

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 171	Date: June 7, 2013
	Change Request 8261

SUBJECT: Implementation of the End Stage Renal Disease (ESRD) Prospective Payment System (PPS)

I. SUMMARY OF CHANGES: The purpose of this change request is to update and reorganize the ESRD chapter in the Medicare Benefit Policy Manual to reflect the ESRD PPS.

EFFECTIVE DATE: January 1, 2011

IMPLEMENTATION DATE: September 9, 2013

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	11/10/Definitions Relating to ESRD
R	11/20/Renal Dialysis Items and Services
R	11/20.1/Composite Rate Items and Services
N	11/20.2/Laboratory Services
N	11/20.3/Drugs and Biologicals
N	11/20.4/Equipment and Supplies
R	11/30/Home Dialysis
R	11/30.1/Home Dialysis Items and Services
R	11/30.2/Home Dialysis Training
D	11/30.2.1/Laboratory Tests for Hemodialysis, Intermittent Peritoneal Dialysis (IPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Hemofiltration
D	11/30.2.2/Automated Multi-Channel Chemistry (AMCC) Tests
D	11/30.3/Requests for Composite Rate Exception
D	11/30.4/Drugs and Biologicals
D	11/30.4.1/Drugs Covered Under the Composite Rate

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
D	11/30.4.2/Separately Billable Drugs
D	11/30.4.2.1/Intravenous Iron Therapy
D	11/30.4.2.2/Levocarnitine for Treatment of Carnitine Deficiency in ESRD Patients
D	11/30.5/ESRD Composite Payment Rates
R	11/40/Other Services
D	11/40.1/Method I and Method II Reimbursement for Patients Dialyzing at Home
D	11/40.2/Items and Services Included Under the Composite Rate for Method I Home Dialysis Patients
R	11/50/ESRD Prospective Payment System (PPS) Base Rate
D	11/50.1/Installation and Delivery of Home Dialysis Equipment
D	11/50.2/Current Use of Equipment
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D	11/50.6.1/Home Health and Hospice Benefits Available for ESRD Beneficiaries
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D	11/50.7/Water Purification and Softening Systems and Ultrafiltration Monitor
D	11/50.8/Coverage of Infacility Dialysis Sessions Furnished to Home Patients Who Are Traveling
D	11/50.9/Antibiotics Furnished to Method II Patients
R	11/60/ESRD PPS Case-Mix Adjustments
D	11/60.1/Hemodialysis Training
D	11/60.2/Intermittent Peritoneal Dialysis Training (IPD)
D	11/60.3/Continuous Ambulatory Peritoneal Dialysis (CAPD) Training
D	11/60.4/Continuous Cycling Peritoneal Dialysis (CCPD) Training
R	11/70/ESRD PPS Transition Period
D	11/70.1/Certification of Facilities Furnishing CAPD Services
D	11/70.2/Institutional Dialysis Services Furnished to CAPD Patients
D	11/70.3/Support Services and Supplies Furnished to Home CAPD Patients

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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D	11/80.1/Physicians' Services to an ESRD Inpatient
D	11/80.2/Physicians' Services - Outpatient Maintenance Dialysis
D	11/80.3/Physicians' Services During Self-Dialysis Training
D	11/80.4/Physicians' Services for Kidney Transplants
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N	11/Appendix B/Composite Rate Tests for CAPD
N	11/Appendix C/Brief History of ESRD Composite Payment Rates for Outpatient Maintenance Dialysis

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; Contractors activities are to be carried out with 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:

**Business Requirements
Manual Instruction**

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

Attachment - Business Requirements

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SUBJECT: Implementation of the End Stage Renal Disease (ESRD) Prospective Payment System (PPS)

EFFECTIVE DATE: January 1, 2011

IMPLEMENTATION DATE: September 9, 2013

I. GENERAL INFORMATION

A. Background: Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 amended section 1881(b) of the Social Security Act requiring the implementation of the ESRD PPS effective January 1, 2011. The ESRD PPS replaced the basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD related items and services. The ESRD PPS provides a single payment to ESRD facilities, that is, hospital-based and independent facilities, that covers all the resources used in providing an outpatient dialysis treatment, including supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, training, and support services.

B. Policy: Effective January 1, 2011, CMS implemented the ESRD PPS.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement.

Number	Requirement	Responsibility										
		A/B MAC		D M E	F I	C A R R I E R	R H I	Shared- System Maintainers				Other
		P a r t A	P a r t B					F I S S	M C S	V M S	C W F	
8261.1	Contractors shall make providers aware of the new and revised information provided in the manual sections attached to this instruction.	X	X	X	X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC		D M E	F I	C A R R I E R	R H H I	Other
		P a r t A	P a r t B	M A C				
8261.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.hhs.gov/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	X	X	X	X		

IV. SUPPORTING INFORMATION

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

Use "Should" to denote 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

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; Contractors activities are to be carried out with 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 do 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.

Medicare Benefit Policy Manual

Chapter 11 - End Stage Renal Disease (ESRD)

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10 - Definitions Relating to ESRD

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

End Stage Renal Disease (ESRD) occurs from the destruction of normal kidney tissues over a long period of time. Often there are no symptoms until the kidney has lost more than half its function. The loss of kidney function in ESRD is usually irreversible and permanent.

Dialysis services furnished to hospital in-patients are covered under Medicare Part A and paid in accordance with applicable payment rules.

ESRD facilities must be certified by Medicare and are required to comply with the Conditions for Coverage set forth in 42 CFR Part 494. Survey and certification information for ESRD facilities can be found at the following CMS website:

<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>.

Medicare Part B covers the services listed below unless otherwise noted.

A. Dialysis

Dialysis is *the* process *of removing* waste products from the body by diffusion from one fluid compartment to another across a semi-permeable membrane. There are two types of renal dialysis procedures in common clinical usage: hemodialysis and peritoneal dialysis. Both hemodialysis and peritoneal dialysis are acceptable modes of treatment for ESRD under Medicare.

1. Hemodialysis - Blood passes through an artificial kidney machine and the waste products diffuse across a manmade membrane into a bath solution known as dialysate after which the cleansed blood is returned to the patient's body. Hemodialysis is accomplished usually in 3 to 5 hour sessions, 3 times a week. *See §50.A.1 of this chapter for payment information.*

2. Peritoneal - Waste products pass from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity where the bath solution (dialysate) is introduced and removed periodically. *See §50.A.4 of this chapter for payment information.*

Peritoneal dialysis is particularly suited for:

- Patients without *caregivers* to assist in self-dialysis;
- Children;
- Patients with no peripheral sites available for fistula or cannula placement;

- Patients who have difficulty learning the more complex hemodialysis technique; and
- Elderly patients with cardiovascular disease who are unable to tolerate intravascular fluid shifts associated with hemodialysis.

The three types of peritoneal dialysis are listed below:

- a. Continuous Ambulatory Peritoneal Dialysis (CAPD) - In CAPD, the patient's peritoneal membrane is used as a dialyzer. The patient connects a 2-liter plastic bag of dialysate to a surgically implanted in dwelling catheter that allows the dialysate to pour into the beneficiary's peritoneal cavity. *Every* 4 to 6 hours the patient drains the fluid out into the same bag and replaces the *empty* bag with a new bag of fresh dialysate. This is done *several* times a day.
- b. Continuous Cycling Peritoneal Dialysis (CCPD) - CCPD is a treatment modality that combines the advantages of the long dwell, continuous steady state dialysis of CAPD, with the advantages of automation inherent in intermittent peritoneal dialysis. The major difference between CCPD and CAPD is that the solution exchanges, which are performed manually during the day by the patient on CAPD, are moved to nighttime with CCPD and are performed automatically with a peritoneal dialysis cyler. Generally, there are three nocturnal exchanges occurring at intervals of 2 1/2 to 3 hours. Upon awakening, the patient disconnects from the cyler and leaves the last 2-liter fill inside the peritoneum to continue the daytime long dwell dialysis.
- c. Intermittent Peritoneal Dialysis (IPD) - Waste products pass from the patient's body through the peritoneal membrane into the peritoneal cavity where the dialysate is introduced and removed periodically by machine. Peritoneal dialysis generally is required for approximately 30 hours a week, either as three 10-hour sessions or less frequent, but longer, sessions. *See §50.A.5 of this chapter for payment information.*

3. Hemofiltration - Hemofiltration is an alternative to peritoneal dialysis and hemodialysis. Hemofiltration (which is also known as diafiltration) removes fluid, electrolytes, and other low molecular weight toxic substances from the blood by filtration through hollow artificial membranes and may be routinely performed in three weekly sessions. In contrast to both hemodialysis and peritoneal dialysis treatments, which eliminate dissolved substances via diffusion across semi permeable membranes, hemofiltration mimics the filtration process of the normal kidney. The technique requires an arteriovenous access. Hemofiltration may be performed either in *an ESRD* facility or at home. For payment information see [§50 A.2](#) of this chapter.

4. Ultrafiltration – *Ultrafiltration is the* process of removing excess fluid from the blood through a dialysis membrane by exerting pressure. *This* is not a substitute for dialysis. *Ultrafiltration is used in cases where excess fluid cannot be removed easily*

during the regular course of hemodialysis. It is commonly done during the first hour or two of hemodialysis on patients who have refractory edema. Occasionally, medical complications may occur which require that ultrafiltration be performed separately from the dialysis treatment. See §50.A.3 of this chapter for payment information.

B. ESRD Facility

An ESRD facility *is an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. ESRD facilities are classified in Section 1881 of the Act and codified in 42 CFR 413.174 as being either hospital-based or independent facilities. There is no distinction between the two facility types for the purposes of payment under the ESRD Prospective Payment System (PPS).*

1. Hospital-Based ESRD Facilities

As defined in 42 CFR 413.65(a) hospital-based or independent ESRD facilities are not considered part of the hospital and do not qualify as provider-based departments of a hospital. Hospital-based ESRD facilities may be located on a hospital campus and may share certain overhead costs and administrative functions with the hospital. However, hospital-based ESRD facilities have separate provider numbers under which they bill Medicare and are subject to unique Conditions for Coverage that differ from hospital Conditions of Participation. Information regarding the survey and certification of ESRD facilities may be found at the following link: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>.

CMS determines that an ESRD facility is hospital-based if:

- The *ESRD* facility and hospital are subject to the bylaws and operating decisions of a common governing board. *This governing board, which has final administrative responsibility*, approves all personnel actions, appoints medical staff, and carries out similar management functions;
- The ESRD facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through that officer to the governing board;
- The *ESRD facility's* personnel policies and practices conform to those of the hospital;
- The administrative functions of the *ESRD* facility (*for example*, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and
- The *ESRD facility* and hospital are financially integrated, as evidenced by the cost report, which must reflect allocation of hospital overhead to the facility through the required step-down methodology.

CMS does not consider the existence of an agreement between *an ESRD* facility and a hospital for *the* referral of patients, a shared service arrangement between a facility and a hospital, or the physical location of a dialysis unit on the premises of a hospital, *to* mean that an ESRD facility is hospital-based.

2. Independent ESRD Facility – *Any facility that does not meet the criteria of a hospital-based ESRD facility.*

There are several terms used to describe dialysis facilities which include the following:

a. Renal Dialysis Center - A hospital-based unit, which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center. Under the ESRD PPS CMS refers to renal dialysis centers as ESRD facilities.

b. Renal Dialysis Facility - An independent unit that is approved to furnish outpatient maintenance dialysis services directly to ESRD patients. Under the ESRD PPS CMS refers to renal dialysis facilities as ESRD facilities.

c. Self-Dialysis Unit - A dialysis unit that furnishes self-dialysis services and is part of a Medicare certified ESRD facility.

d. Home Dialysis Training and Support ESRD Facility – A Medicare certified ESRD facility that furnishes home dialysis training and support services. See 42 CFR 494.100 for more information regarding Medicare certification requirements.

e. Special Purpose Renal Dialysis Facility – An ESRD facility that is approved to furnish dialysis at special locations, on a short-term basis, to a group of dialysis patients otherwise unable to obtain treatment in their geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

C. Renal Dialysis Services

Renal dialysis services are all items and services used to furnish outpatient maintenance dialysis in the ESRD facility or in a patient's home.

Renal dialysis services include but are not limited to:

- All items and services included under the composite rate as of December 31, 2010 (see §20.2.E, §20.3.F, and §70.B of this chapter for more information);

- ESRD-related erythropoiesis stimulating agents (ESAs) and their oral or other forms of administration (see §20.3.A of this chapter for more information);
- ESRD-related injectable drugs and biologicals and their oral or other forms of administration (see §20.3.B, §20.3.C and §20.3.D of this chapter for more information);
- ESRD-related oral or other forms of non-injectable drugs and biologicals (see §20.3 of this chapter for more information);
- ESRD-related diagnostic laboratory tests (see §20.2 of this chapter for more information);
- Home and self-dialysis training (see §30.2 of this chapter for more information); and
- All supplies, equipment, and support services necessary for the effective performance of a patient's dialysis furnished in the ESRD facility or in a patient's home (see §20.4 of this chapter for more information).

See §20 of this chapter for more information regarding renal dialysis items and services.

Services Provided Under an Arrangement

A Medicare certified ESRD facility may enter into written arrangements with a second ESRD facility to provide certain covered outpatient dialysis items or services to patients. When services are provided under an arrangement, the first ESRD facility retains professional and financial responsibility for those services and also for obtaining reimbursement for them. The first ESRD facility may bill the patient for the applicable coinsurance and deductible amounts. The second ESRD facility is permitted to seek payment only from the first ESRD facility, and may not bill the patient or Medicare.

D. Types of Dialysis

1. Types of Outpatient Maintenance Dialysis - Outpatient maintenance dialysis is furnished on an outpatient basis by a Medicare certified ESRD facility and is paid under the ESRD PPS. Outpatient maintenance dialysis is not acute dialysis. Medicare defines acute dialysis services as dialysis that is not covered and paid under the ESRD benefit in 42 CFR 413.174. For billing and payment instructions of acute dialysis services furnished in the hospital see Pub. 100-04, chapter 4, §200.2 and Pub. 100-02, chapter 1, *section 10*.

- a. In-facility Dialysis** - Dialysis furnished on an outpatient basis in *a Medicare certified ESRD facility*.

- b. Home Dialysis - Dialysis performed at home, *including a nursing home, by an ESRD patient or caregiver who has completed an appropriate course of training as specified at 42 CFR §494.100(a).*
- c. Staff-Assisted Dialysis - Dialysis performed by the staff of the *ESRD facility in the ESRD facility.*
- d. Self-Dialysis - *Dialysis performed by an ESRD patient in-facility with the expectation that the patient performs their dialysis treatment with little or no professional assistance. The patient must have completed an appropriate course of training as specified at 42 CFR §494.100(a).*

NOTE: Self-dialysis and home dialysis training are programs that educate ESRD patients and/or other individuals to assist the patient in performing self-dialysis or home dialysis with little or no professional assistance.

2. Back-Up Dialysis - Dialysis given to patients under special circumstances. Examples are: dialysis of a home dialysis patient in *an ESRD* facility when the patient's equipment fails, inpatient dialysis when a patient's illness requires more comprehensive care, and preoperative and postoperative dialysis provided to transplant patients.

E. Home Dialysis - Supplies, Equipment, and Support Services

ESRD facilities are responsible for furnishing supplies, equipment, and support services for home dialysis. ESRD facilities are financially responsible and may not bill Medicare or the patient for separate payment. If an ESRD facility arranges for a supplier to furnish ESRD-related supplies and equipment, the supplier may seek payment only from the ESRD facility and may not bill Medicare or the patient for separate payment.

Method Selection – For home dialysis *services furnished prior to January 1, 2011*, a beneficiary *selected* one of two methods *to secure home dialysis items and services*. Under Method I, the *ESRD* facility with which the patient is associated, assumes *total* responsibility for *furnishing* all home dialysis items *or* services. Under Method II, the beneficiary *dealt* directly with a dialysis supplier to secure *home dialysis items and services*. Beginning January 1, 2011, Method II is no longer an option for home dialysis items and services under Medicare. Therefore, beginning January 1, 2011, all home dialysis patients are Method I.

Under Method I, Medicare payment for all modalities of home dialysis is made to the ESRD facility under the ESRD PPS. Renal dialysis items and services may be furnished directly by the facility or under arrangement with a supplier.

The ESRD facility or home dialysis supplier may not bill the beneficiary directly for ESRD related supplies, services, or equipment. *For further discussion on Method I payment refer to §20.1 of this chapter.*

1. Home Dialysis Equipment - Home dialysis equipment includes all of the medically necessary equipment *ordered* by the attending physician, including (but not limited to) artificial kidneys, automated peritoneal dialysis machines, and support equipment.

Home dialysis supplies and equipment may be covered if used by an ESRD beneficiary in a nursing home *or a SNF*. *See §40.C and §40.D of this chapter for more information.*

2. Installation - Installation includes (but is not limited to) the identification of any minor plumbing and electrical changes required to accommodate the equipment, the ordering and performing of these changes, delivery of the equipment and its actual installation (i.e., hookup), as well as any necessary testing to assure proper installation and function.

Minor plumbing and electrical changes include those parts and labor required to connect the dialysis equipment to plumbing and electrical lines that already exist in the room where the patient will dialyze. Medicare does not cover wiring or rewiring of the patient's home or installing any plumbing to the patient's home or to the room of the home where the patient will dialyze.

3. Maintenance - Maintenance includes (but is not limited to) travel to the patient's home, transportation of the equipment to a repair site, the actual performance of the maintenance or repair, and necessary parts. Water purification equipment maintenance includes replacing the filter on a reverse osmosis device, regenerating the resin tanks on a deionization device, using chemicals in a water softener, and periodic water testing to assure proper performance.

Routine maintenance customarily performed by a patient is not a covered service except for the cost of parts involved in *the* maintenance furnished by the *ESRD* facility to the patient.

4. Supplies - Supplies include all durable and disposable items and medical supplies necessary for the effective performance of a patient's dialysis. Supplies include (but are not limited to): dialyzers, forceps, sphygmomanometer with cuff and stethoscope, scales, scissors, syringes, alcohol wipes, sterile drapes, needles, topical anesthetics, and gloves.

5. Support Services – *See §30.1.A of this chapter.*

6. Support Equipment - Support equipment is equipment used in conjunction with the basic dialysate delivery system. Such equipment includes (but is not limited to) pumps, such as blood and heparin pumps, alarms, such as bubble detectors, water purification equipment used to improve the quality of the water used for dialysis, and adjustable dialysis chairs.

F. Overview of Medicare's ESRD Payment Policy

1. ESRD Prospective Payment System (ESRD PPS) – Section 153(b) of Pub. L. 110-275, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1881(b) of the Social Security Act to require the implementation of an ESRD bundled payment system effective January 1, 2011. Under MIPPA, the ESRD PPS replaced the basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD-related items and services.

The ESRD PPS provides a case-mix adjusted single payment to ESRD facilities for renal dialysis services provided in an ESRD facility or in a beneficiary's home. See §10.C of this chapter on renal dialysis services.)

To account for higher resource utilization, the ESRD PPS applies case-mix adjusters to the base rate and, when applicable, also includes an add-on for home dialysis training and an outlier payment.

The ESRD PPS provides for a 4 year transition period under which facilities may receive a blend of the payment methodology prior to January 1, 2011, (that is, the basic case-mix adjusted composite rate payment system) and the ESRD PPS. In 2014, all ESRD facilities that receive Medicare payment will be paid 100 percent under the ESRD PPS.

The ESRD PPS combines payment for what had previously been composite rate and separately billable outpatient ESRD-related items and services into a single base rate for both adult and pediatric patients. The per dialysis treatment base rate is subsequently adjusted to reflect:

- *Patient-level adjustments for case-mix, (see §60.A.1 of this chapter for adult adjustments and §60.A.6 of this chapter for pediatric patient adjustments);*
- *An onset of dialysis adjustment for adult patients that have Medicare ESRD coverage during their initial 4 months of dialysis, (see §60.A.4 of this chapter);*
- *A low-volume facility adjustment for ESRD facilities that meet certain criteria, (see §60.B.1 of this chapter);*
- *Differences in wage levels among the urban and rural areas in which ESRD facilities are located, (see §60.B.2 of this chapter);*
- *A training add-on, (see §60.C of this chapter);*
- *Outlier payments, (see §60.D of this chapter); and*
- *A budget neutrality adjustment during the transition period through 2014, (see §70.C of this chapter).*

The ESRD PPS implemented consolidated billing requirements for limited ESRD-related Part B items and services. Certain ESRD-related laboratory services, limited drugs and

biologicals, equipment, and supplies are subject to consolidated billing and no longer separately payable when provided to ESRD beneficiaries by providers other than the ESRD facility. Renal dialysis services furnished to an ESRD patient that is not for the treatment of ESRD must be submitted with an AY modifier to allow for separate payment outside of the ESRD prospective payment system. The list of drugs and biologicals used for the ESRD PPS consolidated billing may be viewed at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. Note that this list is not an all-inclusive list and any ESRD-related item or service is paid to the ESRD facility under the ESRD PPS.

2. Basic Case-Mix Adjusted Composite Rate Payment System – The basic case-mix adjusted composite rate payment system applied patient-level case-mix adjusters, additional payment for training, and a drug add-on to the composite rate.

The drug add-on is an additional payment added to the composite rate to account for the difference between the methodologies of payment for separately billed drugs prior to the enactment of the revised drug pricing specified in The Medicare Modernization Act of 2003. The basic case-mix adjusted composite rate payment system is maintained for purposes of the blended payment during the transition period of the ESRD PPS. For more information on the history of the composite rate see Appendix C and for more information regarding the transition period see §70 of this chapter.

Medicare payment under the basic case-mix adjusted composite rate will no longer be made as of January 1, 2014.

3. Composite Rate – Prior to the implementation of the basic case-mix adjusted composite rate payment system, there was a composite rate which covered routine laboratory services, drugs and biologicals, equipment and supplies, and support services furnished for outpatient maintenance dialysis in Medicare certified ESRD facilities or for Method I home patients. The composite rate was the first step made by Medicare in creating a bundled payment for renal dialysis items and services. The composite rate is also referred to as “composite payment rate.” For more information regarding composite rate items and services, see §20.1, for composite rate laboratory services, see §20.2.E, and for composite rate drugs, see §20.3.F of this chapter.

20 - Renal Dialysis Items and Services

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Medicare provides payment under the ESRD PPS for all renal dialysis services for outpatient maintenance dialysis when they are furnished to Medicare ESRD patients by a Medicare certified ESRD facility or a special purpose dialysis facility. Renal dialysis services are the items and services included under the composite rate and the ESRD-related items and services that were separately paid as of December 31, 2010.

Renal dialysis services are furnished in various settings including hospital outpatient ESRD facilities, independent ESRD facilities, or in the patient's home. Renal dialysis items and services furnished at ESRD facilities differ according to the types of patients being treated, the types of equipment and supplies used, the preferences of the treating physician, and the capability and makeup of the staff. Although not all facilities provide an identical range of services, the most common elements of dialysis treatment include:

- *Laboratory Tests;*
- *Drugs and Biologicals;*
- *Equipment and supplies - dialysis machine use and maintenance;*
- *Personnel services;*
- *Administrative services;*
- *Overhead costs;*
- *Monitoring access and related declotting or referring the patient, and*
- *Direct nursing services include registered nurses, licensed practical nurses, technicians, social workers, and dietitians.*

20.1 - Composite Rate Items and Services

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Beginning January 1, 2011, all renal dialysis services (defined at §10.C of this chapter) are included in the ESRD PPS. Renal dialysis services include, but are not limited to, the items and services included under the composite rate as of December 31, 2010.

The composite payment rate *(defined at §10.F.3 of this chapter)* was a comprehensive payment for all modes of in-facility and Method I home dialysis. Most items and services related to the treatment of the patient's end-stage renal disease *were* covered under the composite rate payment with the exception of physicians' professional services, separately billable laboratory services, and separately billable drugs. If *a facility failed* to furnish, either directly or under *an* arrangement, any part of the items and services covered under the composite rate, then the *ESRD* facility could not be paid any amount for the *service*. This payment was subject to the normal Part B deductible and coinsurance requirements.

Below are examples of items and services included under the composite rate and furnished by the ESRD facility, either directly or under arrangement.

- Dialysate;
- Cardiac monitoring;
- Catheter changes;
- Suture removal;
- Dressing changes;
- Crash cart usage for cardiac arrest;

- Dec clotting of shunt performed by *ESRD* facility staff in the dialysis unit;
- All oxygen and its administration furnished in the dialysis unit;
- Staff time to administer blood;
- Staff time used to administer separately billable parenteral items; and
- Staff time used to collect specimens for laboratory tests.

20.2 - Laboratory Services

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

All laboratory services furnished for the treatment of ESRD are included in the ESRD PPS as Part B services and are not paid separately as of January 1, 2011. The laboratory services include but are not limited to:

- *Laboratory tests included under the composite rate as of December 31, 2010 (discussed below); and*
- *Former separately billable Part B laboratory tests that were billed by ESRD facilities and independent laboratories for ESRD patients.*

Composite rate laboratory tests are listed in §20.2.E of this chapter. More information regarding composite rate laboratory tests can be found in Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §50.1, §60.1, and §80. As discussed below, composite rate laboratory services should not be reported on claims.

The distinction of what is considered to be an ESRD-related laboratory test is a clinical decision determined by the ESRD patient's ordering practitioner. If a laboratory test is ordered for an ESRD-related condition, then the laboratory test is considered to be a renal dialysis service and is not paid separately.

Payment for all ESRD-related laboratory tests furnished under the ESRD PPS is made directly to the ESRD facility responsible for the patient's care. The ESRD facility must furnish the laboratory tests directly or under arrangement and report ESRD-related laboratory tests on the ESRD facility claim (with the exception of composite rate laboratory services).

An ESRD facility must report ESRD-related laboratory services on its claims in order for the laboratory tests to be included in the outlier payment calculation. ESRD-related laboratory services that were or would have been paid separately under Medicare Part B prior to January 1, 2011, are priced for the outlier payment calculation using the Clinical Laboratory Fee Schedule. Further information regarding the outlier policy can be found in §60.D of this chapter.

Certain laboratory services will be subject to Part B consolidated billing requirements and will no longer be separately payable when provided to ESRD beneficiaries by providers other than the renal dialysis facility. The items and services subject to

consolidated billing may be found at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. This link includes the list of ESRD-related laboratory tests that are routinely performed for the treatment of ESRD. Payment for the laboratory tests identified on this list is included in the ESRD PPS. The laboratory tests listed in the table are used to enforce consolidated billing edits to ensure that payment is not made for ESRD-related laboratory tests outside of the ESRD PPS. The list of ESRD-related laboratory tests is not an all-inclusive list. If any laboratory test is ordered for the treatment of ESRD, then the laboratory test is considered to be ESRD-related and is the responsibility of the ESRD facility. Additional ESRD-related laboratory tests may be added through administrative issuances in the future.

A. Automated Multi-Channel Chemistry (AMCC) Tests

During the ESRD PPS transition period (see §70 of this chapter) ESRD facilities are required to report the ESRD-related AMCC tests with the appropriate modifiers (CD, CE, or CF) on their claims for purposes of applying the 50/50 rule under the composite rate portion of the blended payment. Refer to §70.B of this chapter for additional information regarding the composite rate portion of the blended payment during the transition.

The 50/50 rule is necessary for those ESRD facilities that chose to go through the transition period. If the 50/50 rule allows for separate payment, then the laboratory tests are priced using the clinical laboratory fee schedule. Information regarding the 50/50 rule can be found in §20.2.E of this chapter and in Pub. 100-04, Medicare Claims Processing Manual, chapter 16, §40.6.

NOTE: *An ESRD facility billing an ESRD-related AMCC test must use the CF modifier when the AMCC is not in the composite rate but is ESRD-related. Non-ESRD related AMCC tests should be billed to Medicare directly by the entity furnishing the service with the AY modifier.*

B. Laboratory Services Furnished for Reasons Other Than ESRD

1. Independent Laboratory

A patient's physician or practitioner may order a laboratory test that is included on the list of items and services subject to consolidated billing edits for a non-ESRD related reason. When this occurs, the patient's physician or practitioner should notify the independent laboratory or the ESRD facility (with the appropriate clinical laboratory certification in accordance with the Clinical Laboratory Improvement Act) that furnished the laboratory service that the test is not ESRD-related and that entity may bill Medicare separately using the AY modifier. The AY modifier serves as an attestation that the item or service is medically necessary for the patient but is not being used for the treatment of ESRD.

2. Hospital-Based Laboratory

Hospital outpatient clinical laboratories furnishing ESRD-related laboratory tests to ESRD patients for reasons other than for the treatment of ESRD may submit a claim for separate payment using the AY modifier. The AY modifier serves as an attestation that the item or service is medically necessary for the patient but is not being used for the treatment of ESRD.

C. Laboratory Services Performed in Emergency Rooms or Emergency Departments

In an emergency room or emergency department, the ordering physician or practitioner may not know at the time the laboratory test is being ordered, if it is being ordered for ESRD-related reasons. Consequently, emergency rooms or emergency departments are not required to append an AY modifier to these laboratory tests when submitting claims with dates of service on or after January 1, 2012.

When an ESRD-related laboratory service is furnished to an ESRD patient in an emergency room or emergency department on a different date of service, hospitals can append an ET modifier to ESRD-related laboratory tests furnished to ESRD patients to indicate that the laboratory test was furnished in conjunction with the emergency visit. Appending the ET modifier indicates that the laboratory service being furnished on a day other than the emergency visit is related to the emergency visit and at the time the ordering physician was unable to determine if the test was ordered for reasons of treating the patient's ESRD.

Allowing laboratory testing to bypass consolidated billing edits in the emergency room or department does not mean that ESRD facilities should send patients to other settings for routine laboratory testing for the purpose of not assuming financial responsibility of ESRD-related items and services. For additional information regarding laboratory services furnished in a variety of settings, see Pub. 100-04, Medicare Claims Processing Manual, chapter 16, §30.3 and §40.6.

D. Hepatitis B Laboratory Services for Transient Patients

Laboratory testing for hepatitis B is an ESRD-related service. Effective January 1, 2011, hepatitis B testing is included in the ESRD PPS and therefore cannot be billed separately to Medicare.

The Conditions for Coverage for ESRD facilities require routine hepatitis B testing (42 CFR §494.30(a)(1)). The ESRD facility is responsible for the payment of the laboratory test, regardless of frequency, if it is being furnished for the treatment of ESRD. If an ESRD patient wishes to travel, the patient's home ESRD facility should have systems in place for communicating hepatitis B test results to the destination ESRD facility.

E. Laboratory Services Included Under Composite Rate

Prior to the implementation of the ESRD PPS, the costs of certain ESRD laboratory services furnished for outpatient maintenance dialysis by either the ESRD facility's staff or an independent laboratory, were included in the composite rate calculations. Therefore, payment for all of these laboratory tests was included in the ESRD facility's composite rate and the tests could not have been billed separately to the Medicare program.

All laboratory services that were included under the composite rate are included under the ESRD PPS unless otherwise specified. Payments for these laboratory tests are included in the ESRD PPS and are not paid separately under the composite rate portion of the blended payment and are not eligible for outlier payments. Therefore, composite rate laboratory services should not be reported on the claim. Laboratory tests included in the composite payment rate are identified below.

1. Routinely Covered Tests Paid Under Composite Rate

The tests listed below are usually performed for dialysis patients and *were* routinely covered at the frequency specified in the absence of indications to the contrary, (i.e., no documentation of medical necessity *was* required other than knowledge of the patient's status as an ESRD beneficiary). When any of these tests *were* performed at a frequency greater than that specified, the additional tests *were* separately billable and *were* covered only if they *were* medically justified by accompanying documentation. A diagnosis of ESRD alone *was* not sufficient medical evidence to warrant coverage of the additional tests. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of the test(s) must *have been* present, *along with ICD diagnosis coding, on the claim for payment.*

a. Hemodialysis, IPD, CCPD, and Hemofiltration

- Per Treatment - All hematocrit, hemoglobin, and clotting time tests furnished incident to dialysis treatments;
- Weekly - Prothrombin time for patients on anticoagulant therapy and Serum Creatinine;
- Weekly or Thirteen Per Quarter - BUN;
- Monthly - Serum Calcium, Serum Potassium, Serum Chloride, CBC, Serum Bicarbonate, Serum Phosphorous, Total Protein, Serum Albumin, Alkaline Phosphatase, aspartate amino transferase (AST) (SGOT) and LDH; and
- *Automated Multi-Channel Chemistry (AMCC)* - If an automated battery of tests, such as the SMA-12, is performed and contains most of the tests listed in one of the weekly or monthly categories, it is not necessary to **separately** identify any tests in the battery that are not listed. Further information

concerning automated tests and the “50 percent rule” can be found below and in Pub. 100-04, Medicare Claims Processing Manual, chapter 16, §40.6.1.

b. CAPD

- *Monthly – BUN, Creatinine, Sodium, Potassium, CO2, Calcium, Magnesium, Phosphate, Total Protein, Albumin, Alkaline Phosphatase, LDH, AST, SGOT, HCT, Hbg, and Dialysate Protein.*

Under the ESRD PPS, frequency requirements do not apply for the purpose of payment. However, laboratory tests should be ordered as necessary and should not be restricted because of financial reasons.

2. Separately Billable Tests Under the Composite Rate

The following list identifies certain separately billable laboratory tests that *were* covered routinely *and* without documentation of medical necessity other than knowledge of the patient’s status as an ESRD beneficiary, when furnished at specified frequencies. If they *were* performed at a frequency greater than that specified, they *were* covered only if accompanied by medical documentation. A diagnosis of ESRD alone *was* not sufficient documentation. The medical necessity of the test(s), the nature of the illness or injury (diagnosis, complaint or symptom) requiring the performance of the test(s) must *have been* furnished *on claims* using the ICD *diagnosis* coding system.

- Separately Billable Tests for Hemodialysis, IPD, CCPD, and Hemofiltration

Serum Aluminum - one every 3 months

Serum Ferritin - one every 3 months

- *Separately Billable Tests for CAPD*

WBC, RBC, and Platelet count – One every 3 months

Residual renal function and 24 hour urine volume – One every 6 months

Under the ESRD PPS frequency requirements do not apply for the purpose of payment. However, laboratory tests should be ordered as necessary and should not be restricted because of financial reasons.

3. Automated Multi-Channel Chemistry (AMCC) Tests Under the Composite Rate

Clinical diagnostic laboratory tests *that comprise the AMCC (listed in Appendix A and B) could be considered to be composite rate and non-composite rate laboratory services. Composite rate payment was paid by the FI or A/B MAC.* To determine if separate payment *was* allowed for non-composite rate tests for a particular date of service, 50 percent or more of the covered tests must be non-composite rate tests. *This policy also applies to the composite rate portion of the blended payment during the transition.*

Beginning January 1, 2014, the 50 percent rule will no longer apply and no separate payment will be made under the composite rate portion of the blended payment.

Medicare *applied* the following to AMCC tests for ESRD beneficiaries:

- Payment *was* the lowest rate for services performed by the same provider, for the same beneficiary, for the same date of service.
- The *FI or A/B MAC identified*, for a particular date of service, the AMCC tests ordered that were included in the composite rate and those that were not included. The composite rate tests *were* defined for Hemodialysis, IPD, CCPD, and Hemofiltration (*see Appendix A*) and for CAPD (*see Appendix B*).
- If 50 percent or more of the covered tests *were* included under the composite rate payment, then all submitted tests *were* included within the composite payment. In this case, no separate payment in addition to the composite rate *was* made for any of the separately billable tests.
- If less than 50 percent of the covered tests *were* composite rate tests, all AMCC tests submitted for that Date of Service (DOS) *were* separately payable.
- A non-composite rate test *was* defined as any test separately payable outside of the composite rate or beyond the normal frequency covered under the composite rate that *was* reasonable and necessary.

Three pricing modifiers identify the different payment situations for ESRD AMCC tests. The physician who ordered the tests *was* responsible for identifying the appropriate modifier when ordering the tests.

- CD - AMCC test *had* been ordered by an ESRD facility or *Medicare capitation payment* (MCP) physician that was part of the composite rate and *was* not separately billable
- CE - AMCC test *had* been ordered by an ESRD facility or MCP physician that *was* a composite rate test but *was* beyond the normal frequency covered under the rate and *was* separately reimbursable based on medical necessity
- CF – AMCC test *had* been ordered by an ESRD facility or MCP physician that *was* not part of the composite rate and *was* separately billable

The ESRD clinical diagnostic laboratory tests identified with modifiers “CD”, “CE” or “CF” may not *have been* billed as organ or disease panels. Effective October 1, 2003, all ESRD clinical diagnostic laboratory tests must be billed individually. See Pub. 100-04, Medicare Claims Processing Manual, chapter 16, §40.6.1, for additional billing and payment instructions as well as examples of the 50/50 rule.

For ESRD dialysis patients, CPT code 82330 Calcium; ionized shall be included in the calculation for the 50/50 rule (Pub. 100-04, *Medicare Claims Processing Manual*, chapter 16, §40.6.1). When CPT code 82330 is billed as a substitute for CPT code 82310, Calcium; total, it shall be billed with modifier CD or CE. When CPT code 82330 is billed in addition to CPT 82310, it shall be billed with CF modifier.

20.3 - Drugs and Biologicals

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

All drugs and biologicals used for the treatment of ESRD are included in the ESRD PPS and are not separately paid as of January 1, 2011. The drugs and biologicals include but are not limited to:

- *Drugs and biologicals included under the composite rate as of December 31, 2010 (discussed below);*
- *Former separately billable Part B injectable drugs;*
- *Oral or other forms of injectable drugs used for the treatment of ESRD formerly billed under Part D; and*
- *Oral or other forms of drugs and biologicals without an injectable form. (Implementation delayed until January 1, 2016.)*

See §60.D of this chapter for details on drug eligibility under the outlier payment policy.

Drugs and biologicals furnished to ESRD beneficiaries that are not used for the treatment of ESRD, may be paid separately. When non-ESRD related drugs or biologicals are furnished to an ESRD beneficiary, the ESRD facility or other provider shall append the claim with the AY modifier to receive separate payment. For more information regarding the AY modifier refer to Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1.

Drugs and biologicals identified for consolidated billing are designated as always ESRD-related and therefore no separate payment is made to ESRD facilities or other providers when these drugs are furnished to ESRD beneficiaries. The list of drugs and biologicals used for the ESRD PPS consolidated billing may be viewed at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. Information regarding consolidated billing requirements for drugs and biologicals can be found in §10.F. of this chapter and in Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1.

*This list is used to enforce consolidated billing edits which ensure that payment is not made for ESRD-related drugs and biologicals outside of the ESRD PPS. **This is not an all-inclusive list and any drug or biological that is used for the same purpose as those drugs and biologicals on the list are also included under the ESRD PPS.** Providers*

other than ESRD facilities furnishing those drugs must look to the ESRD facility for payment.

NOTE: *Effective January 1, 2012, ESRD facilities and other providers may receive separate payment for vancomycin by placing the AY modifier on the claim when vancomycin is furnished to treat non-ESRD related conditions. The ESRD facility must indicate the appropriate ICD diagnosis code for which the vancomycin is indicated.*

NOTE: *Effective January 1, 2013, ESRD facilities and other providers may receive separate payment for daptomycin by placing the AY modifier on the claim when daptomycin is furnished to treat non-ESRD related conditions. The ESRD facility must indicate the appropriate ICD diagnosis code for which the daptomycin is indicated.*

See Pub.100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1 for additional information.

A. Drug Categories Always Considered to be ESRD Related

Drugs and biologicals always considered to be ESRD-related are those used for access management, anemia management, bone and mineral metabolism management, cellular management, and antibiotics used to treat access site infections. ESRD facilities are responsible for furnishing these drugs directly or under arrangement. This includes any drug or biological that is furnished in the ESRD facility or taken by the patient outside of the ESRD facility. For example, if oral antibiotics are furnished for an access infection to be taken at times other than during a dialysis treatment, the ESRD facility is responsible for furnishing the antibiotics.

Erythropoiesis stimulating agents (ESAs), such as epoetin alfa (EPOGEN®), darbepoetin alfa (ARANESP®), and peginesatide (OMONTYS®) when furnished to Medicare ESRD patients are always considered ESRD-related and included in the ESRD PPS. Monthly dosages of these ESAs are subject to Medicare's ESA claims monitoring policy. See Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.4.1 for more information on the ESA monitoring policy.

NOTE: *ESA dose edits are applied prior to pricing so that ESAs are not overvalued in determining eligibility for outlier payments.*

ESRD facilities are responsible for furnishing antibiotics for access site infections. When antibiotics are used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis, the antibiotics are included in the ESRD PPS and may not be paid separately. This includes antibiotics that may be added to a patient's dialysate solution.

Any other drugs (other than those categories described above) when used for ESRD-related conditions are also included in the ESRD PPS. For example,

- *Patient A experiences nausea or pain during a hemodialysis dialysis treatment and requires medications. Any medication furnished during the dialysis treatment or after the treatment is considered ESRD related and may not be billed separately.*
- *Patient B experiences anxiety with dialysis treatments and is prescribed anti-anxiety medication during and between the dialysis treatments. Any medications furnished during the dialysis treatment or after the treatment is considered ESRD related and may not be billed separately.*
- *Any drug or biological added to patient dialysate solutions.*

B. Injectable Drugs and Biologicals

All injectable drugs or biologicals used for the treatment of ESRD-related conditions are included in the ESRD PPS and are not separately paid. This includes ESRD-related drugs and biologicals that prior to the implementation of the ESRD PPS were separately billable under Part B. However, ESRD facilities receiving a blended payment during the transition period will continue to receive a separate payment for these drugs and biologicals under the composite rate portion of the blend during the transition. For more information on the transition, see §70 of this chapter.

Injectable drugs and biologicals furnished to Medicare ESRD patients that are not used to treat ESRD-related conditions may continue to be paid separately, when reported on the claim with an AY modifier. See §20.4.C of this chapter for more information on the AY modifier.

NOTE: *ESRD patients should not be sent to other settings for the purpose of receiving separate payment for ESRD-related injectable drugs and biologicals or for the purpose of not assuming financial responsibility for renal dialysis items and services.*

ESRD facilities must report the appropriate Healthcare Common Procedure Coding System (HCPCS) codes used for the administration and furnishing of ESRD-related drugs and biologicals. This includes drugs and biologicals that are furnished in the beneficiary's home. These supplies include:

- *A4657: Injection administration-supply charge (includes the cost of alcohol swab, syringe, and gloves) and*
- *A4913: IV administration-supply charge (includes the cost of IV solution administration set, alcohol swab, syringe, and gloves). A4913 should only be used when an IV solution set is required for a drug to be given.*

See Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1 for billing procedures. These supplies are eligible for payment as outlier services in accordance with §60.D of this chapter.

C. Oral or Other Forms of Injectable Drugs and Biologicals

The ESRD PPS includes certain drugs and biologicals that were previously paid under Part D. Oral or other forms of injectable ESRD-related drugs and biologicals, for example, Vitamin D analogs, Levocarnitine, antibiotics or any other oral or other form of injectable drug or biological furnished for ESRD-related purposes are also included in the ESRD PPS and may not be separately paid.

The ESRD facility should report any drug or biological furnished on the ESRD claim with the line item date of service and the quantity of the drug or biological furnished at the time of the visit. For claims processing instructions see Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.2.

For ESRD-related oral or other forms of drugs that are filled at the pharmacy for home use, ESRD facilities should report one line item per prescription, but only for the quantity of the drug expected to be taken during the claim billing period.

Example: A prescription for oral vitamin D was ordered for one pill to be taken 3 times daily for a period of 45 days. The patient began taking the medication on April 15, 2011. On the April claim, the ESRD facility would report the appropriate National Drug Code (NDC) code for the drug with the quantity 45 (15 days x 3 pills per day). The remaining pills which would be taken in May would appear on the May claim for a quantity of 90 (30 days x 3 pills per day). Prescriptions for a 3 month supply of the drug would never be reported on a single claim. Only the amount expected to be taken during the month would be reported on that month's claim.

ESRD-related oral and other forms of injectable drugs are eligible for consideration as outlier services. See the CMS website at http://www.cms.gov/ESRDPayment/30_Outlier_Services.asp#TopOfPage for a list of these drugs. CMS prices these drugs using national average drug prices based on the Medicare Prescription Drug Plan Finder. Payment also includes a mean dispensing fee that is applied to each NDC included on the monthly claim, in accordance with Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.2.

Payments for ESRD-related oral or other forms of injectable drugs or biologicals are included in the ESRD PPS and are only made to the ESRD facility. ESRD facilities should report all oral or other forms of ESRD-related injectable drugs and biologicals furnished to their patients on the claim. ESRD facilities that are receiving a blended payment during the transition period will receive an additional payment to account for these drugs under the composite rate portion of the blend. For more information on the transition, see §70 of this chapter.

For ESRD facilities receiving transition payments under the ESRD PPS, payment for intravenous iron, such as, sodium ferric gluconate complex in sucrose injection is reimbursed at the Average Sales Price (ASP) plus 6 percent. For ESRD facilities which

have elected to be paid exclusively under the ESRD PPS, intravenous iron is included as part of the payment bundle. For more information regarding the transition period, see §70 of this chapter.

D. Oral Forms of Non-Injectable Drugs

ESRD-related oral forms of non-injectable drugs and biologicals will be included in the ESRD PPS as a Part B renal dialysis service.

NOTE: *Implementation of ESRD-related oral-only drugs has been delayed until January 1, 2016.*

E. Non-ESRD Related Drugs and Biologicals

Drugs and biologicals furnished by an ESRD facility that are not used for the treatment of ESRD may be billed separately when coded with the AY modifier. The AY modifier serves as an attestation that the item or service is deemed medically necessary for the dialysis patient but is not being used for the treatment of ESRD. See Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1 for more information.

F. Drugs and Biologicals Under the Composite Rate

Prior to the implementation of the ESRD PPS, certain drugs used in furnishing outpatient maintenance dialysis treatments were considered composite rate drugs and not billed separately. Payments for these drugs are included in the ESRD PPS and are not paid separately under the composite rate portion of the blended payment. All payment policies in effect for drugs and biologicals prior to the implementation of the ESRD PPS remained after implementation unless otherwise noted.

Because composite rate drugs may not be billed separately when used in connection with the treatment of ESRD, they are not considered eligible outlier services under the ESRD PPS. See §60 D of this chapter for information on outlier payments.

Drugs that were used as a substitute for any of these drugs or are used to accomplish the same effect are also covered under the composite rate.

The following list is comprised of drugs and biologicals under the composite rate. Staff time and supplies used to furnish these drugs are covered under the composite rate and are not billed separately.

- Heparin
- Mannitol
- Glucose
- Antiarrhythmics
- Saline

- Antihypertensives
- Protamine
- Pressor Drugs
- Antihistamines
- Local Anesthetics
- Heparin Antidotes
- Dextrose
- Apresoline (hydralazine)
- Benadryl
- Inderal
- Dopamine
- Hydralazine
- Levophed
- Insulin
- Lanoxin
- Verapamil
- Lidocaine
- Solu-cortef
- Antibiotics*

**Antibiotics - Effective January 1, 2012, antibiotics when used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis are no longer considered composite rate drugs and may be billed separately by ESRD facilities, under the composite rate portion of the blended payment during the transition. Under the ESRD PPS, all antibiotics including those furnished in the home are included in the ESRD PPS and are not eligible for separate payment, although they may be eligible for outlier payments. For more information regarding the outlier policy see §60.D of this chapter.*

Thrombolytic drugs (such as heparin) furnished by ESRD facilities to Medicare ESRD beneficiaries for access management purposes are recognized as composite rate drugs under the ESRD PPS. Effective January 1, 2012, thrombolytics are not eligible for outlier payments. Effective January 1, 2013, payment for thrombolytic drugs is included in the ESRD PPS and may not be separately paid when furnished to an ESRD Medicare beneficiary. Refer to 42 CFR §413.237 (a)(1)(i) for more information.

G. Separately Billable Drugs and Biologicals

The staff time used to furnish the separately billable drugs is included in the ESRD PPS and should not be billed separately.

- Albumin may be reasonable and medically necessary for the treatment of certain medical complications in renal dialysis patients. In such cases, facilities must document medical need to the satisfaction of the *FI's or A/B MAC's* medical staff. If the *FI or A/B MAC determined* that the drug was medically necessary, then separate payment in addition to the *ESRD* facility's composite rate *could have been* made.

However, if albumin *was* used as a substitute for any drug covered under the composite rate or used to accomplish the same effect, for example, as a volume expander, then payment for it must *have been included in the ESRD* facility's composite rate payment for maintenance dialysis.

- *Payment for furnishing blood, blood products, or blood supplies is excluded from the ESRD PPS and will remain separately billable when they are administered in an ESRD facility. For further detail, see Pub. 100-04, chapter 8, §60.3.*
- *Immunizations may be separately billed when furnished by an ESRD facility to a Medicare ESRD Beneficiary. For further detail, see Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.6.*

H. Drug Overfill Policy

Medicare does not pay for additional medications in drug containers provided at no cost to the ESRD facility. ESRD facilities may not receive additional payment under the ESRD PPS when they furnish drug overfill medications to Medicare beneficiaries. Drug overfill amounts are not eligible for outlier payments. In addition, ESRD facilities may not receive separate payment under the composite rate portion of the blended payment under the transition.

20.4 - Equipment and Supplies

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

All medically necessary equipment and supplies used to furnish dialysis (in-facility or in a patient's home) are included in the ESRD PPS and are not separately paid as of January 1, 2011. The equipment and supplies include but are not limited to

- *Equipment and supplies included under the composite rate (see §20.1 of this chapter) as of December 31, 2010,*
- *Equipment and supplies that were billed by ESRD facilities and paid separately by Medicare, and*
- *Equipment and supplies furnished to home patients that were under Method II prior to January 1, 2011, and billed by Durable Medical Equipment (DME) suppliers and paid separately by Medicare.*

ESRD facilities and monthly capitation payment practitioners may determine that it is medically necessary for a dialysis patient to use dressings or protective access coverings, including catheter coverings, on their access site. All medically necessary dressings or protective access coverings used during or after dialysis to protect a dialysis patient's access site including for example, coverings used for day-to-day activities such as bathing, are considered to be ESRD-related items. To the extent that dressings and protective access coverings, including catheter coverings, are determined to be medically necessary, an ESRD facility should provide them. Medicare payment for vascular access equipment and supplies is included in the ESRD PPS for all dialysis patients regardless of the method of dialysis or where they receive dialysis treatments.

Separate payment for ESRD-related equipment and supplies is not made under the ESRD PPS or under the blended payment during the ESRD PPS transition.

ESRD facilities may not receive payment for ESRD-related equipment and supplies from ESRD beneficiaries.

A. Home Dialysis Equipment and Supplies

All home dialysis equipment, supplies, and other medically necessary items for home dialysis ordered by a physician were included in the composite rate and are therefore included under ESRD PPS. The ESRD facility with which the patient is associated assumes responsibility for providing all home dialysis equipment, supplies, and support services either directly or under arrangements to all of its home dialysis patients.

1. Home Dialysis Equipment Provided to Home Hemodialysis and Peritoneal Dialysis Patients

Coverage of any item of home dialysis equipment used for home dialysis depends on its medical necessity. Medical necessity is established by the physician's *order*, and by the equipment meeting Medicare guidelines that define home dialysis equipment.

Nonmedical items are also included in the ESRD PPS and may not be billed separately. For example, if a home patient is wheelchair bound and it is medically necessary for the patient to weigh themselves before and after a dialysis treatment, the ESRD facility is responsible for furnishing the patient with a wheelchair scale.

a. Installation and Delivery of Home Dialysis Equipment

ESRD facilities are responsible for all reasonable and necessary expenses incurred in the original installation of home dialysis equipment. This coverage is not extended to expenses attributable to home improvement (e.g., plumbing or electrical work beyond that necessary to tie in with existing plumbing and power lines). Testing and assurance of equipment performance, which may be billed for as part of the basic delivery charge, are also covered. Medicare does not cover maintenance contracts on equipment, since Medicare pays only for costs that are

actually incurred. The delivery and installation charge should be itemized, either on the face of the bill or an attached invoice.

b. Other Requirements for Coverage of Home Dialysis Equipment

Effective for renal dialysis services provided on or after January 1, 2011, the ESRD facility is responsible for fulfilling the requirements necessary for furnishing home dialysis.

This includes but is not limited to:

- Supportive equipment that is used in conjunction with the basic dialysate delivery system. This includes blood, heparin pumps, air bubble detectors, blood leak detectors, and unipuncture devices.
- Adjustable chairs, such as recliners, as these chairs serve to preserve patients' health by allowing rapid manipulation in body position when medical circumstances warrant such changes during dialysis (e.g., when acute hypotension occurs and the patient is in danger of going into shock).

Home dialysis equipment must also meet the requirements outlined in the Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, §110.

2. Home Dialysis *Supplies* Provided to Home Hemodialysis and Peritoneal Dialysis Patients

ESRD facilities are responsible for supplies necessary for the effective performance of all modalities of home dialysis, for example, alcohol wipes, sterile drapes, gloves, telfa pads, bandages, etc. Necessary supplies could also include but are not limited to start-up durable supplies (whether or not they are part of a start-up kit) such as weight scales, sphygmomanometer, I.V. stand, and dialysate heaters; and consumable and disposable supplies such as dialysate, tubing, and gauze pads.

Instruments and nonmedical supplies, such as scales, stopwatches, and blood pressure apparatus (this does not include automatic blood pressure monitoring devices such as those mentioned in *Pub. 100-03*, Medicare National Coverage Determinations Manual, Chapter 3, are *included in the ESRD PPS*, regardless of whether provided separately or as part of a start-up kit.

B. Coverage for Surgical Dressings

When dialysis access has been surgically placed in a patient to enable an ESRD facility to provide dialysis treatment, and the patient has started dialysis, the dressing changes are part of the home support provided by the ESRD facility. When surgical wounds are not related to ESRD, the patient may be eligible for care under the home health benefit found in §20.4.C of this chapter.

C. Non-ESRD Related Equipment and Supplies

1. ESRD Facilities

Occasionally ESRD facilities furnish items and services that are not used for the treatment of ESRD. When this occurs, ESRD facilities can bill separately by using the AY modifier for the appropriate HCPCS codes used for the administration-supply of the non-ESRD related drug and biological. These supplies include:

- A4657: Injection administration-supply charge (includes the cost of alcohol swab, syringe, and gloves) and*
- A4913: IV administration-supply charge (includes the cost of IV solution administration set, alcohol swab, syringe, and gloves). A4913 should only be used when an IV solution set is necessary for non-ESRD related drugs or biologicals to be given. Any non-ESRD related equipment or supply billed using the AY modifier will not be considered an eligible outlier service.*

For additional information regarding billing procedures for ESRD facilities that are transitioning into the ESRD PPS and that are furnishing non-ESRD related drugs and biologicals, see Pub. 100-04, chapter 8, §60.2.1.

2. Other Providers

There are equipment and supplies that are ESRD-related but may also be used in other provider settings for reasons other than for the treatment of ESRD. These equipment and supplies can be found in the document titled “Items and Services Subject to Consolidated Billing for the ESRD PPS” located at the ESRD Payment website: http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage. To allow DME suppliers to receive payment for furnishing these services to other provider types, the DME suppliers can bill the DME MAC the supplies included on this list with the AY modifier to indicate that the equipment is used for reasons other than for the treatment of ESRD.

There are equipment and supplies that are ESRD-related and are not used in other provider settings. These equipment and supplies are also listed in the document titled “Items and Services Subject to Consolidated Billing for the ESRD PPS.” These supplies and equipment are not otherwise covered by Medicare; therefore DME suppliers are not able to bill any of the supplies on this list using the AY modifier.

30 - Home Dialysis

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

For home dialysis services furnished prior to January 1, 2011, a beneficiary selected one of two methods to secure home dialysis items and services. Method I was when the

ESRD facility with which the patient is associated assumes total responsibility for furnishing all home dialysis items or services. The second was Method II, which was when the beneficiary dealt directly with a single dialysis supplier to secure home dialysis items and services. Beginning January 1, 2011, Method II is no longer an option for home dialysis under Medicare. Therefore, all home dialysis patients are under Method I. For more information on Method II, see §10.E of this chapter.

30.1 - Home Dialysis Items and Services

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Effective January 1, 2011, payment for renal dialysis services furnished for home dialysis are covered under the ESRD PPS and are not separately paid. ESRD facilities shall not bill Medicare beneficiaries directly when they furnish ESRD-related items and services included under the ESRD PPS. The ESRD facility receives the same Medicare dialysis payment rate for home patients as it would receive for an in-facility patient under the ESRD PPS.

The ESRD facility is responsible for the overall management of the home dialysis patient, including assuring that the patient is provided with equipment and supplies that are functional. This means the ESRD facility is responsible for delivering, installing, monitoring and maintaining supplies and equipment necessary to furnish all modalities of home dialysis.

All renal dialysis items and services described in this section were included under the composite rate and are included under the ESRD PPS. Therefore these items and services must be furnished by the ESRD facility, either directly or under arrangement. The ESRD facility is responsible for all renal dialysis items and services which include but is not limited to:

- *Medically necessary home dialysis equipment (see §20.4.A of this chapter);*
- *Home dialysis support services (see below), which include but is not limited to the delivery, installation, maintenance, repair and testing of home dialysis equipment and support equipment;*
- *Procurement and delivery of all necessary home dialysis supplies;*
- *ESRD-related laboratory tests;*
- *ESRD-related drugs and biologicals; and*
- *All dialysis services furnished by the ESRD facility's staff.*

*Some examples (but not an all-inclusive list) of renal dialysis items and services included in the ESRD PPS and may **not** be billed separately when furnished by an ESRD facility are:*

- *Staff time used to administer blood;*
- *Dec clotting of shunts and any supplies used to declot shunts;*
- *Oxygen and the administration of oxygen; and*
- *Staff time used to administer separately billable items.*

For additional information regarding conditions for coverage for home dialysis services, refer to 42 CFR §494.

A. Home Dialysis Hemodialysis and Peritoneal Support Services

Home dialysis support services identified at 42 CFR 494.100 may be furnished in the home or in the ESRD facility. Support services may be provided directly or via an agreement or arrangement with another approved ESRD facility. Support services include (but are not limited to):

1. *Periodic monitoring of a patient's adaptation to home dialysis and performance of dialysis, including provisions for visits to the home or the ESRD facility;*
2. *Emergency visits by qualified ESRD facility personnel;*
3. *Services provided by a qualified social worker and a qualified dietitian, made in accordance with a plan prepared and periodically reviewed by a professional team which includes the physician;*
4. *Individual's unscheduled visits to an ESRD facility made on an as-needed basis; e.g., assistance with difficult access situations;*
5. *ESRD-related laboratory tests covered under the ESRD PPS;*
6. *Providing, installing, repairing, testing, and maintaining home dialysis equipment, including appropriate water testing and treatment;*
7. *Ordering of supplies on an ongoing basis;*
8. **Maintaining and submitting all required documentation to the ESRD network;**
9. *A record keeping system that ensures continuity of care;*
10. *Changing necessary tubing;*
11. *Watching the patient perform dialysis to assure that it is done correctly and to review any aspects of the technique that may require modification; and*
12. *Inspecting the access site and document any access site infections that may require a physician intervention or hospitalization.*

The full range of home dialysis support services required by home patients are included in the ESRD PPS. ESRD support services must be furnished periodically. These services will usually be furnished during a periodic follow-up visit, but they may be furnished at separate times. They may be furnished in the ESRD facility or in the home.

***NOTE:** For additional information on renal dialysis services furnished on or after January 1, 2011, and paid under the ESRD PPS, refer to §20 of this chapter.*

B. In-facility Dialysis Sessions Furnished to Home Patients Who Are Traveling

Patients who are normally home dialysis patients may be dialyzed by a *Medicare* certified *ESRD* facility on an in-facility basis when traveling away from home. Patients who normally dialyze in *an ESRD* facility may wish to dialyze temporarily in another facility or as home dialysis patients while they travel or vacation. See Medicare Claims Processing Manual, Chapter 8, “Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” §100, for billing services when traveling.

C. Staff Assisted Home Dialysis

Effective January 1, 2011, renal dialysis services for patients receiving home dialysis may only be billed under Method I. Staff-assisted home dialysis using nurses to assist ESRD beneficiaries is not included in the ESRD PPS and is not a Medicare covered service.

If an entity wishes to bill Medicare for a non-covered ESRD-related service they provide to Medicare beneficiaries, they must first enroll with the appropriate Medicare contractor (assuming that Medicare recognizes such type of provider/supplier for billing purposes). Providers/suppliers must enroll in the jurisdiction(s) where they intend to provide services and follow the jurisdiction rules specified in Pub. 100-04, chapter 1, §10.

Once the ESRD facility is enrolled with the appropriate Medicare contractor(s), they should work with the contractor(s) to determine the appropriate code to bill for the service, if any. Finally, entities enrolled in Medicare as Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) suppliers may not bill the DME MACs for professional or quasi-professional services, including but not limited to nurse caregiver staff-assistance services. Instead, if a DMEPOS supplier is permitted under State law to furnish such services under its licensure and wishes to bill Medicare for such services, it must enroll with the appropriate Medicare contractor under such professional or quasi-professional service category as Medicare may recognize for Medicare billing purposes, if any.

For additional information, contact your appropriate Medicare contractor.

30.2 - Home Dialysis Training

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Self-dialysis and home dialysis training are programs *provided by Medicare certified ESRD facilities that educate ESRD patients and their caregivers* to perform self-dialysis in the *ESRD* facility or home dialysis (including CAPD and CCPD) with little or no professional assistance. *Self-dialysis training can occur in the patient's home or the in-facility when it is provided by the qualified staff of the ESRD facility. CMS expects that the patients who elect for home dialysis are good candidates for home dialysis training, and therefore, will successfully complete their method of training before reaching the maximum number of sessions allotted.* Dialysis training services are reimbursed in accordance with Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §50.8.

Home dialysis training services and supplies may include but are not limited to personnel services; dialysis supplies, parenteral items used in dialysis, written training manuals and materials, and ESRD-related laboratory tests. For more information on the requirements for ESRD facilities, see 42 CFR Part 494.

An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD. For information on how home dialysis training treatments are paid, see §60.C of this chapter.

NOTE: *ESRD facilities that are certified for home dialysis training and support services are expected to provide training throughout the home dialysis experience. Information regarding home dialysis training certification may be found at the following link: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>.*

A. Hemodialysis Training

The average training time for hemodialysis patients is *based upon* 5-hour sessions given 3 times per week. In some dialysis programs, the dialysis partner is trained to perform the dialysis treatment in its entirety. The patient plays a secondary role. In other programs, the patient performs most of the treatment and is only aided by a helper.

B. Intermittent Peritoneal Dialysis Training (IPD)

The IPD patients can be trained in approximately 4 weeks. IPD is usually accomplished in sessions of 10-12 hours. It is sometimes accomplished in fewer sessions of longer duration. In the IPD program, the patient's partner is usually trained to carry out the dialytic care. The patient plays a secondary or minimal role, as most are unable to perform self-care dialysis. IPD patients are usually unable to perform self-care dialysis because of other debilitating conditions.

C. Continuous Ambulatory Peritoneal Dialysis (CAPD) Training

The CAPD training is furnished in sessions that can last up to 8 hours (one session per day) 5 - 6 days per week. Typically, 6 - 8 CAPD exchanges can be performed per day for the purpose of teaching the patient the CAPD technique; however, no specific number of exchanges is required. Normally patients are trained within 2 weeks (5 - 6 training sessions per week); however, up to 15 sessions (i.e., 15 training days) may be covered routinely. Additional CAPD training sessions are covered only when documented for medical necessity. Extra training sessions raise questions about either the adequacy of CAPD for the patient or the patient's capacity to learn or perform the CAPD technique. The patient's physician should address these questions in the explanation of the need for extra training sessions. The *FI or A/B MAC* will make a determination whether or not to permit training sessions in excess of 15.

Once the patient is trained, CAPD is primarily a home service because the patient performs CAPD 24 hours a day. Therefore, renal dialysis services that are specifically CAPD services are training services and include associated services that are furnished in the ESRD facility during training. Persons who are primarily treated by CAPD may also require in-facility dialysis, either intermittent peritoneal or hemodialysis, occasionally.

*Prior to the implementation of the ESRD PPS, there were specific frequency coverage requirements of the routine laboratory services furnished for CAPD. The CAPD laboratory tests that were included under the composite rate are those monthly tests listed in (§20.2.E.1.b of this chapter) and they are covered during training. The coverage frequency screens for these laboratory tests *did not* apply during training, as these tests *were* commonly given during each training session. All of these tests *were* included in the training screen, regardless of how frequently they *were* given, and may *have been* billed separately. *Under the composite rate*, separately billable laboratory tests must *have been* documented for medical necessity. *However, under the ESRD PPS all renal dialysis laboratory services are included in the bundle regardless of the frequency they are furnished.**

Supplemental Dialysis during CAPD Training

It may be necessary to supplement the patient's dialysis during CAPD training with intermittent peritoneal dialysis because the patient has not yet mastered the CAPD technique. Generally, no more than three supplemental intermittent peritoneal dialysis sessions are required during the course of CAPD training, and these may be covered routinely. If more than three sessions are billed during training, the claims must be documented for medical necessity. Under certain circumstances, the form of supplemental dialysis may be hemodialysis.

D. Continuous Cycling Peritoneal Dialysis (CCPD) Training

Continuous cycling peritoneal dialysis training is furnished in sessions of 8 hours per day 5 days per week. Typically, five exchanges can be performed per day to teach the patient the technique; however, no specific number of exchanges is required. Most patients are trained within 2 weeks; however, up to 15 sessions may be covered routinely. The *FI or*

A/B MAC will determine whether or not training sessions over 15 are medically necessary.

E. Retraining

Payment is made for retraining self-dialysis education after a patient or caregiver has completed the initial program if the patient continues to be an appropriate candidate for home dialysis. Most patients receive additional training on the use of new equipment, a change in their caregiver, or a change in modality. The ESRD facility may not bill for retraining services when they install home dialysis equipment or furnish monitoring services. For example, an ESRD facility nurse may not bill for retraining sessions to update treatment records, order new supplies, or add additional medicine for the treatment of infection.

NOTE: *When retraining and educational services are furnished to a patient or caregiver already knowledgeable in some other form of self-dialysis or if training is being done for a change of equipment, fewer sessions are necessary because of the transferability of certain basic skills.*

Criteria for retraining are explained in greater detail in Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §50.8.

40 - Other Services

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

ESRD beneficiaries may receive other services that may be related to their ESRD diagnosis but are excluded from the ESRD PPS payment.

A. Coverage under the Home Health Benefit for ESRD Patients

Services that are covered under the ***ESRD PPS*** are excluded from coverage under the Medicare home health benefit.

Services can be provided to dialysis patients under the home health benefit as long as the condition that necessitates home health care is not ***ESRD-related***. A beneficiary, entitled to Medicare under the ESRD program, is eligible for home health benefits as is any other Medicare beneficiary if coverage conditions are met provided the patient's condition is not covered by the ***ESRD PPS***. This is true even where the primary condition is related to kidney failure. *For example, Medicare will pay for home health care, such as decubitus care or for severe hypotension that is not included in the ESRD PPS.*

Medicare patients can receive care under both the ESRD benefit and the home health benefit. *The key is whether or not the services are related to ESRD. Surgical dressing changes that are related to an ESRD condition are to be provided by the ESRD facility, but dressing changes for non-ESRD conditions may be provided under the home health benefit provided all eligibility criteria have been met. See 42 CFR 409.49(e).*

B. Coverage under the Hospice Benefit

If the patient's terminal condition is not related to ESRD, the patient may receive covered services under both the ESRD benefit and the hospice benefit. Hospice agencies can provide hospice services to patients who wish to continue dialysis treatment.

C. Skilled Nursing Facility (SNF) Patients Needing Dialysis Services

Section 4432(b) of the Balanced Budget Act (BBA) requires consolidated billing for SNFs. Dialysis and certain dialysis-related services including covered ambulance transportation to obtain the dialysis services are excluded from *SNF* consolidated billing and the services may be billed separately. *For more information regarding ESRD patients also receiving services in a SNF, see Pub. 100-02, chapter 8, §10.2 and Pub. 100-04, chapter 6, §20.2.1.*

D. Nursing Homes and/or Long Term Care Facility (LTC) Patients Needing Dialysis Services

Medicare ESRD beneficiaries who permanently reside in a nursing home or LTC facilities and who meet the home dialysis requirements set forth under 42 CFR §494.100 are considered home dialysis patients. All home dialysis items and services will be paid under the ESRD PPS and no separate payment will be made to the facility.

E. Physician's Services for ESRD Beneficiaries

Physician services are excluded from the ESRD PPS. Payment for physician's services is subject to the guidelines in Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, §30. Medicare pays physician's services furnished in connection with dialysis sessions for outpatients who are on maintenance dialysis in *an ESRD* facility or at home by the monthly capitation payment method or the initial method. *See Pub. 100-04, Medicare Claims Processing Manual, Chapter 8, for payment instructions. For physician responsibilities, refer to 42 CFR §414.310.*

F. The Sudden Onset of Acute Symptoms During Renal Dialysis Services

Renal dialysis services furnished in other settings, such as declotting of shunts, suture removal, or furnishing ESRD-related drugs may be paid separately only if the services could not have been furnished in the ESRD facility.

Emergency renal dialysis services furnished in a hospital emergency room are separately paid when medical justification is submitted on the claim and when the absence of immediate medical attention in the emergency room could reasonably be expected to result in either:

- *Placing the patient's health in serious jeopardy;*

- *Serious impairment to bodily functions; or*
- *Serious dysfunction of any bodily organ or part.*

G. Renal Dialysis Services Furnished During the Creation or Revision of a Vascular Access

The creation or revision of an ESRD patient's vascular access is usually performed in hospital outpatient departments. ESRD-related laboratory services, drugs and biologicals, and equipment and supplies furnished to ESRD beneficiaries on the day a procedure is performed to create or revise a vascular access site is not considered to be ESRD-related. Providers furnishing renal dialysis services that are subject to the ESRD PPS consolidated billing requirements during the creation or revision of a vascular access for an ESRD beneficiary should bill those services separately with an AY modifier. The appropriate HCPCS or CPT code indicating the creation or revision of an access site is required on the claim. Items and services that are subject to the ESRD PPS consolidated billing requirements may be found at http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage.

H. Noninvasive Vascular Studies for ESRD Patients

For dialysis to take place there must be a means of access so that the exchange of waste products may occur. As part of the dialysis treatment, ESRD facilities are responsible for monitoring access to determine if the access site is functioning correctly.

An ESRD facility must furnish all necessary services, equipment, and supplies associated with a dialysis treatment, either directly or under arrangements. The ESRD facility is financially responsible for the service. If an ESRD facility or a renal physician decides to monitor the patient's access site with a non-invasive vascular study and does not have the equipment to perform the procedure, the ESRD facility or physician may arrange for the service to be furnished by another source. The alternative source, such as an independent diagnostic testing facility must look to the ESRD facility for payment.

Procedures associated with monitoring access may include activities such as, but not limited to, taking venous pressure, aspirating thrombus, observing elevated recirculation time, reduced urea reduction ratios, or collapsed shunt, etc. All such procedures are included under the ESRD PPS. Non-invasive vascular studies such as duplex and Doppler flow scans are not covered as separately billable services if used to monitor a patient's vascular access site.

Doppler flow studies may be considered appropriate in the presence of signs or symptoms of possible failure of the ESRD patient's vascular access site, and when the results are used in determining the clinical course of the treatment for the patient. Routine monitoring by noninvasive Doppler flow studies is included under the ESRD PPS.

Examples supporting the medical necessity for Doppler flow studies include:

- *Elevated dynamic venous pressure >200mm HG when measured during dialysis with the blood pump set on a 200cc/min.,*
- *Access recirculation of 12 percent or greater,*
- *An otherwise unexplained urea reduction ratio <60 percent, and*
- *An access with a palpable “water hammer” pulse on examination, (which implies venous outflow obstruction).*

Unless the documentation is provided supporting the necessity of more than one study, Medicare will limit payment to either a Doppler flow study or an arteriogram (fistulogram, venogram), but not both. An example of when both studies may be clinically necessary is when a Doppler flow study demonstrates:

- *Reduced flow (blood flow rate less than 800cc/min or*
- *A decreased flow of 25 percent or greater from previous study) and*
- *The physician requires an arteriogram to define the problem.*

This policy is applicable to claims from ESRD facilities and all other sources, such as independent diagnostic testing facilities and hospital outpatient departments.

The professional component of the procedure is included in the MCP. The professional component is denied if billed by the MCP physician. Medically necessary services that are included or bundled into the MCP (e.g., test interpretations) are separately payable when furnished by physicians other than the MCP physician. The MCP physician is identified by the performing provider number that billed MCP services identified by the HCPCS code 90995.

I. Nutritional Services

ESRD facilities are required, in accordance with 42 CFR §494.80(a)(6) and §494.90(a)(2), to evaluate a patients’ nutritional status and expected to assist the patient in achieving their nutritional goals by providing education, counseling, and encouragement. These services are included in the ESRD PPS. Nutritional items, such as nutritional supplements, are not considered related to the treatment of ESRD and are not included in the ESRD PPS as renal dialysis services.

50 - ESRD Prospective Payment System (PPS) Base Rate (Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

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**

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

** 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 $24/7 \times 3$ 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 cyclor 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:

<i>Home CCPD HD-equivalent sessions</i>	<i>$21/7 \times 3 = 9$</i>
<i>In-center PD HD-equivalent sessions (limited to 3)</i>	<i>3</i>
<i>Total HD-equivalent sessions</i>	<i>12</i>

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. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

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.

<u>Adult Patient-Level Characteristics</u>	<u>Adjustment Value</u>
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

<i>Hereditary hemolytic or sickle cell anemia</i>	<i>1.072</i>
<i>Myelodysplastic syndrome</i>	<i>1.099</i>
<i>Monoclonal gammopathy</i>	<i>1.024</i>

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.

$$\begin{aligned}
 BMI_{\text{patient}} &= \text{weight}_{\text{kg}} / \text{height (m}^2\text{)} \\
 &= 95 / 1.8796^2 \\
 &= 95 / 3.5329 \\
 &= 26.89
 \end{aligned}$$

The formula for calculation of a patient's body surface area (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:

$$\begin{aligned}
 BSA_{\text{patient}} &= 0.007184 * 187.96^{.725} * 95^{.425} \\
 &= 0.007184 * 44.5346 * 6.9268 \\
 &= 2.2161
 \end{aligned}$$

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:

$$\begin{aligned} PM_{BSA} &= 1.020^{(2.2161-1.87)/0.1} \\ &= 1.020^{3.461} \\ &= 1.0709 \end{aligned}$$

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:

$$\begin{aligned} PM_{Patient} &= PM_{age} * PM_{BSA} \\ &= 1.013 * 1.0709 \\ &= 1.0848 \end{aligned}$$

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 \times 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 Body Mass Index (BMI) and Body Surface Area (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 $18.5\text{kg}/\text{m}^2$ which is a clinical measure of being underweight and an indicator of malnutrition.

*The formula for the calculation of the BSA is $\text{BSA} = w^{0.425} * h^{0.725} * 0.007184$ 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 $1.020^{(\text{BSA}-1.87)/0.1}$. 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 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_Comorbidty_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 four 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).*
- *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.

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

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 $(21/7) \times 3$ 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 Core-Based Statistical Area (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

The training add-on 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 is computed by using the national average hourly wage for nurses from the Bureau of Labor Statistics. For example, the amount for the training add-on under the ESRD PPS for CY 2011 was \$33.44 per treatment. This dollar amount reflects an hour of nursing time for each training treatment that is furnished and is adjusted by the geographic area wage index. The training add-on 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 that 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 are \$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:

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

<u><i>Pediatric Characteristics</i></u>	<u><i>Adjustment Value</i></u>
<i>Age: <13, Modality: PD</i>	<i>0.319</i>
<i>Age: <13, Modality: Hemo</i>	<i>1.185</i>
<i>Age: 13-17, Modality: PD</i>	<i>0.476</i>
<i>Age: 13-17, Modality: Hemo</i>	<i>1.459</i>

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 body surface area (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.

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

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

$$\begin{aligned} &66 \text{ years old: } 1.000, \text{ BSA: } 1.037, \text{ and GI bleeding: } 1.571: \\ &= 1.000 * 1.037 * 1.571 \\ &= 1.6291 \end{aligned}$$

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.

70 - ESRD PPS Transition Period

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

The ESRD PPS provides ESRD facilities a 4-year transition period under which the ESRD facilities receive a blend of payments comprised of the ESRD PPS and the basic case-mix adjusted composite payment system. For CY 2011 through 2013, CMS will continue to update the basic case-mix composite payment system for purposes of determining the composite rate portion of the blended payment amount, including adjusting payments for geographic differences in area wage levels. CMS continues to apply the budget neutrality adjustment to the wage index values for the composite rate portion of the ESRD PPS during the transition.

- As of January 1, 2011, the blended amount consists of 25 percent based on the ESRD PPS payment and 75 percent of the basic case-mix adjusted composite payment system.*
- For CY 2012, payment will be based on 50 percent of the payment rate under the ESRD PPS and 50 percent of the payment rate under the basic case-mix adjusted composite payment system.*
- For CY 2013, payment will be based on 75 percent of the payment rate under the ESRD PPS and 25 percent of the payment rate under the basic case-mix adjusted composite payment system.*
- For renal dialysis services furnished on or after January 1, 2014, payments to ESRD facilities will be based on 100 percent of the payment amount under the ESRD PPS. See §60 of this chapter for examples of how the ESRD PPS payment amount is calculated and see §50 of this chapter for more information to the ESRD PPS base rate.*

<i>Calendar Year</i>	<i>ESRD PPS Portion During Transition</i>	<i>Basic Case-Mix Adjusted Composite Payment System Portion During Transition</i>
<i>2011</i>	<i>25%</i>	<i>75%</i>
<i>2012</i>	<i>50%</i>	<i>50%</i>
<i>2013</i>	<i>75%</i>	<i>25%</i>
<i>2014 and beyond</i>	<i>100</i>	<i>0%</i>

A. ESRD PPS Portion of the Blended Payment

The ESRD PPS portion of the blended payment is comprised of the ESRD PPS base rate (which is adjusted by any applicable patient-level and facility-level case-mix adjusters and a wage index), any applicable training add-ons, and any applicable outlier payments. See §10.F.1 of this chapter for more on the ESRD PPS.

For CY 2011, the ESRD PPS base rate was adjusted by an ESRD market basket. For CY 2012 and all subsequent years, the ESRD PPS base rate is updated by an ESRD market basket minus a productivity adjustment. See §50.B of this chapter for more on the market basket.

The following table summarizes the features of the ESRD PPS portion of the blended payment rates for two different scenarios (adult and pediatric) in CY 2011.

<i>Feature</i>	<i>Adult Scenario</i>	<i>Pediatric Scenario</i>
<i>ESRD PPS base rate</i>	<i>Yes</i>	<i>Yes</i>
<i>Wage index adjustments</i>	<i>Yes, reflecting current wage data, including any applicable floor</i>	<i>Yes, reflecting current wage data, including any applicable floor</i>
<i>Patient-level case-mix adjustments</i>	<i>Yes, Adult</i>	<i>Yes, Pediatric</i>
<i>Low-volume adjustment</i>	<i>Yes, if applicable</i>	<i>No</i>
<i>Training add-on</i>	<i>Yes, if applicable</i>	<i>Yes, if applicable</i>
<i>Outlier payment</i>	<i>Yes, if applicable</i>	<i>Yes, if applicable</i>

B. Composite Rate Portion of the Blended Payment

Under the composite rate, hemodialysis is paid for at 3 treatments per week and peritoneal dialysis is paid based on hemodialysis equivalent sessions (see §50.A.1 and §50.A.4, respectively, of this chapter). For per treatment unit of payment information for hemofiltration, ultrafiltration, and IPD, respectively, see §50.A.2, §50.A.3, and §50.A.5. Additional composite rate payments 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. Additional information regarding home dialysis can be found in §30. ESRD facilities furnishing dialysis in-facility or in a patient's home are paid for up to 13 treatments during a 30 day month and 14

treatments during a 31 day month unless there is medical justification for additional treatments.

The composite rate portion of the blended payment rate is based on the payment amount under the basic case-mix adjusted composite payment system. It is comprised of the composite payment rate, which is adjusted by both the basic case-mix adjustments and a wage index.

The composite rate portion of the blended payment may include adjustments for:

- A drug add-on amount,
- Applicable home training add-ons for ESRD facilities going through the transition will continue to be paid the current training add-on rates of \$12 for CAPD and \$20 for CCPD and home hemodialysis for the portion of the blended payment that is based on the basic case-mix adjusted composite payment system. For more information on training and retraining, see §60.C.
- Payment amounts for renal dialysis services furnished to dialysis patients that were separately paid under Part B.
- Under the blended payment rate, the composite rate includes a \$0.49 per treatment amount to account for oral and other forms of injectable drugs that had previously been paid under Part D. Beginning in CY 2012, the composite payment rate is updated annually by applying a market basket minus a productivity adjustment factor.

As of January 1, 2011, CMS will not accept any new applications for composite rate exceptions. Those facilities with existing exceptions will continue with those exceptions, which do not include any case-mix adjustments. Any existing exceptions will terminate effective for ESRD treatments on or after January 1, 2014. In the event that an ESRD facility elects to receive full payment on or after January 1, 2011, any current exception will terminate. In the event that an ESRD facility receives payment under the transition period, any exceptions would be recognized for purposes of the basic case-mix adjusted composite payment system portion of the blended payment through the transition.

The following table presents the features of the composite rate portion of the blended payment rates for three different scenarios (adult, pediatric, and exception), using CY 2011 as the timeframe.

Feature	Adult Scenario	Pediatric Scenario	Exception Scenario
Rate Type	Composite payment rate	Composite payment rate	Exception rate (type and dollar amount unique to the ESRD facility)

<i>Rate updated by an ESRD market basket</i>	<i>Yes</i>	<i>Yes</i>	<i>No</i>
<i>Drug add-on adjustment</i>	<i>Yes</i>	<i>Yes</i>	<i>No</i>
<i>Case-mix adjustment(s)</i>	<i>Age, BSA, and BMI</i>	<i>Single pediatric adjustment factor</i>	<i>No</i>
<i>Wage index adjustments</i>	<i>Yes, reflecting current wage data, including any applicable floor</i>	<i>Yes, reflecting current wage data, including any applicable floor</i>	<i>No</i>
<i>Adjustment for ESRD-related drugs and biologicals previously paid under Part D</i>	<i>Yes</i>	<i>Yes</i>	<i>No</i>
<i>Training add-ons</i>	<i>Yes, if applicable</i>	<i>Yes, if applicable</i>	<i>Yes, but only applies to ESRD facilities that have exceptions for reasons other than training</i>
<i>Payment amounts for renal dialysis services furnished to dialysis patients that had been separately paid under Part B</i>	<i>Yes</i>	<i>Yes</i>	<i>Yes</i>

C. Transition Budget Neutrality Factor

An adjustment to payments for renal dialysis services provided by ESRD facilities during the transition will be made so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. The transition budget neutrality adjustment factor is applied to the blended payment amount if the ESRD facility is going through the transition. If the ESRD facility is not going through the transition, then the transition budget neutrality adjustment factor is applied to the ESRD PPS payment. The adjustment factor is addressed in the ESRD PPS through rulemaking during the transition period. After the transition period, the transition budget neutrality adjustment factor no longer applies.

80 - Bad Debt

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Bad debt payments will continue to be made for the unpaid Medicare deductibles and co-insurance amounts for only those items and services associated with the composite rate. For payments made under the ESRD PPS for items and services included in the composite rate and for drugs and laboratory tests, only the bad debt amounts associated

with the composite rate portion of the single ESRD payment rate will be used to determine an ESRD facility's allowable bad debt payments. A facility-specific composite cost percentage will be applied to the total bad debt amount associated with the ESRD PPS payment to compute the bad debt amount for only the composite rate services.

Bad debt payments for ESRD facilities will continue to be made in accordance with 42CFR413.89 and §413.178. However, effective January 1, 2013, the cap on bad debt reimbursement is no longer applied. General requirements and policies for payment of bad debts attributable to unpaid Medicare deductibles and co-insurance are found in chapter 3 of the Provider Reimbursement Manual, Part 1 (PRM) (CMS Pub. 15-1) and cost reporting worksheets and instructions in the PRM Part 2 (CMS Pub. 15-2).

90 – Medicare as a Secondary Payer (MSP)

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

The implementation of the ESRD PPS does not have an effect on the 30 month coordination period and MSP rules. See Pub. 100-05, Chapter 2, §20 for the MSP and coordination of benefit provisions that are applicable to ESRD beneficiaries.

100 Reserved

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

110 Reserved

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

120 Reserved

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

130 Reserved

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Appendix A

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Composite Rate Tests for Hemodialysis, IPD, CCPD, and Hemofiltration (Items in bold are non composite rate test)

Chemistry	CPT Code	Monthly	Weekly	13 x Quarter
Albumin	82040	X		
Alkaline Phosphates	84075	X		
ALT (SGPT)	84460			
AST (SGOT)	84450	X		
Bilirubin, total	82247			
Bilirubin, direct	82248			
Calcium	82310	X		
Calcium ionized (billed with modifier CD or CE)	82330	X		
Calcium ionized (billed with modifier CF)	82330	X		
Chloride	82435	X		
Cholesterol	82465			
CK, CPK	82550			
CO2 (bicarbonate)	82374	X		
Creatinine	82565		X	
GGT	82977			
Glucose	82947			
LDH	83615	X		
Phosphorus	84100	X		
Potassium	84132	X		
Protein, total	84155	X		
Sodium	84295			
Triglycerides	84478			
Urea nitrogen (BUN)	84520			X
Uric Acid	84550			

Appendix B

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Composite Rate Tests for CAPD (Items in bold are non composite rate test)

Chemistry	CPT Code	Monthly	Weekly	13 x Quarter
Albumin	82040	X		
Alkaline Phosphatase	84075	X		
ALT (SGPT)	84460			
AST (SGOT)	84450	X		
Bilirubin, total	82247			
Bilirubin, direct	82248			
Calcium	82310	X		
Calcium ionized (billed with modifier CD or CE)	82330	X		
Calcium ionized (billed with modifier CF)	82330	X		
Chloride	82435			
Cholesterol	82465			
CK, CPK	82550			
CO2 (bicarbonate)	82374	X		
Creatinine	82565	X		
GGT	82977			
Glucose	82947			
LDH	83615	X		
Phosphorus	84100	X		
Potassium	84132	X		
Protein, total	84155	X		
Sodium	84295	X		
Triglycerides	84478			
Urea nitrogen (BUN)	84520	X		
Uric Acid	84550			

Appendix C

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Brief History of ESRD Composite Payment Rates for Outpatient Maintenance Dialysis

Effective January 1, 2005, section 623 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) amended section 1881(b)(7) of the Act to require a 1.6 percent increase to the ESRD composite payment rate. The MMA also required a drug add-on adjustment to the composite payment rate to account for the difference between pre-MMA payments for separately billable drugs and payments based on revised drug pricing for 2005 which used average acquisition costs. For CY 2005, CMS computed a drug add-on adjustment of 8.7 percent.

Effective January 1, 2006, section 5106 of the Deficit Reduction Act of 2005 amended section 1881(b)(12) of the Act to require a 1.6 percent increase to the ESRD composite payment rate. In addition, because the drug add-on adjustment is determined as a percentage of the composite payment rate, CMS must adjust the drug add-on adjustment to account for the 1.6 percent increase to the composite payment rate in order to ensure that the total dollars allocated from the drug add-on adjustment remains constant. The growth update to the drug add-on adjustment of 1.4 percent was unchanged; therefore the total drug add-on adjustment to the composite payment rate for 2006 was 14.5 percent.

For dialysis services furnished on or after January 1, 2007 through March 31, 2007, the growth update to the drug add-on adjustment to the composite payment rate was 0.5 percent. As a result, the drug add-on adjustment to the composite payment rate for 2007 increased from 14.5 percent to 15.1 percent.

For dialysis services furnished on or after April 1, 2007, section 103 of the Tax Relief and Health Care Act of 2006 amended section 1881(b)(12) of the Act to require a 1.6 percent increase to the ESRD composite payment rate. The effect of the 1.6 percent increase to the composite payment rate was a reduction in the drug add-on adjustment from 15.1 percent to 14.9 percent.

Effective January 1, 2008, there was no increase to the composite payment rate however; the drug add-on adjustment to the composite payment rate was increased by a growth update of 0.5 percent. As a result, the drug add-on adjustment to the composite payment rate for CY 2008 increased from 14.9 percent to 15.5 percent.

Effective January 1, 2009, section 153 of the Medicare Improvements for Patients and Providers Act of 2008 amended section 1881(b)(12) of the Social Security Act to require a 1 percent increase to the ESRD composite payment rate and that hospital-based ESRD facilities are paid the same composite payment rate as independent ESRD facilities. The effect of the 1 percent increase in the composite payment rate is a reduction in the drug add-on adjustment from 15.5 percent to 15.2 percent.

Effective January 1, 2010, CMS continued to apply the growth update to the drug add-on adjustment to the composite payment rate, which was 0.percent. As a result, the drug add-on adjustment to the composite payment rate for 2010 was reduced from 15.2 to 15.0 percent. Also, as required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS applied a 1.0 increase to the ESRD composite payment rate.

Section 153 of the MIPPA amended section 1881(b)(12) of the Social Security Act to require a 4-year transition (phase-in) from the current composite payment system to the ESRD Prospective Payment System (PPS). Effective January 1, 2011, CMS continued to apply the growth update to the drug add-on adjustment to the composite payment rate portion of the blended payment rate, which was 0.percent. As a result, the drug add-on adjustment to the composite payment rate portion of the blended payment for 2010 is reduced from 15.0 to 14.7 percent. For a detailed description of the transition period, see §70 of this chapter.

For further information on the drug add on amounts for CY 2012 and 2013, see the respective ESRD final rules.

Effective 2014, the drug add-on will no longer be applied.

Future updates will be issued via Recurring Update Notifications.