CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 177	**Date: December 13, 2013**
	Change Request 8472

Transmittal 174, dated November 29, 2013 is being rescinded and replaced by Transmittal 177, dated December 13, 2013 to include a business requirement (BR 8472-02.5) to eliminate the transitional budget neutrality adjustment. All other information remains the same.

SUBJECT: Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2014

I. SUMMARY OF CHANGES: This Change Request implements the fourth year of the ESRD PPS 4-year transition period and the CY 2014 rate updates for the ESRD PPS. This recurring update notification applies to chapter 11, section 50.

EFFECTIVE DATE: January 1, 2014
IMPLEMENTATION DATE: January 6, 2014

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	11/50/ESRD Prospective Payment System (PPS) Base Rate
R	11/60/ESRD PPS Case-Mix Adjustments

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; contractor's activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment – Recurring Update Notification

Pub. 100-02	Transmittal: 177	Date: December 13, 2013	Change Request: 8472

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SUBJECT: Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2014

EFFECTIVE DATE: January 1, 2014
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I. GENERAL INFORMATION

A. Background: In accordance with Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA), The Centers for Medicare & Medicaid Services (CMS) implemented the ESRD bundled Prospective Payment System (PPS) effective January 1, 2011.

CY 2014 implements the fourth year of the transition where all ESRD facilities will be paid 100 percent of the ESRD PPS payment amount. Accordingly, a blended rate of the basic case-mix composite rate payment system and the ESRD PPS will no longer be provided and there will no longer be a transition budget neutrality adjustment factor applied to the payment. Therefore, it is no longer necessary to update the basic case-mix adjusted composite rate payment system.

Section 153(b) was amended by section 3401(h) of the Affordable Care Act, and stated that for 2012 and each subsequent year the Secretary shall reduce the ESRD bundled (ESRDB) market basket increase factor by a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Social Security Act (the Act). The ESRDB market basket increase factor minus the productivity adjustment will update the ESRD PPS base rate.

Section 1881(b)(14)(I) of the Act, as added by section 632(a) of the American Taxpayer Relief Act of 2012 (ATRA), requires that, for services furnished on or after January 1, 2014, the Secretary shall make reductions to the single payment for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs) by comparing per patient utilization data from 2007 with such data from 2012.

B. Policy: Calendar Year (CY) 2014 Rate Updates

For CY 2014, CMS will make the following updates to the CY 2013 ESRD PPS base rate:

1. The ESRDB market basket minus a productivity adjustment of 2.8 which results in $247.09 ($240.36 x 1.028 = $247.09).

2. The wage index budget neutrality adjustment factor of 1.000454 which results in $247.20 ($247.09 x 1.000454 = $247.20).

3. The home dialysis training add-on budget neutrality adjustment factor of 0.99912 which results in $247.18 ($247.20 x 0.99912 = $247.18)

4. After the application of the ESRDB market basket, the wage index budget neutrality adjustment factor, and the home dialysis training add-on budget neutrality adjustment factor, the ESRD PPS base rate will be reduced by the drug utilization reduction of $8.16. Therefore, the ESRD PPS base rate for CY 2014 is $239.02 ($247.18 - $8.16 = $239.02).

For CY 2014, CMS will make the following updates to the wage index:

1. The wage index adjustment will be updated to reflect the latest available wage data.

2. The wage index floor will be reduced from 0.50 to 0.45.

Transition Budget Neutrality Adjustment

Beginning CY 2014, there will no longer be a transition budget-neutrality adjustment.

Home Dialysis Training Add-On Payment

The home dialysis training add-on payment will increase from $33.44 to $50.16.

Outlier Policy Changes

For CY 2014, CMS will make the following updates to the adjusted average outlier service MAP amount per treatment:

1. For adult patients, the adjusted average outlier service MAP amount per treatment is $50.25.

2. For pediatric patients, adjusted average outlier service MAP amount per treatment is $40.49.

For CY 2014, CMS will make the following updates to the fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold:

1. The fixed dollar loss amount is $98.67 for adult patients.

2. The fixed dollar loss amount is $54.01 for pediatric patients.

For CY 2014, CMS will make the following changes to the list of outlier services:

1. The ESRD-related Part D drugs which are based on the most recent prices retrieved from the Medicare Prescription Drug Plan Finder will be updated to reflect the most recent mean unit cost. The list of ESRD-related Part D drugs will also be updated to reflect the most recent list of ESRD-related Part D drugs that are eligible for outlier payment. See attachment A.

2. The mean dispensing fee of the National Drug Codes (NDC) qualifying for outlier consideration is revised to $1.42 per NDC per month for claims with dates of service on or after January 1, 2014. See attachment A.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility											
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		A	B	HHH					FISS	MCS	VMS	CWF	
8472-02.1	Medicare contractors shall load the 2014 ESRD PPS PRICER.								X				
8472-02.2	Medicare contractors shall update the provider file for ESRD facilities as necessary to reflect: 1. Attested low volume facilities if applicable; 2. Revised CBSA codes if applicable; 3. Quality indicator for any applicable QIP adjustments.	X											
8472-02.3	Medicare contractors shall update the Part D outlier drug list and mean unit costs for claims with dates of service in 2014. See Attachment A.								X				
8472-02.4	Medicare contractors shall update the NDC dispensing fee for ESRD outlier services to $1.42 for claims with dates of service in 2014.								X				
8472-02.5	Medicare contractors shall eliminate the transitional budget neutrality adjustment for claims with dates of service on or after January 1, 2014. (TBNA = 1.00).								X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility							
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Other
		A	B	HHH					
8472-02.6	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X							

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Michelle Cruse, 410-786-7540 or michelle.cruse@cms.hhs.gov, Stephanie Frilling, 410-786-4507 or stephanie.frilling@cms.hhs.gov, Wendy Tucker, 410-786-3004 or wendy.tucker@cms.hhs.gov (Claims Processing)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:
No additional funding will be provided by CMS; contractor's activities are to be carried out within their operating budgets.

Section B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Attachment

Attachment A

Outlier Services

Oral and Other Equivalent Forms of Injectable Drugs[1]

NDC[2]	Drug Product	Mean Unit Cost
30698014301 30698014323 54868346100	Rocaltrol (calcitriol) 0.25 mcg capsules	$ .72
30698014401	Rocaltrol (calcitriol) 0.5 mcg capsules	$ 2.32
30698091115	Rocaltrol (calcitriol) 1 mcg/mL oral solution (15ml/bottle)	$ *12.61*
00054000725 00054000713 00093065701 43353063381 00440721599 54868458400 63304023901 63304023930 67544103581 *23155011801*[3] *23155011803*[3] *43353003481*[3] *66336085190*[3]	Calcitriol 0.25 mcg capsules	$ *0.79*
00093065801 54868458200 63304024001 *23155011901*[3]	Calcitriol 0.5 mcg capsules	$ *1.50*
00054312041 63304024159	Calcitriol 1 mcg/mL oral solution (15ml/bottle)	$ *9.14*
00074431730	Zemplar (paricalcitol) 1 mcg capsule	$ *10.70*
00074431430	Zemplar (paricalcitol) 2 mcg capsule	$ *21.41*
00074431530	Zemplar (paricalcitol) 4 mcg capsule	$ *42.99*
58468012001	Hectorol (doxercalciferol) 0.5 mcg capsule	$ *2.10*
58468012401	Hectorol (doxercalciferol) 1 mcg capsule	$ *4.19*
58468012101	Hectorol (doxercalciferol) 2.5 mcg capsule	$ *28.04*
54482014407	Carnitor (levocarnitine) 330 mg tablet	$ *0.85*
54482014508	Carnitor (levocarnitine) 1GM/10ML oral solution (118mL/bottle)	$ *0.26*
54482014701	Carnitor (levocarnitine) 1 g/5 mL injection	$ *6.72*
64980050312 50383017104	Levocarnitine 1GM/10ML oral solution (118mL/bottle)	$ 0.20
64980013009 50383017290	Levocarnitine 330 mg tablet	$ *0.63*

[1] Outlier services imputed payment amounts. Oral or other equivalent forms of Part B injectable drugs included in the ESRD PPS bundle (notwithstanding the delayed implementation of ESRD-related oral-only drugs effective 1/1/2014).

[2] The mean dispensing fee of the NDCs listed above is $*1.42*. This amount will be applied to each NDC included fee on the monthly claim. We will limit 1 dispensing per NDC per month. Providers should report the quantity in the smallest available unit. This is necessary because Medicare is using the mean per unit cost in calculating the outlier. For example, if the provider reports NDC 00054312041 Calcitriol 1 mcg/ml oral solution (15/ml/bottle) reported and uses the full 15 ml bottle, the quantity is as 15, not 1. This allows for the most accurate calculation for the outlier.

[3] Effective January 1, 2014, this ESRD-related item or service is eligible for outlier payment and is therefore being added to the list of outlier services.

Laboratory Tests

CPT/HCPCS	Short Description
82108	Assay of aluminum
82306	Vitamin d, 25 hydroxy
82379	Assay of carnitine
82570	Assay of urine creatinine
82575	Creatinine clearance test
82607	Vitamin B-12
82652	Vit d 1, 25-dihydroxy
82668	Assay of erythropoietin
82728	Assay of ferritin
82746	Blood folic acid serum
83540	Assay of iron
83550	Iron binding test
83970	Assay of parathormone
84134	Assay of prealbumin
84466	Assay of transferrin
84540	Assay of urine/urea-n
84545	Urea-N clearance test
85041	Automated rbc count
85044	Manual reticulocyte count
85045	Automated reticulocyte count
85046	Reticyte/hgb concentrate
85048	Automated leukocyte count
86704	Hep b core antibody, total
86705	Hep b core antibody, igm
86706	Hep b surface antibody
87040	Blood culture for bacteria
87070	Culture, bacteria, other
87071	Culture bacteria aerobic other
87073	Culture bacteria anaerobic
87075	Culture bacteria, except blood

87076	Culture anaerobe identify, each
87077	Culture aerobic identify
87081	Culture screen only
87340	Hepatitis b surface ag, eia

Equipment and Supplies

HCPCS	Short Description
A4657	Syringes with or with needle, each
A4913	Miscellaneous dialysis supplies, not otherwise specified

50 - ESRD Prospective Payment System (PPS) Base Rate

(Rev. 177, Issued: 12-13-13, Effective: 01-01-14, Implementation: 01-06-14)

Updates to the provisions under the ESRD PPS are discussed through rulemaking on a yearly basis. The updates are implemented through Recurring Update Notifications.

A. Per Treatment Unit of Payment

Under the ESRD PPS payment is made on a per treatment basis. The ESRD PPS base rate is the per treatment unit of payment that applies to both adult and pediatric patients. ESRD facilities furnishing dialysis treatments in-facility are paid for up to 3 treatments per week, unless there is medical justification for more than 3 weekly treatments. ESRD facilities treating patients at home regardless of modality may not receive payment for more than 3 hemodialysis (HD) equivalent treatments per week (for more information regarding home dialysis, see §30 of this chapter). ESRD facilities furnishing dialysis in-facility or in a patient's home are paid for a maximum of 13 treatments during a 30 day month and 14 treatments during a 31 day month unless there is medical justification for additional treatments.

Frequency of Dialysis Sessions by Dialysis Modality and Treatment Setting*

	In-Facility	**Home**
Hemodialysis	3 per week	Maximum of 3 per week regardless of frequency
Hemofiltration	3 per week	3 per week
Ultrafiltration	3 per week	Maximum of 3 per week, regardless of frequency
Peritoneal Dialysis (e.g., CAPD and CCPD)	HD-equivalent sessions	HD-equivalent sessions
Intermittent Peritoneal Dialysis (IPD)	3 per week	HD-equivalent sessions

* Regardless of dialysis modality or treatment setting, payments for additional treatments may be made when they are medically justified. The FI or A/B MAC reviews the medical justification and is responsible for making the decision on the appropriateness of the extra treatment.

1. Hemodialysis: Payment Based on Standard of Three Treatments per Week

Hemodialysis is typically furnished 3 times per week in sessions of 3 to 5 hours in duration. If the ESRD facility bills for any treatments in excess of this frequency, medical justification is required to be furnished to the FI or A/B MAC and must be based upon an individual patient's need. The FI or A/B MAC reviews the medical justification for each additional treatment and is responsible for making the decision on the appropriateness of the extra treatment(s) and payments for these additional treatments.

The case-mix adjusted ESRD PPS payment rate is paid for each hemodialysis treatment furnished in-facility up to 3 treatments per week.

Home hemodialysis, regardless of frequency, is paid up to a maximum of 3 treatments per week.

2. Hemofiltration

Hemofiltration is an alternative to peritoneal dialysis and hemodialysis. Hemofiltration may be routinely performed either in an ESRD facility or at home in 3 weekly sessions. See §10.A.3 of this chapter.

3, Ultrafiltration

When ultrafiltration is performed the same day as the dialysis treatment; there is no separate payment. When ultrafiltration is performed on a day other than the day of a dialysis treatment, the ESRD facility must document in the medical record why the ultrafiltration could not have been performed at the time of the dialysis treatment. For the ESRD facility to be paid for the ultrafiltration, the ESRD facility must report the appropriate diagnosis code and the FI or A/B MAC must verify the medical justification to determine appropriate payment. If the FI or A/B MAC considers the medical justification appropriate, the ESRD facility will receive the ESRD PPS base rate. For more information regarding ultrafiltration, see Pub. 100-04, Chapter 8, §50.7.

4. Peritoneal Dialysis: Payment Based on Hemodialysis Equivalent Sessions

For home patients undergoing peritoneal dialysis (PD), the number of days of PD regardless of the number of dialysate exchanges performed each day, is converted to HD-equivalent sessions. This is accomplished by dividing the number of days of PD by 7, and multiplying the result by 3.

> **Example:** Joe is a home CCPD patient who undergoes PD for 24 days. The number of HD-equivalent sessions is 24/7 x 3 or 10.28571. The number of HD-equivalent sessions or treatments for which case-mix adjusted prospective payments are applicable, is 10.28571.

Although CAPD and CCPD patients are home dialysis patients, occasionally it may be necessary to perform dialysis in-facility. The number of HD-equivalent sessions for PD performed in-facility is limited to 3 weekly, regardless of the number of days PD is furnished in-facility. However, each day of in-facility PD is treated as one HD-equivalent session, up to a maximum of 3 per week.

Example: Mary is a home CCPD patient. After 21 days on CCPD in a month, Mary's cycler required repair. Mary received CCPD in-center for 4 consecutive days before returning to home CCPD. The number of HD-equivalent sessions for which payments under the ESRD PPS may be made is 12, determined as follows:

Home CCPD HD-equivalent sessions	21/7 x 3 = 9
In-center PD HD-equivalent sessions (limited to 3)	3
Total HD-equivalent sessions	12

Mary's ESRD facility would receive the case-mix adjusted ESRD PPS base rate for 12 treatments in the month.

5. Intermittent Peritoneal Dialysis (IPD)

Maintenance Intermittent Peritoneal Dialysis (IPD) is usually accomplished in sessions of 10 to 12 hours in duration. Sometimes it is accomplished in fewer weekly sessions of longer duration. The payment applicable for maintenance IPD, as well as the ESRD facility's actual payment for maintenance IPD, depends on the treatment setting (in-facility or at home). Payment for in-facility IPD follows the same payment rules as hemodialysis, i.e., 3 sessions per week (see Pub. 100-04, chapter 8, §50.5 and §50.6.2). Payment for home IPD is based on a weekly equivalence of 3 sessions per week (see Pub. 100-04, chapter 8, §80.3, §80.3.1, and §80.4). If additional dialysis beyond the usual weekly maintenance dialysis is required because of special circumstances, the ESRD facility's claim for these extra services must be accompanied by a medical justification for payment to be made.

6. Uncompleted Dialysis Treatments under the ESRD PPS

If a dialysis treatment is started, (i.e., a patient is connected to the machine and a dialyzer and blood lines are used), but the treatment is not completed for some unforeseen, but valid reason, (e.g., a medical emergency when the patient must be rushed to an emergency room), the ESRD facility is paid based on the ESRD PPS base rate. This is a rare occurrence and must be medically justified. If the patient returns the same day and completes the treatment, the facility is only paid for one treatment.

If a patient was taken to a hospital and was furnished a dialysis treatment while in the emergency room, then the ESRD facility will not receive payment for the treatment and only the hospital will be paid. See Pub.100-04, chapter 4, section 200.2 for additional information.

B. Market Basket

For renal dialysis services furnished on or after January 1, 2011 and before January 1, 2012, CMS adjusts the composite rate portion of the basic case-mix adjusted composite payment system described in 42 CFR 413.220 by the ESRD bundled market basket percentage increase factor. For renal dialysis services furnished on or after January 1, 2012, CMS updates on an annual basis, the ESRD PPS base rate and the composite rate portion of the basic case-mix adjusted composite payment described in 42 CFR 413.220 by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor. Effective for renal dialysis services furnished on or after January 1,

2014, there is no longer a transition, therefore only the ESRD PPS base rate would be updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor.

60 - ESRD PPS Case-Mix Adjustments

(Rev. 177, Issued: 12-13-13, Effective: 01-01-14, Implementation: 01-06-14)

The ESRD PPS includes patient-level adjustments (also known as the case-mix adjustments), facility-level adjustments, and training adjustments, as well as an outlier payment. Under the ESRD PPS, the beneficiary co-insurance amount is 20 percent of the total ESRD PPS payment, after the deductible (see §60.E of this chapter).

A. Patient-level case-mix adjustments

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients to account for case-mix variability. The adult case-mix adjusters include variables (age, body surface area (BSA), and low body mass index (BMI)) that have been part of the basic case-mix adjusted composite rate payment system. In addition, the ESRD PPS includes adult case-mix adjustments for six co-morbidity categories (three acute and three chronic) as well as the onset of renal dialysis. Pediatric patient-level adjusters (see §60.A.6 of this chapter), consist of combinations of two age categories and two dialysis modalities.

1. Adult case-mix adjusters

This section presents a list of the ESRD PPS case-mix adjusters for adults and provides several examples using the adult case-mix adjusters implemented in calendar year (CY) 2011. Any revisions to the case-mix adjusters will be published in subsequent rulemaking.

Adult Patient-Level Characteristics	Adjustment Value
Age: 18-44	1.171
Age: 45-59	1.013
Age: 60-69	1.000
Age: 70-79	1.011
Age: 80+	1.016
Body Surface Area	1.020
Underweight (BMI <18.5)	1.025

Onset of Dialysis	1.510
Pericarditis	1.114
Bacterial pneumonia	1.135
Gastro-intestinal tract bleeding	1.183
Hereditary hemolytic or sickle cell anemia	1.072
Myelodysplastic syndrome	1.099
Monoclonal gammopathy	1.024

Calculating the ESRD PPS Case-Mix Adjusted Base Rate

The following example demonstrates the calculation of the ESRD PPS payment rate for an ESRD patient who receives dialysis at an ESRD facility that elected to be reimbursed 100 percent under the ESRD PPS and is located in an urban area with a wage index of 1.10. Before giving the particulars of the dialysis patient for the example, shown first is how to calculate the labor-adjusted base rate, which is the starting point for the computation of the case-mix adjusted base rate.

- Base rate: $229.63
- Labor-related share of base rate: $229.63 * 0 .41737 = $95.84
- Wage index adjusted labor-related share: $95.84 * 1.1000 = $105.42
- Non labor-related share of base rate: $229.63 * (1 - .41737) = $133.79
- Wage index adjusted base rate: $105.42 + $133.79 = $239.21

Provided next is the patient characteristics and continue with the example.

> A 45 year old male Medicare beneficiary is 187.96 cm. (1.8796 m.) in height and weighs 95 kg. He receives dialysis in an ESRD facility which has selected 100 percent ESRD PPS payments beginning January 1, 2011.

Using the formula for body mass index (BMI), note that the patient is not underweight, having a BMI of 26.89 kg/m2, which is greater than the threshold value of 18.5.

$$BMI_{Patient} = weight_{kg} / height\ (m^2)$$
$$= 95/1.8796^2$$
$$= 95/3.5329$$
$$= 26.89$$

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

- 0.007184 multiplied by height in meters $^{0.725}$ multiplied by weight in kg. $^{0.425}$
- or BSA = 0.007184 * $height_{cm}^{.725}$ * $weight_{kg}^{.425.}$

The BSA for the patient in this example is calculated as:

$$BSA_{Patient} = 0.007184 * 187.96^{.725} * 95^{.425}$$
$$= 0.007184 * 44.5346 * 6.9268$$
$$= 2.2161$$

Using the adult case-mix adjusters table shown above, the BSA multiplier of 1.020 is used. The patient's case-mix adjustment or payment multiplier (PM) based on his BSA of 2.2161 is computed as follows:

$$PM_{BSA} = 1.020^{(2.2161-1.87)/0.1}$$
$$= 1.020^{3.461}$$
$$= 1.0709$$

The example patient's PM would reflect the applicable case-mix adjustments from the adult case-mix adjusters table above for both age and BSA and may be expressed as:

$$PM_{Patient} = PM_{age} * PM_{BSA}$$
$$= 1.013 * 1.0709$$
$$= 1.0848$$

The example patient's ESRD payment rate for treatments furnished in his ESRD facility would be:

$$\$239.21 * 1.0848 = \$259.50$$

NOTE: This example is computed without regard to transition payments or other adjustments (e.g., outlier payments, training add-on, low-volume adjustment, etc.).

2. Patient Age

There are 5 age categories for adults (18-44; 45-59; 60-69; 70-79; and 80 and above) in the ESRD PPS and each category has a separate case-mix adjuster. Note that, when a beneficiary reaches a birthday that results in a different age category, the age change is effective from the first day of the birthday month, regardless of the date the birthday occurs in that month. The case-mix adjustment factor corresponding to the age of the dialysis patient is multiplied by the wage index adjusted base rate as a step in the calculation of the ESRD PPS per treatment payment amount. The examples shown below draw on values from the table of adult case-mix adjusters as well as the discussion of the ESRD PPS base rate found in the section above.

- Example 1: Mr. Taylor was born on July 14, 1972. For a dialysis treatment occurring on May 31, 2011, Mr. Taylor is 38 years of age and is classified in the

18-44 age group with an associated case-mix adjuster of 1.171. Applying the case-mix adjuster of 1.171 to the wage index adjusted base rate of $239.21 yields the age adjusted base rate amount of $280.11 ($239.21 x 1.171 = $280.11).

- Example 2: Mrs. Williams was born on July 4, 1941. On June 15, 2011, she is 69 years old and is classified in the 60-69 age category with a case-mix adjustment of 1.000 (the reference group). However, beginning with dialysis treatments occurring on and after July 1, 2011, she will move into the 70-79 age group with an associated case-mix multiplier of 1.011.

- Example 3: Mr. Davis was born on September 29, 1966. For dialysis treatments occurring in August 2011, he is 44 years old and would be classified in the 18-44 age group with an associated case-mix adjuster of 1.171. Beginning with dialysis treatments occurring on and after September 1, 2011, he is classified in the 45-59 age category with a case-mix adjuster of 1.013 because he is considered to have attained age 45 on September 1.

3. Body Size: Low Body Mass Index (BMI) and/or Body Surface Area (BSA)

Low BMI and BSA are two measures used to estimate body size. Both measures are strong predictors of variation in costs and are closely associated with the duration and intensity of dialysis necessary to achieve a therapeutic dialysis target for ESRD patients. Both are objective measures that are computed using height and weight data located on the patient claim. The BMI and BSA are calculated for all beneficiaries.

Although height and weight are taken at intervals throughout any given month of dialysis treatment, the measurements for the purpose of payment must be taken as follows:

- The dry weight of the patient is measured and recorded in kilograms immediately following the last dialysis session of the month.

- The patient height is measured and recorded in centimeters during the last dialysis session of the month.

The formula for the calculation of the BMI is weight in kilograms divided by height in meters squared, or kg/m^2. As an example, the designated BMI adjustment factor of 1.025 (see §60.A.1 of this chapter) is only applied for those beneficiaries with a BMI value that is less than $18.5 kg/m^2$ which is a clinical measure of being underweight and an indicator of malnutrition.

The formula for the calculation of the BSA is $BSA = w^{0.425} * h^{0.725} * 0.007184$ where w and h represent weight in kilograms and height in centimeters. The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.87 divided by 0.1. Using the example of adult adjusters above, the BSA adjustment factor of 1.020 is then exponentiated based on the calculated BSA factor as $1.020^{(BSA-1.87)/0.1}$. The reference BSA used to calculate the BSA is the national average among Medicare

dialysis patients and this value is recomputed every 5 years. The recomputed value will be addressed in administrative issuances, rather than in rules.

4. Onset of Dialysis

An ESRD facility may only receive the onset of dialysis adjustment for adult Medicare ESRD beneficiaries. The onset period is defined as the initial 120 days of outpatient maintenance dialysis, which is designated by the first date regular chronic dialysis began as reported on the CMS Form 2728. The onset of dialysis adjustment factor is a multiplier used in the calculation of the ESRD PPS per treatment payment amount for dialysis furnished in either an ESRD facility or home setting. For example, when a dialysis patient is not eligible for the Medicare ESRD benefit at the initiation of their maintenance dialysis, but is Medicare eligible at the end of 85 days, the onset of dialysis adjustment will be applied to the ESRD facility's ESRD PPS base rate for each treatment furnished in the following 35 days. However, if the patient is not Medicare eligible at any time during the initial 120 days of receiving maintenance dialysis, the onset of dialysis adjustment will not apply.

The onset of dialysis adjustment is a one-time adjustment. It is not applied when a patient changes ESRD facilities or after a failed transplant. If a patient changes or transfers to another ESRD facility during the initial 120 days, the new ESRD facility will only receive the onset of dialysis adjustment for the remaining time. In other words, the 120 day "clock" does not start over.

If the onset of dialysis adjustment is being applied to the ESRD PPS base rate, then those treatments would not be eligible for the co-morbidity adjustment nor any applicable training adjustment(s). However, those treatments are eligible for an outlier payment when appropriate.

5. Co-morbidity Categories

Six co-morbidity categories (three acute and three chronic) have demonstrated an effect on the cost of dialysis treatments. The three acute co-morbidity categories are pericarditis, bacterial pneumonia, and gastro-intestinal tract bleeding with hemorrhage. The three chronic co-morbidity categories are myelodysplastic syndrome, monoclonal gammopathy (excluding multiple myeloma), and *hereditary* hemolytic anemia (including sickle cell anemia). The related co-morbidity diagnosis codes can be found at the CMS ESRD Payment Web site located at http://www.cms.gov/ESRDPayment/40_Comorbidity_Conditions.asp#TopOfPage

The ESRD facility is responsible for determining the presence of an acute or chronic co-morbidity. If an ESRD facility is unaware of the existence of a co-morbidity, then the ESRD facility should not expect to receive a co-morbidity adjustment. The co-morbidity payment adjustment is only applied if the appropriate diagnosis code, specified under one of the categories above, is identified on the ESRD claim. Co-morbidities other than the three acute and the three chronic conditions identified above do not qualify for a co-

morbidity adjustment. Even if an ESRD patient has or has had one of the six conditions that would qualify for a co-morbidity payment adjustment, the condition must be currently active and have an effect on the cost of care for the ESRD facility to be eligible to receive the adjustment.

To qualify for the co-morbidity adjustment there must be:

- Clear documentation in the beneficiary's medical record, and
- Adherence to diagnosis coding requirements.

Diagnosis codes are updated annually as stated in Pub. 100-04, chapter 23, section 10.2 and are published in the Federal Register in April/May of each year as part of the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and are effective each October.

For transfer patients, it is expected that ESRD facilities will work together on the appropriate transfer of information to facilitate appropriate billing for dialysis services. The counting of treatments for an acute co-morbidity adjustment is based on the patient and not on the ESRD facility. Therefore, counting does not restart when a beneficiary moves to a new ESRD facility, but rather continues for the remaining 4 months.

a. Duration of Acute Co-morbidity Adjustment

Payment for an acute co-morbidity adjustment begins in the month in which the diagnosis is established, and lasts for the next 3 consecutive patient months. A patient month is any month in which a dialysis treatment is furnished, and an acute co-morbidity applies.

The acute diagnosis co-morbidity adjustment is applied to each dialysis treatment for 4 patient months. If a second co-morbidity is diagnosed during that period (either acute or chronic), then the adjustment is made using the higher adjustment factor. At no time is an adjustment applied for more than one co-morbidity.

When there is a recurrence of an acute co-morbidity within the 4 patient month period, there will not be an extension of the 4 patient month adjustment. A recurrence is defined as a new episode of a co-morbidity that was previously experienced by an individual beneficiary. However, if the recurrence happens after the completion of the 4 month period, then a new co-morbidity adjustment for 4 months would start.

- Example – A male patient has been receiving hemodialysis since January 2010. He had a 2 week hospitalization due to a fracture in mid July 2011. During his stay in the hospital, he was diagnosed with bacterial pneumonia on July 20, 2011. He resumed his outpatient maintenance dialysis on July 29, 2011. The 4 patient months in which the patient's ESRD facility would be

eligible to have the co-morbidity adjustment applied to each dialysis treatment for bacterial pneumonia are July through October 2011.

Acute Co-morbidity Eligibility Criteria

In order to receive the co-morbidity payment adjustment, validation of the existence of the co-morbidity should be established and the co-morbidity should have an effect on the cost of the dialysis treatment. The following guidelines are to be used:

- Pericarditis - At least two of the four following criteria must be met: atypical chest pain; pericardial friction rub; suggestive electrocardiogram changes (e.g., widespread ST segment elevation with reciprocal ST segment depressions and PR depressions) not previously reported; and new or worsening pericardial effusion.

- Bacterial Pneumonia - A definitive diagnosis includes consistent clinical manifestations, radiographic evidence of pulmonary parenchymal consolidation, and sputum culture demonstrating pathogenic bacteria with laboratory screening for appropriateness of sputum collection (i.e., it is not oral secretion culture). The Infectious Disease Society of America and the American Thoracic Society, evidence-based consensus guidelines recommend that, "In addition to a constellation of suggestive clinical features, a demonstrable infiltrate by a chest radiograph or other imaging technique, with or without supporting microbiological data is required for the diagnosis of pneumonia. Auscultation of the patient's chest or a diagnosis of pneumonia based on observation of the patient would not meet the diagnosis criteria.

- Gastro-intestinal tract bleeding with hemorrhage - At least one of the following objective criteria must be met: endoscopy, colonoscopy, adionuclide scanning, radionuclide imaging, and/or angiography. Absence of bleeding such as bleeding hemorrhoids without objective diagnosis of hemorrhaging would not meet the diagnosis criteria.

b. Duration of Chronic Co-morbidity Adjustment

The chronic diagnosis co-morbidity adjustment is applicable only when a chronic diagnosis co-morbidity has an effect on the cost of dialysis care and when that chronic diagnosis co-morbidity appears on the claim. The adjustment does not automatically continue each month. When an acute diagnosis co-morbidity with a higher adjustment value is applicable at the same time a chronic co-morbidity applies, then the higher adjustment will be applied for 4 patient months, and then revert to the lower chronic co-morbidity payment adjustment factor.

c. Chronic Co-morbidity Eligibility Criteria

In order to receive the co-morbidity payment adjustment, validation of the existence of the co-morbidity should be established and the co-morbidity should have an effect on the cost of the dialysis treatment. Testing patients for the presence of a chronic co-morbidity in absence of medical necessity for the purpose of receiving a payment adjustment is not appropriate. The following guidelines are to be used:

- Myelodysplastic Syndrome – Evidence of dysplasia in >10% of cells with at least one cell lineage on bone marrow aspiration and biopsy.

- Monoclonal Gammopathy (excluding multiple myeloma) - The following three criteria must be met: The presence of a serum monoclonal protein (M-protein, whether IgA, IgG, or IgM), at a concentration <3 g/dL, fewer than 10 percent clonal plasma cells in the bone marrow and the absence of other end-organ manifestations of the plasma cell proliferative process (lytic bone lesions, anemia, hypercalcemia, and renal insufficiency.

- *Hereditary* hemolytic anemia (including sickle cell anemia) - One or more of the following must be present: an abnormal peripheral smear; evidence of increased serum lactate dehydrogenase with a decrease in haptoglobin; an abnormal absolute reticulocyte count response or an abnormal reticulocyte production index. For sickle cell anemia specifically, an abnormal electrophoresis test as a definitive test, but the hemolytic criteria could be used.

6. Pediatric case-mix adjusters: Age and dialysis modality

Pediatric patients are beneficiaries with ESRD who are under the age of 18. The same base rate is used for adult and pediatric patients, which is also adjusted by the area wage index. However, the base rate for pediatric patients is not adjusted for case-mix as adjustments used for adult patients. The pediatric payment adjustments use only two age categories (<13, age 13-17) and dialysis modality (PD or HD).

The pediatric case-mix adjusters, applicable for calendar year (CY) 2011, are shown below. These values are presented for the purpose of demonstrating the computations shown in the examples in the following sections. Any revisions to the case-mix adjusters will be published in subsequent rulemaking.

Based on the two classification categories for age and modality, there are four pediatric classification groups.

Pediatric Patient-Level Characteristics	**Adjustment Value**
Age: <13, Modality: PD	1.033
Age:<13, Modality: Hemo	1.219
Age:13-17, Modality: PD	1.067
Age:13-17, Modality: Hemo	1.277

ESRD facilities do not receive the low-volume adjustment, described in §60.B.1 for pediatric beneficiaries. However, they are eligible for training add-on and outlier payments (described in §60.C and §60.D, of this chapter respectively).

The following example demonstrates the calculation of the payment rate for a pediatric patient who receives dialysis at an ESRD facility that elected to be reimbursed 100 percent under the ESRD PPS and is located in an urban area with a wage index of 1.10. The example also shows the application of the training add-on for eligible training treatments. Before giving the particulars of the pediatric dialysis patient, shown first is the calculation of the labor-adjusted base rate of $239.21, which is the starting point for the computation of the case-mix adjusted base rate.

Base rate: $229.63
Labor-related share of base rate: $229.63* .41737 = $95.84
Wage index adjusted labor-related share: $95.84 * 1.1000 = $105.42
Non labor-related share of base rate: ($229.63 * (1 - .41737) = $133.79
Wage index adjusted base rate: $105.42+ $133.79 = $239.21

Provided next is the characteristics of the pediatric patient and continue with the example.

- Andrew, a 12 year old male, has been on CCPD since June 2010. His mother, who assists him with his dialysis at home, is no longer able to assist with dialysis beginning May 10, 2011. His aunt, who lives nearby, has agreed to be the caregiver and assist him with his dialysis. The aunt required 17 training sessions at an ESRD facility in order to become knowledgeable and skilled sufficiently to perform this role. These training sessions began May 16 and ended June 10. The above pediatric classification table reveals that Andrew's pediatric dialysis classification group is cell 1, with an associated patient multiplier of 1.033. During the months of May and June 2011, the ESRD payment rate per HD-equivalent treatment would be:

  $239.21 * 1.033 = $247.10

- However, the ESRD facility is entitled to receive payment for a maximum of 15 training treatments furnished in connection with a new caregiver. Because the

amount of the training add-on is adjusted by the ESRD facility's wage index (1.10), the amount of the training add-on is calculated as follows:

Training rate: $33.44
Wage index: 1.10
Training payment: $33.44 * 1.10 = $36.78

- For the maximum number of 15 training treatments for which the training adjustment may be provided in connection with a PD patient, the payment rate, including the training add-on, would be:

($239.21 * 1.033 + $36.78) = $283.88

NOTE: This example is computed without regard to transition payments or other adjustments (e.g., outlier payments.)

B. Facility-level adjustments

There are two facility-level adjustments in the ESRD PPS. The first adjustment accounts for ESRD facilities furnishing a low-volume of dialysis treatments. The second adjustment reflects urban and rural differences in area wage levels using an area wage index developed from Core Based Statistical Areas (CBSAs).

1. Low-Volume Adjustment

ESRD facilities that qualify as being low-volume can receive the low-volume payment adjustment applied to each dialysis treatment they furnish beginning on or after January 1, 2011. For example, for calendar year (CY) 2011 the payment adjustment was 18.9 percent.

a. Low-Volume Criteria

To be eligible for the low-volume adjustment, an ESRD facility must meet specific criteria:

- The ESRD facility must have furnished less than 4,000 dialysis treatments in each of the 3 cost reporting years preceding its payment year. This 3 year eligibility period is based on the ESRD facility's as-filed or final settled 12-consecutive month cost reports.

    - The term "payment year" is the period of time that is used for determining payment to ESRD facilities, which is a calendar year. The ESRD PPS is based on a calendar year which begins January 1 of each year.

- The eligibility years are defined as the 3 years preceding the payment year and are based on cost reporting periods. Specifically, the cost reporting periods that end in the 3 years immediately preceding the payment year. The cost reporting periods must report costs for 12 consecutive months. If the FI or A/B MAC receives two short cost reporting periods they should not add them together to create a 12 month cost report. The FI or A/B MAC should not consider cost reports that exceed 12 months for the low-volume payment.

- For purposes of determining eligibility for the low-volume adjustment, the number of "treatments" is the total number of treatments furnished to Medicare and non-Medicare patients. For peritoneal dialysis (PD) patients, 1 week of PD is considered equivalent to 3 hemodialysis (HD) treatments. For example, a patient on PD for 21 days would have (21/7) x 3 or 9 HD-equivalent treatments. See §50.A.4 of this chapter for more information on hemodialysis equivalent treatments.

- The ESRD facility must not have opened, closed, or received a new provider number due to a change in ownership, (see Pub. 100-07, chapter 3, §3210), in the 3 years preceding the payment year. As stated above, this 3 year period is based on the ESRD facility's as-filed or final settled 12-consecutive month cost reports that end in the 3 years immediately preceding the ESRD PPS payment year. An ESRD facility is determined to be "opened" when the ESRD facility is a new establishment newly surveyed by the State and Medicare, is certified for Medicare participation, receives a provider number, and begins furnishing Medicare certified outpatient maintenance dialysis treatments. If there is a change in ownership that does not result in a change in provider number but does cause a short period cost report, the ESRD facility is not eligible for the low-volume adjustment.

- The ESRD facility must not be located within 25 road miles of another ESRD facility under common ownership. The geographic proximity criterion is only applicable to ESRD facilities that are Medicare certified on or after January 1, 2011, to furnish outpatient maintenance dialysis treatments. For the purpose of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments furnished by the other ESRD facilities that are both under common ownership, and 25 road miles or less from the ESRD facility in question.

  For example, ESRD facility A received its Medicare certification on February 1, 2011, allowing them to bill and receive payment for outpatient maintenance dialysis that they furnish to Medicare beneficiaries. ESRD facility A will need to meet the low-volume criteria for 3 years. When the ESRD facility A submits its attestation to the FI or A/B MAC, the FI or A/B MAC will need to consider ESRD facility A's ownership and the ownership of all of the ESRD

facilities located within a 25 road mile radius or less when determining total treatments. FIs or A/B MACs shall use the Provider Enrollment, Chain, and Ownership System (PECOS) (or the most recent available Medicare enrollment system) to locate the ESRD facility's ownership information. FIs or A/B MACs shall refer to 42 CFR §421.404(a) when determining common ownership.

NOTE: The low-volume adjustment does not apply to dialysis treatments provided to pediatric patients.

b. ESRD Facility Attestation Instruction for Low-Volume Adjustment

In order to receive the low-volume adjustment under the ESRD PPS, each individual ESRD facility must submit an attestation statement each year to its FI or A/B MAC. The attestation must state that the ESRD facility qualifies as a low-volume facility in accordance with 42 CFR §413.232 as described above. Specifically, the attestation states that the ESRD facility was low-volume for the first 2 eligibility years and that they will be for the third eligibility year, that is, the cost reporting period ending in the year that immediately precedes the payment year. In most cases, the FIs or A/B MACs will not have received the third eligibility year's cost report and will rely on the attestation in order to allow the application of the adjustment. November 1st of each year is the mandatory deadline for the submission of attestations for ESRD facilities that believe they are eligible to receive the low-volume payment adjustment. FIs or A/B MACs have a maximum of 60 days to verify attestations for implementation of the low-volume adjustment beginning January 1 of the following payment year.

FIs or A/B MACs shall notify the ESRD facilities no later than September 1 of each year that they need to submit the low-volume attestation no later than November 1st of each year in order to receive the adjustment the following payment year. FIs or A/B MACs may not accept attestations submitted after the mandatory deadline. If an ESRD facility is receiving the low-volume payment adjustment and will qualify for the adjustment in the subsequent payment year they must submit another attestation. If the ESRD facility does not submit an attestation, the FI or A/B MAC should no longer apply the low-volume payment adjustment beginning January 1st of the next payment year and the ESRD facility cannot receive the low-volume payment adjustment until the following payment year.

An ESRD facility should notify its FI or A/B MAC if it determines that it did not maintain low-volume status for its cost reporting period ending immediately preceding the payment year or if it finds that it will not remain low-volume for any subsequent cost reporting year. The FI or A/B MAC is responsible to reconcile incorrect payments made to ESRD facilities retroactively, if needed, to ensure overpayments have not been made. If an FI or A/B MAC determines that an ESRD facility has received the low-volume adjustment in error, the FI or A/B MAC is

required to adjust all of the ESRD facility's affected claims to remove the adjustment within 6 months of finding the error.

The FI or A/B MAC shall:

- Recoup low-volume adjustment payments made to an ESRD facility that failed to meet the low-volume adjustment criteria defined in 42 CFR §413.232(b)(1). Recoupment shall occur when the FI or A/B MAC receives the as-filed cost report for the third eligibility year and finds that the ESRD facility did not meet the eligibility criteria. Recoupment shall also occur if any cost reports used for eligibility are subsequently found to have not met the low-volume criteria, for example, reopening or appeals. FIs or A/B MACs shall reprocess claims paid during the payment year in which the ESRD facility incorrectly received the low-volume payment adjustment.

- Recoup low-volume adjustment payments made to an ESRD facility that failed to meet the low-volume adjustment criteria defined in 42 CFR §413.232(b)(2). FIs or A/B MACs shall use PECOS to locate the ESRD facility's ownership information at the time of verification to determine if the ESRD facility is in the process of a change of ownership (CHOW). FIs or A/B MACs shall use the current owner provided in PECOS. If the ESRD facility was in the process of a CHOW, recoupment shall occur when the CHOW is effective and the new owner is assigned a new provider number. FIs or A/B MACs shall reprocess claims paid during the payment year in which the ESRD facility incorrectly received the low-volume payment adjustment.

If an ESRD facility does not remain low-volume for each of the 3 years (described above in §60.B.1.a) immediately preceding the payment year, the ESRD facility cannot be eligible for the adjustment until it can demonstrate again that for 3 years it has met the low-volume criteria.

Example - Provider 21-25XX is an independent ESRD facility that has a June 30th cost report year end.

> The ESRD facility concluded in October 2010 that it met the criteria of a low-volume facility. For its cost reporting periods, 7/1/2007 – 6/30/2008, 7/1/2008 – 6/30/2009, and 7/1/2009 – 6/30/2010, it did not open, close, or have a change of ownership and furnished less than 4,000 dialysis treatments in each of those cost reporting periods. In October 2010, the ESRD facility sent its FI or A/B MAC an attestation stating that it believes that it meets the low-volume criteria and would like to begin to receive the low-volume adjustment. The FI or A/B MAC receives the attestation on November 1st and then has 60 days (that is, until December 30th) to verify if the ESRD facility qualifies as a low-volume facility. On December 28th the FI or A/B MAC was able to verify that provider 21-25XX met the criteria and allowed for the adjustment to be applied to each dialysis treatment the ESRD facility furnished beginning January 1, 2011.

Determining Low-Volume Eligibility in Hospitals with Multiple Subunits and Satellites

A hospital may be affiliated with multiple hospital-based ESRD facilities. In addition, an individual hospital-based ESRD facility may have several locations that are subsumed under it, billing under the same ESRD facility provider number.

Verification of an ESRD facility's low-volume status is based on the FI's or A/B MAC's review of the total treatment count on an ESRD facility's (or a hospital's) cost report. In the situation where a hospital has multiple locations of a hospital-based ESRD facility under its governing body, the aggregate cost and treatment data of all of the locations (not just the treatment count of one of the subunits or satellite entities) are reported on the hospital's cost report (I series) and it is this information that the FIs or A/B MACs are required to review to make their determination. The FIs or A/B MACs are not required to consider specific worksheets created by providers.

2. Wage index

The wage index adjustment is applied when calculating the ESRD PPS payment in order to account for geographic differences in area wage levels. Each ESRD facility's payment is adjusted using the wage index for the CBSA in which the ESRD facility is located. Rural ESRD facilities use the statewide average.

The wage index values and the budget neutrality adjustment factor are updated during rulemaking, are issued via annual Recurring Update Notifications, and are posted on the ESRD Payment Webpage.

C. Training and Retraining Add-On *Payment*

The training add-on *payment* has been applied to dialysis treatments under the basic case-mix adjusted composite rate and is applied as well to dialysis treatments under the ESRD PPS. For purposes of the ESRD PPS, the training add-on *payment* is computed by using the national average hourly wage for nurses from the Bureau of Labor Statistics. For example, the training add-on *payment* under the ESRD PPS for CY 2011 was $33.44 per treatment. *The payment accounts for* nursing time for each training treatment that is furnished and is adjusted by the geographic area wage index. The training add-on *payment* applies to both peritoneal dialysis and hemodialysis training treatments. This amount will be added to the ESRD PPS payment, each time a training treatment is provided by the Medicare certified training ESRD facility. An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training. ESRD facilities should not expect additional reimbursement beyond the maximum sessions. CMS expects that ESRD patients who opt for home dialysis are good candidates for home dialysis training, and will successfully complete their method of training before reaching the maximum number of allotted training treatments. For more information regarding dialysis training, see §30.2 of this chapter. For more information regarding retraining, see §30.2.E of this chapter.

D. Outlier Policy

The ESRD PPS provides additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable. Outlier payments are based on a comparison of the predicted Medicare allowable payment (MAP) per treatment to actual incurred expenditure per treatment for services which were or would have been considered separately billable prior to the implementation of the ESRD PPS. ESRD outlier services include:

- ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
- ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
- Medical or surgical supplies used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and
- Renal dialysis services that were or would have been, prior to January 1, 2011, separately billable under Part D. Implementation of ESRD-related oral-only drugs has been delayed until January 1, 2016.

The list of ESRD-related outlier services may be found at http://www.cms.gov/ESRDPayment/30_Outlier_Services.asp#TopOfPage .

NOTE: All ESRD-related Part B drugs and biologicals reported with a HCPCS code that is on the ASP List are included for outlier payments (with the exception of composite rate drugs). The laboratory tests that comprise the AMCC panel do not qualify for an outlier, see §20.2.A for information regarding the 50/50 rule.

ESRD facilities may receive outlier payments for the treatment of both adult and pediatric dialysis patients. An ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed dollar loss amount. In accordance with 42 CFR §413.237(c), facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold.

For example, the average outlier services MAP amount per treatment for pediatric and adult dialysis patients for CY 2011 *were* $53.06 and $82.78, respectively. After multiplication by applicable patient and facility specific adjusters to yield a predicted

outlier services MAP amount, a fixed amount is added (the "fixed dollar loss" amount) to determine the outlier threshold. The fixed dollar loss amounts for CY 2011 were $195.02 for pediatric patients and $155.44 for adult patients. The CY 2011 values of the average outlier services MAP amount and the fixed dollar loss amount are used below for the purpose of following the outlier payment computation. These values may be revised as a result of subsequent rulemaking.

In computing the MAP amount, the adjusters used are:

Adult Characteristics	**Adjustment Value**
Age: 18-44	0.996
Age: 45-59	0.992
Age: 60-69	1.000
Age: 70-79	0.963
Age: 80+	0.915
Body Surface Area	1.014
Underweight (BMI <18.5)	1.078
Onset of Dialysis	1.450
Pericarditis	1.354
Bacterial pneumonia	1.422
Gastro-intestinal tract bleeding	1.571
Hereditary hemolytic or sickle cell anemia	1.225
Myelodysplastic syndrome	1.309
Monoclonal gammopathy	1.074
Low-volume facility adjustment	0.975

Pediatric Characteristics	**Adjustment Value**

Age: <13, Modality: PD	0.319
Age: <13, Modality: Hemo	1.185
Age: 13-17, Modality: PD	0.476
Age: 13-17, Modality: Hemo	1.459

Both the adult and pediatric CY 2011 separately billable case-mix adjusters are presented for the purpose of following the outlier payment computations shown below and may be revised as a result of subsequent rulemaking.

1. Outlier Payment Calculation

The outlier payment computations use the case-mix adjusters for separately billable services. These adjusters are applied to the relevant outlier services MAP amount for either adult or pediatric patients discussed above to obtain the predicted MAP amount for outlier services, reflecting all patient-specific and any facility-specific adjustments.

The following example shows how outlier payments are calculated under the ESRD PPS. For further information on the calculation of a patient's BSA, see §60.A.1. The pricing amounts for laboratory services qualifying as outlier services are based on the clinical laboratory fee schedule. For injectable drugs and biologicals, pricing is based on the latest available quarterly average sales price plus 6 percent (ASP + 6) methodology. For formerly Part D drugs with an injectable version, pricing is based on national average drug prices based on the Medicare Prescription Drug Plan Finder. For medical/surgical supplies, pricing is based on prices established by the local FI or A/B MAC. For further information regarding FI or A/B MAC pricing of medical/surgical supplies, see Pub. 100-04, chapter 8, §20.1.

2. Example of Outlier Payment

Ms. Brown is a 66 year old ESRD patient and is 167.64 cm. tall, weighs 105 kg., and has a recent diagnosis of GI bleeding. She does not qualify for a low BMI adjustment.

Ms. Brown's BSA is 2.1284.

The list of adjusters in §D reveals that the separately billable multiplier for BSA is 1.014.

Ms. Brown's case-mix adjustment based on her BSA of 2.1284 is 1.037.

<u>Step 1: Determine the predicted, ESRD outlier services MAP amount using the product of all applicable case-mix adjusters</u>.

The patient-level outlier services case-mix adjusters are identified in the list in §D:

66 years old: 1.000, BSA: 1.037, and GI bleeding: 1.571:
= 1.000 * 1.037 * 1.571
= 1.6291

The adjusted, average, ESRD outlier services MAP amount
= $82.78

The adjusted, average ESRD outlier services MAP amount * product of the outlier services case-mix adjusters:
= $82.78 * 1.6291 = $134.86

Step 2: Determine the imputed average, per treatment, ESRD outlier services MAP amount based on utilization of all separately billable services on the monthly ESRD facility bill

Assume the imputed monthly ESRD outlier services amount = $4,000 and that the corresponding total number of treatments in the month = 10

The imputed, average, per treatment, outlier services MAP amount
= $4,000/10 = $400

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

The fixed dollar loss amount = $155.44. The predicted ESRD outlier services MAP amount = $134.86
= $134.86 + $155.44 = $290.30

Step 4: Calculate outlier payment per treatment

Outlier payment = imputed average, per treatment, outlier services MAP amount minus (predicted ESRD outlier services MAP amount plus the fixed dollar loss amount) * loss sharing percentage:
= ($400.00-$290.30) * .80 = $109.70 * .80 = $87.76

The outlier payments for Ms. Browns' 10 treatments, without regard to any transition budget neutrality adjustment, would be:
10 * $87.76 = $877.60

E. Co-Insurance

Eighty percent of the total ESRD PPS payment amount for renal dialysis services furnished by ESRD facilities to ESRD beneficiaries is paid by Medicare. ESRD

beneficiaries are responsible for the remaining 20 percent after the deductible. Therefore, the beneficiary co-insurance amount under the ESRD PPS is 20 percent of the total ESRD PPS payment, which includes the ESRD PPS base rate, all applicable adjustments, any applicable training add-on amounts, and any applicable outlier payments. For example, under the ESRD PPS the patient's co-insurance liability is based on the payment made to the ESRD facility and NOT on specific renal dialysis items and services. Therefore, any ESRD-related drug or biological or laboratory service furnished to a beneficiary would NOT require a co-insurance amount because the ESRD-related drug or biological or laboratory service is included in the payment made to the ESRD facility.

During the transition period before January 1, 2014, ESRD facilities that have not elected to be paid 100 percent under the ESRD PPS in 2011 will receive a blended payment amount. The blended monthly payment amount is subject to the 20 percent beneficiary co-insurance. See §70 of this chapter for further details regarding the transition period.

In the event a claim is reprocessed and the amount that was paid to the ESRD facility changes, the ESRD facility is responsible for reconciling with the ESRD patient any overpayment or underpayment of co-insurance or deductible amounts paid to the ESRD facility.