

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

## B. Proposed Patient-Level Adjustments

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

### 1. Patient Age

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

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

**Table 12**  
**Age Adjustment in the Current Basic Case-Mix Adjusted Composite Payment System**

<b>Variable</b>	<b>Multiplier</b>
Pediatrics <18	1.62
Ages 18-44	1.223
Ages 45-59.	1.055
Ages 60-69	1.000
Ages 70-79	1.094
Ages 80+	1.112

As we found when we developed the current basic case-mix adjusted composite payment system, the regression analysis for the proposed ESRD PPS indicates that MAPs rise as a patient's age increases. We analyzed information on patient age from the REMIS system and compared the costs for each age group to a reference group. Although the reference group for age under the current basic case-mix adjusted composite payment system was ages 60-69, the reference group used for the proposed ESRD PPS was determined to be ages 45-59. We selected the 45-59 age range as the reference group because it was identified as the lowest cost group and results in positive adjustments for all age categories except for the 45-59 age group, and avoids age adjustments that are less than one. In

addition, we determined the age groupings based upon stability of the data and the similarity of the adjustments for the ages within the group.

The proposed regression analysis for the proposed ESRD PPS revealed the following: (1) Patients in the 18-44 age grouping were 19.4 percent more costly than the reference group; (2) Patients age 45-59 were the reference group; (3) Patients age 60-69 were 1.2 percent more costly than the reference group; (4) Patients age 70-79 were 5.7 percent more costly than the reference group; and (4) Patients over 80 years of age were 7.6 percent more costly than patients in the reference group.

This U-shaped relationship of age with average composite rate per treatment costs in the proposed ESRD PPS is similar to the pattern we observed in developing the current basic case-mix adjusted composite payment system. That is, elevated costs were observed for the youngest and oldest adult age groups (ages 18-44 and 80+, respectively) compared to the reference age group.

Based on age, the model indicates that one of the largest increments in cost is for pediatric patients. We note, however, that using the current regression-based approach, the precision of the pediatric multiplier is limited by the small fraction of pediatric patients in most

ESRD facilities and would distort the results. Due to the relatively small number of pediatric patients, we are proposing to use a separate regression analysis for pediatric patients, as discussed in section IX of this proposed rule.

Under the ESRD PPS, we are proposing payment adjustment factors for five age groups as shown in Table 13 below.

**Table 13 - Patient Age**

<b>Variable</b>	<b>Multiplier</b>
Ages 18-44	1.194
Ages 45-59	1.000
Ages 60-69	1.012
Ages 70-79	1.057
Ages 80+	1.076

## 2. Patient Sex

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

ESRD PPS, we found that female ESRD patients are more costly to treat than male ESRD patients. We discuss below, prior research related to patient adjusters for males/females in prior rulemaking for the current basic case-mix adjusted composite payment system, before addressing our proposal for such a case-mix adjuster.

In the CY 2005 Physician Fee Schedule (PFS) proposed rule (69 FR 47487 through 47730), published August 5, 2004, we included an adjustment for gender as part of our proposal for the current basic case-mix adjusted composite payment system. We analyzed the effect of a combination of gender and age on composite rate costs compared to the lowest cost combination (that is, female ages 65-79). No data on separately billable services was analyzed because those services are excluded from the basic case-mix adjusted composite payment system. We found that male patients were consistently more costly than females. However, we did not include an adjustment for gender because of the availability of certain data.

As we explained in the CY 2005 PFS final rule with comment period (69 FR 66235 through 66915), published on November 15, 2004, gender was proposed as a surrogate measure for body size. We believed that using height and weight to measure body size would be better predictors of

facility variation in composite rate costs, however, that information was not available on claims at the time the CY 2005 PFS proposed rule was published, whereas gender was reported on the outpatient bill.

During development of the final basic case-mix adjusted composite payment system, we became aware that the National Uniform Billing Committee would be approving the use of two new value codes for reporting weight and height after publication of the final rule. We determined that mandatory reporting of such data would enable the development of case-mix measures that reflected the superior predictors related to body size, that is BMI and BSA. As a result, we adopted in the final rule BSA and low BMI, and eliminated gender as a patient classification variable for purposes of case-mix adjustment.

In developing the proposed ESRD PPS, we again analyzed the extent to which the regression model explains composite rate and separately billable payments based on a patient's sex and, as a result of that analysis, are proposing an adjustment based on a patient's sex. (We believe using the term sex is a more accurate term than gender. Sex is defined as a classification according to an individual's reproductive function while gender is defined in terms of masculine/feminine characteristics). In analyzing more

current data on patient sex from the REMIS system, we found that MAPs (including both composite rate and separately billable services) were higher for female patients even when body size measures are included. In the regression analysis, we found that females were 13.2 percent more costly on a per treatment basis than males primarily due to differences in use of ESAs between male and female patients. Therefore, we are proposing an adjustment of 13.2 percent for female patients. We are soliciting public comments around unintended consequences of providing a payment adjustment for female patients that may lead to admission practices favoring female patients. Decisions for the final rule regarding this adjustment would be made based on analysis of more current data and public comments received on this issue.

### 3. Body Surface Area and Body Mass Index

Section 1881(b)(14)(D)(i) of the Act requires that the bundled ESRD PPS must include a payment adjustment based on case-mix that may take into account patient weight, BMI, and other appropriate factors. Consequently, we evaluated height and weight because the combination of these two characteristics allows us to analyze two measures of body size; BSA and BMI. For this proposed rule, we analyzed both BSA and low BMI ( $< 18.5\text{kg/m}^2$ ) individually as part of

the regression analysis and found that both body size measures are strong predictors of variation in payments for ESRD patients. In addition, both BSA and low BMI are objective measures and the necessary data, that is, height and weight, to compute the BSA and low BMI are readily available from patient claims.

a. Body Surface Area

As discussed previously in section I.B.3, the current basic case-mix adjusted composite payment system includes a payment adjustment for BSA. The regression analysis conducted for the current basic case-mix adjusted composite payment system indicated that composite rate costs rise as a patient's BSA increases. The payment adjustment factor for BSA in the current basic case-mix adjusted composite payment system is 1.037. This adjustment factor implies a 3.7 percent elevated cost for every 0.1m<sup>2</sup> increase in BSA. The increased costs suggest that there are longer treatment times and additional resources for larger patients.

As discussed in the CY 2005 PFS final rule with comment period, we chose to include BSA as a payment variable because effective January 1, 2005, we were able to collect height and weight data from patient claims (for purposes of calculating the BSA) and determined that including the BSA variable improved the model's ability to

predict the costs of the composite rate service compared to using BMI or weight alone. We adopted the DuBois and DuBois formula for BSA because based on our research, this formula was the most widely known and accepted. This formula is:  $BSA=W^{0.425}*H^{0.725}*0.007184$  (DuBois D. and DuBois, EF. "A Formula to Estimate the Approximate Surface Area if Height and Weight be Known": Arch. Int. Med. 1916 17:863-71.), where w and h represent weight in kilograms and height in centimeters, respectively.

In addition, we explored a number of options for setting the reference values for the BSA. We examined the distributions for both the midpoint of the BSA and the count of dialysis patients by age, body surface and low BMI. Based on that analysis, we set the reference point at a BSA of 1.84 (the national patient average). Setting the reference point at the average BSA reflects the relationship of a specific patient's BSA to the average BSA of all patients. Therefore, some adjusters would be greater than 1.0 and some would be less than 1.0. In this way, we were able to minimize the magnitude of the budget neutrality offset to the composite payment rate. (For more information on this discussion, we refer readers to 69 FR 66239).

The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.84 divided by 0.1. The BSA adjustment factor of 1.037 is then exponentiated based on the calculated BSA factor as  $1.037^{(BSA - 1.84)/0.1}$

As we found when we developed the current basic case-mix adjusted composite payment system, the regression analysis conducted for this proposed rule indicates that MAPs rise as a patient's BSA increases. However, we have found that the case-mix adjustment based on a patient's BSA under the proposed ESRD PPS reflects slightly different values from those used in connection with the current basic case-mix methodology under the composite payment system. The BSA case-mix adjustment factor in connection with the current basic case-mix adjustment was 3.7 percent for every 0.1 m<sup>2</sup> change in BSA from the national average of 1.84. The BSA case-mix adjustment factor under the proposed ESRD PPS is 3.4 percent for every 0.1 m<sup>2</sup> change in BSA from a national average of 1.87 based on updated and more complete data.

In the regression analysis we conducted for this proposed rule, we found that BSA continues to be a strong predictor of cost variation among ESRD patients.

Accordingly, we are proposing 1.034 as a payment adjustment factor for BSA in the proposed ESRD PPS.

b. BMI

As discussed previously in section I.B.3, the current basic case-mix adjusted composite payment system includes a payment adjustment for low BMI ( $<18.5 \text{ kg/m}^2$ ). The regression analysis conducted for the current basic case-mix adjusted composite payment system indicated that those patients who are underweight consume more resources than other patients. The payment adjuster factor for low BMI in the current basic case-mix adjusted composite payment system is 1.112. This adjustment serves as a surrogate for the severity of co-morbid conditions associated with malnourishment in the dialysis population.

As discussed in the CY 2005 PFS final rule with comment period, we elected to include low BMI as a payment variable because effective January 1, 2005, we were going to be able to collect height and weight data from patient claims and including the low BMI variable improved the model's ability to predict the costs of the composite rate services compared to using BMI or weight alone. We chose the measure of low BMI as less than  $18.5 \text{ kg/m}^2$  because it was consistent with the CDC and the NIH's definition for malnourishment. Furthermore, our exploration of

alternative BMI thresholds did not improve the model's ability to predict the costs of composite rate services. (For more information on this discussion, we refer readers to 69 FR 66329).

Based on the regression analysis conducted for this proposed rule, we found that low BMI continues to be a strong predictor of cost variation among ESRD patients. For the proposed ESRD PPS, we are proposing 1.020 as a payment adjustment factor for low BMI. Further discussion of co-morbidities and low BMI as case-mix adjusters can be found below in section VIII.B. of this proposed rule.

#### 4. Onset of Dialysis (New Patient Adjustment)

Section 1881(b)(14)(D)(i) of the Act, as added by MIPPA, requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's length of time on dialysis. Consequently, we analyzed length of time patients have been receiving dialysis. The regression analysis performed for this proposed rule showed that patients who are in their first four months of dialysis have higher costs. This means that individuals who have been newly diagnosed with ESRD have higher costs for the first 4 months of dialysis. We looked at the amount of separately billable payments relative to the number of months the patient has been on dialysis.

After reviewing the separately billable payment amounts for patients ranging from one month to twelve months since onset of dialysis, we found that there was a drop in the amount of separately billable payments after four months on dialysis. These higher costs for new patients may be due to stabilization of the patient's condition; administrative and labor costs associated with the patients being new to dialysis either in-center or home setting; or initial costs incurred to train patients and their caregivers to perform home dialysis.

Based on our analysis and for purposes of the ESRD PPS, we propose to define onset of dialysis beginning with the starting date as reported on the ESRD Medical Evidence Report Form through the first 4 months a patient is receiving dialysis.

Accordingly, we are proposing an adjustment of 1.473 for patients in their first 4 months of dialysis. This adjustment factor is based on the results of regression analysis conducted for this proposed rule as described above. We are proposing that this adjustment be applied to both in-facility and home dialysis patients. We acknowledge that there may be patients whose first 4 months of initial dialysis occur when they are not eligible for the Medicare ESRD benefit. In these circumstances, no

adjustment would be made. We also acknowledge that eligibility for the ESRD benefit may occur during the first 4 months. In that situation, only the period of time in the first 4 months of dialysis that occurs while the patient is under the ESRD benefit would apply. In other words, the onset of dialysis adjustment is made only in the initial first 4 months of dialysis and for the period of time that the individual is eligible for the ESRD benefit.

#### 5. Co-morbidities

As discussed above, section 1881(b)(14)(D)(i), as added by section 153(b) of MIPPA, requires that the bundled ESRD PPS include a payment adjustment based on case-mix that may take into account patient co-morbidities. Consequently, we analyzed co-morbidities as part of the regression analysis and found that certain co-morbidities are predictors of variation in payments for ESRD patients. The intent of the proposed co-morbidity adjustment is to recognize the increased costs associated with co-morbidities by providing additional payments for certain conditions that occur concurrently with the need for dialysis. In other words, co-morbidities are specific patient conditions that are secondary to the patient's principal diagnosis that necessitates dialysis, yet have a

direct affect on dialysis. In addition, co-morbidities are an objective measure and data are readily available.

In the CY 2005 PFS proposed rule (69 FR 47529 through 47533), we proposed case-mix adjustments for a limited number of patient characteristics including a large number of specific co-morbidities. Using linear regression analyses, we assessed the relationship of patient characteristics and co-morbidity measures to per session cost and Medicare payments to ESRD facilities. We noted that we were able to develop case-mix adjustment factors for a limited number of patient characteristics, which were modest predictors of variation in average costs for composite rate services. However, as ESRD facilities did not list individual composite rate items and services on dialysis claims, the available data did not identify use of resources by individual patients. We acknowledged that ESRD facilities could under report or not report co-morbidities as there was no requirement to do so as the current basic case-mix adjusted composite payment system does not provide for co-morbidity payment adjusters. In an attempt to obtain information on co-morbidities, in the CY 2005 PFS final rule with comment, ESRD facilities were encouraged to report co-morbidities. Therefore, we used a

combination of data sources (discussed below), to determine co-morbidities for ESRD patients on maintenance dialysis.

A stepwise regression analysis was conducted for the current basic case-mix adjusted composite payment system to identify case-mix factors that explained statistically significant variation in ESRD facility costs. Stepwise regression is used when there are a large number of potential explanatory variables with variables added or removed from the regression model to identify a subset of predictors and the highest  $R^2$ . The forward (step-up) method begins with no variables in the model with variables individually included if they are statistically significant (no additional variables have a p-value level  $<0.05$ ). Backward (step-down) method begins with a model of all variables and eliminates the least significant variables until no nonsignificant variables remain (until all remaining variables have a p-value  $<0.10$ ). The step-up method was performed to identify payment variables while the step-down method was performed to determine how much co-morbidity categories affected the  $R^2$ . As a result of our analysis, four patient characteristic variables (sex, age, AIDS and peripheral vascular disease) were found to be modest predictors of cost variation among ESRD facilities.

In the CY 2005 PFS proposed rule, we explained that a number of co-morbidities were analyzed, including several that did not have statistically significant relationships to facility costs, as well as co-morbidity conditions that were excluded due to lack of data. For example, we explained that a patient's history of cancer was associated with higher costs; however, we found the measure too broad to be clinically meaningful. We indicated that we would continue to evaluate cancer as a potential variable for refinement purposes.

We also discussed in that proposed rule that we explored whether diabetes as a co-morbidity is predictive of high resource use and found that the predictive power of diabetes was dependent on whether peripheral vascular disease (PVD) was part of the model. We explained that PVD was always statistically significant, when accounted for, while most diabetic measures were not strongly associated with facility costs. Therefore, we proposed a case-mix adjustment for PVD diagnoses. We note that 73 percent of patients with diabetes also included PVD. (For more information on this discussion, we refer readers to 69 FR 47531).

In the CY 2005 PFS final rule with comment period, which implemented the current basic case-mix adjusted

composite payment system, we acknowledged that although the regression modeling suggested the inclusion of co-morbidities in the basic case-mix adjusted composite payment system, we were concerned that the available data to determine patient level co-morbidities might not accurately reflect relevant diagnoses. For example, we explained that AIDS would not likely be recorded on claims for outpatient dialysis patients and that requiring its inclusion could create powerful incentives for ESRD facilities to circumvent confidentiality requirements (69 FR 66326). We also explained that we found that the predictive power of diabetes was dependent on whether PVD, which was statistically significant, was part of the model (69 FR 47531). However, most measures of diabetes were not strongly associated with ESRD facility costs. While we proposed a case-mix adjustment for PVD in the CY 2005 PFS proposed rule (69 FR 47531), we received comments indicating that there was apparent disagreement among clinicians as to whether certain diagnoses are reflective of PVD in ESRD patients. Therefore, we eliminated the case-mix adjustment for PVD in the CY 2005 PFS final rule with comment period.

There also were other factors that contributed to our decision not to include patient-level co-morbidities in the

basic case-mix adjusted composite payment system. For example, with regard to substance abuse, we acknowledged in the CY 2005 PFS proposed rule, while the presence of alcohol and drug dependence was found to be predictive of higher facility level costs, we did not propose an adjustment as we believed substance abuse was underreported. Accordingly, we concluded that we would not include co-morbidities as a case-mix adjustment. However, we did establish the case-mix adjustments based on age, BMI, and BSA. Our analysis indicated that patients with extremely low or high BMI were costly to treat and included these as we believed this factor could be an important measure of resource consumption related to the composite rate services and could serve as a surrogate for the severity of co-morbidities. We also noted that the average patient BSA was found to be statistically significant and a consistent predictor of average treatment costs, indicating higher costs for larger adult patients. As discussed above, in the CY 2005 PFS final rule with comment period, we indicated that while co-morbidities were not part of the current basic case-mix adjusted composite payment system, we encouraged all facilities to report co-morbid conditions on the claims in order to enable future refinements to the basic case-mix adjustments that would reflect the type of

co-morbidities that beneficiaries receiving ESRD services have which would provide a better database from which we can develop future case-mix measures for a the ESRD PPS.

As discussed in section VIII.A, we retained UM-KECC to assist us in developing a case-mix adjustment for the proposed ESRD PPS. One of the tasks was the identification of specific diagnoses within co-morbidity categories. For this proposed rule, to capture changes in patient conditions, patient co-morbidities were measured using a combination of the co-morbidities reported on the Medical Evidence Form (CMS-2728) to obtain co-morbidities at the onset of dialysis adjustment, and diagnoses reported on the Medicare claims to identify co-morbidities not obtained from the Medical Evidence Form (CMS-2728).

We began with a long list of patient characteristics based on diagnostic categories developed for the Medicare Advantage Program and categories developed for the co-morbidities on the Medical Evidence Form (CMS 2728). We also used co-diagnoses reported in multiple types of Medicare claims (inpatient dialysis and other outpatient, skilled nursing facility, physician/supplier, hospice, and home health). We are soliciting recommendations on the type of claims that reflect the co-morbidities for

beneficiaries receiving renal dialysis services that could be used in future analyses.

We acknowledge the likelihood that some diagnoses reported on laboratory claims may represent a condition being excluded by the test, and therefore, diagnoses reported on laboratory claims were not used. A potential limitation of excluding laboratory claims from the identification process is that we may have underestimated the frequency of certain conditions. Patient characteristics considered for inclusion in the model are based on the magnitude and statistical significance of relationship to composite rate costs and separately billable payments.

To ensure that each potential case-mix adjuster has a relationship to cost which is statistically significant and to ensure that the magnitude of the relationship is economically meaningful, patient co-morbidities having statistically significant, low magnitude association with cost, as well as co-morbidities with ambiguous definitions were excluded. Several patient co-morbidities having statistically significant, low magnitude association with cost in the preliminary models and additional co-morbidities with ambiguous definitions, high prevalence, or both, were excluded.

A refined list of case-mix co-morbidities comprised of 1,022 ICD-9-CM diagnoses codes were evaluated for persistence of effect and cost. The resulting co-morbidity categories were cardiac arrest; pericarditis; substance abuse; positive HIV status and AIDS; gastrointestinal tract bleeding; cancer since 1999 (excludes non-melanoma skin cancer); septicemia/shock; opportunistic infections (pneumonias); aspiration and specified bacterial pneumonias; pneumococcal pneumonia, empyema, lung abscess; monoclonal gammopathy; myelodysplastic syndrome; leukemia; hereditary hemolytic anemias and sickle cell anemia; lymphoma; hepatitis B; and multiple myeloma.

We used the stepwise regression model in analyzing co-morbidity data for case-mix adjustments in the proposed ESRD PPS. The relationship between patient characteristics and cost for composite rate services was estimated using a facility level regression model, as patient level data are not available. In other words, the average patient characteristics are related to the reported facility costs.

A patient level model was used to identify potential payment adjusters for separately billable services. The regression model, weighted by the number of dialysis sessions examined the same refined list of patient characteristics used in the model of composite rate costs.

Eleven co-morbidity variables had statistically significant relationships to cost. However, the magnitude of the co-morbidity effects varied substantially. The largest payment multipliers were associated with gastrointestinal (GI) bleeding (31.6 percent), HIV/AIDS (31.6 percent), bacterial and other pneumonias/opportunistic infections (30.7 percent, hereditary hemolytic/sickle cell anemias (22.6 percent) and pericarditis (19.5 percent). As infections, GI bleeding and pericarditis are acute conditions with a diagnosis not exceeding 3 months, these diagnoses would result in a temporary payment adjustment. The chronic conditions result in a permanent increase on payment which we believe may tend to have a more persistent effect on cost. For example, cancer diagnosis would be eligible for a payment adjustment if the cancer diagnosis has a direct affect on the cost of ESRD treatment. In other words, the fact that an individual has or had cancer would not in itself imply that a co-morbidity payment adjustment is warranted as the adjustment is intended to adjust for higher patient costs. The same applies for any diagnosis in any of the co-morbidity categories.

While the modeling approach used separate equations for the composite rate and separately billable services to select patient characteristics as payment variables, we

combined the estimated payment multipliers for composite rate and separately billable services. The payment multipliers were calculated as the weighted average of the composite rate and separately billable multipliers. The weights reflect each component's proportion of the total estimated costs, so that the resulting case-mix adjustment reflects the overall relationship between patient characteristics and estimated costs for the proposed ESRD PPS.

We note that cancer is included in the proposed comorbidity adjustment diagnoses. As discussed above, we indicated in the CY 2005 PFS proposed rule that although a history of cancer was associated with higher costs, it was found that the measure was too broad to be meaningful. Subsequent to the research we performed in support of the basic case-mix adjusted composite payment system, we investigated the relationship between specific categories of cancer and costs. In an effort to create more clinically homogenous groups, we began with clinical categories that were developed for risk adjustment under the Medicare Advantage program. The source for these cancer diagnoses was the Medicare claims, based on any occurrence since 1999. Starting with all cancers except for non-melanoma skin cancers, we split them into groups of

cancers that were used by the Medicare Advantage Program namely, lung; upper digestive tract and other severe cancers; lymphatic system, head, and other major cancers; metastatic cancers; breast, prostate, colorectal, and other cancers and tumors; lymphoma; multiple myeloma; and leukemia. We performed analyses to estimate the relationship between these diagnostic categories and separately billable MAPs. These analyses demonstrated statistically significant associations between each of the cancer categories and SB MAP. In fact, the coefficient estimates were similar across categories. To advance the goal of parsimony in the model, we recombined the categories.

We also note that AIDS is included as a co-morbidity case-mix adjustment although it had been eliminated as an adjustment from the current basic case-mix adjusted composite payment system as reporting of AIDS was limited due to confidentiality requirements (69 FR 66326.) However, we found that inclusion of HIV/AIDS in the proposed ESRD PPS increases the explanatory power of the model and provides higher payments for patients who are substantially more costly to treat. We recognize that these benefits must be balanced against the goal to maintain patient confidentiality in this sensitive clinical

area. The model that we are currently proposing is the result of applying a combination of empirical results and our policy decision regarding the appropriateness of adjusting for specific patient characteristics. We recognize that this may result in difficulties for ESRD facilities required by State law to maintain patient confidentiality and therefore are unable to comply with reporting HIV/AIDS diagnoses on claims. We also acknowledge facilities may not be aware of patients' HIV/AIDS status. We are specifically soliciting comments on our proposal to include HIV/AIDS diagnoses in the proposed model.

Based upon our analysis, we are proposing adjustments for the following eleven co-morbidity categories under the proposed ESRD PPS as indicated in table 14 below, and seek comment on each adjustment.

**Table 14**  
**Co-morbidity case-mix adjustment**

<b>Case-mix adjustment co-morbidity</b>	<b>Modeled case-mix adjustment<sup>1</sup></b>
Alcohol/Drug Dependence	1.150
Cardiac Arrest	1.032
Pericarditis (0-3 months ago)	1.195
HIV/AIDS	1.316
Hepatitis B	1.089
Infection (0-3 months ago)	
Septicemia	1.234
Bacterial Pneumonia and Other Pneumonias/Opportunistic Infections	1.307
Gastrointestinal Tract Bleeding (0-3 months ago)	1.316
Hereditary Hemolytic or sickle cell anemias	1.226

Cancer Since 1999 (exclude nonmelanoma skin cancer)	1.128
Myelodysplastic Syndrome	1.084
Monoclonial Gammopathy	1.021

<sup>1</sup>Payment multipliers were calculated as the weighted average of the composite rate and separately billable multipliers. The weights used reflect each component's proportion of the total estimated costs so that the resulting case-mix adjustment reflects the overall relationships between patient characteristics and estimated costs for an expanded bundle of services.

Diagnoses that relate to earlier periods of care and have no bearing on the current RRT are excluded from the proposed co-morbidity case-mix adjustment. Therefore, we are proposing that in order to be eligible for the proposed co-morbidity payment adjustment, the co-morbid condition must exist (or have existed within the past 3 months for the diagnoses, as noted above) and affect treatment. For each claim, we are proposing that an ESRD facility may receive only one co-morbidity case-mix adjustment per co-morbidity category, but it may receive an adjustment for more than one co-morbidity category.

We are proposing that in order to receive a co-morbidity payment adjustment, the appropriate ICD-9-CM code that corresponds to the specific condition/disease that results in increased costs to ESRD facilities is to be placed on the claims and that coding guidelines are to be used in determining the appropriate codes. This includes using V codes for those conditions that reflect that a

patient had a disease/condition in the past and that the disease/condition has no effect on the cost of providing RRT. That is to say, we propose that these V codes (that is, history of a disease) for past disease/condition are not subject to any co-morbidity payment adjustment. We note we will issue through sub-regulatory guidance, any changes in codes eligible for a co-morbidity payment adjustment in the event of any changes in coding (for example, ICD-10-CM) in the future.

We performed analyses on FY 2007 dialysis claims to determine the extent that specific diagnoses within the eleven co-morbidity categories are on ESRD claims. We found that less than 50,000 claims out of three million (representing 1.7 percent of 3 million claims) had a diagnostic code corresponding to the co-morbidity categories eligible for a co-morbidity payment adjustment. Of these, 40,609 diagnoses related to septicemia and shock; 2,853 related to cancer; 1,933 related to Hepatitis B, and 973 with HIV/AIDS.

We also analyzed the ICD-9-CM diagnostic codes as identified by UM-KECC. A complete list of the codes identified by UM-KECC is found in Table A of the Addenda.

Table B, which can be found in the Addenda represents the codes associated with diseases/conditions that would be

recognized for the purposes of an ESRD co-morbidity payment adjustment.

Please note that we have eliminated specific ICD-9-CM codes associated with specific diseases/conditions that we propose would not be recognized for purposes of a co-morbidity payment adjustment. These ineligible codes are discussed further below.

ICD-9 CM Codes With Their Associated Conditions/Diseases  
Not recognized For the Purposes of a Co-morbidity Payment  
Adjustment

Based on our analyses, we are proposing that conditions/diseases associated with the following ICD-9 codes will not be recognized for the purposes of a co-morbidity case-mix adjustment. We explain the reason for not recognizing these codes in the sections discussed below. We are soliciting comments regarding the conditions/diseases associated with the excluded codes. We are also soliciting suggestions of ICD-9-CM codes for conditions/diseases associated with which we should consider for future refinements.

1. ICD-9-CM Co-morbidities Not Affecting Costs in  
Outpatient ESRD Facility and Not Recognized For Co-  
morbidity Payment Adjustment(s)

We believe that patients with the following co-morbidity condition(s) in Table 15 below, would not result in higher costs in an ESRD facility. We believe that patients with these acute conditions/diseases, many which are highly communicable, would not receive dialysis in an outpatient setting and therefore, a history of these conditions/diseases would not have an impact on ESRD provider/facility costs. Therefore, we are proposing that these conditions would not be recognized for purposes of the proposed co-morbidity adjustment. We are soliciting comments on these ICD-9 CM codes and their associated diseases/conditions.

**Table 15**  
**ICD-9-CM Co-morbidities Not Affecting Costs in**  
**Outpatient ESRD Facility and Not Recognized For Co-**  
**morbidity Payment Adjustment(s)**

<b>Drug and/or Alcohol Induced Mental Disorders</b>
291.0 Delirium Tremors
291.1 Alcohol psychosis, alcoholic amnestic syndrome
291.2 Alcoholic psychosis, other alcohol dementia
291.3 Alcoholic psychosis, alcoholic withdrawal hallucinosis
291.4 Alcoholic psychosis, idiosyncratic alcohol intoxication
291.5 Alcoholic psychoses, alcohol jealousy
<b>Hepatitis B</b>
070.20 Viral hepatitis B with hepatic coma acute or unspecified w/o hepatitis delta

070.21	Viral hepatitis B w/hepatic coma acute or unspecified w/ hepatitis delta
070.22	Viral hepatitis B w/hepatic coma chronic w/o hepatitis delta
070.23	Viral hepatitis B w/hepatic coma chronic w/hepatitis delta
<b>Septicemia and Shock</b>	
020.2	Septicemic plague
020.3	Primary pneumonic plague
036.2	Meningococcemia
038.3	Septicemia due to anaerobes
040.82	Toxic shock syndrome
054.5	Herpetic septicemia
771.81	Newborn septicemia
<b>Bacterial pneumonias/opportunistic infections/pneumococcal pneumonias</b>	
003.22	Salmonella pneumonia
006.4	Amebic lung abscess
007.4	Cryptosporidiosis
020.4	Secondary pneumonic plague
021.2	Pulmonary Tularemia
022.1	Pulmonary anthrax
031.2	Disseminated mycobacteria
039.1	Pulmonary Actinomycosis
078.5	Cytomagalovirus Disease
112.4	Candidiasis lung
112.5	Candidiasis disseminated
114.0	Primary coccidioidomycosis pulmonary
114.4	Chronic pulmonary coccidioidomycosis
115.05	Histoplasma capsulatum pneumonia

115.15	Histoplasma duboisii pneumonia
115.95	Histoplasmosis unspecified pneumonia
117.3	Aspergillosis
117.5	Cryptococcosis
117.7	Zygomycosis (phycomycosis/mucomycosis)
121.2	Paragonimiasis
122.1	Echinococcus granulosus lung
130.0	Toxoplasmosis meningoencephalitis
130.4	Toxoplasmosis pneumonitis (strep pneumoniae pneumonia)
130.8	Multisystemic disseminated toxoplasmosis
136.3	Pneumocytosis

2. ICD-9-CM NEC/NOS/Unspecified Codes Not Recognized for Purposes of a Co-morbidity Payment Adjustment(s) Payment

The following ICD-9 CM codes/diagnoses in Table 16 are designated as not otherwise specified (NOS); not elsewhere specified (NEC) or are unspecified. As these codes are general and do not provide meaningful identification of a disease, we are proposing that these ICD-9-CM codes/diagnoses will not be recognized for purposes of a co-morbidity case-mix adjustment.

**Table 16**  
**ICD-9-CM NEC/NOS/Unspecified Codes Not Recognized for Purposes of a Co-morbidity Payment Adjustment(s) Payment**

<b>Cancer (Excludes Non-Melanoma Skin Cancer)</b>	
141.9	malignant neoplasm tongue NOS

142.8	malignant neoplasm major salivary NEC
142.9	malignant neoplasm salivary NOS
143.8	malignant neoplasm gum NEC
143.9	malignant neoplasm gum NOS
144.9	malignant neoplasm mouth floor NOS
145.5	malignant neoplasm palate NOS
145.9	malignant neoplasm mouth NOS
146.9	malignant neoplasm oropharynx NOS
147.8	malignant neoplasm nasopharynx NEC
147.9	malignant neoplasm nasopharynx NOS
148.9	malignant neoplasm hypopharynx NOS
149.0	malignant neoplasm pharynx NOS
150.8	malignant neoplasm esophagus NEC
150.9	malignant neoplasm esophagus NOS
151.8	malignant neoplasm stomach NEC
151.9	malignant neoplasm stomach NOS
152.9	malignant neoplasm small bowel NOS
153.8	malignant neoplasm colon NEC
153.9	malignant neoplasm colon NOS
154.3	malignant neoplasm anus NOS
154.8	malignant neoplasm rectum/anus NEC
155.2	malignant neoplasm liver NOS
156.9	malignant neoplasm biliary NOS
157.9	malignant neoplasm pancreas NOS
158.9	malignant neoplasm peritoneum NOS
159.0	malignant neoplasm intestine NOS
159.1	malignant neoplasm spleen NEC

159.8	malignant neoplasm gastrointestinal/intra-abdominal NEC
159.9	malignant neoplasm gastrointestinal tract ill-defined
160.9	malignant neoplasm access sinus NOS
161.9	malignant neoplasm larynx NOS
162.8	malignant neoplasm bronchus/lung NEC
162.9	malignant neoplasm bronchus/lung NOS
163.8	malignant neoplasm pleura NEC
163.9	malignant neoplasm pleura NOS
164.8	malignant neoplasm mediastinum NEC
164.9	malignant neoplasm mediastinum NOS
165.0	malignant neoplasm upper respiratory NOS
165.9	malignant neoplasm respiratory system NOS
170.9	malignant neoplasm bone NOS
171.7	malignant neoplasm trunk NOS
171.8	malignant neoplasm soft tissue NEC
171.9	malignant neoplasm soft tissue NOS
172.8	malignant melanoma skin NEC
172.9	malignant melanoma skin NOS
172.3	malignant melanoma face NEC/NOS
174.8	malignant neoplasm breast NEC
174.9	malignant neoplasm breast NOS
175.9	malignant neoplasm male breast NEC
176.9	Kaposi's sarcoma NOS
179.9	malignant neoplasm uterus NOS
180.9	malignant neoplasm cervix uteri NOS
183.8	malignant neoplasm adnexa NEC
183.9	malignant neoplasm adnexa NOS

184.4	malignant neoplasm vulva NOS
184.8	malignant neoplasm female genitals NEC
184.9	malignant neoplasm female genitals NOS
187.4	malignant neoplasm penis NOS
187.9	malignant neoplasm male genital NOS
187.8	malignant neoplasm male genital NEC
188.8	malignant neoplasm bladder NEC
188.9	malignant neoplasm bladder NOS
189.8	malignant neoplasm urinary NEC
189.9	malignant neoplasm urinary NOS
190.9	malignant neoplasm eye NOS
191.6	mal neoplasm cerebellum NOS
191.8	malignant neoplasm brain NEC
191.9	malignant neoplasm brain NOS
192.8	malignant neoplasm nervous system NEC
192.9	malignant neoplasm nervous system NOS
194.8	malignant neoplasm endocrine NEC
194.9	malignant neoplasm endocrine NOS
195.8	malignant neoplasm site NEC
196.9	malignant neoplasm lymph node NOS
197.3	secondary malignant neoplasm respiratory NEC
197.8	secondary malignant neoplasm gastrointestinal NEC
198.82	secondary malignant neoplasm genital
198.89	secondary malignant neoplasm NEC
199.1	malignant neoplasm NOS
200.80	other variant unspecified extranodal
208.20	subacute leukemia unspecified cell without remission

208.21	subacute leukemia unspecified cell with remission
208.80	other leukemia unspecified cell type without remission
208.81	other leukemia unspecified cell type with remission
208.90	leukemia NOS without remission
208.91	leukemia NOS with remission
209.00	malignant carcinoid tumor small intestine unspecified portion
209.10	malignant carcinoid tumor large intestine unspecified portion
209.20	malignant carcinoid tumor of unknown primary site
209.25	malignant carcinoid tumor of foregut, NOS
209.26	malignant carcinoid tumor of midgut, NOS
209.27	malignant carcinoid tumor of hindgut, NOS
209.29	malignant carcinoid tumor of other sites
209.30	malignant poorly differentiated neuroendocrine cancer, any site
237.70	neurofibromatosis NOS
237.9	uncharacteristic behavior neurologic nervous system NEC
239.6	brain neoplasm NOS
259.2	other endocrine disorders, carcinoid syndrome
<b>Drug and/or alcohol induced mental disorders</b>	
291.81	alcohol psychosis other specified alcohol psychosis/alcohol withdrawal
291.89	alcohol psychosis, other specified alcohol psychosis, other
291.9	alcoholic psychoses/unspecified alcohol psycho
292.0	drug withdrawal
292.11	paranoid/hallucinatory drugs induced, drug-induced organic delusion syndrome
292.12	drug psychiatric disorder with hallucinations
292.2	pathologic drug intoxication
292.81	other specified drug-induced mental disorders, drug-induced delirium
292.82	other specified drug-induced mental disorders, drug-induced dementia

292.84	other specified drug-induced mental disorders, drug-induced organic affective syndrome
292.89	other specified drug-induced mental disorders, other
292.9	unspecified drug-induced mental disorders
303.00	acute alcohol intoxication-unspecified
303.01	alcohol dependant syndrome, acute alcohol intoxication, continuous
303.90	alcohol dependence syndrome, other & unspecified alcohol dependence unspecified
304.00	drug dependence, opioid, unspecified
304.10	drug dependence barbiturate/similarly acting sedative/hypnotic dependence unspecified
304.20	drug dependence, cocaine unspecified
304.30	drug dependence, cannabis unspecified
304.40	drug dependence amphetamine/other psychostimulator unspecified
304.50	drug dependence hallucinogen unspecified
304.60	other specified drug dependence unspecified
304.70	drug dependence opioid type w/other drug unspecified
304.80	drug depend comb w/o opioid type unspecified
304.90	drug dependence unspecified depend unspecified
305.00	nondependence drug abuse alcohol unspecified
571.3	alcoholic liver damage unspecified
V11.3	personal mental disorder history alcoholism
<b>Pericarditis</b>	
420.0	acute pericarditis in diseases classified elsewhere
420.99	other/unspecified pericarditis other
<b>HIV/AIDS</b>	
079.53	HIV-2 infection other disease

<b>Septicemia and shock</b>	
038.10	septicemia, staphylococcal unspecified
038.19	septicemia, staphylococcal other
038.9	septicemia other unspecified
785.59	other shock: endotoxic, gram negative hypovolemia
<b>Bacterial Pneumonias/Oppportunistic Infections/Pneumococcal Pneumonias</b>	
482.30	streptococcus pneumonia unspecified
482.39	streptococcus other strep pneumonia
482.40	pneumonia due to staphylococcus unspecified
482.49	pneumonia due to other staphylococcus pneumonia
482.83	pneumonia due to other gram negative bacteria
482.89	pneumonia due to other specified bacteria
484.7	other systemic mycoses pneumonia
<b>Gastrointestinal tract bleeding</b>	
531.40	chronic/unspecified gastric ulcer w/hemorrhage w/o obstruction
531.41	chronic/unspecified gastric ulcer w/hemorrhage w/obstruction
531.60	chronic/unspecified gastric ulcer w/hemorrhage/perforation w/o obstruction
531.61	chronic/unspecified gastric ulcer w/hemorrhage/perforation w/obstruction
532.40	chronic/unspecified duodenal ulcer w/hemorrhage w/o obstruction
532.41	chronic/unspecified duodenal ulcer w/hemorrhage w/obstruction
532.60	chronic/unspecified duodenal ulcer w/hemorrhage/perforation w/o obstruction
532.61	chronic/unspecified duodenal ulcer w/hemorrhage/perforation w/obstruction
533.40	chronic/unspecified peptic ulcer w/hemorrhage w/o obstruction
533.41	chronic/unspecified peptic ulcer w/hemorrhage w/obstruction
533.60	chronic/unspecified peptic ulcer w/hemorrhage/perforation w/o obstruction
533.61	chronic/unspecified peptic ulcer w/hemorrhage/perforation w/obstruction
534.40	chronic/unspecified gastrojejunal ulcer w/hemorrhage w/o obstruction

534.41	chronic/unspecified gastrojejunal ulcer w/hemorrhage w/obstruction
534.60	chronic/unspecified gastrojejunal ulcer w/hemorrhage/perforation w/o obstruction
534.61	chronic/unspecified gastrojejunal ulcer w/hemorrhage/perforation w/obstruction
<b>Hereditary hemolytic anemias/sickle cell anemias</b>	
282.69	sickle-cell disease other sickle-cell disease w/crisis
282.9	hereditary hemolytic anemia unspecified

3. ICD-9-CM Benign Tumor Codes Not Recognized for Co-morbidity Payment Adjustment(s)

As noted previously, the intent of the case-mix adjustment is to provide additional payment for conditions which are predictors of variation of average costs. Although the regression analysis identified cancer as a co-morbidity category because it resulted in higher costs, we believe that this would exclude benign tumors. Therefore, we are proposing that the following benign tumor codes/diagnoses in Table 17 will not be recognized for the proposed cancer co-morbidity payment adjustment.

**Table 17****ICD-9-CM Benign Tumor Codes Not Recognized for Co-morbidity Payment Adjustment(s)**

209.40	Benign carcinoid tumor small intestine unspecified portion
209.41	Benign carcinoid tumor of the duodenum
209.42	Benign carcinoid tumor of the jejunum
209.43	Benign carcinoid tumor of the ileum
209.50	Benign carcinoid tumor large intestine, unspecified portion
209.51	Benign carcinoid tumor of the appendix
209.52	Benign carcinoid tumor of the cecum
209.53	Benign carcinoid tumor ascend colon
209.54	Benign carcinoid tumor of the transverse colon
209.55	Benign carcinoid tumor descend colon
209.56	Benign carcinoid tumor of the sigmoid colon
209.57	Benign carcinoid tumor of the rectum
209.60	Benign carcinoid tumor unknown primary site
209.61	Benign carcinoid tumor bronchus/lung
209.62	Benign carcinoid tumor thymus
209.63	Benign carcinoid tumor of the stomach
209.64	Benign carcinoid tumor of the kidney
22.5	Benign neoplasm brain/other nervous system parts
225.0	Benign neoplasm brain
225.1	Benign neoplasm cranial nerves
225.2	Benign neoplasm cerebral meninges
225.3	Benign neoplasm spinal cord
225.4	Benign neoplasm spinal meninges
225.8	Benign neoplasm nervous system NEC
225.9	Benign neoplasm nervous system NOS

226	Benign neoplasm thyroid
227.3	Benign neoplasm pituitary
227.4	Benign neoplasm pineal gland

4. ICD-9 Codes as Category Headings and Not Recognized for Co-morbidity Payment Adjustment(s)

We are proposing that the following ICD-9-CM codes/diagnoses in Table 18 will not be recognized for purposes of a co-morbidity case-mix adjustment because these codes are ICD-9-CM category headings not be used to identify diagnoses.

**Table 18**  
**ICD-9 Codes as Category Headings and Not Recognized for Co-morbidity Payment Adjustment(s)**

<b>Cancer (excludes non-melanoma skin cancer)</b>	
141	malignant neoplasm tongue
142	malignant neoplasm major salivary/parotid
143	malignant neoplasm gum
144	malignant neoplasm floor of mouth
145	malignant neo other/unspecified mouth parts
146	malignant neoplasm oropharynx
147	malignant neoplasm nasopharynx
148	malignant neoplasm hypopharynx
149	mal neoplasm other/ill-defined lip/oral cavity/pharynx
150	malignant neoplasm esophagus
151	malignant neoplasm stomach

152	malignant neoplasm intestine/duodenum
153	malignant neoplasm colon
154	malignant neo rectum/rectosigmoid junction/anus
155	malignant neoplasm liver/intrahepatic bile ducts
156	malignant neoplasm gall bladder/extrahepatic bile ducts
157	malignant neoplasm pancreas
158	malignant neoplasm retroperitoneum/peritoneum
159	malignant neoplasm other/ill-defined digest org/peritoneum
160	malignant neoplasm nasal cavities/middle ear/access sinuses
161	malignant neoplasm larynx
162	malignant neoplasm trachea/bronchus/lung
163	malignant neoplasm pleura
164	malignant neoplasm thymus/heart/mediastinum
<b>Cancer (excludes non-melanoma skin cancer)</b>	
165	malignant neoplasm other/ill-defined respiratory system/intrathoracic
170	malignant neoplasm bone/articular cartilage
171	malignant neoplasm connective/other soft tissue
172	malignant melanoma skin
174	malignant neoplasm female breast
175	malignant neoplasm male breast
176	Kaposi's sarcoma
180	malignant neoplasm cervix uteri
182	malignant neoplasm uterine body
183	malignant neoplasm ovary/other uterine adnexa
184	malignant neoplasm other/unspecified female genitals
186	malignant neoplasm testis
187	malignant neoplasm penis/other male genitals

188	malignant neoplasm bladder
189	malignant neoplasm kidney/other/unspecified urinary organs
190	malignant neoplasm eye
191	malignant neoplasm brain
192	malignant neoplasm other/unspecified nervous system
194	malignant neoplasm other endocrine/related structures
195	malignant neoplasm other/ill-defined sites
196	secondary/unspecified malignant neoplasm lymph nodes
197	secondary malignant neoplasm respiratory/digestive systems
198	secondary malignant neoplasm other specified sites
199	malignant neoplasm without site specification
200	lymphosarcoma & reticulosarcoma
200.1	lymphosarcoma/reticulosarcoma/lymphosarcoma
200.2	lymphosarc/reticulosarcoma, Berkett tumor/lymphoma
<b>Cancer (excludes non-melanoma skin cancer)</b>	
200.8	lymphosarcoma/reticulsarcoma other variants
201	Hodgkin's disease
201.0	Hodgkin's disease Hodgkin's paragranuloma
201.1	Hodgkin's disease Hodgkin's granuloma
201.2	Hodgkin's disease Hodgkin's sarcoma
201.4	Hodgkin's disease lymphocystic-histiocytic
201.5	Hodgkin's disease nodular sclerosis
201.6	Hodgkin's disease mixed cellularity
201.7	Hodgkin's disease lymphocytic depletion
201.9	Hodgkin's disease unspecified
202	other malignant neoplasm lymphoid/histiocytic tissue
202.0	nodular lymphoma

202.1	other malignant neoplasm lymphoid/histiocytic tissue; mycosis fungoides
202.2	other malignant neoplasm lymphoid/histiocytic tissue; Sezary's disease
202.3	other malignant neoplasm lymphoid/histiocytic tissue; malignant histiocytosis
202.4	other malignant neoplasm lymphoid/histiocytic tissue, leukemic reticuloendotheliosis
202.5	other malignant neoplasm lymphoid/histiocytic tissue, Letterer-Siwe disease
202.6	other malignant neoplasm lymphoid/histiocytic tissue, malignant mast cell tumors
202.8	other lymphomas
202.9	other malignant neoplasm lymphoid/histiocytic tissue, other/unspecified
203	multiple myeloma/immunoproliferative neoplasms
203.0	multiple myeloma
203.1	plasma cell leukemia
203.8	other immunoproliferative neoplasms
204	lymphoid leukemia
204.0	acute lymphoid leukemia
204.1	chronic lymphoid leukemia
<b>Cancer (excludes non-melanoma skin cancer)</b>	
204.2	subacute lymphoid leukemia
204.8	lymphoid leukemia other
204.9	lymphoid leukemia unspecified
205	myeloid leukemia
205.0	acute myeloid leukemia
205.1	chronic myeloid leukemia
205.2	subacute myeloid leukemia
205.3	myeloid leukemia, myeloid sarcoma
205.8	myeloid leukemia other
205.9	myeloid leukemia unspecified
206	monocytic leukemia

206.0	acute monocytic leukemia
206.1	chronic monocytic leukemia
206.2	subacute monocytic leukemia
206.8	monocytic leukemia other
206.9	monocytic leukemia unspecified
207	other specified leukemia
207.0	other specified leukemia, acute erythremia/erythroleukemia
207.1	other specified leukemia, chronic erythremia
207.2	other specified leukemia megakaryocytic leukemia
207.8	other specified leukemia other
208	leukemia unspecified cell type
208.0	acute leukemia unspecified cell type
208.1	chronic leukemia unspecified cell type
208.2	subacute leukemia unspecified cell type
208.8	leukemia unspecified cell type other
208.9	leukemia unspecified cell type unspecified
22.5	benign neoplasm brain/other nervous system parts
237.7	neurofibromatosis

<b>Drug and/or Alcohol Induced Mental Disorders</b>	
291	Alcoholic psychosis
291.8	Alcohol psychoses, other specified alcohol psychosis
292	Drug psychoses
292.1	Paranoid/hallucinatory induced by drugs
292.8	other specified drug-induced mental disorders
303	alcohol dependence syndrome
303.0	alcohol dependence syndrome, acute alcohol intoxication
303.9	alcohol dependence syndrome, other & unspecified alcohol dependence

304	drug dependence
304.0	drug dependence, opioid
304.1	drug dependence barbiturate/similarly acting sedative/hypnotic dependence
304.2	drug dependence, cocaine
304.3	drug dependence, cannabis
304.4	drug dependence, amphetamine/other psychostimulant
304.5	drug dependence hallucinogen
304.6	other specified drug dependence
304.7	drug dependence opioid type with other drug
304.8	drug depend combination without opioid
304.9	drug dependence unspecified dependence
305.0	nondependence drug abuse alcohol

<b>Pericarditis</b>	
420	acute pericarditis
420.9	other/unspecified pericarditis
<b>Hepatitis B</b>	
070.2	viral hepatitis B w/hepatic coma
070.3	viral hepatitis B w/o hepatic coma
<b>Septicemia and Shock</b>	
031	diseases due to other mycobacteria
038	septicemia
038.1	septicemia, staphylococcal
038.4	septicemia due to other gram negative organisms
<b>Bacterial pneumonias/opportunistic infections/pneumococcal pneumonias</b>	
482	other bacterial pneumonias

482.3	streptococcus pneumonia
482.4	pneumonia due to staphylococcus
482.8	pneumonia due to other specified bacteria
507	pneumonitis due to solids & liquids
510	empyema
513	lung/mediastinum abscess
<b>Gastrointestinal Tract Bleeding</b>	
531.0	acute gastric ulcer w/hemorrhage
531.2	acute gastric ulcer w/hemorrhage/perforation
531.4	chronic/unspecified gastric ulcer w/hemorrhage
531.6	chronic/unspecified gastric ulcer w/hemorrhage/perforation
532.0	acute duodenal ulcer w/hemorrhage
532.2	acute duodenal ulcer w/hemorrhage/perforation
532.4	chronic/unspecified duodenal ulcer with hemorrhage
532.6	chronic/unspecified duodenal ulcer without hemorrhage/perforation
533.0	acute peptic ulcer w/hemorrhage
533.2	acute peptic ulcer w/hemorrhage/perforation
533.4	chronic/unspecified peptic ulcer w/hemorrhage
533.6	chronic/unspecified peptic ulcer w/hemorrhage/perforation
534.0	acute gastrojejunal ulcer w/hemorrhage
534.2	acute gastrojejunal ulcer w/hemorrhage/perforation
534.4	chronic/unspecified gastrojejunal ulcer w/hemorrhage
534.6	chronic/unspecified gastrojejunal ulcer w/hemorrhage/perforation
<b>Hereditary hemolytic anemias/sickle cell anemias</b>	
282	hereditary hemolytic anemias
282.4	Thalassemias
282.6	sickle-cell disease

<b>Myelodysplastic Syndrome</b>
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238.7 neoplasm other lymphatic/hematopoietic tissues includes myelodysplastic syndrome
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## 6. Race/Ethnicity

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's race and ethnicity. Consequently, we analyzed race and ethnicity as part of the regression analysis for the proposed ESRD PPS to inform our proposal for this rule.

Prior to the enactment of MIPPA, we considered race and ethnicity as potential patient level payment adjusters. First, race was one of the 35 patient characteristics that were examined in developing the basic case-mix adjustments to the ESRD composite rate required under section 1881(b)(12) of the Act. Ultimately, however, the final basic case-mix adjusted composite payment system published in the CY 2005 PFS final rule with comment period did not include adjustments for race and ethnicity. (For more information, we refer readers to 69 FR 66330.)

We again considered race and ethnicity as potential patient level payment adjusters as part of our research for the Secretary's 2008 Report to Congress. In the Report, we concluded that although race and ethnicity perhaps had a

statistically significant relationship with costs and payments, such indicators were judged not to be suitable for making payment distinctions in a bundled ESRD PPS given that race/ethnicity is not objectively measured.

Specifically, because there is no quantifiable mechanism by which to measure one's race or ethnicity, the classification is commonly based on self-reported information. We believed that more measurable indicators of cost and payment would be the patient's underlying clinical conditions. We further noted in the Report a demonstrated significance that race has on provider costs and drug utilization, indicating that this adjustment may warrant further consideration in the development and implementation of a new ESRD PPS. We note that any relationship between race/ethnicity and costs and payments revealed in the analyses conducted for purposes of this ESRD PPS proposed rule is discussed further in the sections that follow.

The regression analysis conducted for purposes of this proposed rule relied on two separate data sources for race and ethnicity status to assess the extent to which race and ethnicity would account for cost factors that are otherwise unexplained in the model. The first analysis was based on race and ethnicity data retrieved from the Renal Management

Information System (REMIS) and the second analysis was based on data retrieved from the Medicare Enrollment Database (EDB). In Table 19 below, the table captures the key differences in racial and ethnic categorizations between the REMIS and EDB databases.

**Table 19**  
**Race/ethnicity of Medicare dialysis patients<sup>1,2</sup>**

REMIS/CMS Form 2728		Medicare Enrollment Database (EDB)	
Race	Percent	Race	Percent
American Indian/Alaskan Native	1.6%	North American Native	1.4%
Asian/Pacific Islander	3.6%	Asian	2.7%
Black	38.5%	Black	37.7%
White	55.2%	White	48.7%
Other	1.1%	Hispanic	5.2%
Unknown	<0.1%	Other	2.1%
<b>Ethnicity</b>		Unknown	2.2%
Hispanic	12.2%		
Not Hispanic	83.8%		
Unknown	4.0%		

<sup>1</sup>n=890,776 patient years.

<sup>2</sup>Hispanic ethnicity is reported separately from race on CMS Form 2728 (the Medical Evidence Form), while Hispanic is a race category in the Medicare Enrollment Database.

Most notably, REMIS data includes both beneficiary race and ethnicity designations whereas EDB data includes ethnicity as a racial category. For example, an individual self-identifying as being of Hispanic ethnicity and White race would be reflected as both Hispanic and White in the REMIS database but this same individual would be categorized as either Hispanic or White in EDB. A summary of each analysis is set forth below.

a. REMIS Data Analysis

REMIS, a tracking system for the ESRD patient population for both Medicare and non-Medicare patients, is

populated by the ESRD Networks with race and ethnicity data that are collected on the ESRD Medical Evidence Report (Form CMS-2728). The form is completed, signed and certified by the patient's physician at the onset of ESRD treatment.

As noted previously, the proposed ESRD PPS model set forth is based on 2004-2006 data. During this 3-year timeframe, two versions of the Medical Evidence Report Form were used, each with differing categorizations for race and ethnicity.

The earlier version (dated 6/1997), included three ethnicity categories from which to choose -- (1) Hispanic: Mexican, (2) Hispanic: Other, and (3) Non-Hispanic. The form did not specify whether to check one or more ethnicity categories. In addition, the form included nine race categories from which to choose -- (1) White, (2) Black, (3) American Indian/Alaskan Native, (4) Asian, (5) Pacific Islander, (6) Mid-East/Arabian, (7) Indian sub-Continent, (8) Other, specify, and (9) Unknown. The form instructed individuals to check the *one* race category that applied.

The later version (dated 6/2004), includes two ethnicity categories from which to choose-- (1) Not Hispanic or Latino and (2) Hispanic or Latino (including country/area of origin or ancestry). While the form does

not include instructions for selecting ethnicity, it is assumed that the individual would choose one of the two categories. In addition, the form includes five race categories from which to choose -- (1) White, (2) Black or African American, (3) American Indian/Alaskan Native, (4) Asian, and (5) Native Hawaiian or Other Pacific Islander. This form instructs individuals to check all race categories that apply.

Reporting using the later version (dated 6/2004) became mandatory on June 1, 2005. Therefore, for purposes of our analysis using REMIS race and ethnicity data, beneficiaries for whom the Medical Evidence Report Form 2728 was completed prior to June 2005 comprise the race and ethnicity categories of the earlier version of the form whereas beneficiaries for whom the Medical Evidence Report Form was completed between June through December of 2005 and 2006 comprise the race and ethnicity categories of the later version of the form. We note that for comparison purposes between the two versions of the Medical Evidence Form, it was necessary to designate the following beneficiaries into the category of "Other": (1) beneficiaries for whom more than one racial category was marked on the 2004 version of the form and (2) beneficiaries for whom the Mid-East/Arabian or the Indian

sub-Continent categories were marked on the 1997 version of the form.

Relying on REMIS as the basis of race and ethnicity data, it was possible to evaluate the potential for race and ethnicity to predict differences in composite rate costs among ESRD facilities as well as differences in MAP for separately billable services at the patient level.

In our analysis using REMIS data in examining race, we found that combined composite rate and separately billable payments are lowest in the category "Asian/Pacific Islander." As a result, this category was used as the reference group. Compared to the reference group, "Native American/Alaskan Natives" are 12.6 percent costlier; "Whites" are 14.2 percent costlier; "Blacks" are 20.7 percent costlier; and individuals in the category "Other" are 64.6 percent costlier. As noted previously, for purposes of our analysis, it was necessary to default beneficiaries into the "Other" category to reconcile differences between the two versions of the Medical Evidence Report Form and in instances where multiple race categories were selected on the form. As a result of defaulting individuals into the "Other" category, we believe that this designation may fail to reflect an individual's true racial status.

In our analysis using REMIS data in examining ethnic background, we found that non-Hispanic patients are 6.5 percent more costly than Hispanic patients.

b. EDB Data Analysis

The EDB is the source of enrollment and entitlement information for all people who are or were ever entitled to Medicare. The EDB is populated with race and ethnicity data that come from the Social Security Administration (SSA). The SSA's race and ethnicity data are collected on the SS-5 form. Unlike CMS' Medical Evidence Report Form that captures both race and ethnicity, the SSA's SS-5 form combines these two elements, instructing the individual to voluntarily select one of the following 5 categories: (1) Asian, Asian-American or Pacific Islander; (2) Hispanic; (3) Black (Not Hispanic); (4) North American Indian or Alaskan Native; or (5) White (Not Hispanic). The SS-5 form is completed when an individual does the following: (1) applies for a social security number; (2) requests a replacement of the social security card; or (3) requests changes to personal information on their record, such as a name change (Social Security Administration web site instructions <http://www.ssa.gov/online/ss-5.pdf>). Prior to 1980, the SS-5 form included 3 categories for race: White, Black or Other.

The EDB is also populated with data collected by the Railroad Retirement Board (RRB). However, the data are not inclusive of race and ethnicity as these elements are not collected or maintained within the RRB's system. In 1964, the RRB began requiring new railroad industry employees to obtain social security numbers from the SSA, despite ineligibility for Social Security benefits. As a result, race or ethnicity data voluntarily specified by these individuals are reflected in EDB. However, the EDB does not include race or ethnicity on behalf of railroad industry beneficiaries lacking social security numbers; that is, those individuals entering the RRB system prior to 1964. As a result, the race and ethnicity of these individuals is defaulted to "Unknown" within EDB.

Each January, CMS creates a finder file consisting of those beneficiaries who were added to CMS' EDB during the previous calendar year as well as all living beneficiaries whose race is identified as "Other" or "Unknown." This finder file is sent to the SSA to be processed against their Numerical Identification file, referred to as "NUMIDENT", which contains the expanded race categories captured on the SS-5 form. When the results are returned to us, the EDB is updated with the latest information. During subsequent iterations of this annual process, we do

not include those beneficiaries that were processed in previous years into the subsequent finder file unless the race was either "Unknown" or "Other."

In addition to the NUMIDENT file provided by the SSA, several other efforts have been undertaken in an attempt to improve the validity of EDB data including (1) a one-time, voluntary survey of beneficiaries, conducted by CMS in 1997, whose race was identified as "Unknown" or "Other," and (2) coordination with the Indian Health Service (IHS) since 2000 on a quarterly basis to record beneficiaries race as American Indian or Alaskan native. Despite these efforts, researchers have identified concerns with CMS' continued reliance on SSA race and ethnicity data collected through the SS-5 form, pointing to deficiencies in data among the smaller minority groups of Asians, Hispanics, and American Indians/Alaskan Natives. A study of 2002 data revealed that only 52 percent of Asian, 33 percent of Hispanic, and 33 percent of American Indian/Alaskan Native Medicare beneficiaries can be correctly identified in the Medicare data (McBean, M, "Medicare Race and Ethnicity Data Report." December 2004.). However, EDB codes are generally reliable for White and Black affiliations (Waldo, D, "Accuracy and Bias of Race/Ethnicity Codes in the Medicare

Enrollment Database." HCFA Review Vol. 26 No. 2 (Winter 2004-2005): 61-72).

Linking race and ethnicity data from the EDB to ESRD patients, we evaluated the potential for race and ethnicity to predict differences in composite rate costs among ESRD facilities, as well as differences in MAP for separately billable services at the patient level.

In our analysis using EDB data in examining race and ethnicity, we found that combined composite rate and separately billable payments are lowest among those individuals categorized as "Other" and "Hispanic." In using the category "Asian" as the reference group, individuals categorized as "Other" and "Hispanic" have approximately 6 percent and 4 percent lower costs, respectively than the reference group. Individuals categorized as "North American Native" have 7.4 percent higher costs; individuals categorized as "White" have 11.9 percent higher costs; and individuals categorized as "Black" have 17.8 percent higher costs. Please see Table 20 below.

**Table 20**

**Modeled case-mix adjustment for an expanded ESRD prospective payment system**

**Comparison of payment models with vs. without patient race/ethnicity**

Variable	Modeled case-mix adjustment <sup>1</sup>		
	Payment model without race/ethnicity	Payment model with race and ethnicity from REMIS/CMS Form 2728	Payment model with race from the Medicare Enrollment Database (EDB)
	Multiplier <sub>EB</sub>	Multiplier <sub>EB</sub>	Multiplier <sub>EB</sub>
<b>Adjustments for dialysis patient characteristics</b>			
Age			
18-44	1.194	1.154	1.158
45-59	1.000	1.000	1.000
60-69	1.012	1.001	1.001
70-79	1.057	1.038	1.011
80+	1.076	1.037	1.008
Female	1.132	1.080	1.058
Race/ethnicity			
American Indian / Alaskan Native (Form 2728) or North American Native (EDB)	--	1.126	1.074
Asian / Pacific Islander (Form 2728) or Asian (EDB)	--	1.000	1.000
Black	--	1.207	1.178
White	--	1.142	1.119
Other	--	1.645	0.939
Hispanic <sup>2</sup>	--	1.000	0.956
Non-Hispanic <sup>2</sup>	--	1.065	--
Body surface area (per 0.1 m <sup>2</sup> )	1.034	1.014	1.006
Underweight (BMI <18.5)	1.020	1.012	1.013
Duration of RRT: <4 months	1.473	1.493	1.439
Alcohol/drug dependence (claims since 2000 or 2728)	1.150	1.085	1.074
Cardiac arrest (claims since 2000 or 2728)	1.032	1.035	1.034
Pericarditis from same month to three months ago	1.195	1.195	1.195
HIV/AIDS (claims since 2000 or 2728)	1.316	1.197	1.237
Hepatitis B (claims since 2000)	1.089	1.083	1.081
Specified infection from same month to three months ago			
Septicemia	1.234	1.230	1.231
Bacterial pneumonia and other pneumonias/opportunistic infections	1.307	1.414	1.407
Gastro-intestinal tract bleeding from same month to three months ago	1.316	1.307	1.307
Hereditary hemolytic or sickle cell anemias (claims since 2000)	1.226	1.188	1.187
Cancer (claims since 2000; excludes non-melanoma skin cancer)	1.128	1.080	1.087
Myelodysplastic syndrome (claims since 2000)	1.084	1.093	1.093
Monoclonal gammopathy (claims since 2000)	1.021	1.017	1.017
<b>Low volume facility adjustment</b>			
Facility size < 3,000 treatments during each year from 2004-06	1.202	1.209	1.202

<sup>1</sup>The combined payment multipliers for patient characteristics were calculated as  $PmtMult_{EB} = Weight_{CR} \times PmtMult_{CR} + Weight_{SB} \times PmtMult_{SB}$ , where  $PmtMult_{CR}$  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 ( $\$82.45/\$252.12$ ).

<sup>2</sup>Hispanic ethnicity is reported separately from race on CMS Form 2728 (the Medical Evidence Form), while Hispanic is a race category in the Medicare Enrollment Database.

c. Concerns with Available Race/Ethnicity Data

There are several specific concerns with the quality of the REMIS and the EDB data. The race and ethnicity data in REMIS have been collected with different versions of the Medical Evidence Report Form, making it difficult to accurately assess the effect of race and ethnicity on composite rate costs and separately billable payments. That is, a significant portion of the payment is reflected in the default category "Other". In addition, while not relevant for purposes of modeling the ESRD PPS, we are concerned about relying on the race and ethnicity data collected from the Medical Evidence Report Form for purposes of future refinements to the ESRD PPS. This form is routinely completed and signed by the physician at the ESRD facility. To mitigate the potential for provider manipulation of Medical Evidence Report Form in the interest of racial or ethnic payment adjustment, we would expect that ESRD facilities would accurately document race or ethnicity within the patient's medical record along with any care planning activities that may be based on the individual's race or ethnicity. There are also concerns related to relying on EDB data for modeling race and

ethnicity data within the proposed ESRD PPS. Specifically, race and ethnicity classification on behalf of some segments of the population is either unavailable or defaulted into the "Unknown" category within EDB, for example, RRB beneficiaries that entered the RRB system prior to 1964. In addition, we have concerns regarding the race and ethnicity data for individuals entering the SSA system via the enumeration at birth (EAB) process that has been in place since 1989. The EAB process allows the parent, at the time of the child's birth, to indicate on the child's birth certificate that they are interested in obtaining a social security number (SSN) for their child. Therefore, the parent is not required to file a separate application for an SSN for the child. The State vital statistics office receives the request with the birth registration data from the hospital and then forwards this information to SSA. Absent the SS-5 form that includes race and ethnicity fields, we are not aware of any current mechanism by which these data elements are captured by the SSA on behalf of individuals entering the SSA system via the EAB process.

We note that relying on EDB data for purposes of ESRD PPS modeling is that they are not updated in real time. To the extent a beneficiary completes a new SS-5 form for any

of the reasons discussed above and there are changes in race information, those changes are not currently reflected in CMS' EDB data in real time. Rather, they occur only after the annual NUMIDENT update.

In addition to the REMIS and EDB data concerns, racial and ethnic categories are not well defined as evidenced by the ongoing changes to the instruments used in collecting these data. Lastly, it is not possible to quantify an individual's race absent a genetic test to determine racial status. This presents the greatest challenge when considering individuals who identify with more than one race. Collection tools such as the SSA's SS-5 form and the Census Bureau's survey instrument depend on the individual to self select the one racial category with which they associate. While the current Medical Evidence Report Form allows for selection of more than one racial category, absent a mechanism for establishing a primary race, it is difficult to conduct comparisons without first defaulting those with multiple race selections into the "Other" category.

In summary, the analyses of REMIS and EDB race and ethnicity data demonstrate associations between these patient characteristics and facility level composite rate costs and patient level separately billable payments. As

such, including these factors may improve the predictive value of the proposed ESRD PPS. However, we have concerns about whether the data are of sufficient quality upon which to base payment adjustments. The race or ethnicity status designations within the current CMS data systems may fall short in assigning individuals to the most correct racial and ethnic categories and reflecting the unique and measurable traits of individuals. As a result, ESRD facilities may be overpaid for certain patients and underpaid for others. However, to the extent that including race and ethnicity in the model explains additional variation in treatment costs not otherwise reflected, such adjustments may be warranted. We specifically invite public comment on the data issues presented in this section, other data sources for race and ethnicity we should consider, and specifically, the need for adjustments for race and ethnicity in the final ESRD PPS. It is important to note that any adjustments for race would result in additional reductions to the base rate through the standardization process described in section VII.C.

d. CMS Initiatives to Evaluate Health Disparities Based on Race and Ethnicity

In accordance with MIPPA, we plan to explore opportunities for improving Medicare program data on race and ethnicity. Specifically, section 185 of MIPPA amends the Act to add new section 1809 entitled "Addressing Health Care Disparities." This section charges the Secretary with several key tasks and goals including (1) evaluating approaches for Medicare data collection that will allow for collection and evaluation of data on disparities in health care services and performance based on race, ethnicity and gender; (2) submitting several Reports to Congress that describe the evaluation of Medicare data and make recommendations for improving the identification of health care disparities for Medicare beneficiaries; and (3) implementing the identified approaches for the ongoing, accurate, and timely collection and evaluation of data on health care disparities on the basis of race, ethnicity and gender.

In addition to the tasks associated with MIPPA section 185 that will focus on addressing health care disparities, health care disparities across several settings of care are currently being monitored by the Quality Improvement Organization (QIO) Program. In three cases, active intervention projects are underway to reduce health care disparities. As part of this department-wide effort, we

will continue to explore additional approaches to improve the accuracy of this data. Some of these approaches will involve cooperation with entities outside of the Department of Health and Human Services (for example, the SSA), as described above. The first Report to Congress summarizing the possible approaches is due January 1, 2010.

In summary, we believe that the analyses that we will conduct for purposes of developing the Reports to Congress will serve as the basis for improving the accuracy of Medicare race and ethnicity data.

#### 7. Modality

Section 1881(b)(14)(D)(iv) of the Act, as added by section 153(b) of MIPPA, gives the Secretary the discretionary authority to establish an ESRD PPS, which may include payment adjustments as the Secretary determines appropriate. PD, which is the primary mode for home dialysis, is a substantially less costly mode of dialysis compared to in-center HD. Therefore, the Act gives the Secretary the authority to develop an ESRD PPS, which would establish payment rates based on dialysis modality.

Table K.5 from the 2008 Annual Data Report of the U.S. Renal Data System indicates that the average annual cost for all HD patients in 2006 was \$71,889, whereas the corresponding figure for PD patients was \$53,327 (Table

K.7). Data from the Medicare cost reports and Medicare claims for CYs 2004-2006 show a similar difference in resource utilization, with PD patients incurring significantly lower composite rate and separately billable expenses.

**Comparison of composite rate costs by modality, CY 2004-06<sup>1</sup>**

Facility type	Hemodialysis		Peritoneal dialysis	
	Facility years (n)	Average composite rate cost per treatment	Facility years (n)	Average composite rate cost per treatment
Freestanding	11,058	\$159.60	3,839	\$150.39
Hospital based	878	\$248.92	349	\$155.99
Total	11,936	\$168.99	4,188	\$151.15

<sup>1</sup>Based on the Medicare Independent Renal Dialysis Facility and Hospital Cost Reports. ESRD facilities that opened or closed or reported less than one full dialysis patient year for the modality (156 hemodialysis-equivalent treatments) during the calendar year were excluded. Excludes potential outliers using a standard outer fence methodology that was applied on the log scale. Average CR costs were weighted by the total hemodialysis-equivalent treatments in the facility.

**Comparison of separately billable Medicare Allowable Payments by modality, CY 2004-06<sup>1</sup>**

Hemodialysis		Peritoneal dialysis	
Patient facility months (n)	Average separately billable MAP per treatment	Patient facility months (n)	Average separately billable MAP per treatment
2,817,067	\$87.20	186,296	\$35.15

<sup>1</sup>Based on the Medicare claims. MAP for the top 11 injectable drugs were repriced to reflect the payment rates used in the first quarter of 2008. MAP for EPO were capped at 30,000 units per treatment. Average SB MAPs were weighted by the Medicare hemodialysis-equivalent treatments in each patient facility month.

Despite this distinction, we are proposing not to develop an ESRD PPS which uses type of dialysis modality as a payment variable, despite the increased predictive power a modality variable would yield in the resulting regression equations. Because composite rate costs and separately billable payments are lower for PD, the use of a modality payment variable would result in substantially lower payments for PD patients. The payment rates for HD patients would be slightly higher, because of the greater volume of HD patients, and the exclusion of PD patients from the average payment amount that would apply to HD patients. We believe that the substantially lower payments for PD patients that would result if modality were used as a payment adjuster in the ESRD PPS would discourage the increased use of PD for patients able to use that modality. Because we want to encourage home dialysis, in which PD is currently the prevailing mode of treatment, we are proposing an ESRD PPS which does not rely on separate payment rates based on modality. By establishing prospective payment rates that are higher for PD patients than they otherwise would be if separate payments were established based on modality, we believe home dialysis will be encouraged for patients able to use PD. We invite comment on this approach.

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.