However, we note that the case-mix adjustments we are proposing for pediatric patients, described in section IX. of the proposed rule, distinguish between HD and PD as a payment variable. The small number of pediatric dialysis patients, the limited ability of the two-equation regression model to accurately predict the separately billable MAP for pediatric patients, and the far greater prevalence of PD among pediatric patients, led us to examine alternative approaches in devising case-mix adjustments for those patients. The pediatric payment adjustments described in section IX., use modality, in part, to determine the case-mix adjusters for pediatric dialysis patients. Except for pediatric patients, modality is not otherwise used in developing the proposed case-mix adjustments under the ESRD PPS.

C. Proposed Facility-Level Adjustments

1. Wage index

Section 1881(b)(14)(D)(iv)(II) of the Act, as added by section 153(b) of MIPPA, specifies that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment by a geographic index, such as the index referred to under the existing basic case-mix adjusted composite payment system, as the Secretary determines to be appropriate.

In the current basic case-mix adjusted composite payment system, we use an index based on hospital wage and employment data from Medicare cost reports. In the CY 2006 PFS final rule with comment period (70 FR 70167), we announced our adoption of the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to develop revised urban/rural definitions and corresponding wage index values for purposes of calculating ESRD composite rates under the basic case-mix adjusted composite payment system. OMB's CBSA-based geographic area designations are described in OMB Bulletin 03-04, originally issued June 6, 2003, and is available online at: http://www.whitehouse.gov/omb/bulletins/b03-04.html. In addition, OMB has published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. We stated that this and all subsequent ESRD rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index (73 FR 69758). The OMB bulletins may be accessed online at: http://www.whitehouse.gov/omb/bulletins/index.html. We also stated that we intended to update the ESRD wage index values annually (70 FR 70167). The ESRD wage index values used in the basic case-mix adjusted composite

payment system are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix (71 FR 69685; 73 FR 69758). We apply the current ESRD wage index to a 53.711 labor share of the composite rate. As we indicated, this labor share was developed from the labor-related components of the ESRD composite rate market basket (70 FR 70168). The ESRD wage index in the current basic case-mix adjusted composite payment system applies a wage index budget neutrality factor to ensure that the ESRD wage index is made in a budget neutral manner (70 FR 70170). As we previously noted, in our current basic case-mix adjusted composite payment system, we incorporate the wage index budget neutrality factor into the wage index. We compute a wage index factor and adjust it so that wage index budget neutrality can be achieved by the labor share component only.

For purposes of the current basic case-mix adjusted composite payment system, section 1881(b)(12)(D) of the Act required the Secretary to adjust payment rates, as the Secretary determined appropriate, and if the Secretary applied a geographic adjustment that differed from the current index applied under the old (composite rate)

system, the Secretary would be required to phase in such an index over a multi-year period. Under this authority, CMS elected a 4-year transition from the wage index based on MSAs to an updated wage index based on CBSAs. This 4-year transition began in CY 2006 and ended in CY 2009, when ESRD facilities receive a wage adjusted composite rate that is computed using 100 percent CBSAs in CY 2009 (70 FR 70167).

For the proposed ESRD PPS, we are proposing to use the same method and source of wage index values as we have been using for the basic case-mix adjusted composite payment system. Specifically, we propose that the ESRD wage index values used in the proposed ESRD PPS be calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act, and utilize pre-floor hospital data that are unadjusted for occupational mix. We also propose to use the OMB's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values. OMB's CBSA-based geographic area designations are described in OMB Bulletin 03-04, originally issued June 6, 2003, and is available online at: http://www.whitehouse.gov/omb/bulletins/b03-04.html.

In addition, as we indicated above, OMB has published subsequent bulletins regarding CBSA changes, including

changes in CBSA numbers and titles. We propose that this and all subsequent ESRD PPS rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index. The OMB bulletins may be accessed online at: http://www.whitehouse.gov/omb/bulletins/index.html. Consistent with those definitions, we are proposing to define urban and rural areas in proposed §413.231(b) of this proposed rule as follows: The term "urban area" would mean a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB. The term "rural area" would mean any area outside an urban area.

Under the current basic case-mix adjusted composite payment system, we apply a floor as a substitute wage index for areas with very low wage index values. However, we have gradually reduced the ESRD wage index floor from 0.90 in CY 2005, to 0.85 in CY 2006, 0.80 in CY 2007, 0.75 in CY 2008, and 0.70 in CY 2009 (73 FR 69758). We also stated that a gradual reduction was needed to ensure that patient access in areas that have low wage index values, and that we would continue to reassess the need for a wage index floor in future years.

For the ESRD PPS proposed rule, we are proposing not to adopt a wage index floor, as we believe we have provided a gradual reduction to the ESRD wage index floor through the existing basic case-mix adjusted composite payment system and that the impact on ESRD facilities will be minimal. We note that ESRD facilities affected by the floor may opt to go through the transition to the ESRD PPS, where the portion of their payment that is based on the ESRD PPS will be gradually increased from 25 percent of their payments in 2011 to 100 percent of their payments in 2014. We intend to continue to gradually reduce the ESRD wage index floor for the portion of the payment that is based on the current basic case-mix adjusted composite payment system. Applying a gradual reduction only to the floor that applies to the existing basic case-mix adjusted composite payment system ESRD wage index will accelerate the decline in the floor so that ESRD facilities are less dependent on the floor and at the end of the transition we would apply their actual wage index values.

In CY 2006, while adopting the CBSA designations, we identified a small number of ESRD facilities in both urban and rural areas where there are no hospital data from which to calculate ESRD wage index values. Since there are ESRD facilities in these areas, we developed policies for each

of these areas, and we provide the details of these policies below (72 FR 66283). The areas with ESRD facilities that have no hospital data are rural Massachusetts, rural Puerto Rico, and Hinesville, GA (CBSA 25980). In the CY 2008 PFS final rule with comment (72 FR 66283), we stated that we would continue to evaluate exiting hospital wage data and possibly wage data from other sources such as the Bureau of Labor Statistics, to determine if other methodologies might be appropriate for imputing wage index values for areas without hospital wage data for CY 2009 and subsequent years. To date, no data from other sources, superior to that currently used in connection with the inpatient hospital PPS wage index, have emerged. Therefore, for purposes of the proposed ESRD PPS, we are proposing to continue with our current policies for rural Massachusetts and Hinesville, Georgia:

- For rural Massachusetts, we propose to adopt the methodology originally adopted for CY 2008 for establishing a wage index value for rural Massachusetts. Because we had used the same wage index value for 2 years with no update, we believed it was appropriate to establish a methodology which employed reasonable proxy data for rural areas (including rural Massachusetts) and also permitted annual updates to the wage index based on

that proxy data. We used the average wage index values from all contiguous CBSAs as a reasonable proxy for rural Massachusetts. In determining an imputed rural wage index, we interpret the term "contiguous" to mean sharing a border. In the case of Massachusetts, the entire rural area consists of Dukes and Nantucket Counties. We determined that the borders of Dukes and Nantucket counties are contiguous with CBSA 12700, Barnstable Town, MA and CBSA 39300, Providence-New Bedford-Fall River, RI-MA. We propose to continue to use this methodology that averages the wage index values for the contiguous CBSAs, Barnstable Town, MA (CBSA 12700) and Providence-New Bedford-Fall River, RI-MA (CBSA 39300) for an imputed wage index value for rural Massachusetts for CY 2011.

- For Hinesville, GA (CBSA 25980), which is an urban area without specific hospital wage data, we propose to continue to use the methodology that was adopted in the CY 2007 PFS final rule (71 FR 231), which was to impute a wage index value for Hinesville, GA, using the average proposed ESRD wage index value for all urban areas within the State of Georgia.

With regard to rural Puerto Rico, we are proposing a different policy under the proposed ESRD PPS. In particular, we have previously applied the ESRD wage index

floor for rural Puerto Rico because all areas in Puerto Rico that have a wage index were eligible for the ESRD wage index floor. However, as we stated earlier in this section, for the proposed ESRD PPS, we are proposing to eliminate the use of a wage index floor under the proposed ESRD PPS wage index. Therefore, for rural Puerto Rico, we propose to use the value for rural Puerto Rico (0.4047) that has been used by other payment systems that do not use a wage index floor. This wage index value is the latest available wage index value for rural Puerto Rico and is currently used for rural Puerto Rico by other payments systems that do not have a wage index floor. We note that there are currently no ESRD facilities located in rural Puerto Rico.

We are also proposing to use the labor share as measured by the proposed ESRD bundled market basket, which is 38.160 percent (as described in section XII. of this proposed rule). We note that the labor-related share from the proposed ESRD bundled market basket (38.160 percent) is lower than the labor-related share from the existing ESRD composite rate index (53.711 percent) because there are no labor costs associated with the separately billable portion of the proposed ESRD bundled market basket. Our proposed adjustment for wages is set forth in proposed §413.231.

For this proposed rule, we used the most current final wage index that was available at the time analysis was completed. This was the final CY 2009 wage index data. As stated earlier in this section, the ESRD wage index values used in the basic case-mix adjusted composite payment system are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix (71 FR 69685; 73 FR 69758). We are proposing to use the same wage index for the ESRD PPS.

As we previously noted, in our current basic case-mix adjusted composite payment system, we incorporate the wage index budget neutrality factor into the wage index values. Since the CY 2009 ESRD wage index has the same values as the FY 2009 SNF PPS wage index, we recommend that entities wishing to replicate our analysis refer to the FY 2009 final rule where the FY 2009 Skilled Nursing Facility (SNF) PPS wage index was published. The FY 2009 SNF PPS final rule (73 FR 46415) includes tables with these wage index values. Table 8 shows the wage index values for urban areas (73 FR 46441 through 46462) and table 9 shows the wage index values for rural areas (73 FR 46462).

Since the ESRD PPS will be implemented in CY 2011, we believe it is appropriate to use CY 2011 wage index values. However, the wage data will not yet be available when the ESRD PPS final rule is published. Therefore, we propose to include the proposed CY 2011 ESRD PPS wage index data for purposes of the ESRD PPS (that would not include any wage index budget neutrality adjustment) along with the CY 2011 proposed update to the existing basic case-mix adjusted composite payment system. We anticipate that this would be published in the CY 2011 Physician Fee Schedule proposed rule, which we expect to be published in the summer of 2010. We also propose to publish the final CY 2011 ESRD PPS wage index along with the CY 2011 final rule update to the existing basic case-mix adjusted composite payment system. We anticipate that this would be published in the CY 2011 Physician Fee Schedule final rule, which we expect to be published in November of 2010.

2. Low-Volume Adjustment

a. Statutory Authority

Section 1881(b)(14)(D)(iii) of the Act requires a payment adjustment that "reflects the extent to which costs incurred by low-volume facilities (as defined by the

Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent."

b. Defining a Low-Volume facility

As indicated above, section 1881(b)(14)(D)(iii) of the Act authorizes the Secretary to define "low-volume facilities" for purposes of a payment adjustment in the proposed ESRD PPS. We believe the low-volume adjustment should encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic. UM-KECC has performed analyses using data from CMS Medicare cost reports, SIMS, and OSCAR for years 2004-2006 to assist us in determining what the ESRD facility-level characteristics are that best demonstrate what is a low-volume facility.

To begin our process of developing the methodology for defining a low-volume facility, we set parameters for ESRD facility size. In this explanation and throughout this section, the term 'year' is established by the ESRD facility's final-settled cost report, where the final-

settled cost report reports costs for 12-consecutive months. Under the initial categorization, an ESRD facility with less than 5,000 treatments per year was considered small, a ESRD facility with 5,000 to 10,000 treatments per year was considered medium, and an ESRD facility with 10,000 treatments per year or more was considered large. The average ESRD facility size is relatively close to 10,000 treatments and this threshold has been used by others, for example, MedPAC.

With the data compiled and analyzed by UM-KECC, we were interested to see the distribution of ESRD facility size across the different ESRD facility ownership types. For purposes of defining a low-volume facility, we chose to categorize all ESRD facilities into four ESRD facility ownership types; (1) independent, (2) regional chains, (3) Large Dialysis Organizations (LDOs), and (4) unknown ownership type. Of the hospital-based ESRD facilities, we found that 75.5 percent are independent, 10.7 percent are members of a regional chain/other category, 0.7 percent are members of an LDO, and 13.2 percent have unknown chain status. UM-KECC's comparison between ESRD facility size and ownership type, (Table 21: ESRD facility size and ownership type, 2004-2006), indicated that ownership varies with ESRD facility size and smaller ESRD facilities,

especially those with less than 3,000 treatments, are relatively more likely to be independent than larger ESRD facilities. For example, 31 percent of ESRD facilities with less than 3,000 treatments are independent while only 18 percent of ESRD facilities with more than 10,000 treatments are independent.

Table 21

ESRD facility size and ownership type, 2004-06

Preliminary

December 4, 2008

Total dialysis sessions at ESRD facility based on Cost Reports	ESRD facility ownership type										
	Independent		Regional chain		Large dialysis organization (LDO)*		Unknown		All		
	Facility years (n)	% of row	Facility years (n)	% of row	Facility years (n)	% of row	Facility years (n)	% of row	Facility years (n)	% of row	% of column
<5,000	588	23.7%	298	12.0%	1,521	61.4%	70	2.8%	2,477	100.0%	20.3%
<2,000	131	37.3%	47	13.4%	147	41.9%	26	7.4%	351	100.0%	2.9%
2 to 3,000	140	27.0%	63	12.1%	301	58.0%	15	2.9%	519	100.0%	4.2%
3 to 4,000	156	20.7%	86	11.4%	493	65.4%	19	2.5%	754	100.0%	6.2%
4 to 5,000	161	18.9%	102	12.0%	580	68.0%	10	1.2%	853	100.0%	7.0%
5 to 10,000	628	15.3%	361	8.8%	3,079	75.2%	29	0.7%	4,097	100.0%	33.5%
Total	2,277	18.6%	1,233	10.1%	8,500	69.6%	203	1.7%	12,213	100.0%	100.0%

* LDO status includes Fresenius, Davita, and Dialysis Clinic Inc. along with the following recent acquisitions: Renal Care (acquired by Fresenius), Gambro (acquired by Davita), and National Nephrology Associates (acquired by Renal Care in 2004 before Renal Care was acquired by Fresenius).

UM-KECC's comparison also indicated that while smaller ESRD facilities are less likely to be members of an LDO than larger ESRD facilities, a relatively large fraction of smaller ESRD facilities are members of an LDO. For an example, 61.4 percent of ESRD facilities with less than 5,000 treatments and 41.9 percent of ESRD facilities with less than 2,000 treatments are members of an LDO. As a

result of the comparison between ESRD facility size and ESRD facility ownership type, we chose to use ESRD facility ownership type as a variable in a two-equation regression analysis to test whether cost varies by ESRD facility ownership type within a ESRD facility size category.

With the data analyzed by UM-KECC, we were also interested to see the distribution of ESRD facility size across ESRD facilities that have an urban or rural status. UM-KECC's comparison of ESRD facility size and urban/rural status, (Table 22: ESRD facility size and rural status, 2004-2006 (n = 11,814)), indicated that nearly half of the small ESRD facilities are rural and larger ESRD facilities are less likely to be rural.

Table 22
ESRD facility size and rural status, 2004-2006 (n=11,814)*
Preliminary

Total dialysis sessions at ESRD facility based on Cost Reports	ESRD facility Rural Status								
	Rural			Urban			All		
	Facility years (n)	% of row	% of column	Facility years (n)	% of row	% of column	Facility years (n)	% of row	% of column
<1,000	11	19.6%	0.4%	45	80.4%	0.5%	56	100%	0.5%
1 to 2,000	78	47.3%	2.9%	87	52.7%	1.0%	165	100%	1.4%
2 to 3,000	210	49.3%	7.7%	216	50.7%	2.4%	426	100%	3.6%
3 to 4,000	312	44.4%	11.5%	390	55.6%	4.3%	702	100%	5.9%
4 to 5,000	334	41.0%	12.3%	481	59.0%	5.3%	815	100%	6.9%
5 to 10,000	1164	28.8%	42.8%	2877	71.2%	31.6%	4041	100%	34.2%
10,000+	611	10.9%	22.5%	4998	89.1%	55.0%	5609	100%	47.5%
Total	2720	23%	100.0%	9094	77%	100.0%	11814	100%	100.0%

* Excludes facilities that opened or closed during the year. Based on data reported in SIMS.

UM-KECC's comparison also indicated that because most ESRD facilities are urban, even with the lower percentage of small ESRD facilities in urban areas, more urban ESRD facilities than rural ESRD facilities would benefit from a low-volume payment adjustment. As a result of the comparison between ESRD facility size and urban/rural status, we chose to use urban/rural status as a variable in a two-equation regression analysis to test whether cost varies by urban/rural status within a ESRD facility size category.

UM-KECC was able to develop a two-equation regression analysis using the variables discussed above (Table 23: Analysis for ESRD facility size, rural/urban status, and ownership type, 2004-2006 Model 2 and Table 24: Analysis for ESRD facility size, rural/urban status, and ownership type, 2004-2006 Model 4).

Table 23
Analysis for facility size, rural/urban status, and ownership type, 2004-2006^, Model 2
Preliminary
December 17, 2008

	***Facility level log-linear model of average cost per session (n=11,814)** R-sq: 46.08% Average $169.67/session		****Patient level log-linear model of MAP per session (n=890,776)** R-sq: 8.73% Average $82.45/session		
Variable	CR Multiplier	p-value	SB Multiplier	p-value	Combined
Facility: < 1,000 treatments, Rural	1.410	0.1396	0.713	<.0001	1.182
Facility: < 1,000 treatments, Urban	1.792	<.0001	0.899	0.0151	1.500
Facility: 1,000 - 1,999 treatments, Rural	1.414	<.0001	0.953	0.012	1.263
Facility: 1,000 - 1,999 treatments, Urban	1.558	<.0001	1.110	<.0001	1.411
Facility: 2,000 - 2,999 treatments, Rural	1.413	<.0001	0.930	<.0001	1.255
Facility: 2,000 - 2,999 treatments, Urban	1.427	<.0001	0.947	<.0001	1.270
Facility: 3,000 - 3,999 treatments, Rural	1.297	<.0001	0.978	0.0027	1.193
Facility: 3,000 - 3,999 treatments, Urban	1.329	<.0001	1.010	0.1501	1.225
Facility: 4,000 - 4,999 treatments, Rural	1.208	<.0001	0.960	<.0001	1.127
Facility: 4,000 - 4,999 treatments, Urban	1.255	<.0001	1.018	0.002	1.177
Facility: 5,000 - 9,999 treatments, Rural	1.121	<.0001	0.984	<.0001	1.076
Facility: 5,000 - 9,999 treatments, Urban	1.122	<.0001	1.017	<.0001	1.087
Facility: 10,000+ treatments, Rural	1.001	0.9319	0.997	0.3507	0.999
Facility: 10,000+ treatments, Urban	1.000	ref	1.000	ref	1.000
Large dialysis organization (chain1-chain6)	1.017	0.0002	1.157	<.0001	1.063
Regional chain	1.024	<.0001	1.059	<.0001	1.036
Unknown chain status	1.049	<.0001	1.002	0.7254	1.034
Independent facility	1.000	ref	1.000	ref	1.000
Hospital-based facility***	1.442	<.0001	1.022	<.0001	1.304

^Excludes facilities that opened or closed during the year and patients treated in those facilities during that year. Based on data reported in SIMS.

*Other variables included in the CR model are age, female, body surface area, duration of RRT:< 4 month, alcohol/drug dependence, hepatitis B, bacterial pneumonia and other pneumonias/opportunistic infections, hereditary hemolytic or sickle cell anemias, cancer, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

**Other variables included in the SB model are age, female, body surface area, low BMI, duration of RRT:< 4 month, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, septicemia, bacterial pneumonia and other pneumonias/opportunistic infections, gastro- intestinal tract bleeding, hereditary hemolytic or sickle cell anemias, cancer, myelodysplastic syndrome, monoclonal gammopathy, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

***Of hospital-based facilities, 75.5% are independent, 10.7% are members of a regional chain/other organization, 0.7% are members of an LDO, and 13.2% have unknown chain status.

Table 24
Analysis for facility size, rural/urban status, and ownership type, 2004-2006, Model 4
Preliminary
December 17, 2008

	***Facility level log-linear model of average cost per session (n=11,814)** R-sq: 46.26% Average $169.67/session		****Patient level log-linear model of MAP per session (n=890,776)** R-sq: 8.71% Average $82.45/session		
Variable	CR Multiplier	p-value	SB Multiplier	p-value	Combined
Fac: <3,000 treatments, rural, LDO	1.480	<.0001	0.917	<.0001	1.296
Fac: <3,000 treatments, rural, not LDO	1.327	<.0001	0.950	0.0002	1.204
Fac: <3,000 treatments, urban, LDO	1.604	<.0001	0.957	0.0012	1.392
Fac: <3,000 treatments, urban, not LDO	1.321	<.0001	1.004	0.7802	1.217
Fac: 3,000-5,000 treatments, rural, LDO	1.288	<.0001	0.983	0.0056	1.188
Fac: 3,000-5,000 treatments, rural, not LDO	1.163	<.0001	0.939	<.0001	1.090
Fac: 3,000-5,000 treatments, urban, LDO	1.318	<.0001	1.010	0.059	1.217
Fac: 3,000-5,000 treatments, urban, not LDO	1.206	<.0001	1.027	0.0011	1.147
Facility: 5,000 - 9,999 treatments	1.122	<.0001	1.007	<.0001	1.084
Facility: 10,000+ treatments	1.000	ref	1.000	ref	1.000
Large dialysis organization (chain1-chain6)	1.010	0.0377	1.157	<.0001	1.058
Regional chain	1.024	<.0001	1.060	<.0001	1.036
Unknown chain status	1.047	<.0001	1.001	0.8261	1.032
Independent facility	1.000	ref	1.000	ref	1.000
Hospital-based facility***	1.438	<.0001	1.021	<.0001	1.302

^Excludes facilities that opened or closed during the year and patients treated in those facilities during that year. Based on data reported in SIMS.

*Other variables included in the CR model are age, female, body surface area, duration of RRT:< 4 month, alcohol/drug dependence, HIV/AIDS, hepatitis B, bacterial pneumonia and other pneumonias/opportunistic infections, hereditary hemolytic or sickle cell anemias, cancer, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

**Other variables included in the SB model are age, female, body surface area, low BMI, duration of RRT:< 4 month, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, septicemia, bacterial pneumonia and other pneumonias/opportunistic infections, gastro-intestinal tract bleeding, hereditary hemolytic or sickle cell anemias, cancer, myelodysplastic syndrome, monoclonal gammopathy, calendar year, composite rate payment exception, and % of patients in facility with URR<65%.

***Of hospital-based facilities, 75.5% are independent, 10.7% are members of a regional chain/other organization, 0.7% are members of an LDO, and 13.2% have unknown chain status.

In Table 23, UM-KECC split the ESRD facility size variable into 7 categories including rural/urban status with increments of 1,000 treatments (<1,000, 1,000-1,999, 2,000-2,999, 3,000-3,999, 4,000-4,999, 5,000-10,000, and 10,000+). They then estimated ESRD facility-level models for composite rate costs and patient-level models for separately billable MAP per treatment. UM-KECC attempted to exclude ESRD facilities whose small number of treatments might be a temporary phenomenon (for example, ESRD facilities that opened, changed ownership, or closed). This was done using the initial certification date reported in OSCAR and the date of ESRD facility closure reported in SIMS. Changes of ownership where the new owner of the existing ESRD facility continues under the existing ESRD facility's provider number were included in the analysis. UM-KECC's analysis indicated that composite rate costs per treatment decline substantially as ESRD facility size increases and separately billable MAPs per treatment do not change substantially by ESRD facility size. UM-KECC's analysis also indicated that by controlling for ESRD facility size, being a member of an LDO does not lower costs and rural ESRD facilities do not report higher costs than urban ESRD facilities.

UM-KECC's two-equation regression analysis gave us the ability to see what other factors can be targeted to ensure that we have the right population of ESRD facilities that are low-volume. From UM-KECC's comparisons discussed above, we were able to determine that small rural ESRD facilities did not have higher composite rate costs in any of the small ESRD facility categories when compared to small urban ESRD facilities. In Table 24 we were able to see interactions between LDO status/small ESRD facility size/rural vs. urban status. We found that small ESRD facilities owned by LDOs were shown to have higher costs than small ESRD facilities that are non-LDOs.

We further evaluated how many dialysis treatments per year would best describe low-volume. As mentioned above, we began with our definition of a small ESRD facility, that is, less than 5,000 treatments. UM-KECC was able to provide us with another two-equation regression analysis that controlled for ESRD facility size and divided the small ESRD facility size variable into 3 categories; less than 2,000 treatments, less than 3,000 treatments, and less than 4,000 treatments. (Table 25: Analysis for low-volume ESRD facility size, 2004-2006).

Table 25

Analysis for low-volume ESRD facility size, 2004-2006
Include additional controls for ESRD facility size:
Model 1
Preliminary
January 29, 2009

	***Facility level log-linear model of average cost per session (n=11,814)** R-sq: 45.8% Average $169.67/session			****Patient level log-linear model of MAP per session (n=890,776)** R-sq: 8.7% Average $82.45/session			
Variable	Modeled CR Multiplier	p-value	CR Payment Multiplier^	Modeled SB Multiplier	p-value	SB Payment Multiplier^	Combined Payment Multiplier^
Facility size < 2,000 treatments during each year from 2004-06	1.497	<.0001	1.439	0.878	0.0929	0.876	1.254
Facility size < 2,000 treatments during current year but not during all 3 years	1.520	<.0001	1.000	1.055	0.0002	1.000	1.000
Facility size 2,000-4,999 treatments	1.290	<.0001	1.000	0.992	0.0101	1.000	1.000
Facility size 5,000-9,999 treatments	1.122	<.0001	1.000	1.011	<.0001	1.000	1.000
Facility size 10,000+ treatments	1.000	ref	1.000	1.000	ref	1.000	1.000
Rural	0.997	0.4674	--	0.981	<.0001	--	--

Table 26
Model 2

	***Facility level log-linear model of average cost per session (n=11,814)** R-sq: 46.0% Average $169.67/session			****Patient level log-linear model of MAP per session (n=890,776)** R-sq: 8.7% Average $82.45/session			
Variable	Modeled CR Multiplier	p-value	CR Payment Multiplier^	Modeled SB Multiplier	p-value	SB Payment Multiplier^	Combined Payment Multiplier^
Facility size < 3,000 treatments during each year from 2004-06	1.383	<.0001	1.330	0.940	<.0001	0.938	1.202
Facility size < 3,000 treatments during current year, but not during all 3 years	1.478	<.0001	1.000	0.976	0.0036	1.000	1.000
Facility size 3,000-4,999 treatments	1.268	<.0001	1.000	1.000	0.9622	1.000	1.000
Facility size 5,000-9,999 treatments	1.122	<.0001	1.000	1.011	<.0001	1.000	1.000
Facility size 10,000+ treatments	1.000	ref	1.000	1.000	ref	1.000	1.000
Rural	0.997	0.4419	--	0.981	<.0001	--	--

Table 27
Model 3

	***Facility level log-linear model of average cost per session (n=11,814)** R-sq: 45.9% Average $169.67/session			****Patient level log-linear model of MAP per session (n=890,776)** R-sq: 8.7% Average $82.45/session			
Variable	Modeled CR Multiplier	p-value	CR Payment Multiplier^	Modeled SB Multiplier	p-value	SB Payment Multiplier^	Combined Payment Multiplier^
Facility size < 4.000 treatments during each year from 2004-06	1.348	<.0001	1.300	0.978	0.0002	0.976	1.194
Facility size < 4,000 treatments during current year, but not during all 3 years	1.373	<.0001	1.000	0.997	0.5825	1.000	1.000
Facility size 4,000-4,999 treatments	1.237	<.0001	1.000	0.999	0.766	1.000	1.000
Facility size 5,000-9,999 treatments	1.122	<.0001	1.000	1.011	<.0001	1.000	1.000
Facility size 10,000+ treatments	1.000	ref	1.000	1.000	ref	1.000	1.000
Rural	0.997	0.427	--	0.981	<.0001	--	--

^The potential low-volume payment adjustment was calculated relative to all other facilities combined (i.e., using a weighted average of the other ESRD facility size coefficients).

*Other variables included in the CR model are age, female, body surface area, duration of RRT:< 4 month, alcohol/drug dependence, HIV/AIDS, hepatitis B, bacterial pneumonia and other pneumonias/opportunistic infections, hereditary hemolytic or sickle cell anemias, cancer, calendar year, ESRD facility ownership type, composite rate payment exception, and % of patients in the ESRD facility with URR<65%.

**Other variables included in the SB model are age, female, body surface area, low BMI, duration of RRT:< 4 month, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, septicemia, bacterial pneumonia and other pneumonias/opportunistic infections, gastro-intestinal tract bleeding, hereditary hemolytic or sickle cell anemias, cancer, myelodysplastic syndrome, monoclonal gammopathy, calendar year, ESRD facility ownership type, composite rate payment exception, and % of patients in the ESRD facility with URR<65%.

We found that the cost multipliers for small ESRD facilities are greater than 1.1 for any of the definitions for small ESRD facility size with respect to number of treatments per year and that they decline for successively higher cutoffs for defining small ESRD facilities. We also found that if a payment multiplier fully reflects the cost multiplier, there will be a strong disincentive for ESRD

facilities to increase volume above cutoff. However, to the extent that a payment multiplier is smaller than the cost multiplier, this disincentive is somewhat diminished.

Since UM-KECC's analyses included data that spanned a 3-year period (2004-2006), we further evaluated the three ESRD facility size categories that we applied in the previous paragraph's regression analysis, that is, less than 2,000 treatments, less than 3,000 treatments, and less than 4,000 treatments per year. We were interested to see the number of small ESRD facilities that were able to maintain their ESRD facility size status each year of the 3-year period.

In this evaluation, we excluded ESRD facilities that opened, changed ownership, or closed during any one of the 3 years used for data. Status as a "closed" ESRD facility was based on information in the SIMS that the ESRD facility closed. Status as an "opening" ESRD facility was based on the initial Medicare certification date reported in OSCAR. Changes of ownership where the new owner of an existing ESRD facility continues under the existing ESRD facility's provider number were included in the analysis. We found there were 25 dialysis ESRD facilities that provided less than 2,000 treatments annually across the 3-year period (2004-2006), 89 ESRD facilities provided less than 3,000

treatments annually across the 3-year period, and 241 ESRD facilities provided less than 4,000 treatments annually across the 3-year period. These data indicate that ESRD facilities that provide less than 2,000 treatments per year across the 3-year period would result in low-volume adjustments being applied to very few ESRD facilities. These data also indicate that ESRD facilities that provide less than 4,000 treatments across the 3-year period would apply to almost 10 times more the number of ESRD facilities that provided less than 2,000 treatments and almost 3 times more the number of ESRD facilities that provided less than 3,000 treatments.

Accordingly, we propose to use a threshold of ESRD facilities that provide less than 3,000 treatments per year across the 3-year period. The threshold at 3,000 treatments strikes a balance between establishing an increment in payment that reflects the substantially higher treatment costs incurred by low-volume facilities (an increment that decreases relatively quickly as the low-volume threshold is raised) but still applies to a sufficiently large number of ESRD facilities to have an impact.

As mentioned above, the statute gives the Secretary the authority to define "low-volume facilities". Based on

the above results, we propose in §413.232, that a "low-volume facility" is an ESRD facility that meets the following criteria: 1) furnished less than 3,000 treatments in each of the 3 years preceding the payment year; and 2) has not opened, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year. In the event an ESRD facility provides 3,000 or more treatments during their payment year, that is, no longer eligible for the low-volume adjustment; the ESRD facility would stop receiving the adjustment at the time they reach their 3,000th treatment. Where a change of ownership occurs and the new owner receives a new provider number during the 3-year period, the ESRD facility would not be eligible for the adjustment until it demonstrates that it meets the low-volume criteria under its new provider number. We are aware that there are Medicare-certified ESRD facilities that solely furnish support services and training for home peritoneal dialysis and home hemodialysis ESRD beneficiaries. Therefore, we are concerned that it may not be appropriate to extend low-volume eligibility to these types of facilities. We also are concerned that a treatment threshold may create an incentive for ESRD facilities to turn away patients rather than lose their low-volume status. We are requesting

comment on the change of ownership element of our proposed definition, the appropriateness of applying the low-volume adjustment to training ESRD facilities, and the possible unintended effects of having a treatment threshold.

We believe that this approach would identify appropriate ESRD facilities for an adjustment and provide access to care for a vulnerable patient population. Under this proposal, new ESRD facilities would not be able to benefit from a low-volume adjustment until the 4th year in operation. For example, an ESRD facility opening in 2008 would need to meet the low-volume criteria for 2009, 2010, and 2011 to be eligible for the low-volume adjustment in 2012.

We are very concerned about potential misuse of the proposed 20.2 percent low-volume adjustment (the proposed figure is discussed below). Specifically, our concern is that the low-volume adjustment could incentivize dialysis companies to establish small ESRD facilities in close geographic proximity to other ESRD facilities, thereby leading to unnecessary inefficiencies, in order to obtain the low-volume adjustment. To address our concern, we are proposing additional criteria described below in connection with the proposed definition discussed above.

We propose, for purposes of determining the number of treatments under the proposed definition of a low-volume facility, that the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments actually furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both: (i) under common ownership with and; (ii) 25 road miles or less from the ESRD facility in question. Under our proposal, "common ownership" means the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more of each ESRD facility. Our intention is to create a disincentive for commonly-owned ESRD facilities to purposively establish new ESRD facilities in close geographic proximity to other ESRD facilities, which could lead to unnecessary inefficiencies. The 25 road mile threshold is a standard that is used for low-volume adjustments in Medicare. For example, this criterion is used in the prospective payment system for inpatient hospital services. We are soliciting comment on our proposed definition of a "low volume facility" and our proposed geographic requirement with regard to determining the number of treatments furnished. We are also requesting

comment concerning other potential vulnerabilities of the proposed low-volume definition and ways to address them.

Although we propose to limit the application of the low-volume adjustment to ESRD facilities with common ownership in a certain geographic location for purposes of determining the number of treatments under the proposed definition, we propose to grandfather those commonly owned ESRD facilities that have been in existence and certified for Medicare participation on or before December 31, 2010. Specifically, ESRD facilities that are in existence and certified for Medicare participation prior to January 1, 2011, will be exempt from treatment determination requirement and the geographic proximity restriction discussed above. We intend to monitor this grandfathering provision for abuse on a going forward basis and invite comment on the vulnerability it may present and ways to address them.

We also intend to work with our Regional Offices to monitor changes in the ESRD industry's behaviors and emerging trends in the ESRD industry nationwide. In this way, we would be able to monitor survey and certification activities and impose additional safeguards that maybe necessary in the interest of program integrity.

In order to identify which existing ESRD facilities meet the low-volume criteria, we propose that ESRD facilities could attest to the FI/MAC that they qualify as a low-volume facility. In this approach the FI/MAC would verify the ESRD facility's attestation of their low-volume status using the ESRD facility's final-settled cost reports. We invite comments on this approach and welcome other suggestions to identify existing low-volume facilities. Instruction as to how the FIs/MACs would implement the proposed ESRD PPS will be provided in future guidance.

c. Defining the percent of increase

As discussed above, section 1881(14)(D)(iii) of the Act also requires the ESRD PPS include a "payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary)… and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment not be less than 10 percent." Based on the definition described above and on the analysis discussed above in Table 26, Model 2, limiting the low-volume category to ESRD facilities that had not open, closed, or received a new provider number due to a change in ownership and remained small, that is, less than 3,000

treatments during all 3 years from 2004-2006 and including additional controls for ESRD facility size, the resulting low-volume payment adjustment was determined to be 20.2 percent. This chart takes into consideration paying the low-volume facilities based on the model's multiplier relative to the weighted average of the multipliers of the other ESRD facility size classes, therefore the extra payment would be calculated relative to an ESRD facility of typical size, not a ESRD facility in the largest size category.

Using our proposed low-volume criteria, we measured the payments received by these ESRD facilities and determined that 76.4 percent of ESRD facilities meeting the proposed low-volume criteria would get an adjustment of 10 percent or more increase in payment relative to what they received under the current system (see Table 28: Measured costs, current payments and proposed payment per dialysis session for an expanded bundle, 2006).

Table 28
Measured costs, current payments and proposed payments per dialysis session for an expanded bundle, 2006*
Low-volume facility definition: did not open or close and reported <3,000 total sessions for each year from 2004-06
Preliminary
February 12, 2009

	Dialysis facilities			Percent of facilities with a given change in payment per session

		Mean	Median	Loss in payment of 10% or more	-10% to -5%	-5% to 0%	0% to 5%	5% to 10%	Gain in payment of 10% or more
Total									
Measured costs for an expanded bundle (CR+SB)	4,286	$256.64	$248.54	--	--	--	--	--	--
Current Medicare Allowable Payments (MAP)									
Composite rate services	4,399	$153.49	$152.67	--	--	--	--	--	--
Separately billable services	4,399	$79.33	$78.66	--	--	--	--	--	--
Total	4,399	$232.82	$232.82	--	--	--	--	--	--
Proposed MAP for an expanded bundle									
No low-volume adjustment	4,399	$232.82	$230.16	10.7%	18.3%	25.1%	21.0%	12.1%	12.8%
Low-volume facility multiplier: 1.100	4,399	$232.82	$230.20	10.5%	18.1%	25.1%	20.8%	12.2%	13.3%
Low-volume facility multiplier: 1.150	4,399	$232.82	$230.25	10.5%	18.2%	25.0%	20.7%	12.1%	13.6%
Low-volume facility multiplier: 1.202	4,399	$232.82	$230.20	10.6%	18.2%	24.9%	20.5%	12.1%	13.7%
Low-volume facilities (as defined above)									
Measured costs for an expanded bundle (CR+SB)	88	$299.31	$289.55	--	--	--	--	--	--
Current Medicare Allowable Payments (MAP)									
Composite rate services	89	$150.25	$148.84	--	--	--	--	--	--
Separately billable services	89	$73.66	$73.46	--	--	--	--	--	--
Total	89	$223.91	$221.93	--	--	--	--	--	--
Low-volume facilities (as defined above)									
Proposed MAP for an expanded bundle									
No low-volume adjustment	89	$224.27	$216.68	15.7%	14.6%	19.1%	19.1%	12.4%	19.1%
Low-volume facility multiplier: 1.100	89	$246.31	$237.73	4.5%	3.4%	9.0%	16.9%	15.7%	50.6%
Low-volume facility multiplier: 1.150	89	$257.32	$248.30	1.1%	3.4%	4.5%	12.4%	13.5%	65.2%
Low-volume facility multiplier: 1.202	89	$268.77	$259.47	1.1%	1.1%	3.4%	4.5%	13.5%	76.4%
Other facilities									
Measured costs for an expanded bundle (CR+SB)	4,198	$256.48	$248.39	--	--	--	--	--	--
Current Medicare Allowable Payments (MAP)									
Composite rate services	4,310	$153.51	$152.71	--	--	--	--	--	--
Separately billable services	4,310	$79.35	$78.69	--	--	--	--	--	--
Total	4,310	$232.86	$232.88	--	--	--	--	--	--
Proposed MAP for an expanded bundle									
No low-volume adjustment	4,310	$232.86	$230.24	10.6%	18.4%	25.3%	21.0%	12.1%	12.7%
Low-volume facility multiplier: 1.100	4,310	$232.76	$230.14	10.6%	18.5%	25.4%	20.9%	12.1%	12.5%
Low-volume facility multiplier: 1.150	4,310	$232.71	$230.10	10.7%	18.5%	25.4%	20.8%	12.1%	12.5%
Low-volume facility multiplier: 1.202	4,310	$232.66	$230.05	10.8%	18.6%	25.3%	20.8%	12.1%	12.4%

Based on the analysis provided by UM-KECC, we are proposing a 20.2 percent increase to the base rate to account for the costs incurred by low-volume facilities for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014.

The proposed low-volume adjustment policy is set forth in proposed §413.232. We invite comments on the low-volume facility proposed adjustment.

For purposes of determining the appropriate adjustment for the low-volume facilities defined above, we are considering other options in addition to the 20.2 percent adjustment we described. As mentioned previously, section 1881(14)(D)(iii) of the Act requires the payment adjustment for low-volume facilities be not less than 10 percent during the transition. We believe that adopting the statutory adjustment of 10 percent would provide relief to low-volume facilities of the costs they incur to provide services. In addition, providing a lower payment adjustment results in less of a decrease in the ESRD PPS base rate which would apply to treatments furnished by all ESRD facilities.

Another option for the low-volume adjustment would be the midpoint between the statutory adjustment of 10 percent and the results of our data analysis which is 20.2 percent. We believe that a 15 percent increase could establish an appropriate adjustment amount that would provide low-volume facilities the incentive to utilize resources more efficiently and control their costs.

We invite comments on these alternative options for determining the percent low-volume adjustment.

3. Alaska/Hawaii Facilities

Section 1881(b)(14)(D)(iv) of the Act permits the Secretary to include other payment adjustments as the Secretary determines appropriate. The basic case-mix adjusted composite payment system currently does not provide a separate adjustment for ESRD facilities located in Hawaii and Alaska. However, some prospective payment systems, such as the hospital inpatient PPS and the inpatient psychiatric facility PPS, provide a cost of living adjustment (COLA) for facilities located in Alaska and Hawaii. These COLA adjustments are applied to the non-labor portion of the payment and are based on the rationale that the wage index adjustment to the labor portion of the payment is not sufficient to provide for the higher costs incurred by facilities in Alaska and Hawaii. For example, the same supplies used by an ESRD facility located in Hawaii cost more because there are additional (higher) transportation costs incurred to receive the same supplies compared to an ESRD facility located in the mainland United States. Analysis completed for the 2008 Report to Congress indicated there was no need for a COLA for these areas. After all adjustments (including wage and other

adjustments), our analysis of ESRD facilities located in Alaska and Hawaii did not demonstrate any adverse impact from the proposed ESRD PPS.

Our analysis continues to support that the proposed ESRD PPS would adequately reimburse ESRD facilities located in Alaska and Hawaii. Therefore, we are not proposing to adopt COLA adjustments for ESRD facilities in Alaska and Hawaii under the proposed ESRD PPS. We invite public comments on this proposal.

4. Rural

Section 1881(b)(14)(D)(iv)(III) of the Act provides that the ESRD PPS may include payment adjustments as the Secretary determines appropriate such as a payment adjustment for facilities located in rural areas. Accordingly, we analyzed rural status as part of the regression analysis for the proposed ESRD PPS to inform our proposal for this rule.

As discussed previously in section VIII. C. 1. of the proposed rule , we are proposing to define rural facilities in proposed §413.231(b)(2) as facilities that are outside a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB. To decrease distortion among independent variables, rural

facilities were considered control variables rather than payment variables.

We do not believe that the proposed ESRD PPS would result in decreased access to care for beneficiaries residing in rural areas based on the results of the impact analysis. Specifically, as illustrated in the impact table in Table 48, the proposed ESRD PPS reveals an overall decrease in payment of 2.5 percent for rural facilities under the proposed ESRD PPS in 2011 as compared to the current basic case-mix adjusted composite payment system. However, 2 percent of this amount is associated with the statutory requirement that payments under the ESRD PPS equal 98 percent of what ESRD facilities would have received had this ESRD PPS not been implemented (98 percent of payments to ESRD facilities under the current payment system). In summary, this analysis reveals that rural ESRD facilities would be adequately reimbursed under the proposed ESRD PPS.

We also included facility treatment volume as a control variable in the payment model. Based on the analysis conducted by UM-KECC, 66 of the 166 ESRD facilities that met the low volume criteria discussed further in section VIII.C.2 of this proposed rule are located in rural areas. Thus, some of the effects of rural

status on cost and payment are captured via the low volume payment adjustments. Therefore, we are not proposing a facility level adjustment that is based on rural location. We invite public comments on this proposal.

5. Site Neutral ESRD PPS Rate

For dialysis services furnished prior to January 1, 2009, the basic case-mix composite rate differentiated between hospital-based and independent ESRD facilities. That is to say, the composite rate for hospital-based facilities was on average $4.00 more per treatment more than the composite rate for independent dialysis facilities.

Section 1881(b)(12)(A) of the Act, as amended by section 153(a)(2), requires a site neutral composite rate so that the payment rate for services furnished on or after January 1, 2009, by hospital-based facilities is the same as the payment rate paid to independent renal dialysis facilities under the current system. In addition, section 1881(b)(12)(A) of the Act, as amended by section 153(a)(2) of MIPPA, requires that in applying the geographic index to hospital-based facilities, the labor share shall be based on the labor share otherwise applied to the renal dialysis facilities. In the CY 2009 final rule (72 FR 69881 and 69935), we revised §413.174, which described the

methodology for prospective rates for ESRD facilities, to conform to the statutory requirement.

Section 1881(b)(14)(A)(i) of the Act, as amended by section 153(b) of MIPPA, provides that for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this title to ESRD facilities for renal dialysis services, in lieu of any other payment. Therefore, the site neutral payment provisions discussed above will automatically be incorporated under the ESRD PPS and used to establish a single base rate that will apply to ESRD facilities.

D. Determination of ESRD PPS Payment Adjusters

We have described the selection of patient characteristics as potential case-mix adjusters using a modeling approach that has relied on separate regression equations for CR and SB services. The predictive power of the separate estimating equation for CR services in terms of the proportion of variance explained (R^2) was 46.0 percent. The comparable figure for the SB regression equation was 8.7 percent. The overall estimated R^2 for the ESRD PPS payment model is 39.0 percent. While the case-mix adjustments were based on separate estimating equations,

the equations can be combined into a single payment formula for the ESRD PPS.

Table 29				
Payment multipliers for an expanded bundle of services, ages 18 and older, 2004-06				
	Estimated payment multipliers based on a two-equation model		Modeled case-mix adjustment[3,4]	
	Composite rate services[1]	Separately billable services[2]		
Variable	$PmtMult_{CR}$	$PmtMult_{SB}$	$PmtMult_{EB}$	
Adjustments for dialysis patient characteristics				
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^2; mean BSA=1.87)	1.035	1.033	1.034	
Underweight (BMI <18.5)	1.000^	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	1.256	1.412	1.307	
pneumonias/opportunistic infections				
Gastro-intestinal tract bleeding from same month to 3 months ago	1.000^	1.965	1.316	

Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.248	1.179	1.226	
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.143	1.097	1.128	
Myelodysplastic syndrome (claims since 2000)	1.000^	1.257	1.084	
Monoclonal gammopathy (claims since 2000)	1.000^	1.063	1.021	
Low volume facility adjustment Facility size < 3,000 treatments during each year from 2004-06	1.383	0.940	1.202	
^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.				
[1]The CR payment multipliers ($PmtMult_{CR}$) 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%).				
[2]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 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%).				
[3]The combined payment multipliers for patient characteristics were calculated as $PmtMult_{EB}$ = $Weight_{CR}$×$PmtMult_{CR}$ + $Weight_{SB}$×$PmtMult_{SB}$, where $PmtMult_{CR}$ is the estimated multiplier from a facility level model of composite rate costs and $PmtMult_{SB}$ 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 $Weight_{CR}$=0.673 for composite rate services ($169.67/$252.12) and $Weight_{SB}$=0.327 for separately billable services ($82.45/$252.12).				
[4]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.				

Table 29 shows how the payment adjusters from the separate CR and SB regressions were combined. The first two columns in Table 29 represent the CR and SB model results for each of the regression equations, carried to three significant figures. The third column of Table 29 presents a single payment multiplier for each patient

characteristic based on its relationship to resource use for both CR and SB services. The payment adjusters in the third column ($PmtMult_{EB}$) were calculated as the weighted average of the CR and SB multipliers. The weights correspond to each component's proportion of the sum of the average CR costs and SB payments per treatment for CYs 2004-2006, as shown in Table 30.

Table 30
Estimated costs for composite rate and separately billable services, CY 2004-06[1]

	2004		2005		2006		Pooled, 2004-2006	
Measure of resource use	n	Average $ per treatment	n	Average $ per treatment	n	Average $ per treatment	n	Average $ per treatment
Facility composite rate costs[2]	3,794	$161.33	3,948	$168.09	4,072	$179.24	11,814	$169.67
Patient separately billable Medicare Allowable Payments (repriced)[3]								
Ages <18	719	$44.76	866	$52.42	790	$49.60	2,375	$49.11
Ages 18 and older	289,587	$82.97	297,718	$84.39	303,471	$80.07	890,776	$82.45

[1]Weighted by the number of hemodialysis-equivalent dialysis treatments.
[2]Source: Medicare cost reports for freestanding and hospital-based dialysis facilities.
[3]Source: Medicare dialysis patient claims. MAP amounts were repriced to reflect 2008Q1 payment rates for the top injectable drugs.

The weights were calculated using the 3 years of pooled data. Based on this analysis, the average cost for CR services per treatment as computed from the Medicare cost reports was $169.67. The average MAP per treatment

for SB services based on Medicare claims for the same period was $82.45. Based on total estimated costs of $252.12 per treatment ($169.67 + $82.45), the relative weights are $weight_{CR}$ = 0.673 for composite rate services ($169.67/$252.12) and $weight_{SB}$ = 0.327 for separately billable services ($82.45/$252.12). The payment multipliers presented in the third column of Table 29 were calculated as $PmtMult_{EB}$ = 0.673 x $PmtMult_{CR}$ + 0.327 x $PmtMult_{SB}$. In this manner, the separate case-mix adjusters for composite rate and separately billable services were combined to obtain a single set of multipliers (shown in the third column of Table 29) to compute the payment rates under the proposed ESRD PPS.

Six co-morbidities were identified as payment adjusters for separately billable services only, as they did not have a statistically significant association with composite rate costs based on the regression results. These patient characteristic variables have a composite rate multiplier in Table 29 of 1.000. For these co-morbidities, there is no payment adjuster for composite rate services. Therefore, the payment multiplier is equal to 0.673 x 1.000 + 0.327 x $PmtMult_{SB}$. The payment multipliers in the third column of Table 29 reflect the

combined results from the two-equation model previously described in this proposed rule, and represent the case-mix adjustment factors that we propose to apply to the base rate to compute the payment amount per treatment under the proposed ESRD PPS.

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