, the latest available in time for the preparation of this proposed rule. This results in an SB adjustment factor of $12.28/$82.38 or 0.1491. This adjustment was applied to each of the modeled SB multipliers in Table 33, and results in SB payment multipliers which range from 0.149 to 1.272 across the 8 pediatric classification groups. These payment multipliers can be applied to the SB portion of the overall base rate described in section VII. under the ESRD PPS.

The pediatric SB MAP for CYs 2004 through 2006 is $49.11. This SB MAP reveals that most pediatric patients use substantially fewer SB services than adult patients, for which the comparable SB MAP is $82.45. Consequently, SB services account for a relatively smaller portion of total ESRD facility costs for pediatric patients. To

develop overall payment adjustments that reflect the different mix of resources required to treat pediatric patients, the CR and SB multipliers were weighted according to the relative utilization of resources among pediatric patients. Based on the average SB MAP of $49.11 per treatment for pediatric patients and an overall average ESRD facility CR cost for CYs 2004 through 2006 of $169.67 per treatment, the resulting SB and CR weights were calculated as follows:

$$SB_{weight} = \$49.11/(\$49.11 + \$169.67) = 0.2245$$

$$CR_{weight} = \$169.67/(\$49.11 + \$169.67) = 0.7755$$

The multipliers from the CR and SB models can be used to calculate combined payment multipliers using the following formula:

$$Mult_{PPS} = (Mult_{CR} * CR_{weight}) + (Mult_{SB} * SB_{AdjFactor} * SB_{weight})$$

Using the SB adjustment factor of 0.1491, and the CR and SB weights of 0.7755 and 0.2245, respectively, that were calculated above, the formula becomes:

$$Mult_{PPS} = (Mult_{CR} * 0.7755) + (Mult_{SB} * 0.1491 * 0.2245)$$

By applying this formula to each of the 8 pediatric classification groups, we obtained the payment multipliers shown in the last column of Table 33.

Table 33

Calculating combined payment multipliers for pediatric patients based on adjustments for age, modality, and co-morbidity

	Patient characteristics				Payment multipliers		
Cell	Age	Modality	Comorbidities[1]	Modeled separately billable (SB) multiplier	SB payment multiplier ($PmtMult_{SB}$)	CR payment multiplier ($PmtMult_{CR}$)	Expanded bundle payment multiplier ($PmtMult_{EB}$)
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

[1]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).

These combined multipliers range from 0.963 to 1.215. These are the proposed pediatric patient-specific case-mix adjustment factors that would be applied to the base rate under the ESRD PPS. For comprehensive examples of how the proposed pediatric payment adjusters would be applied, see examples 6 and 7 in section XI. of this proposed rule.

Using CY 2007 claims data, we calculated combined payment multipliers for pediatric patients. The average pediatric patient-specific payment adjustment multiplier was 1.067, without any adjustment for budget neutrality.

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