CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13599	**Date: January 30, 2026**
	Change Request 13944

SUBJECT: Update to Pub. 100-02, Chapter 11 End-Stage Renal Disease (ESRD) through Calendar Year (CY) 2026

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update the End-Stage Renal Disease (ESRD) chapter in the Medicare Benefit Policy Manual to reflect the provisions up to CY 2026 ESRD Prospective Payment System (PPS) final rule.

EFFECTIVE DATE: May 1, 2026
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 1, 2026

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	11/ TOC/ Table of Contents
R	11/ 10/ Definitions Relating to End Stage Renal Disease Prospective Payment System
R	11/ 20/ Renal Dialysis Items and Services
R	11/ 20.1/ Composite Rate Items and Services
R	11/ 20.2/ Laboratory Services
R	11/ 20.3/ Drugs and Biological Products
R	11/ 20.3.1/ Drug Designation Process
R	11/ 20.4/ Equipment and Supplies
N	11/ 20.4.1/ Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)
N	11/ 20.4.2/ Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Eligibility Criteria
N	11/ 20.4.3/ Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) that are Capital-related Assets
R	11/ 30/ Home Dialysis
R	11/ 30.1/ Home Dialysis Items and Services
R	11/ 30.2/ Home Dialysis Training
R	11/ 40/ Other Services
R	11/ 50/ ESRD Prospective Payment System (PPS) Base Rate
N	11/ 50.1/ Inclusion of Calcimimetics in the ESRD PPS Base Rate
R	11/ 60/ ESRD PPS Case-Mix Adjustments
D	11/ 70/ Reserve for future use
R	11/ 80/ Bad Debt
R	11/ 100/ Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)
R	11/ 100.4/ Other Adjustments to the AKI Dialysis Payment Rate
R	11/ 100.5/ Renal Dialysis Services Included in the AKI Dialysis Payment Rate
R	11/ 100.6/ Applicability of Specific ESRD PPS Policies to AKI Dialysis
R	11/ 100.6.1/ Dialysis Modality
R	11/ 100.6.2/ Uncompleted Dialysis Treatment

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	11/ 100.6.3/ Home and Self-Dialysis
R	11/ 100.6.4/ Vaccines and Their Administration
R	11/ 100.6.5/ Telehealth
R	11/ 100.6.6/ ESRD Conditions for Coverage (CfCs)
N	11/ 100.6.7/ Payment for Erythropoietin Stimulating Agents (ESAs) and the ESA Monitoring Policy for AKI Patients
N	11/ 100.6.8/ Transition from AKI to ESRD
N	11/ 100.6.9/ Transitional Drug Add-On Payment Adjustment (TDAPA) and Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)
R	11/ 140/ Kidney Transplantation
R	11/ 140.1/ Identifying Candidates for Kidney Transplantation
R	11/ 140.2/ Identifying Suitable Living Kidney Donors
R	11/ 140.3/ Pre-transplant Outpatient Services
R	11/ 140.4/ Pre-transplant Inpatient Services
R	11/ 140.5/ Living Kidney Donor Evaluation, Patient Has Entitlement or is in Pre-entitlement Period
R	11/ 140.6/ Kidney Recipient Admitted for Transplant Evaluation
R	11/ 140.7/ Kidney Recipient Evaluated for Transplant During Inpatient Stay
R	11/ 140.8/ Kidney Recipient Admitted for Transplantation and Evaluation
R	11/ 140.9/ Post-transplant Services Provided to Living Kidney Donor
R	11/ 140.10/ Coverage After Kidney Recipient Has Exhausted Part A
R	11/ 140.11/ Deceased Donor Kidneys Acquisition Costs
R	11/ 140.12/ Services Involved
R	11/ 140.13/ Tissue Typing Services for Deceased Donor Kidney
R	11/ 140.14/ Kidneys Procured En Bloc
R	11/ 140.15/ Provider Costs Related to Deceased Donor Kidney Excisions
R	11/ 140.16/ Non-covered Transplant Related Items and Services
R	11/ 140.17/ Other Covered Services
R	11/ 140.18/ Hospitals that Excise but Do Not Transplant Kidneys

III. FUNDING:

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

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-02	Transmittal: 13599	Date: January 30, 2026	Change Request: 13944

SUBJECT: Update to Pub. 100-02, Chapter 11 End-Stage Renal Disease (ESRD) through Calendar Year (CY) 2026

EFFECTIVE DATE: May 1, 2026
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 1, 2026

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update the End-Stage Renal Disease (ESRD) chapter in the Medicare Benefit Policy Manual to reflect the provisions up to CY 2026 ESRD Prospective Payment System (PPS) final rule.

II. GENERAL INFORMATION

A. Background: Effective January 1, 2011, CMS implemented the ESRD PPS based on the requirements of section 1881(b)(14) of the Social Security Act (the Act). The ESRD PPS provides a single per treatment payment to ESRD facilities that covers all the resources used in furnishing an outpatient dialysis treatment. The ESRD PPS base rate is adjusted to reflect patient and facility characteristics that contribute to higher per treatment costs.

In accordance with section 1834(r) of the Act, as added by section 808(b) of the Trade Preferences Extension Act of 2015, CMS pays ESRD facilities for furnishing renal dialysis services to Medicare beneficiaries with Acute Kidney Injury (AKI). CR 9598 implemented the payment for renal dialysis services and provides detailed information regarding payment policies.

The ESRD PPS includes consolidated billing requirements for limited Part B services included in the ESRD facility's bundled payment. CMS periodically updates the lists of items and services that are subject to Part B consolidated billing and are therefore no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

The ESRD PPS includes the Transitional Drug Add-on Payment Adjustment (TDAPA) and the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

B. Policy: This transmittal is solely an update to Chapter 11 of the Benefit Policy Manual. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements for the ESRD PPS, renal dialysis payments for patients with AKI, ESRD Quality Incentive Program (QIP), and ESRD Treatment Choices (ETC) model were promulgated through past notice and comment rulemaking and in Change Requests 9807, 10312, 11021, 11244, 11506, 11869, 12011, 12188, 12347, 12499, 12978, 13445, 13865, 14313. Specific policy changes for organ acquisition payment were effectuated in the Fiscal Year (FY) 2022 inpatient prospective payment system final rule with comment period (86 FR 73468 through 73505) and the CY 2023 outpatient prospective payment system final rule with comment period (87 FR 72150 through 72159).

III. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13944.1	Contractors shall make providers aware of the revisions made to Pub. 100-02, chapter 11 ESRD Benefit Policy Manual in all sections.	X	X							

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part A, A/B MAC Part B, A/B MAC Part A

V. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

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

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

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

ATTACHMENTS: 0

Medicare Benefit Policy Manual
Chapter 11 - End Stage Renal Disease (ESRD) *and Acute Kidney Injury (AKI)*

Table of Contents
(Rev.13599 , Issued: 01-30-26)

10 - Definitions Relating to *End-Stage Renal Disease Prospective Payment System and Acute Kidney Injury Dialysis Payment*

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

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. *At this advanced stage of kidney disease, the kidneys do not perform effectively and dialysis or a kidney transplant is needed to live.* The loss of kidney function in ESRD is usually irreversible and permanent.

The term "individual with acute kidney injury" means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) of the Social Security Act (the Act).

Renal dialysis services furnished to hospital in-patients are covered under Medicare Part A and paid in accordance with applicable payment rules. *Renal dialysis services furnished by ESRD facilities to individuals with ESRD who need outpatient dialysis are covered under Medicare Part B and paid under the ESRD Prospective Payment System (PPS). Medicare Part B also covers and pays for AKI dialysis, as discussed in §10.E.3 of this chapter.*

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 Centers for Medicare *&* Medicaid Services *(CMS)* website: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>.

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 *(dialyzer)*. *This process involves using a bath solution known as dialysate to remove waste products from the blood.* Dialysis procedures can include*: 1)* hemodialysis*; 2)* peritoneal dialysis*; 3)* hemofiltration*;* and *4)* ultrafiltration. Of these types of dialysis procedures*, the* two *most* commonly used for the treatment of ESRD *are* hemodialysis and peritoneal dialysis.

1. Hemodialysis *– In Hemodialysis, b*lood passes *from the access site* through an artificial kidney machine and the waste products diffuse across a man-made membrane *(dialyzer)* into a bath solution *(*dialysate*),* after which the cleansed blood is returned to the patient's body. Hemodialysis is usually *accomplished* in 3 to 5-hour *sessions with an average of 4 hours per session*, 3 times a week. *Hemodialysis paid for under the ESRD PPS can be performed in an ESRD facility or at home.* See §50.A.1 of this chapter for payment information *related to hemodialysis*.

2. Peritoneal – *In Peritoneal dialysis, w*aste products *are* pass*ed* from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity*. A* bath solution (dialysate) is introduced *into the body* and removed periodically *to extract the waste products*. See §50.A.4 of this chapter for payment information *related to peritoneal dialysis*.

The three types of peritoneal dialysis are listed below:

a. Continuous Ambulatory Peritoneal Dialysis (CAPD) - In CAPD, *the dialyzer is* the patient's peritoneal membrane. The patient connects a 2-liter plastic bag of dialysate to a surgically implanted indwelling catheter *(a synthetic tube is placed into the abdominal cavity)* that allows the dialysate to pour into the *patient'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 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 are performed manually during the day by the patient on CAPD, *but for the patient on CCPD the solution exchanges occur instead at night* and are performed automatically with a peritoneal dialysis cycler. Generally, there are three nocturnal exchanges occurring at intervals of 2 1/2 to 3 hours. Upon awakening, the patient disconnects from the cycler 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. *IPD is* generally 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 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 (AV)* 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 *by exerting pressure* through a dialysis membrane. 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 *(collection of fluid that is unresponsive to maintenance dialysis)*. 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. *Per s*ection 1881 of the Act*, ESRD facilities are designated* in 42 CFR *§* 413.174 as being either hospital-based or independent facilities. There is no distinction between the two facility types for payment *purposes* under the ESRD PPS.

1. Hospital-Based ESRD Facilities

In accordance with 42 CFR *§§* 413.65(a) *and 413.174(c),* hospital-based ESRD facilities *may be located on a hospital campus and may share certain overhead costs and administrative functions with the hospital but* do not qualify as provider-based departments of a 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 *all of the following criteria are met*:

- 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 (*e.g.*, 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 following to mean that an ESRD facility is hospital based:* 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.

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

The following **are** ***some*** **terms used to describe independent** ***ESRD*** **facilities:**

a. Renal Dialysis Facility - An independent, *Medicare-certified* unit that is approved to furnish outpatient maintenance dialysis services directly to ESRD patients *and individuals with AKI*. Under the ESRD PPS, CMS refers to renal dialysis facilities as ESRD facilities.

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

c. 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.

d. Special Purpose Renal Dialysis Facility – A *Medicare-certified* 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 to individuals for the treatment of ESRD in the ESRD facility or in a beneficiary's home.

Renal dialysis services include but are not limited to:

- All items and services included under the composite rate *for renal dialysis services* as of December 31, 2010 (see §20.2.E, §20.3.F, and §70.B of this chapter for more information);
- Erythropoiesis stimulating agents (ESAs) and their oral or other forms of administration (see §20.3.A of this chapter for more information);
- Injectable drugs and biological *products* and their oral or other forms of administration *furnished for the treatment of ESRD* (see §20.3.B, §20.3.C and §20.3.D of this chapter for more information);
- *N*on-injectable drugs and biological *products and other forms of administration with no injectable functional equivalent furnished for the treatment of ESRD* (*effective January 1, 2025,* see §20.3 of this chapter for more information);
- 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 *beneficiary's* dialysis furnished in the ESRD facility or in a *beneficiary'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.

D. 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 *this type of* arrangement, the first ESRD facility retains professional and financial responsibility for those services and also for *billing Medicare* 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.

E. Types of Dialysis

1. Outpatient Maintenance Dialysis - Outpatient maintenance dialysis is furnished *to ESRD patients* on an outpatient basis by a Medicare certified ESRD facility and is paid under the ESRD PPS.

Types of outpatient maintenance dialysis include:

a. In-*F*acility Dialysis - Dialysis furnished on an outpatient basis in a Medicare-certified ESRD facility. *This could include staff-assisted dialysis, self-dialysis, or nocturnal dialysis provided at an ESRD facility.*

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

e. *Nocturnal Dialysis – Dialysis performed overnight at home or in-facility for >5 hours per treatment, 3-7 days a week*.

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

3. Acute Kidney Injury (AKI Dialysis) *– AKI dialysis is furnished to individuals with AKI on an outpatient basis by a Medicare certified ESRD facility or a hospital outpatient dialysis unit. When AKI dialysis is furnished in a Medicare certified ESRD facility, it is paid under the ESRD PPS. When AKI dialysis is furnished in a hospital outpatient dialysis unit, it is paid under the hospital outpatient prospective payment system.*

For billing and payment instructions for AKI dialysis furnished in a hospital outpatient dialysis unit see Pub. 100-04, chapter 4, §200.2 and Pub. 100-02, chapter 1, section 10. Payment policy for AKI dialysis in an ESRD facility is available in section §100.2 of this chapter.

F. 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 renal dialysis supplies and equipment, the supplier may seek payment only from the ESRD facility and may not bill Medicare or the patient for separate payment.

The ESRD facility may not bill the beneficiary directly for *any* renal dialysis supplies, services, or equipment. For further discussion on *ESRD PPS* 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, *for example:* 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 facility or a *skilled nursing facility*. 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. *Disposal of equipment is also included.*

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 *(but is not limited to):* 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 – *Home dialysis support services identified at 42 CFR §§ 410.52 and 494.100 may be furnished in the home or in the ESRD facility. These services include (but are not limited to): Monitoring home dialysis progress, emergency visits to the home by ESRD facility personnel, unscheduled visits to an ESRD facility as needed and renal dialysis laboratory tests covered under the ESRD PPS.* See §30.1.A of this chapter *for more information*.

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.

G. Overview of Medicare's ESRD Payment Policy

1. 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 rate payment system and the methodologies for the reimbursement of separately billable outpatient renal dialysis items and services.

The ESRD PPS provides a case-mix and facility-level 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 for the items and services considered to be *"*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 and self-dialysis training and an outlier payment.

The ESRD PPS provided for a 4-year transition period under which facilities may have received 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. *Since* 2014, all ESRD facilities that receive Medicare payment *have been* paid 100 percent under the ESRD PPS.

The ESRD PPS combines payment, for what had previously been composite rate and separately billable outpatient renal dialysis 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 patient adjustments and §60.A.6 of this chapter for pediatric patient adjustments)
  - An onset of dialysis adjustment for adult patients that have Medicare ESRD *entitlement* during their initial 4 months of dialysis, (see §60.A.4 of this chapter)
- Facility-level adjustments for:
  - A low-volume facility adjustment for ESRD facilities that meet certain criteria, (see §60.B.1 of this chapter)
  - A wage index adjustment to reflect differences in wage levels among the urban and rural areas in which ESRD facilities are located, (see §60.B.2 of this chapter)
  - A rural adjustment, effective January 1, 2016
- Other adjustments:
  - A home or self-dialysis training add-on, (see §60.C.*1* of this chapter)
  - An outlier payment, (see §60.D of this chapter)
  - *A transitional drug add-on payment adjustment (TDAPA), (see §20.3.1.C of this chapter)*
  - *A transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES), (see §20.4.1 of this chapter)*
  - *A post-TDAPA add-on payment adjustment, (see §60.C.5 of this chapter)*
  - *A transitional pediatric ESRD add-on payment adjustment (TPEAPA), (see §60.C.6 of this chapter)*

The ESRD PPS implemented consolidated billing edits for certain renal dialysis laboratory services, drugs and biological *products*, equipment, and supplies to ensure that payment for renal dialysis services is not made to *providers or suppliers* other than the ESRD facility. A service furnished by an ESRD facility that is not for the treatment of ESRD must be submitted with an AY modifier to allow for separate payment outside of the ESRD PPS. The list of renal dialysis services identified 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 *exhaustive*, and ESRD facilities are responsible and *are paid* for furnishing all renal dialysis services under the ESRD PPS.

2. Basic Case-Mix Adjusted Composite Rate Payment System – The basic case-mix adjusted composite rate payment system was implemented in CY 2005 and maintained until 2014 for purposes of the blended payment during the ESRD PPS transition period. It applied patient-level case-mix adjusters, additional payment for home and self-dialysis training, and a drug add-on to the composite rate.

The drug add-on accounted for the difference between the methodologies of payment for separately billed drugs and biological *products* prior to the enactment of the revised drug pricing specified in the Medicare Modernization Act of 2003 (MMA). For more information on the history of the composite rate see Appendix C.

3. Composite Rate –The composite rate was the first step Medicare made toward creating a bundled payment for renal dialysis items and services. It covered routine laboratory testing, certain drugs, equipment and supplies, and support services furnished for outpatient maintenance dialysis in Medicare-certified ESRD

facilities. Under the composite rate methodology, separate payment was made to ESRD facilities for most drugs and biological *products* furnished to ESRD patients. 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.

4. Formerly Separately Billable Services (FSBs) *– Services which were not included in the composite rate and were therefore separately billable while the composite rate system was in effect before the ESRD PPS was implemented on January 1, 2011. FSBs are included in the ESRD PPS bundled payment. FSBs consist mainly of certain drugs and biological products and certain laboratory tests furnished for the treatment of ESRD, including ESAs.*

5. "Time on Machine" Data *– Beginning January 1, 2025, ESRD facilities must report "time on machine" data (the number of minutes between the start and end of hemodialysis treatment, without accounting for interruptions, a beneficiary receives during the billing period in center in an ESRD facility) using the D6 value code on ESRD PPS claims for all in-center hemodialysis treatments. The CY 2024 ESRD PPS final rule finalized the addition of § 413.198(b)(5), which states that ESRD facilities must submit data and information in the formats established by CMS for the purpose of estimating patient-level and facility level variation in resource use, including "time on machine" data.*

20 - Renal Dialysis Items and Services

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

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

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 *or in the patient's home* 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 *renal* dialysis treatment include:

- Laboratory *t*ests;
- Drugs and *b*iological *products*;
- Equipment and supplies - dialysis machine use and maintenance;
- Personnel services;
- Administrative services;
- Overhead costs;
- Monitoring access and related de-clotting or referring the patient, and
- Direct nursing services*, which* include registered nurses, licensed practical nurses, technicians, social workers, and dietitians.

20.1 - Composite Rate Items and Services

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

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.

Historically the composite payment rate (defined at §10.G.3 of this chapter) was the methodology for paying for dialysis services. The composite rate was a comprehensive payment for all modes of in-facility and home dialysis. On January 1, 2011, the composite rate was incorporated into the ESRD PPS payment methodology. Most items and services related to the treatment of the patient's end-stage renal disease were covered under the composite rate payment*, except* physicians' professional services, separately billable laboratory services, and separately billable drugs. If a facility*, either directly or under an arrangement,* failed to furnish 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 co-insurance requirements.

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

- Dialysate;
- Cardiac monitoring;
- Catheter changes;
- Suture removal;
- Dressing changes;

- Crash cart usage for cardiac arrest;
- De-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 to administer separately billable parenteral items; and
- Staff time to collect specimens for laboratory tests.

20.2 - Laboratory Services

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

All laboratory services furnished to individuals for the treatment of ESRD are included in the ESRD PPS *and* are not paid separately as of January 1, 2011. *Payments for these services were incorporated into the ESRD PPS base rate.* The laboratory services include, but are not limited to:

- Laboratory tests included under the composite rate as of December 31, 2010 (discussed below); and

- *Formerly* 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 following table lists the drug categories that were excluded from the ESRD PPS and the rationale for their exclusion. Laboratory services furnished to monitor the medication levels *of these* drugs and biological *products* would not be considered *for* the treatment of ESRD. *For example, laboratory testing for anti-psychotics is not included in the ESRD PPS. However, laboratory testing for drugs that regulate bone and mineral metabolism (e.g., calcimimetics) is included.*

DRUG CATEGORIES EXCLUDED FROM THE ESRD PPS BASE RATE FOR THE PURPOSE OF REPORTING *LABORATORY TESTS*

Drug Category	Rationale for Exclusion
Anticoagulant	Drugs labeled for non-renal dialysis conditions and not for vascular access.
Antidiuretic	Used to prevent fluid loss.
Antiepileptic	Used to prevent seizures.
Anti-inflammatory	May be used to treat kidney disease (glomerulonephritis) and other inflammatory conditions.
Antipsychotic	Used to treat psychosis.
Antiviral	Used to treat viral conditions such as shingles.
Cancer management	Includes oral, parenteral and infusions. Cancer drugs are covered under a separate benefit category.
Cardiac management	Drugs that manage blood pressure and cardiac conditions.
Cartilage	Used to replace synovial fluid in a joint space.
Coagulants	Drugs that cause blood to clot after anti-coagulant overdose or factor VII deficiency.
Cytoprotective agents	Used after chemotherapy treatment.

Drug Category	Rationale for Exclusion
Endocrine/metabolic management	Used for endocrine/metabolic disorders such as thyroid or endocrine deficiency, hypoglycemia, and hyperglycemia.
Erectile dysfunction management	Androgens were used prior to the development of ESAs for anemia management and currently are not recommended practice. Also used for hypogonadism and erectile dysfunction.
Gastrointestinal management	Used to treat gastrointestinal conditions such as ulcers and gallbladder disease.
Immune system management	Anti-rejection drugs covered under a separate benefit category.
Migraine management	Used to treat migraine headaches and symptoms.
Musculoskeletal management	Used to treat muscular disorders such as prevent muscle spasms, relax muscles, improve muscle tone as in myasthenia gravis, relax muscles for intubation and induce uterine contractions.
Pharmacy handling for oral anti-cancer, anti-emetics and immunosuppressant drugs	Not a function performed by an ESRD facility.
Pulmonary system management	Used for respiratory/lung conditions such as opening airways and newborn apnea.
Radiopharmaceutical procedures	Includes contrasts and procedure preparation.
Unclassified drugs	Should only be used for drugs that do not have a HCPCS code and therefore cannot be identified.
Vaccines	Covered under a separate benefit category.

The distinction of what is considered to be a *"*renal dialysis laboratory test*"* is a clinical decision determined by the ESRD patient's ordering practitioner. If a laboratory test is ordered for the treatment of ESRD, then the laboratory test is not paid separately.

Payment for all renal dialysis laboratory tests furnished under the ESRD PPS is *included in the base rate, which is paid* 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 *such* tests on the ESRD facility claim.

An ESRD facility must report renal dialysis laboratory services on its claims in order for the laboratory tests to be included in the outlier payment calculation *(with the exception of composite rate laboratory tests)*. Renal dialysis 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 are subject to Part B consolidated billing requirements and are no longer separately payable when provided to ESRD beneficiaries by providers other than the ESRD facility. The list *at the following website* includes the renal dialysis laboratory tests that are routinely performed for the treatment of ESRD *and that are used to enforce consolidated billing edits to ensure that payment is not made for renal dialysis laboratory tests outside of the ESRD PPS: < https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.>* Payment for the laboratory tests identified on this list is included in the ESRD PPS. If any laboratory test is ordered for the treatment of ESRD, then the laboratory test is considered to be included in the ESRD PPS

and is the responsibility of the ESRD facility. Additional renal dialysis laboratory tests may be added *to the consolidated billing list* through administrative issuances in the future.

A. Laboratory Services Furnished for Reasons Other Than for the Treatment of ESRD

1. Independent Laboratory

A patient's physician or practitioner *responsible for their ESRD care* may order a laboratory test that is included on the list of items and services subject to consolidated billing edits for reasons other than for the treatment of ESRD. 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 *Amendments*) that furnished the laboratory service that the test is not a renal dialysis service*, so* 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.

***NOTE**: The ESRD PPS base rate accounts for all ESRD facility staff time during a dialysis session. Therefore, ESRD facility staff time used to furnish laboratory services for reasons other than for the treatment of ESRD is included in the ESRD PPS and is not billed separately.*

2. Hospital-Based Laboratory

Hospital outpatient clinical laboratories furnishing renal dialysis laboratory tests to ESRD patients for reasons other than 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.

***NOTE**: The ESRD PPS base rate accounts for all ESRD facility staff time during a dialysis session. Therefore, ESRD facility staff time used to furnish laboratory services for reasons other than for the treatment of ESRD is included in the ESRD PPS and is not billed separately.*

B. 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 as a renal dialysis service. 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 a renal dialysis 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 the 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 *an emergency room or department to bypass consolidated billing edits for laboratory testing* does not mean that ESRD facilities should send patients to other settings for routine laboratory testing for the purpose of *avoiding* financial responsibility *for* renal dialysis 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.

C. Hepatitis B Laboratory Services for Transient Patients

Laboratory testing for hepatitis B is a renal dialysis 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 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.

D. Laboratory Services *Routinely Furnished* Under *the* Composite Rate *Payment System*

*Historically (i.e., p*rior 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. 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.

The following three sections discuss laboratory tests that, prior to the ESRD PPS, were furnished to ESRD beneficiaries on a routine basis under the composite rate payment system. Some laboratory tests were included in the composite payment rate and some were separately payable.

Under the ESRD PPS, to the extent any of the laboratory tests discussed below are furnished for the treatment of ESRD and were included in the composite payment rate, these tests are not eligible for outlier payment and are not reported on the ESRD claim.

Note: There are no requirements under the ESRD PPS regarding frequency, as it relates to payment for renal dialysis laboratory tests. Laboratory tests should be ordered as medically necessary and should not be restricted due to financial reasons.

1. *Laboratory tests routinely furnished and included in the composite payment rate when they met coverage requirements with regard to frequency*

If any of these tests were performed at a frequency greater than that specified, the additional tests were separately billable *but* covered only if they *were reasonable and medically necessary.*

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; *and*
- 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.

b. CAPD

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

2. *Laboratory tests routinely furnished that were separately payable to the ESRD facility and not included in the composite payment rate*

- Hemodialysis, IPD, CCPD, and Hemofiltration
    - Serum Aluminum - one every 3 months
    - Serum Ferritin - one every 3 months
- CAPD
    - WBC, RBC, and Platelet count – One every 3 months
    - Residual renal function and 24-hour urine volume – One every 6 months

3. Automated Multi-Channel Chemistry (AMCC) Tests

Clinical diagnostic laboratory tests that comprise the AMCC (listed in Appendix A and B) could *either* be considered *included in the* composite *payment* rate *or considered to be non-composite rate (that is, separately billable)* laboratory services. 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.

Under the composite payment system prior to 2011, 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 A/B *Medicare Administrative Contractor (*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.

20.3 - Drugs and Biological *Products*

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

*Except as noted below, a*ll drugs and biological *products* used for the treatment of ESRD are included in the ESRD PPS and are not separately paid as of January 1, 2011*, as payments for these items were incorporated into the base rate*. The drugs and biological *products* include, but are not limited to:

- *Renal dialysis drugs* and biological *products* included under the composite rate as of December 31, 2010 (discussed below);
- Former separately billable Part B injectable drugs *and biological products used for the treatment of ESRD*;
- Oral or other forms of drugs *and biological products with an injectable functional equivalent* used for the treatment of ESRD formerly billed under Part D; and
- Oral or other forms of drugs and biological *products used for the treatment of ESRD* without an injectable *functional* equivalent (*effective* January 1, 2025.)

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

Drugs and biological *products* furnished to ESRD beneficiaries that are not used for the treatment of ESRD may be paid separately. When drugs or biological *products* are furnished to an ESRD beneficiary and are not a renal dialysis service, the ESRD facility or other provider *can* append the claim *line* 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 biological *products* identified for consolidated billing are *always considered to be* renal dialysis services *when furnished by the ESRD facility or physician receiving the Monthly Capitation Payment (MCP) (discussed in §40.E of this chapter),* and therefore no separate payment is made to ESRD facilities *with or without the AY modifier. With regard to* other providers *and suppliers,* when these *products* are furnished to ESRD beneficiaries *they are usually not separately payable. That is, other providers and suppliers furnishing drugs and biological products subject to the ESRD PPS consolidated billing could only receive separate payment under another payment system in certain circumstances: For example, if the drug or biological product was furnished for other labeled indications or the ESRD beneficiary received emergency dialysis in a hospital. Information regarding consolidated billing requirements for drugs and biological products can be found in §20.3.F of this chapter and in Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1.*

The list of drugs and biological *products* 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. *This list is used to enforce consolidated billing edits, which ensure that payment is not made outside of the ESRD PPS for these renal dialysis drugs and biological products.* ***This is not an all-inclusive list, and any drug or biological product that falls within an ESRD PPS functional category is also included under the ESRD PPS*** *(see §20.3.A below).* ***Providers*** *and suppliers other than ESRD facilities furnishing those drugs and biological products for the treatment of ESRD must look to the ESRD facility for payment.*

NOTE: Effective January 1, 2012, *and January 1, 2013,* ESRD facilities and other providers may receive separate payment for vancomycin *and daptomycin, respectively,* by placing the AY modifier on the claim, when *the drug* is furnished for reasons other than the treatment of ESRD. The ESRD facility must indicate the appropriate ICD diagnosis code for which the vancomycin *or daptomycin* is indicated.

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

A. ESRD PPS Functional Categories

The ESRD PPS functional category is a distinct grouping of drugs *or* biological *products*, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. The Drug Designation Process is dependent on the *ESRD PPS* functional categories, as discussed in section 20.3.1.

Drugs and biological *products included in the ESRD PPS base rate that are "*always*"* considered to be renal dialysis services are those used for access management, anemia management, bone and mineral metabolism management, and cellular management. ESRD facilities are responsible for furnishing these drugs directly or under arrangement. This includes any drug or biological *product* that is furnished *by* the ESRD facility *either in the facility or taken by the patient at home.*

Erythropoiesis stimulating agents (ESAs), such as epoetin alfa (EPOGEN®) and darbepoetin alfa (ARANESP®), when furnished *by an ESRD facility,* are always considered to be renal dialysis services and included in the ESRD PPS. *Prior to January 1, 2020, monthly* dosages of these ESAs *were* subject to Medicare's ESA claims monitoring policy *as discussed in Pub.100-04, Medicare Claims Processing Manual, chapter 8, §60.4.1. Prior to January 1, 2020, edits were applied prior to pricing so that ESAs were not overvalued in determining eligibility for outlier payments.*

Effective January 1, 2020, the ESA monitoring policy is no longer applicable under the ESRD PPS.

Functional Categories Included in the ESRD PPS Base Rate, Always Considered to be Renal Dialysis Services, and Not Separately Payable *for ESRD Facilities*

***ESRD PPS Functional* Category**	***Description and Examples***
Access Management	Drugs*/biological products* used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs*/biological products* used to stimulate red blood cell production and/or treat or prevent anemia. *Examples of drugs/biological products in t*his category include ESAs *and* iron.
Bone and Mineral Metabolism	Drugs*/biological products* used to prevent/treat bone disease secondary to dialysis. *Examples of drugs/biological products in t*his category include phosphate binders and calcimimetics.
Cellular Management	Drugs*/biological products* used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.

Drugs and *biological products* included in the ESRD PPS base rate that may be used for both the treatment of ESRD and for reasons other than the treatment of ESRD are those used as antiemetics, anti-infectives, antipruritics, anxiolytics, excess fluid management, fluid and electrolyte management *(*including volume expanders*)*, and pain management. ESRD facilities are responsible for furnishing these drugs directly or

under arrangement when they are prescribed for the treatment of ESRD. This includes any drug or biological *product* that is furnished in the ESRD facility or taken by the patient outside of the ESRD facility.

ESRD facilities are responsible for furnishing antibiotics for access site infections directly or under arrangement. 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 for the purposes of vascular access-related and peritonitis infections.

Any other drugs *or biological products* (other than those categories described above and below), when used for the treatment of ESRD, are also included in the ESRD PPS. For example,

- Patient A experiences nausea or pain during a hemodialysis treatment and requires medications. Any medication furnished during the dialysis treatment or after the treatment is considered a renal dialysis service 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 medication furnished in preparation for the dialysis treatment, during the dialysis treatment or after the dialysis treatment, is considered a renal dialysis service and may not be billed separately.

- Any drug or biological *product* added to patient dialysate solutions.

Functional Categories Included in the ESRD *PPS* Base Rate but May be Used for Dialysis and Non-Dialysis Purposes

***ESRD PPS Functional* Category**	***Description and Examples***
Antiemetic	*Drugs/biological products u*sed to prevent or treat nausea and vomiting *secondary* to dialysis. Excludes antiemetics used in conjunction with chemotherapy, as these are covered under a separate benefit category.
Anti-infectives	*Drugs/biological products u*sed to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs*/biological products* in this *category are included for their action to treat* itching *secondary* to dialysis *but may have multiple clinical indications.*
Anxiolytic	Drugs*/biological products* in this *category are included for the* treatment of restless leg syndrome *secondary* to dialysis *but may have multiple clinical indications*.
Excess Fluid Management	Drug/*biological products/*fluids used to treat fluid excess *or fluid* overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs*/biological products*/fluids used to treat fluid and electrolyte needs.

Pain Management	Drugs/*biological products* used to treat vascular access site pain and to treat pain medication overdose.

B. Injectable Drugs and Biological *Products*

All injectable drugs or biological *products* used for the treatment of ESRD are included in the ESRD PPS and are not separately paid. This includes renal dialysis drugs and biological *products* that, prior to the implementation of the ESRD PPS, were separately billable under Part B.

Injectable drugs and biological *products that may be used for both the treatment of ESRD and for treatment of non-ESRD conditions continue to be paid separately when used for non-ESRD conditions and* 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 renal dialysis injectable drugs and biological *products* or for the purpose of *avoiding* financial responsibility for renal dialysis items and services.

ESRD facilities must report the appropriate Healthcare Common Procedure Coding System (HCPCS) codes used for *supplies utilized during* the administration and furnishing of renal dialysis drugs and biological *products*, *including* drugs and biological *products* 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 Biological *Products*

The ESRD PPS includes certain drugs and biological *product*s that were previously paid under Part D. Oral or other forms of injectable renal dialysis drugs and biological *products*—for example, Vitamin D analogs, Levocarnitine, antibiotics or any other oral or other form of injectable drug or biological *product* furnished as renal dialysis services—are also included in the ESRD PPS and may not be separately paid.

***NOTE**: Beginning January 1, 2019, oral levocarnitine is no longer considered a renal dialysis service, since the oral form is not indicated for dialysis related carnitine deficiency*.

The ESRD facility should report any drug or biological *product* furnished on the ESRD claim with the line item date of service and the quantity of the drug or biological *product* 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 oral or other forms of renal dialysis 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. *For 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 *claim billing period* would be reported on that claim.

Oral and other forms of injectable renal dialysis drugs are eligible for consideration as outlier services. See the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.html for a list of these drugs. CMS prices these drugs using *the best available data from Part D, which is generally* 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.

***NOTE**: Oral antibiotics are not listed as outlier services due to the administrative burden of maintaining an accurate and timely list of all antibiotics covered under Part D.*

D. Oral-Only Renal Dialysis Service Drugs and Biological *Products*

Oral-only forms of renal dialysis drugs and biological *products with no injectable functional equivalent or* other form of administration *other than an oral form are* included in the ESRD PPS as Part B renal dialysis service*s effective January 1, 2025.*

NOTE: *As discussed in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49044), the incorporation of oral-only drugs and biological products was originally delayed until January 1, 2014. As a result of legislation, i*mplementation of renal dialysis oral-only drugs *and biological products was* delayed until January 1, 2025.

E. Drugs and Biological *Products* Furnished for Reasons Other than for the Treatment of ESRD

Drugs and biological *products* 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 *reasonable and* necessary for the dialysis patient but is not being used for the treatment of ESRD. *Drugs and biological products furnished by the ESRD facility that are considered to always be renal dialysis services are not paid separately with or without the AY modifier*. See Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1 for more information.

***NOTE**: The ESRD PPS base rate accounts for all ESRD facility staff time during a dialysis session. Therefore, staff time used to furnish drugs and biological products for reasons other than for the treatment of ESRD is included in the ESRD PPS and is not billed separately*.

F. Drugs and Biological *Products* 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.

*Historically, d*rugs that were used as a substitute for any of these drugs*,* or *were* used to accomplish the same effect*, were* also covered under the composite rate.

The following list is comprised of drugs and biological *products* under the composite rate. Staff time and supplies used to furnish these drugs *were* covered under the composite rate*, are currently included under the ESRD PPS, 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***

**Albumin may be reasonable and medically necessary for the treatment of certain medical complications in renal dialysis patients. If albumin is used for fluid management as a volume expander, then payment for it is included in the ESRD facility's ESRD PPS payment for maintenance dialysis.*

***Used in delivery of other drugs, such as Albumin.*

***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. Under the ESRD PPS, all antibiotics used to treat vascular access-related and peritonitis infections*,* 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.

Composite rate drugs are eligible for bad debt payments and, effective January 1, 2025, eligible for outlier payments. For more information regarding the bad debt policy, see §80 of this chapter.

H. Drug Overfill *and Discarded Drug* 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, beginning January 1, 2025, ESRD facilities must report and document any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS using the JW or JZ modifier in accordance with 42 CFR § 413.198(b)(5)(ii), (ii), and (6). For additional information about the use of the JW and JZ modifiers, please see Pub. 100-04, Chapter 17, § 40.*

20.3.1 – Drug Designation Process

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

A. Definition of a New *Renal Dialysis Drug or Biological* Product

A "new renal dialysis drug or biological product" is an injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be: (1) approved by the Food and Drug Administration (FDA) on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act; (2) commercially available, and; (3) designated by CMS as a renal dialysis service under §413.171.

B. Determination *of Whether a New Renal Dialysis Drug or Biological Product is Included in the ESRD PPS Bundled Payment*

To *determine when a new renal dialysis drug or biological product is included in the ESRD PPS bundled payment*, CMS will:

- Review the new product's FDA labeling data and information;
- Review the new product's information presented for obtaining a HCPCS code; and
- Conduct an internal medical review following the announcement of the new product's FDA and HCPCS decision.

1. *If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is an existing ESRD PPS functional category, the new renal dialysis drug or biological product is considered included in the ESRD PPS bundled payment, and the following steps occur:*

- *The new renal dialysis drug or biological product is added to the existing ESRD PPS functional category.*
- *Unless excluded, the new renal dialysis drug or biological product is paid for using the Transitional Drug Add-On Payment Adjustment (TDAPA) (see section 20.3.1.C below) if it meets the TDAPA*

eligibility requirements outlined at §413.234(c)(5). Drugs excluded from TDAPA eligibility, effective January 1, 2020, include drugs approved by the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and drugs approved under section 505(c) of the FD&C Act that are classified by FDA as new drug application (NDA) Types 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, Type 5 in combination with Type 2, or Type 9 when the "parent NDA" is Type 3, 5, 7 or 8.

***NOTE**: If not eligible for the TDAPA, the new renal dialysis drug or biological product qualifies as an ESRD outlier service.*

For more information regarding the outlier policy see §60.D of this chapter.

2. If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is not an existing ESRD PPS functional category, the new renal dialysis drug or biological product is not considered included in the ESRD PPS bundled payment and the following steps occur:

- *CMS notifies the TDAPA applicant of its TDAPA determination.*
- *CMS adds a new ESRD PPS functional category or revises an existing ESRD PPS functional category through rulemaking for the condition that the new renal dialysis drug or biological product is used to treat or manage.*
- *The new renal dialysis drug or biological product is paid for using the TDAPA for a period of at least 2 years until sufficient claims data for rate setting analysis is available.*
- *Following payment of the TDAPA, CMS undertakes rulemaking to modify the ESRD PPS base rate, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment.*

***NOTE**: Following payment of the TDAPA, the new renal dialysis drug or biological product qualifies as an ESRD outlier service.*

C. Transitional Drug Add-On Payment Adjustment *(TDAPA)*

The TDAPA is a payment adjustment under the ESRD PPS for certain new renal dialysis drugs and biological products. To be eligible for the TDAPA a drug must have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures and have submitted an application for the TDAPA prior to January 1, 2028, or within three years of FDA approval under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act. Applications for the TDAPA under the ESRD PPS must be submitted in the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™). Information regarding the application process, any renal dialysis drugs and biological products that have been determined eligible for the TDAPA, and their respective payment amounts is available on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug

1. New renal dialysis drugs and biological products that fall in an existing ESRD PPS functional category and are eligible for the TDAPA.

Basis of Payment

The TDAPA is based on 100 percent of average sales price (ASP), which CMS receives from the drug or biological product manufacturer. Subject to the ASP conditional policy (described below in § 20.3.1.C.3), if ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

Duration of the TDAPA

The TDAPA for these products is paid for 2 years. The TDAPA payment period begins on the effective date of the CMS Change Request (CR) implementing the TDAPA for the drug or biological product. During the time a new renal dialysis drug or biological product is eligible for the TDAPA, it is not an eligible ESRD outlier service as defined under 42 CFR § 413.237(a)(1) and therefore is ineligible for outlier payment.

2. New renal dialysis drugs and biological products that do not fall in an existing ESRD PPS functional category and are eligible for the TDAPA.

Basis of Payment

In general, the TDAPA is based on 100 percent of ASP, which CMS receives from the drug or biological product manufacturer. Subject to the ASP conditional policy (described below in 20.3.1.C.3), if ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice. Under 42 CFR § 413.234(c)(4), the TDAPA for phosphate binders is based on 100 percent of ASP plus an additional amount derived from 6 percent of per-patient phosphate binder spending based on utilization and cost data.

Duration of the TDAPA

The TDAPA is paid until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years. The TDAPA payment and data collection periods for these drugs and biological products begin on the effective date of the applicable CMS ESRD PPS annual update CR for MACs and ESRD facilities. During the time a new renal dialysis drug or biological product is eligible for the TDAPA, it is not an eligible outlier service as defined under 42 CFR § 413.237(a)(1) and therefore is ineligible for outlier payment.

3. ASP conditional policy

If CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after CMS begins applying the TDAPA for the product, CMS will no longer apply the TDAPA for that product beginning no later than 2-calendar quarters after CMS determines a full calendar quarter of ASP data is not available.

If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period the TDAPA is applied, CMS will no longer apply the TDAPA for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

NOTE: for purposes of this conditional policy, in circumstances where a manufacturer submitted ASP data reflecting zero or negative sales during the TDAPA period, CMS is considered to have received the latest full calendar quarter of ASP data, and CMS would not discontinue TDAPA payment under the conditional policy in § 413.234(c).

Information regarding the submission of ASP data is available on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.

D. Determination of When an Oral-Only Drug is No Longer Oral-Only

An *"*oral-only drug*"* is a drug or biological *product* with no injectable *functional* equivalent or other form of administration other than an oral form.

An *"*oral-only drug*"* is no longer considered *"*oral-only*" if an injectable functional equivalent or other form of administration* of the oral-only drug is approved by the FDA.

20.4 - Equipment and Supplies

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

All medically necessary equipment and supplies used to furnish dialysis (in-facility or in a patient's home) *are not separately paid as of January 1, 2011, and payments for these items were incorporated into the ESRD PPS base rate. These* equipment and supplies include*:*

- Equipment and supplies included under the composite rate (see §20.1 of this chapter) as of December 31, 2010,
- Equipment and supplies that were *formerly* billed by ESRD facilities and paid separately by Medicare *(i.e., supplies used to administer drugs and biological products)*, and
- Equipment and supplies furnished to home patients that were under Method II* prior to January 1, 2011, and billed by Durable Medical Equipment*, Prosthetics, Orthotics, and Supplies* (DME*POS*) suppliers and paid separately by Medicare.

** Prior to the ESRD PPS, under Method II, the beneficiary dealt directly with a DMEPOS supplier to secure home dialysis equipment and supplies (including supportive equipment). Beginning January 1, 2011, Method II is no longer an option for home dialysis items and services under Medicare.*

As a result, effective January 1, 2011, the ESRD facility assumes responsibility for furnishing all equipment and supplies for all its patients who dialyze in-facility and those who dialyze at home.

ESRD facilities and *MCP physicians and* practitioners may *order* dressings or protective access coverings, including catheter coverings, *for a patient to use* on their *dialysis* access site*. These* 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 renal dialysis *services, and the ESRD facilities is responsible for providing 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.

For more information on MCP physicians and practitioners, see Pub. 100-04, chapter 8, section 140.

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 included in the ESRD PPS whether they are furnished in the facility or in the home by the ESRD facility.

ESRD facilities may not receive payment for renal dialysis equipment and supplies from ESRD beneficiaries.

A. Equipment and Supplies Used for Reasons Other Than for the Treatment of ESRD

1. ESRD Facilities

Occasionally ESRD facilities furnish items and services that are not used for the treatment of ESRD*, primarily drugs and biological products*. 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 drug or biological *product* that is being used for reasons other than for the treatment of ESRD. Any equipment or supply billed using the AY modifier will not be considered an eligible *ESRD* outlier service. 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 drugs or biological *products* given for reasons other than for the treatment of ESRD.

2. Other Providers *and Suppliers*

There are renal dialysis equipment and supplies that 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 *entitled* "Items and Services Subject to Consolidated Billing for the ESRD PPS" located at the ESRD Payment website: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. To allow *DMEPOS* suppliers to receive payment for furnishing these services to other provider types, the *DMEPOS* suppliers can bill the *DME* MAC for 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 renal dialysis equipment and supplies that are not used in other provider settings. These equipment and supplies are also listed in the document *entitled* "Items and Services Subject to Consolidated Billing for the ESRD PPS." These supplies and equipment are not otherwise covered by Medicare; therefore, *DMEPOS* suppliers are not able to bill any of the supplies on this list using the AY modifier.

20.4.1 – Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Beginning January 1, 2020, CMS provides a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) to ESRD facilities for furnishing a covered equipment or supply that meets certain eligibility criteria.

The intent of the TPNIES, as established in § 413.236, is to facilitate beneficiary access to certain qualifying, new and innovative renal dialysis equipment and supplies by providing an add-on payment adjustment to support ESRD facilities in the uptake of these new and innovative equipment and supplies under the ESRD PPS. CMS considers whether a new renal dialysis equipment or supply meets the eligibility criteria and announces the results in the Federal Register as part of the annual ESRD PPS rulemaking. Applications for the TPNIES under the ESRD PPS must be submitted in the electronic application intake system, MEARIS™, accessible at https://mearis.com.gov. The annual ESRD PPS proposed rule will describe each complete application received by the deadline. The annual ESRD PPS final rule will address public comments received and include the final CMS determination on the TPNIES application. CMS approvals included in the annual ESRD PPS final rule will be implemented via the ESRD PPS annual update change request that will provide technical instructions on how ESRD facilities are to report the equipment or supply on the ESRD claim. This change request will initiate the TPNIES period for the equipment or supply, and it will end 2 years from the change request's effective date. For example, any equipment or supply approved for the TPNIES for CY 2021, the TPNIES will begin on January 1, 2021 and end on December 31, 2022.

Annual TPNIES application deadlines are available on the CMS website: https://www.cms.gov/medicare/esrd-pps/esrd-pps-transitional-add-payment-adjustment-new-and-innovative-equipment-and-supplies-tpnies

The TPNIES is paid to an ESRD facility for furnishing a covered equipment or supply only if the item meets the eligibility criteria described in section 20.4.2.

Basis of Payment

The TPNIES is based on 65 percent of the MAC-determined price. The MACs, on behalf of CMS, will establish prices for new and innovative renal dialysis equipment and supplies that meet the TPNIES eligibility criteria using verifiable information from the following sources, if available:

1. *The invoice amount, facility charges for the item, discounts, allowances, and rebates;*
2. *The price established for the item by other MACs and the sources of information used to establish that price;*
3. *Payment amounts determined by other payers and the information used to establish those payment amounts; and*
4. *Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.*

Duration of the TPNIES

The TPNIES is paid for 2 calendar years, beginning on January 1 and ending on December 31. Following payment of the TPNIES, the ESRD PPS base rate will not be modified, and the new and innovative renal dialysis equipment or supply will be an eligible outlier service. For more information regarding the outlier policy see §60.D of this chapter.

20.4.2 –TPNIES Eligibility Criteria
(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Effective January 1, 2021, the eligibility criteria for TPNIES require that the equipment or supply:

1. *Has been designated by CMS as a renal dialysis service under § 413.171;*
2. *Is new, meaning a complete application has been submitted to CMS within 3 years of the date of the FDA marketing authorization;*
3. *Is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect;*
4. *Has a Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle II for non-drug and non-biological items, supplies, and services as specified in the HPCPCS Level II coding guidance on the CMS website prior to the particular calendar year. HCPCS coding procedures and deadlines are available on the CMS website:* https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS;
5. *Is innovative, meaning it meets the criteria specified in § 412.87(b)(1).*

An equipment or supply is considered innovative if it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (i.e., it offers a "Substantial Clinical Improvement" over existing technologies).

6. *Is not a capital-related asset, except for capital-related assets that are home dialysis machines.*

***Note:** In the CY 2021 ESRD PPS final rule CMS finalized an exception for capital related assets which are home dialysis machines when used in the home for a single patient (see §20.4.3 of this chapter for more information)*

CMS uses the following parameters to evaluate Substantial Clinical Improvement for purposes of the TPNIES (see 42 CFR § § 413.236(b)(5) and 412.87(b)(1)):

(i) The totality of the circumstances is considered when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

(ii) A determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

(A) The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

(B) The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient.

(C) The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the outcomes described below.

(1) A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.
(2) A decreased rate of at least one subsequent diagnostic or therapeutic intervention.
(3) A decreased number of future hospitalizations or physician visits.
(4) A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time.
(5) An improvement in one or more activities of daily living.
(6) An improved quality of life.
(7) A demonstrated greater medication adherence or compliance.

(D) The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

(iii) Evidence from published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an

advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Information source may include the following:

(A) Clinical trials;
(B) Peer reviewed journal articles;
(C) Study results;
(D) Meta-analyses;
(E) Consensus statements;
(F) White papers;
(G) Patient surveys;
(H) Case studies;
(I) Reports;
(J) Systematic literature reviews;
(K) Letters from major healthcare associations;
(L) Editorials and letters to the editor; and,
(M) Public comments.
(N) Other appropriate information sources may be considered.

(iv) The medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

(v) The new renal dialysis equipment or supply may represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply; and

20.4.3 -- TPNIES for Capital-related Assets
(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Effective January 1, 2021, eligibility for the TPNIES is extended to capital-related assets that are home dialysis machines when used in the home for a single patient that meet the eligibility requirements in section 20.1.2. As with other renal dialysis equipment and supplies potentially eligible for the TPNIES, CMS will evaluate the application to determine whether the home dialysis machine represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries, and meets the other requirements under 42 CFR § 413.236(b). For additional information on payment of the TPNIES for capital-related assets, see Pub 100-04 Chapter 8 § 20.

30 - Home Dialysis
(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Home dialysis is performed at an ESRD patient's home, including in skilled nursing facilities and nursing facilities, by the ESRD patient or a caregiver who has completed an appropriate course of training as specified in 42 CFR § 494.100(a).

30.1 - Home Dialysis Items and Services
(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

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 renal dialysis items and services included under the ESRD PPS.* The ESRD facility receives the same *bundled payment* for home patients as it would receive for an in-facility patient under the ESRD PPS. *Note: this includes all renal dialysis services furnished by the ESRD facility's staff.*

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 either directly or under arrangement.

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

A. Home Dialysis Equipment and Supplies

All *medically necessary* equipment *(including supportive equipment)*, supplies, and other items for home dialysis ordered by a*n MCP* physician *or practitioner that* were included in the composite rate*, are* included under the ESRD PPS*, and payments for these items were incorporated into the base rate. The MCP physician's or practitioner's order determines that an equipment or supply is furnished for the treatment of ESRD and therefore the responsibility of the ESRD facility. The order also provides documentation for CMS to use in determining if the equipment or supply is reasonable and necessary.* The ESRD facility with which the patient is associated assumes responsibility for furnishing all home dialysis equipment, supplies, and support services either directly or under arrangements to all of its home dialysis patients.

1. Home Dialysis Equipment *Furnished* to Home Hemodialysis and Peritoneal Dialysis Patients *Can Include:*

- *All* reasonable and necessary expenses incurred in the original installation of home dialysis equipment. *Medicare does not pay for* expenses attributable to home improvement (e.g., plumbing or electrical work)*, and there is no separate payment under the ESRD PPS for installation expenses even when covered*. *ESRD facilities are responsible for testing* and assurance of equipment performance *as specified in the ESRD Facility Conditions for Coverage in 42 CFR Part 494*.

- Supportive equipment that is used in conjunction with the basic dialysate delivery system*, including* blood *pumps*, 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 *of* 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).

- Nonmedical items are also included in the ESRD PPS *base rate* 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.

2. Home Dialysis Supplies Furnished to Home Hemodialysis and Peritoneal Dialysis Patients

ESRD facilities are responsible for supplies reasonable and necessary for the effective performance of all modalities of home dialysis, for example, alcohol wipes, sterile drapes, gloves, telfa pads, bandages, etc. *Reasonable and* necessary supplies *may* 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 are included in the ESRD PPS.

C. Home Dialysis Hemodialysis and Peritoneal *Dialysis* Support Services

Home dialysis support services identified at 42 CFR *§§ 410.52 and* 494.100 may be furnished in the home or in the ESRD facility. Support services include (but are not limited to):

1. Periodic monitoring of *the* patient's *home* adaptation*, including visits to the patient's home by facility personnel in accordance with the patient's plans of care*;

2. Emergency visits *to the home* 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. Renal dialysis 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 *and delivering renal dialysis* supplies on an ongoing basis;

8. Maintaining and submitting all required documentation to the ESRD network;

9. A *complete medical* record keeping system that ensures continuity of care;

10. Changing *essential* 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*ing* 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. *Home dialysis* 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

Staff-assisted home dialysis *may include ESRD facilities sending staff to assist with home dialysis, but such services may not be billed to Medicare separately, because the cost of all ESRD facility staff time is included in the base rate.*

30.2 - Home Dialysis Training

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

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 in *the* facility when it is provided by the qualified staff of the ESRD facility. CMS expects that the patients who elect 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 *paid for* in accordance with Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §50.8.

Effective January 1, 2025, ESRD facilities may bill for the home and self-dialysis add-on training adjustment described at §60.C.1 for training sessions for AKI patients.

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 renal dialysis 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.*1* 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 is based upon 5-hour sessions given 3 times per week. *Training programs are designed to accommodate the caregiver and the beneficiary when appropriate. Specifically,* both can be trained to perform the dialysis treatment in its entirety. *Sometimes the beneficiary* plays a secondary role. In other programs, the *beneficiary* performs most of the treatment and is only aided *or overseen by their caregiver.*

B. Peritoneal Dialysis *(PD)* Training

The *home peritoneal dialysis training is covered for up to 15 sessions. Additional CAPD training sessions are covered only when documented as being reasonable and necessary. However, extra training sessions raise questions about either the adequacy of PD for the patient or the patient's capacity to learn or perform the PD technique. The patient's physician should address these questions in the explanation of the need for extra training sessions. The MAC will make a determination whether or not to cover training sessions in excess of 15.*

1. 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.

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.

Once the patient is trained, CAPD is primarily a home service, because the patient performs CAPD 24 hours a day. Persons who are primarily treated by CAPD may also require in-facility dialysis, either intermittent peritoneal or hemodialysis, occasionally.

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

3. 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 *or upon* 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. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

ESRD beneficiaries may receive other services that may be related to their ESRD diagnosis but are excluded from the ESRD PPS payment. *Similarly, for AKI beneficiaries, some services related to their diagnosis may be excluded from the AKI dialysis 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.

Under the home health benefit, services can be provided to dialysis patients as long as the condition that necessitates home health care is not *ESRD and as long as home health coverage conditions are met*. This is true even where the primary condition *relates* to kidney failure. For example, Medicare will pay for home health care, such as *for* 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 being furnished for the treatment of the patient's ESRD. Surgical dressing changes that are furnished for the treatment of ESRD are to be provided by the ESRD facility, but dressing changes furnished for reasons other than for the treatment of ESRD 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 *unrelated* 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 reside in a SNF or NF 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 are paid under the ESRD PPS, *and no separate payment will be made to the SNF or NF.*

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 *MCP* method or the initial method. *For patients who dialyze at home, the ESRD-related services included in the MCP may be provided via telehealth. The MCP physician (or practitioner) must furnish at least one face-to-face patient visit per month for the home dialysis MCP service.* See Pub. 100-04, Medicare Claims Processing Manual, Chapter 8 *§ 140 and Chapter 12 § 190.3.4,* for payment instructions. For physician responsibilities, refer to 42 CFR §414.310.

F. 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. Laboratory services, drugs and biological *products*, and equipment and supplies furnished to ESRD beneficiaries for the treatment of ESRD on the day a procedure is performed to create or revise a vascular access site *are* not considered to be renal dialysis services. *The physicians* 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.

G. Noninvasive Vascular Studies for ESRD Patients

For dialysis to *be performed,* 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.

Procedures associated with monitoring access may include, but *are* 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.

If an ESRD facility or a renal physician determines it is reasonable and necessary to monitor the patient's access site with a non-invasive vascular study (e.g. duplex or Doppler) 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.

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 is included under the ESRD PPS *and includes monitoring by noninvasive Doppler flow studies.*

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).

Absent documentation supporting the necessity of more than one study, Medicare will limit payment to either a Doppler flow study or an arteriogram (fistulogram, venogram). 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.

Additional information can be found in Pub. 100-04, Medicare Claims Processing Manual, chapter 8 § 180.

H. 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.

Intradialytic Parenteral Nutrition (IDPN) and Intraperitoneal Nutrition (IPN) are not considered renal dialysis services and are therefore not included in the ESRD PPS bundled payment. IDPN and IPN are covered under Medicare Part D. Part B coverage for parenteral nutrition is limited to individuals with a non-functioning digestive tract. When an ESRD facility furnishes a non-ESRD drug, including IDPN or IPN, the staff time is already included in the ESRD PPS payment and, therefore, such costs should not be included in Part D payments. Payment under Part D is limited to the drug ingredients that meet the definition of a Part D drug, subject to the relevant requirements of 42 CFR § 423.120(d), and may include a dispensing fee to cover certain labor costs and pharmacy overhead as permitted under 42 CFR § 423.100.

In the case that a pharmacy extemporaneously compounds IPN by adding amino acids to a dialysate, there has been confusion as to whether this falls under Part B or Part D. Dialysate is considered to be a supply related to the renal dialysis treatment, which falls under the ESRD PPS payment and is not separately billable under Part B. Although the dialysate is not separately billable, it is still considered a Part B drug. Therefore, IPN is a Part B compound in accordance with 42 CFR § 423.120(d)(1)(i), and coverage for the entire compound, including ingredients that would independently meet the definition of a Part D drug, would not be available under Medicare Part D.

I. Immunizations

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.

J. Blood Products

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.

50 - ESRD Prospective Payment System (PPS) Base Rate

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

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

A. Per Treatment Unit of Payment

Under the ESRD PPS payment is made on a per treatment basis. The ESRD PPS base rate is the per treatment unit of payment that applies to both adult and pediatric patients. ESRD facilities furnishing dialysis treatments in-facility are paid for up to 3 treatments per week. ESRD facilities treating patients at home regardless of modality receive payment for 3 hemodialysis (HD) equivalent treatments per week. Payment for additional treatments may be considered when there is medical justification for more than 3 weekly treatments. 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 justification *that* additional treatments *are reasonable and necessary*.

Frequency of Dialysis Sessions by Dialysis Modality and Treatment Setting*

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

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

*** Hemodialysis-equivalent home CCPD and CAPD is paid for using a daily rate. This daily rate is equal to 3/7ths of the payment amount for an in-center hemodialysis treatment, as one week of daily home CCPD or CAPD treatments is considered equivalent to 3 in-center hemodialysis treatments.*

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, *a* medical justification *that the treatment is reasonable and necessary* is required to be furnished to the A/B MAC (A) and must be based upon an individual patient's need. The A/B MAC (A) 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.

When treatments are given in excess of 13 or 14 treatments per month (depending on the number of days in the month) without medical justification, the CG modifier shall be appended to the claim line for the date of service associated with the excess treatment. This modifier indicates that the facility attests the additional treatment does not meet medical justification requirements and should not be paid separately.

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 A/B MAC (A) must verify the medical justification to determine *that the ultrafiltration services were reasonable and necessary*. If the A/B MAC (A) considers the justification appropriate, the ESRD facility will receive the ESRD PPS per *treatment payment*. For more information regarding ultrafiltration, see Pub. 100-04, Chapter 8, §50.7.

4. Peritoneal Dialysis: Payment Based on Hemodialysis Equivalent Sessions

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

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

Note: because home CAPD and CCPD patients generally receive dialysis treatments daily, these modalities are paid a daily rate, which is calculated by multiplying the in-center hemodialysis payment rate for that patient by 3 and dividing by 7. This is an alternative method of paying a comparable rate for hemodialysis-equivalent sessions, which is more appropriate for these daily modalities. The daily rate is not paid for IPD, since IPD may not be furnished every day (as discussed in the next subsection).

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

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

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

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

5. Intermittent Peritoneal Dialysis (IPD)

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

6. Uncompleted Dialysis Treatments under the ESRD PPS

Medicare only pays for one completed dialysis treatment per day. 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), and the patient returns the same day and completes the treatment, the facility is paid for one treatment.

When there is a sudden onset of acute symptoms during the dialysis treatment and there is an emergency, the ESRD facility does what is necessary to provide the beneficiary emergency care (including calling 911). The hospital outpatient department provides emergency care and if it is unlikely the patient is able to return to the ESRD facility, the hospital outpatient department furnishes the dialysis treatment for the day. Emergency renal dialysis services furnished in a hospital emergency room are separately paid, when justification that they are reasonable and necessary 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.*

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.

Renal dialysis services, such as de-clotting of shunts, suture removal, or furnishing renal dialysis drugs that may be furnished in other settings such as a hospital outpatient department or physician's office, are paid separately only if the services could not have been furnished in the ESRD facility.

7. Vaccines and Their Administration

ESRD facilities may bill separately for both the vaccine and the administration of the vaccine under Chapter 18 of the Provider Reimbursement Manual (PRM) (Section 10.2.2.1). Independent ESRD facilities are paid at the Medicare Physician Fee Schedule rate, and Hospital Based ESRD facilities are paid reasonable cost. Vaccinations for COVID-19 are paid at a reasonable cost when performed at a renal dialysis facility. The general rates for COVID-19 vaccines do not apply for renal dialysis facilities.

B. Market Basket

For renal dialysis services furnished on or after January 1, 2012, CMS *annually updates* the *ESRD PPS base rate by the* ESRD bundled market basket percentage increase factor *minus a productivity adjustment factor (the growth in the multifactor productivity is derived by subtracting the contribution of labor and capital input growth from output growth).*

The market basket is routinely rebased periodically so that the cost weights reflect changes between base periods in the mix of goods and services that ESRD facilities purchase to furnish ESRD treatment.

50.1- Inclusion of Calcimimetics in the ESRD PPS Base Rate

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

As discussed in 20.3.D of this chapter, CMS finalized a policy in the CY 2011 ESRD PPS final rule (75 FR 49044) to delay payment for oral-only renal dialysis drugs and biological products under the PPS until January 1, 2014. This was further delayed until CY 2025 as a result of legislation. Calcimimetics are a renal dialysis drug that falls within the bone and mineral metabolism functional category. Prior to CY 2018, calcimimetics were considered oral-only and were excluded from the ESRD PPS; however, an injectable calcimimetic was approved by the FDA in 2017. Beginning January 1, 2018, injectable and oral calcimimetics were incorporated into the ESRD PPS and paid under the TDAPA for an initial TDAPA period of 2 years, which was extended in the CY 2020 ESRD PPS final rule to include a third year. Effective January 1, 2021, the ESRD PPS base rate increased by $9.93 to account for oral and injectable calcimimetics. Using the total units of oral and injectable calcimimetics and the total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims (that is, the 837-institutional form with bill type 072X) for the third and fourth quarters of calendar year 2018 and for the full calendar year 2019 and the weighted average ASP based on the most recent determinations by CMS, CMS used the following methodology to calculate the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate (see 42 CFR § 413.234(f)).

60 - ESRD PPS *Payment* Adjustments

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

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. *In addition, the ESRD PPS includes certain add-on payment adjustments as discussed in § 60.C of this chapter.* 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).

Note: In general, the ESRD PPS case-mix adjustments, facility level adjustments and add-on payment

adjustments do not apply to AKI beneficiaries. The only payment adjustments that apply to AKI dialysis claims are the ESRD PPS wage index and, beginning January 1, 2025, the add-on payment adjustment for home and self-dialysis training.

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. *Pediatric patient-level adjusters (see §60.A.6 of this chapter), consist of combinations of two age categories and two dialysis modalities.* The adult case-mix adjusters include age, body surface area (BSA), low body mass index (BMI)*, and* six comorbidity categories (three acute and three chronic), *and* the onset of renal dialysis. Based on the refinement of the ESRD PPS, effective January 1, 2016, adult case-mix payment adjustments are made for four comorbidity categories (two acute and two chronic) as *indicated in the chart* below. *The comorbidity categories of bacterial pneumonia monoclonal gammopathy were removed.*

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 CY 2011 and refined in CY 2016. Any revisions to the case-mix adjusters will be *addressed* in subsequent rulemaking.

Adult Patient-Level Characteristics	Adjustment Value	
	CY 2011-2015	Beginning CY 2016
Age: 18-44	1.171	1.257
Age: 45-59	1.013	1.068
Age: 60-69	1.000	1.070
Age: 70-79	1.011	1.000
Age: 80+	1.016	1.109
Body Surface Area *(per 0.1 m^2)*	1.020	1.032
Low Body Mass Index (BMI <18.5)	1.025	1.017
Onset of *Renal* Dialysis *<4 Months*	1.510	1.327
Pericarditis *(acute)*	1.114	1.040
Bacterial pneumonia *(acute)**	1.135	---
Gastro-intestinal tract bleeding *(acute)*	1.183	1.082
Hereditary hemolytic or sickle cell anemia *(chronic)*	1.072	1.192
Myelodysplastic syndrome *(chronic)*	1.099	1.095

Monoclonal gammopathy *(chronic)**	1.024	---

**Were removed effective January 1, 2016.*

Calculating the ESRD PPS *Bundled* Payment *Amount*

The following example demonstrates the calculation of the ESRD PPS *bundled* payment 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 *(the examples below use rates effective January 1, 2026).*

- Base rate: $*281.71*
- Labor-related share of base rate: $*281.71* * 0.*552* = $*155.50*
- Wage index adjusted labor-related share: $*155.50* * 1.1000 = $*171.05*
- Non labor-related share of base rate: $*281.71* * (1 - *0.552)* = $*126.21*
- Wage index adjusted base rate: $*171.05* + $*126.21* = $*297.26*

Provided next is the continuation of the example with the inclusion of the patient characteristics portion of the payment.

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 on January 1, 20*26*. Using the formula for BMI, note that the patient is not underweight, having a BMI of
26.89 kg/m^2, which is greater than the threshold value of 18.5 kg/m^2.

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

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

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

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

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

Using the adult case-mix adjusters table shown above, the BSA multiplier *is* 1.032. The patient's case-mix adjustment or payment multiplier (PM) based on his BSA of 2.2161 is computed as follows:

$PM_{BSA} = 1.032^{(2.2161-1.90)/0.1}$
$= 1.032^{3.161}$
$= 1.1047$

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

$PM_{Patient} = PM_{age} * PM_{BSA}$
= 1.068 * 1.1047
= 1.1798

The example patient's ESRD payment rate for treatments furnished in his ESRD facility *(assuming a wage index of 1.000)* would be:

$*281.71** 1.1798 = $*332.36*

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

Additionally, this case-mix adjustment multiplier would be applied to any post-TDAPA add-on payment adjustment amounts applicable for the claim. For example, if the post-TDAPA add-on payment adjustment amount for the quarter of the claim in question was $0.50, the post-TDAPA add-on to the per-treatment payment rate would be:

*$0.50*1.1798 = $0.59*

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 the CY 2016 adult case-mix adjusters as well as the discussion of the wage adjusted ESRD PPS base rate found in the section above *(examples below are using rates effective January 1, 2026).*

- Example 1: Mr. Taylor is 38 years of age and is classified in the 18-44 age group with an associated case-mix adjuster of 1*.257.* Applying the case-mix adjuster of 1.257 to the wage index adjusted base rate of $*281.71 (assuming a wage index of 1.000)* yields the age adjusted base rate amount of $*354.11* ($*281.71* x 1.257 = $*354.11*).

- Example 2: Mrs. Williams was born on July 4, 1936. On June 15, 2016, she is 79 years old and is classified in the 70-79 age category with a case-mix adjustment of 1.000 (the reference group). However, beginning with dialysis treatments occurring on and after July 1, 2016, she will move into the 80+ age group with an associated case-mix multiplier of 1.109.

- Example 3: Mr. Davis was born on September 29, 1971. For dialysis treatments occurring in August 2016, he is 44 years old and would be classified in the 18-44 age group with an associated case-mix adjuster of 1.257. Beginning with dialysis treatments occurring on and after September 1, 2016, he is classified in the 45-59 age category with a case-mix adjuster of 1.068 because he is considered to have attained age 45 on September 1.

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

Low BMI and BSA are two measures used to estimate body size. Both measures are strong predictors of variation in costs and are closely associated with the duration and intensity of dialysis necessary to achieve a therapeutic dialysis target for ESRD patients. Both are objective measures that are computed using height and weight data located on the patient claim. The BMI and BSA are calculated for all beneficiaries. Low BMI is associated with higher costs due to additional resources that may be necessary to address malnutrition or frailty. BSA is associated with higher costs due to more time on the dialysis machine.

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 measurement is required no less frequently than once per year.

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 low BMI adjustment factor of 1.017 (see §60.A.1 of this chapter) is only applied for those beneficiaries with a BMI value that is less than $18.5 kg/m^2$ which is a clinical measure of being underweight and an indicator of malnutrition.

The formula for the calculation of the BSA is $BSA = w^{0.425} * h^{0.725} * 0.007184$ where w and h represent weight in kilograms and height in centimeters. The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.90 divided by 0.1. Using the example of adult adjusters above, the BSA adjustment factor of 1.032 is then exponentiated based on the calculated BSA factor as $1.032^{(BSA-1.90)/0.1}$. The reference BSA used to calculate the BSA is the national average among Medicare dialysis patients.

4. Onset of Dialysis

Effective January 1, 2016, the ESRD PPS onset of renal dialysis adjustment is 1.327. 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 of when 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 comorbidity adjustment nor any applicable training adjustment(s). However, those treatments are eligible for an outlier payment when appropriate.

5. Comorbidity Categories

The two acute comorbidity categories are pericarditis and gastro-intestinal tract bleeding with hemorrhage. The two chronic comorbidity categories are myelodysplastic syndrome and hereditary hemolytic anemia (including sickle cell anemia). *For each patient only the single comorbidity with the largest adjustment factor will be applied to the payment calculation, as explained in the CY 2011 ESRD PPS final rule (75 FR 49106).* The related comorbidity diagnosis codes can be found at the CMS ESRD Payment Web site located at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Patient-Level-Adjustments.html

NOTE: Prior to *January 1, 2016*, the ESRD PPS included payment adjustments for the comorbidity categories of bacterial pneumonia and monoclonal gammopathy, *which were removed effective January 1, 2016*.

The ESRD facility is responsible for obtaining documentation of the presence of an acute or chronic comorbidity. If an ESRD facility is unaware of the existence of a comorbidity because it does not impact the facility's costs, then the ESRD facility should not expect to receive a comorbidity adjustment. The comorbidity payment adjustment is only applied if the appropriate diagnosis code, specified under one of the categories above, is identified on the ESRD claim. Comorbidities other than the two acute and the two chronic conditions identified above do not qualify for a comorbidity adjustment. Even if an ESRD patient has or has had one of the four conditions that would qualify for a comorbidity 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 comorbidity adjustment there must be adherence to diagnosis coding requirements. Diagnosis codes are updated annually as stated in Pub. 100-04, Chapter 23, section 10, are posted at http://www.cms.gov/Medicare/Coding/ICD10/index.html, and are effective each October 1st.

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 comorbidity 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 Comorbidity Adjustment

Payment for an acute comorbidity 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 comorbidity applies.

The acute diagnosis comorbidity adjustment is applied to each dialysis treatment for 4 patient months. If a second comorbidity 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 comorbidity.

When there is a recurrence of an acute comorbidity within the 4 patient-month period, there will not be an extension of the 4 patient-month adjustment. A recurrence is defined as a new episode of a comorbidity that was previously experienced by an individual beneficiary. However, if the recurrence happens after the completion of the 4-month period, then a new comorbidity 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-January 2016. During his stay in the hospital, he was diagnosed with gastro-intestinal tract bleeding with hemorrhage on January 20, 2016. He resumed his outpatient

maintenance dialysis on January 29, 2016. The 4 patient-months in which the patient's ESRD facility would be eligible to have the comorbidity adjustment applied to each dialysis treatment are January through April 2016.

b. Duration of Chronic Comorbidity Adjustment

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

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

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

Pediatric Patient-Level Characteristics	Adjustment Value	
	CY 2011-2015	Beginning CY 2016
Age: <13, Modality: PD	1.033	1.063
Age:<13, Modality: Hemo	1.219	1.306
Age:13-17, Modality: PD	1.067	1.102
Age:13-17, Modality: Hemo	1.277	1.327

ESRD facilities receive an additional transitional pediatric ESRD add-on payment adjustment (TPEAPA) for renal dialysis services furnished to pediatric ESRD patients (as defined at §413.171). This TPEAPA represents an increase in payment of 30% of the per-treatment payment amount. The TPEAPA is not an increase to the case-mix adjustment factors displayed above, but it functions similarly to an increase to the above case-mix adjustment factors of 30% (1.3 multiplier). The TPEAPA applies for calendar years 2024, 2025 and 2026 as CMS collects additional data on the costs associated with treating pediatric ESRD patients. The TPEAPA does not impact the outlier services multipliers or the outlier payment in any way.

ESRD facilities do not receive the low-volume adjustment, described in §60.B.1, or the rural adjustment, described in §60.B.3, for pediatric beneficiaries. However, they are eligible for training add-on and outlier payments (described in §60.C.*1* 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 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 $2*97.26*, which is the starting point for the computation of the case-mix adjusted base rate *(the examples below use rates effective January 1, 2026).*

- Base rate: $*281.71*
- Labor-related share of base rate: $*281.71* * 0*.552* = $*155.50*
- Wage index adjusted labor-related share: $*155.50* * 1.1000 = $*171.05*
- Non labor-related share of base rate: $*281.71* * (1 - *0.552)* = $*126.21*
- Wage index adjusted base rate: $*171.05* + $*126.21* = $*297.26*

Provided next is the *continuation of the example with the* characteristics of the pediatric patient.

- Andrew, a 12-year-old male, has been on CCPD since June 20*20*. His mother, who assists him with his dialysis at home, is no longer able to assist with dialysis beginning May 10, 20*26*. 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 1.063. During the months of May and June 20*26*, the ESRD payment rate per HD- equivalent treatment *at a facility with a wage index of 1.1* would be:

  $*297.26* * 1.063 = $*315.99*

- 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: $*95.60*
  Wage index: 1.10
  Training payment: $*95.60* * 1.10 = $*105.16*

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

- *For treatments furnished to pediatric ESRD patients in calendar years 2024, 2025 and 2026, a TPEAPA of 30% of the per treatment payment amount would be added to the payment amount.*

  Case-mix adjusted payment rate: $315.99
  TPEAPA multiplier: 0.3
  TPEAPA amount: : $315.99 0.3 = $94.80*

- *Additionally, the above case-mix adjustment multiplier and the TPEAPA would be applied to any post-TDAPA add-on payment adjustment amounts applicable for the claim. For example, if the post-TDAPA add-on payment adjustment amount for the quarter of the claim in question was $0.50, the post-TDAPA add-on to the per-treatment payment rate would be:*

*$0.50 * 1.063 * 1.3 = $0.69*

***NOTE:** the post-TDAPA add-on payment adjustment amount is only adjusted by the patient-level case-mix adjusters and the TPEAPA. Facility level adjustment factors (e.g. LVPA, rural adjustment) and other add-on payment adjustments (home and self-dialysis training add-on, outlier payment) are not applied to the post-TDAPA add-on payment adjustment.*

- 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 add-on payment adjustments, would be:

  *($297.26 * 1.063) + $105.16 + $94.80 + 0.69 = $516.64*

B. Facility-level adjustments

There are three 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). The third is a rural adjustment beginning in CY 2016.

1. Low-Volume Adjustment

ESRD facilities that qualify as being low-volume can receive the low-volume payment adjustment (LVPA) applied to each dialysis treatment they furnish beginning on or after January 1, 2011. For CY 2011 the payment adjustment was 18.9 percent, and beginning January 1, 2016, the payment adjustment was 23.9 percent. *Beginning January 1, 2025, the payment adjustment will be 28.4 percent for facilities furnishing less than 3,000 treatments and 18.1 percent for facilities furnishing between 3,000 and 3,999 treatments.*

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—*s*pecifically, 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.

- For purposes of determining eligibility for the low-volume adjustment, the number of "treatments" is the total number of treatments furnished to Medicare and non-Medicare patients. For peritoneal dialysis (PD) patients, 1 week of PD is considered equivalent to 3 hemodialysis (HD) treatments. For example, a patient on PD for 21 days would have (21/7) x 3 or 9 HD-equivalent treatments. See §50.A.4 of this chapter for more information on hemodialysis equivalent treatments. The ESRD facility must not have opened, closed, or received a new provider number due to a change in ownership, (see Pub. 100-07, chapter 3, §3210), in the 3 years preceding the payment year.

- 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 change in the fiscal year reporting to that of the new provider, the A/B MAC (A) should combine the reporting periods for determining eligibility to the LVPA.

  For example, prior to a change of ownership (CHOW), Facility A had a cost reporting period that spanned January 1 through December 31. Facility A had a CHOW mid-year that did not result in a new provider transaction access number (PTAN) but caused a break in the cost reporting period. The A/B MAC (A) would add Facility A's cost report that spanned January 1 through May 31 to its cost report that spanned June 1 through December 31 to verify the total treatment count. The other situation that could occur is when a CHOW results in a change of the original fiscal period. For example, prior to a CHOW, Facility B had a cost reporting period that spanned January 1 through December 31 and, based on its cost reports for 2012 and 2013, it met the LVPA eligibility criteria. Then, Facility B had a CHOW in the beginning of 2014 that did not result in a new PTAN but changed its cost reporting period to that of its new owner, October 1, 2014, through September 30, 2015. This scenario would create a short and a long cost report that would not total 12 months that the A/B MAC (A) would need to review for verification. That is, Facility B would have a cost report that spanned January 1, 2014, through July 31, 2014 (7 months) and a cost report that spanned August 1, 2014 through September 30, 2015 (14 months). In this situation, the A/B MAC (A) should combine the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorate the data to equal a full 12-consecutive month period.

- Beginning January 1, 2019, if there is a CHOW that results in a change in provider number due to a facility-type change (for example, hospital based dialysis facility to independent dialysis facility) and the new owner accepts the Medicare agreement, the ESRD facility can qualify for the LVPA if they otherwise meet the LVPA eligibility criteria. This policy does not extend to CHOWs where a new PTAN is issued for any other reason.

- Effective January 1, 2019, ESRD facilities that change their fiscal year end for cost reporting purposes, outside of a CHOW, qualify for the LVPA if they otherwise meet the LVPA eligibility criteria. When this occurs, the MACs will combine the two nonstandard cost reporting periods of less than 12 months to equal a full 12- consecutive month period or combine the two non-standard cost reporting periods, that in combination may exceed 12-consecutive months, and prorate the data to equal a full 12-consecutive month period. This does not impact or change requirements for reporting, as established by the MACs, or those set forth in § 413.24(f)(3).

- Effective January 1, 2016, the ESRD facility must not be located within 5 road miles of another ESRD facility under common ownership. The geographic proximity criterion is applicable to all ESRD facilities that are Medicare certified 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 5 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 A/B MAC (A), the A/B MAC (A) will need to consider ESRD facility A's ownership and the ownership of all of the ESRD facilities located within a 5 road mile radius or less when determining total treatments. A/B MACs (A) 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. A/B MACs (A) shall refer to 42 CFR §421.404(a) when determining common ownership.

Prior to January 1, 2016, ESRD facilities that were Medicare certified prior to January 1, 2011, were grandfathered into the geographic proximity criterion.

Beginning January 1, 2025, the structure of the LVPA will change to include two tiers. ESRD facilities that furnish fewer than 3,000 treatments will fall into the first tier, and facilities that furnish 3,000 or more treatments but fewer than 4,000 treatments will fall into the second. An ESRD facility's LVPA tier will be determined based on the median treatment count of the last three cost-reporting years, rather than using a single year treatment count. Facilities that fall into the first tier will receive a 28.4 percent adjustment, and facilities that fall into the second tier will receive an 18.1 percent adjustment. Should a facility receive an exception under § 413.232(g)(5) in one or more of the past three cost-reporting years, the median treatment count of the unaffected cost-reporting years will be used to make the facility's tier determination. In the case that a facility does not have cost-reporting data from the last 3 years that are unaffected by a disaster or other emergency, the facility will be assigned to a tier based on their last full year of unaffected treatment volume, assuming all LVPA eligibility criteria are met.

Two-Tier LVPA Structure Effective January 1, 2025

Tier	*LVPA Adjuster*
Tier 1 *(less than 3,000)*	*28.4%*
Tier 2 *(3,000 – 3,999)*	*18.1%*

For example, if cost-reporting data indicated that an ESRD facility furnished 2,500, 2,999, and 4,500 treatments in the 3 years preceding the payment year, but the facility received an exception under § 413.232(g)(5) during the year it furnished 4,500 treatments, the median treatment count from the two prior years (2,500 and 2,999) would be used determine the facility's LVPA tier, which would place the facility in tier 1. The facility would then receive a 28.4 percent payment adjustment for all of the treatments furnished during the payment year.

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 A/B MAC (A).
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 A/B MACs
(A) 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.

If the ESRD facility qualifies for LVPA based on the three prior years (i.e., the treatment counts in each of the three cost reports) then it will receive the LVPA adjustment in that 4th year, which is the payment year. Should the facility exceed the 4,000 treatment count in that payment year, it will qualify for the full LVPA adjustment during the entire payment year; however, the facility will not qualify for three subsequent payment years.

Beginning January 1, 2019, ESRD facilities may request an extraordinary circumstance exception to the November 1 deadline. In order to request an extraordinary circumstance exception, the facility is required to submit a narrative explaining the rationale for the exception to their MAC. The MAC will evaluate the narrative to determine if an exception is justified. The determination will be final, with no appeal.

However, for new or resubmitted attestations applicable to payment years 2011 to 2015, to allow A/B MACs (A) and facilities adequate time to review policy clarifications related to the low volume adjustment, the attestation deadline was extended to December 31, 2014. For attestations applicable to payment year 2016, the attestation deadline was extended to December 31, 2015, to allow A/B MACs (A) and facilities adequate time to review policy changes finalized in the CY 2016 ESRD PPS final rule. *The attestation deadline for payment year 2021 was extended until December 31, 2020, due to the extraordinary circumstance of COVID-19 for all ESRD facilities requesting the LVPA.*
A/B MACs (A) have a maximum of 60 days to verify attestations for implementation of the low-volume adjustment beginning January 1 of the following payment year.

A/B MACs (A) 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 1 of each year in order to receive the adjustment the following payment year. A/B MACs (A) 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 A/B MAC (A) should no longer apply the low-volume payment adjustment beginning January 1 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 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 A/B MAC (A) is responsible to reconcile incorrect payments made to ESRD facilities retroactively, if needed, to ensure overpayments have not been made. If an A/B MAC (A) determines that an ESRD facility has received the low-volume adjustment in error, the A/B MAC (A) is required to adjust all of the ESRD facility's affected claims to remove the adjustment within 6 months of finding the error.

The A/B MAC (A) 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 A/B MAC (A) 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. A/B MACs (A) 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). A/B MACs (A) shall use PECOS (or most recent Medicare enrollment system) 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 CHOW. A/B MACs (A) 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. A/B MACs(A) 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 A/B MAC (A) 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 A/B MAC (A) 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 A/B MAC (A) 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 A/B MAC's (A) 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. In the case where a hospital has multiple locations and treatment counts are aggregated in the hospital's cost report, the A/B MAC (A) may consider other supporting documentation which may include individual facility treatment counts, rather than the hospital's cost report alone. The hospital must provide the documentation to support the total treatment count for all the facilities that make up the total treatment count on the cost report for the A/B MAC (A) to review, even if not all the facilities are applying for the low volume adjustment.

LVPA Eligibility for Cost Reporting Periods Ending in 2020

For ESRD facilities that have an increase in their treatment counts for cost reporting periods ending in 2020 that are COVID-related such that the increase prevents them from qualifying for the LVPA, CMS will hold these facilities harmless from losing the LVPA. For purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, CMS will only consider total dialysis treatments furnished for any 6 months of a facility's cost-reporting period ending in 2020; ESRD facilities will select those 6 months

(consecutive or nonconsecutive) during which treatments will be counted for purposes of the LVPA determination. ESRD facilities will attest that their total dialysis treatments for those 6 months of their cost-reporting period ending in 2020 are less than 2,000 and that, although the total number of treatments furnished in the entire year otherwise exceeded the LVPA threshold, the excess treatments furnished were due to temporary patient shifting resulting from the COVID–19 PHE. MACs will annualize the total dialysis treatments for the total treatments reported in those 6 months by multiplying by 2. ESRD facilities will be expected to provide supporting documentation to the MACs upon request.

c. LVPA Emergency Provisions

Beginning January 1, 2024, ESRD facilities that are affected by disasters and other emergencies may qualify for exceptions to certain eligibility requirements for the LVPA. These exceptions affect both an ESRD facility that closes as a result of a disaster or other emergency, along with a facility that surpasses the LVPA treatment threshold eligibility requirement due to treating patients with ESRD who are displaced from their usual ESRD facility because of the disaster or other emergency.

First, an ESRD facility may request an exception to the eligibility requirement at 42 CFR § 413.232(b)(2). This exception would allow the ESRD facility to close and reopen in response to a disaster or other emergency and still receive the LVPA. If an ESRD facility is affected by a disaster or other emergency and the ESRD facility closes and re-opens later, the ESRD facility must request an exception from CMS in writing in order to continue to be eligible for the LVPA. Written requests must be sent to the ESRD Payment Mailbox (ESRDPAYMENT@cms.hhs.gov) within 60 days of the facility's closure. Additionally, the ESRD facility must inform the MAC of the request. CMS will review the request within 30 days of receipt and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and would inform both the ESRD facility and the MAC of its decision.

Second, an ESRD facility may request an exception to the eligibility requirement at 42 CFR § 413.232(b)(1). This exception would allow the ESRD facility to receive the LVPA even if it exceeds the LVPA treatment volume threshold (i.e., 4,000 treatments) if its treatment count increases due to temporary patient shifting due to a disaster or other emergency. For the purposes of this exception, temporary patient shifting is defined as providing renal dialysis services to one or more patient(s) at any time through the end of the calendar year following the 12-month period. This 12-month period begins on the date the accepting ESRD facility first begins providing renal dialysis services to the displaced patient(s). The accepting ESRD facility must submit to CMS a written request for this exception. These written requests must be sent to the ESRD Payment Mailbox (ESRDPAYMENT@cms.hhs.gov) no later than the annual attestation deadline of November 1st or 30 days after the end of the cost reporting year for which the ESRD facility is attesting, whichever is later. In addition, the accepting ESRD facility must attest to its MAC that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility due to a disaster or other emergency. CMS will review the exception request and notify the ESRD facility and the MAC within 30 days if the ESRD facility qualifies for the exception. If CMS approves the request, the ESRD facility is paid the low-volume adjustment on claims for Medicare beneficiaries, on the basis of the exception during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume adjustment are met. For any future payment year, the ESRD facility would not be prevented from receiving the low-volume adjustment if the ESRD facility meets or exceeds the 4,000 treatment threshold in a cost reporting year due to temporary patient-shifting as a result of the disaster or other emergency that resulted in another ESRD facility's closure or operational disruption, so long as all other requirements for the low-volume adjustment are met.

These exceptions are set forth at 42 CFR §§ 413.232(g)(5) and (g)(6).

2. Wage index

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

Rural ESRD facilities use the statewide average.

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

Prior to 2025, the ESRD PPS used the wage index calculated based on data collected from CMS-certified hospitals nationwide for purposes of the acute care hospital inpatient prospective payment system (IPPS). CMS used the IPPS wage index values for each CBSA prior to the application of certain adjustments and modifications applicable to hospitals under the IPPS (i.e., the pre-floor, pre-reclassification wage index). When this IPPS-based wage index was in use, CMS also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For urban areas with no hospital data, CMS computed the average wage index value of all urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA, that is, CMS used that value as the wage index. For rural areas with no hospital data, CMS computed the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. For a full discussion, see CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively.
For CY 2021, CMS adopted the CBSA delineations as described in the September 14, 2018 Office of Management and Budget (OMB) Bulletin No. 18-04. As a result, several counties now have new CBSA numbers. In addition, CMS applied a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's final wage index in CY 2020. This transition was phased in over 2 years, where the reduction in an ESRD facility's wage index was capped at 5 percent in CY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (CY 2022)). These policies were applied budget neutrally and incorporated into the overall ESRD PPS wage index budget neutrality adjustment.
In the CY 2023 ESRD PPS final rule CMS finalized making the 5 percent cap on decreases in wage index permanent. This rule also finalized a wage index floor of 0.600. These policies are applied budget neutrally and incorporated into the overall ESRD PPS wage index budget neutrality adjustment.
Beginning for CY 2025 the ESRD PPS uses a new wage index methodology, which uses data from the Bureau of Labor Statistics (BLS) Occupational Employment Wages & Statistics (OEWS). The new methodology uses mean hourly wage data from BLS OEWS data, which is then weighted by a national ESRD facility occupational mix derived from freestanding ESRD facility cost report data. The BLS OEWS wage data includes data from freestanding ESRD facilities and similar care locations, whereas the prior ESRD PPS wage index methodology was based on the IPPS wage index, which is derived from inpatient acute care hospital data. CMS still applies the wage index floor of 0.600 and the 5 percent cap on wage index decreases finalized in CY 2023.
For CY 2025, CMS adopted the most recent CBSA delineations as described in the July 21, 2023, OMB Bulletin No. 23-01. As a result, several counties now have new CBSA numbers.
ESRD facilities may confirm their CBSA delineation status and wage index value on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.

3. Rural adjustment

Beginning January 1, 2016, the ESRD PPS provides a 1.008 percent payment adjustment for ESRD facilities located in a rural CBSA.

When CMS adopted the newest CBSA definitions according to OMB Bulletin 23-01, CMS also adopted a phase-out policy for ESRD facilities which were located in a rural CBSA in CY 2024 but were re-designated to an urban CBSA in CY 2025. These facilities, which would otherwise lose the rural adjustment for CY 2025 instead receive 2/3rd of the rural adjustment for 2025, a 1.0053 percent payment adjustment, and 1/3rd of the rural adjustment for 2026, a 1.0027 percent payment adjustment.

4. *Non-Contiguous Areas Payment Adjustment*

Beginning January 1, 2026, ESRD facilities located in certain non-contiguous areas of the United States for which CMS has identified as having higher non-labor costs receive an increase to the non-labor portion of the ESRD PPS bundled payment. This increase is 1.21 for ESRD facilities in Hawaii and 1.25 for ESRD facilities in Alaska, Guam, American Samoa, and the Northern Marianas Islands. The non-labor related share of the ESRD PPS base rate is 44.8%. Below is an example calculation using the CY 2026 ESRD PPS final base rate of 281.71 for an ESRD facility in Alaska with a wage index of 1.0775:

CY 2026 Base Rate: $281.71
Labor related share: 0.552
Non-labor related share: 0.448
Wage index: 1.0775
Alaska NAPA Factor: 1.25

*Labor related portion: $281.71 * 0.552 * 1.0775 = $167.56*
*Non-labor related portion: $281.71 * 0.448 * 1.025 = $157.76*
Wage-adjusted base rate: $167.56 + $157.76 = $325.32

The wage-adjusted base rate of $325.32 is the figure to which other case-mix and facility level adjustment factors would be applied.

C. *Add-On Payment Adjustments*

Payment amounts under the ESRD PPS are adjusted by several add-on payment adjustments as described below.

1. Training and Retraining Add-On Payment *Adjustment*

A training add-on payment adjustment is available under the ESRD PPS. The training add-on payment is computed by using the national average hourly wage for nurses from the Bureau of Labor Statistics. The payment accounts for 1.5 hours of nursing time for each training treatment that is furnished and is adjusted by the geographic area wage index. The training add-on payment applies to both peritoneal dialysis and hemodialysis training treatments, and added to the ESRD PPS payment, when a training treatment is provided by a 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.

Beginning for CY 2025, the training and retraining add-on payment adjustment is allowed for claims for renal dialysis services provided to AKI beneficiaries. This is the only add-on payment adjustment extended to AKI dialysis claims.

2. Outlier Payment

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 that were or would have been considered separately billable prior to the implementation of the ESRD PPS. The ESRD PPS outlier policy is set forth at 42 CFR § 413.237. For more information regarding the ESRD outlier services included in the outlier calculation and an example of the outlier calculation, see §60.D of this chapter.

3. TDAPA

The Transitional Drug Add-on Payment Adjustment (TDAPA) is an add-on payment adjustment for claims for services provided to patients who utilize certain new renal dialysis drugs and biological products. The TDAPA is set forth at 42 CFR § 413.234(c). The TDAPA is explained in further detail in §20.3.1 of this chapter.

4. TPNIES

The Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) is an add-on payment adjustment for claims for services provided to patients who utilize certain new and innovative renal dialysis equipment and supplies. The TPNIES is set forth at 42 CFR § 413.236. The TPNIES is explained in further detail in §20.4.1 of this chapter.

5. Post-TDAPA Add-on Payment Adjustment

The post-TDAPA add-on payment adjustment is an add-on payment adjustment for all ESRD PPS patients for 3 years following the end of the TDAPA period for certain renal dialysis drugs and biological products. The amount of the post-TDAPA add-on payment adjustment for a drug or biological product is calculated based on 65% of the total payment for that drug or biological product across the most recent available 12 months of claims data and is published in the annual ESRD PPS rule. The post-TDAPA add-on payment amount for a claim is adjusted by the patient-level case-mix adjusters described in §60.A of this chapter (for pediatric patients this includes the TPEAPA described below and in §60.C.6 of this chapter). The post-TDAPA add-on payment adjustment is only calculated for new renal dialysis drugs and biological products in existing ESRD PPS functional categories. The application of the post-TDAPA add-on payment adjustment is set forth at 42 CFR § 413.234(c)(3), and the methodology for calculating the post-TDAPA add-on payment adjustment is set forth at § 413.234(g).

For drugs and biological products for which there is not 12 months of claims data available at the time of rulemaking, CMS publishes the post-TDAPA add-on payment adjustment amount in a change request 2 calendar quarters before the end of the TDAPA payment period for that drug or biological product.

6. TPEAPA

The Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) is an add-on payment adjustment of 30 percent of the per-treatment payment amount applied to all claims for renal dialysis services provided to ESRD patients aged 18 or younger. The TPEAPA is 30 percent of the per-treatment payment amount for a patient, which reflects both the patient-level case mix adjusters, described in §60.A of this chapter, and the facility level adjusters, described in §60.B of this chapter, but does not include any of the other add-on payment adjustments described in this §60.C. The TPEAPA is a temporary adjustment, which is applied only for CYs 2024, 2025 and 2026. The TPEAPA is set forth at 413.235(b)(2).

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:

- Drugs and biological *products* used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
- Laboratory tests used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
- Medical or surgical supplies used to administer drugs and biological *products* used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and
- Drugs and biological *products* used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Part D*, including renal dialysis oral-only drugs effective January 1, 2025.*
- *New and innovative renal dialysis equipment or supplies previously paid for using the TPNIES, regardless of whether the equipment or supply would have been separately billable prior to 2011 (excluding capital-related assets that are home dialysis machines).*
- *Drugs and biological products that were historically included in the composite rate, as well as newer drugs and biological products that are currently included in the calculation of the post-TDAPA add-on payment adjustment.*

The list of renal dialysis services that are included as outlier services may be found at *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-pps-outlier-services*.

NOTE: All renal dialysis service Part B drugs and biological *products* reported with a HCPCS code that is on the ASP List are included for outlier payments. The laboratory tests that comprise the AMCC panel do not qualify for an outlier *payment*, 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 *ESRD* 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 *(FDL)* 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. *In the CY 2025 ESRD PPS final rule, CMS finalized a change that adds the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for a patient.*

The MAP and FDL amounts are prospectively calculated each year with a target that outlier payments equal 1% of total ESRD PPS payments. For example, the average outlier services MAP amount*s* per treatment for pediatric and adult dialysis patients for CY *2026* were $*50.19* and *$23.68,* 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 20*26* were *$162.43* for pediatric patients and *$14.80* for adult patients. The CY *2026* values of the average outlier services MAP amount and the fixed dollar loss amount are used below for the purpose of following the outlier payment computation. These values may be revised as a result of subsequent rulemaking.

In computing the MAP amount, the adjusters used are:

Adult Characteristics — Adjustment Value

	CY 2011-2015	Beginning CY 2016
Age: 18-44	0.996	1.044
Age: 45-59	0.992	1.000
Age: 60-69	1.000	1.005
Age: 70-79	0.963	1.000
Age: 80+	0.915	0.961
Body Surface Area	1.014	1.000
Low Body Mass Index (BMI <18.5)	1.078	1.090
Onset of Dialysis	1.450	1.409
Pericarditis	1.354	1.209
Bacterial pneumonia	1.422	---
Gastro-intestinal tract bleeding	1.571	1.426
Hereditary hemolytic or sickle cell anemia	1.225	1.999
Myelodysplastic syndrome	1.309	1.494
Monoclonal gammopathy	1.074	---
Low-volume facility adjustment *(either tier)*	0.975	0.955
Rural facility adjustment*	---	0.978

**For CY 2025 and 2026 ESRD facilities that were redesignated from rural to urban will receive 2/3rds and 1/3rd of the rural adjustment respectively. For the outlier services adjustment these values are 0.9853 for CY 2025 and 0.9927 for CY 2026.*

Pediatric Characteristics Adjustment Value

	CY 2011-2015	Beginning CY 2016
Age: <13, Modality: PD	0.319	0.410
Age: <13, Modality: Hemo	1.185	1.406
Age: 13-17, Modality: PD	0.476	0.569
Age: 13-17, Modality: Hemo	1.459	1.494

Both the adult and pediatric CY 2016 separately billable case-mix adjusters are presented for the purpose of following the outlier payment computations shown below and may be revised as a result of subsequent rulemaking.

1. Outlier Payment Calculation

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

The following example shows how outlier payments are calculated under the ESRD PPS. For further information on the calculation of a patient's BSA, see §60.A.1. The pricing amounts for laboratory services qualifying as outlier services are based on the *Medicare C*linical *L*aboratory *F*ee *S*chedule. For injectable drugs and biological *products*, 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 *generally* 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 A/B MAC (A). For further information regarding A/B MAC (A) pricing of medical/surgical supplies, see Pub. 100- 04, chapter 8, §20.1.

2. Example of Outlier Payment

The following is an example of the calculation of the outlier payment *using rates effective January 1, 2026.*

John, a 68 year old male Medicare beneficiary, is 187.96 cm. in height and weighs 95 kg. John receives hemodialysis 3 times weekly. In January 2026, he was hospitalized for 4 days for a compound ankle fracture. During the hospitalization John did not undergo any dialysis treatments. After discharge John resumed his dialysis treatments but required additional laboratory testing and above-average doses of several injectable drugs, particularly EPO, to return his hemoglobin levels to the normal range. During January 2026, John received 9 hemodialysis treatments at his usual ESRD facility. The facility submitted a claim for eligible ESRD outlier services including drugs and biological products, laboratory tests, and supplies totaling $3,000.00.

Begin by computing the predicted MAP amount per treatment based on the ESRD outlier services case-mix adjustment factors applicable to John. These factors are age and BSA. John's BSA is 2.2161.

Applying the ESRD outlier services multiplier from the table in §60.D for BSA, John's ESRD outlier

services payment multiplier for BSA is computed as follows:

$$\{1.000\}^{\{(2.2161-1.9)/0.1\}} = \{1.000\}^{\{3.16135\}} = 1.000$$

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

Using this calculated multiplier for BSA and the multiplier for age from the table in §60.D, John's outlier services PM is calculated as:

*1.005 * 1.000 = 1.005*

*As described in §60.C of this chapter, the (case-mix adjusted) post-TDAPA add-on payment adjustment amount is added to the predicted MAP for a patient. Supposing the post-TDAPA add-on payment adjustment amount for Q1 2025 is $0.50 and John's applicable patient-level case-mix adjustment factors are age (1.070) and BSA ($\{1.032\}^{\{(2.2161-1.9)/0.1\}} = \{1.032\}^{\{3.16135\}} = 1.105$) the post-TDAPA add-on payment adjustment amount for John is $0.59 ($0.50*1.070*1.105).*

*For CY 2026, the national average MAP amount per treatment for adult patients is $23.68. Therefore, the predicted MAP amount per treatment for John is: $23.68 * 1.005 + $0.59 = $24.39.*

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

John's imputed MAP amount per treatment is equal to the total amount of drugs and biological products, laboratory tests, and supplies submitted on the claim, divided by the number of treatments. This is calculated as:

$3000.00 / 9 = $333.33.

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount
Calculate the threshold per treatment by adding the CY 2026 FDL amount to the predicted MAP amount for John.
The threshold amount for John is calculated to reflect the case-mix adjustments for age and BSA.

Threshold = Predicted MAP amount ($24.39) + FDL ($14.80) = $39.19

Because John's imputed MAP amount per treatment was $333.33, which exceeds the sum of the predicted MAP amount and FDL amount ($39.19), John's ESRD facility is eligible for outlier payments.

Step 4: Calculate outlier payment per treatment

The outlier payments for John's 9 treatments are calculated as the amount by which the imputed MAP amount exceeds the threshold, then multiplied by the 80 percent loss-sharing ratio.

Imputed MAP amount minus Threshold: $333.33 - $39.19 = $294.14
*Outlier payments per treatment: $294.14 * .80 = $235.31*
*Total outlier payments: $235.31 * 9 = $2117.79*

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 *and* all applicable *payment* adjustments, *including any applicable add-on payment adjustments such as the TPNIES and the*

TDAPA, 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 renal dialysis service drug or biological *product* or laboratory service furnished to a beneficiary would NOT require a *separate* co-insurance amount*,* because the renal dialysis service drug or biological *product* or laboratory service is included in the *single* payment made to the ESRD facility.

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 - *Reserved*

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

80 - Bad Debt

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

In accordance with 42 CFR §§ 413.89 and 413.178, bad debt payments *are* made for unpaid Medicare deductibles and co-insurance amounts for only those items and services associated with the composite rate *that was in effect prior to the implementation of the ESRD PPS on January 1, 2011. That is, only the bad debt amounts associated with the composite rate portion of the single ESRD PPS bundled payment will be used to determine an ESRD facility's allowable bad debt payments. The composite rate portion of the ESRD PPS payment includes* drugs*, biological products,* and laboratory tests *that were included in the composite rate and their substitutes which would have been included.* 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.

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).

100 - Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

On June 29, 2015, the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114-27) was enacted. In the TPEA, Congress amended the *Social Security* Act *(the Act)* to include coverage and provide for payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act by including coverage for renal dialysis services furnished on or after January 1, 2017*,* by a renal dialysis facility or provider of services currently paid under section 1881(b)(14) of the Act to an individual with AKI. In addition, section 808(b) of *the* TPEA amended section 1834 of the Act by adding a new subsection (r).

Subsection (r)(1) of section 1834 of the Act provides that in the case of renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or a

provider of services paid under such section during a year (beginning with 2017) to an individual with AKI, the amount of payment under Part B for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

100.4 Other Adjustments to the AKI *Dialysis* Payment Rate

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Beginning for 2025 ESRD facilities are allowed to bill for the ESRD PPS home and self-dialysis training add-on payment adjustments on claims for renal dialysis services provided to AKI beneficiaries. For these beneficiaries, the add-on payment adjustment is applied in the same way as under the ESRD PPS, a payment of $95.60 multiplied by the ESRD facility's wage index value, as described in §60.C of this chapter. As this adjustment is required to be extended in a budget neutral basis under section 1834(r) of the Act, we finalized a reduction that rounds to $0.00 per treatment to the AKI dialysis payment rate in the CY 2025 ESRD PPS final rule based on a calculation of estimated training payments. For more information, please see Pub 100-04 Chapter 8 § 40.

100.5 Renal Dialysis Services Included in the AKI *Dialysis* Payment Rate

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Drugs, biological *products*, laboratory services, and supplies that are considered to be renal dialysis services under the ESRD PPS as defined in 42 CFR *§* 413.171, are considered to be renal dialysis services for patients with AKI. As such, no separate payment would be made for renal dialysis drugs, biological *products*, laboratory services, and supplies that are included in the ESRD PPS base rate when they are furnished by an ESRD facility to an individual with AKI.

Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in 42 CFR *§* 413.171, but that are related to their dialysis treatment as a result of their AKI and that an ESRD facility might furnish to a beneficiary with AKI, would be separately payable. In particular, an ESRD facility could seek separate payment for drugs, biological *products*, laboratory services, and supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting. Items and services included on the consolidated billing list are not separately payable for patients with AKI*, except for items and services that are not considered included in the ESRD PPS base rate.*

All dialysis treatments, that is, hemodialysis and peritoneal dialysis, furnished to individuals with AKI in an ESRD facility will be paid the AKI *dialysis* payment rate. This includes any treatments that exceed the three times-weekly limitation applied to treatments furnished to ESRD beneficiaries. CMS expects that individuals with AKI will need renal dialysis services for a finite number of days since the intent of the dialysis for these patients is curative.

100.6 Applicability of Specific ESRD PPS Policies to AKI Dialysis

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

100.6.1. Dialysis Modality

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Beneficiaries with AKI can receive their dialysis via the most clinically appropriate modality.

100.6.2 Uncompleted *AKI* Dialysis Treatment
(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Generally, CMS only pays for one treatment per day across all settings. However, similar to the policy applied under the ESRD PPS for treatments for patients with ESRD, if a dialysis treatment is started, that is, 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, for example, a medical emergency when the patient must be rushed to an emergency room, both the ESRD facility and the hospital would be paid. This is considered to be a rare occurrence that must be fully documented to the A/B MAC's satisfaction. *Please see §50.A.6 of this chapter or Pub. 100-04 Chapter 8 §10.2 for additional information.*

100.6.3 Home and Self-Dialysis
(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Beginning on January 1, 2025, the home dialysis benefit defined at 42 CFR § 410.52 will be extended to beneficiaries with AKI for both PD and HD. The payment amount for home dialysis for AKI beneficiaries will be the same as the payment amount for in-center dialysis for AKI beneficiaries, consistent with payment parity within the ESRD PPS (based on the ESRD PPS base rate adjusted for geographic area according to the wage index, described in §60.B.2 of this chapter). The ESRD PPS add-on payment adjustment for home and self-dialysis training will also be extended to AKI beneficiaries using a home modality, in the same amount as for patients with ESRD ($95.57). The limit for training treatments for PD and HD will be 15 and 25 per patient, respectively, excluding retraining sessions.

100.6.4 Vaccines and Their Administration
(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Section 1881(b)(14)(B) of the Act specifically excludes vaccines covered under section 1861(s)(10) of the Act from the ESRD PPS. However, ESRD facilities are identified as an entity that can bill Medicare for vaccines and their administration. Therefore, ESRD facilities may furnish vaccines to beneficiaries with AKI and bill Medicare in accordance with billing requirements in the Medicare Claims Processing Manual (Pub. 100-04, Chapter 18 Preventive and Screening Services, section 10.2). The staff time associated with vaccine administration is covered in the AKI dialysis payment rate.

100.6.5 Telehealth
(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Telehealth dialysis services are limited to renal dialysis services for home dialysis patients. *See Pub. 100-04, Chapter 12 §190.3.4 for more information about telehealth services.*

100.6.6 ESRD *Facility* Conditions for Coverage (CfCs)
(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

The ESRD *Facility* CfCs at 42 CFR part 494 are health and safety standards that all Medicare participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all patients, including ESRD and AKI patients, receive safe and appropriate care.

100.6.7 Payment for Erythropoietin Stimulating Agents (ESAs) and the ESA Monitoring Policy for AKI Patients

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

ESAs are included in the bundled payment amount for treatments administered to patients with AKI. The Non-ESRD HCPCS codes should be used (J0881, J0883, J0885, J0888, Q0138, Q5106) and reported using revenue code 0636.

100.6.8 Transition from AKI to ESRD

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

Regarding transitioning patients from AKI to ESRD, CMS maintains flexibility for physicians to determine when an AKI patient has regained kidney function, or whether the transition must be made to ESRD treatment. This is a medical decision that should be supported by laboratory tests and the withdrawal of dialysis to determine the extent of recovery of renal function. The goal of AKI treatment should be to have the kidneys return to normal functioning. Physicians complete the ESRD Medical Evidence Report for Medicare Entitlement and/or Patient Registration (CMS 2728, OMB No. 0938-0046) to formally transition the patient from AKI to ESRD for the purposes of registering the patient as an ESRD beneficiary and ensuring appropriate payment under the Medicare ESRD benefit.

100.6.9 Transitional Drug Add-On Payment Adjustment (TDAPA) and Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

As of January 1, 2021, the TDAPA and TPNIES are payment policies under the ESRD PPS and are only applicable for ESRD beneficiaries; therefore, the TDAPA and TPNIES are not applicable to renal dialysis services provided to beneficiaries who have AKI.

140 – *Kidney* Transplantation

(Rev. 13599, Issued: 01-30-26 , Effective: 05-01-26, Implementation: 05-01-26)

A3-3178, RDF-230

Introduction

Kidney transplantation is *the preferred* form of treatment for patients with ESRD. Medicare has developed a method of *payment* for the variety of medical services required to support a *kidney* transplant program, including payment for Medicare's share of the costs of *kidney* procurement. *See 42 CFR § 413.400, et seq. for Medicare's organ acquisition payment regulations.*

In addition, Medicare has developed coverage and *payment* criteria for medical*ly necessary* services provided to potential *kidney* donors and recipients. In some situations, these services are provided before the effective date of Medicare entitlement for the potential *kidney* transplant recipient.

Medicare pays for the covered services provided *to* a Medicare patient who receives a *kidney transplant from a* living or *deceased donor*. *Expenses in providing kidneys to a* transplant *hospital (TH) (a transplant program within a hospital that meets that meets Medicare conditions of participation)* or organ procurement organization (OPO) are included in the *TH's* living or *deceased donor* kidney acquisition cost center*, or the OPO's kidney acquisition cost center, respectively*. To participate in the Medicare program, any *TH* or OPO must be a member of the Organ Procurement and Transplantation Network (OPTN). H*ospitals* are required to notify the OPO designated for *their* service areas of *individuals whose death is imminent or who have died in the hospital (See 42 CFR § 482.45(a)(1) for notification requirements, and 42 CFR § 413.404*, for rules *pertaining to THs and OPOs* in developing a living and *deceased donor standard* acquisition charge *for organs*.)

See the OPTN Web site at *https://optn.transplant.hrsa.gov/about/search-membership/ to search* for transplant *hospitals*, including *hospitals that have* kidney transplant *programs*.

140.1 - Identifying Candidates for *Kidney* Transplantation

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A3-3178.1, RDF-231

After a patient is diagnosed as having ESRD, the physician should determine if the patient is suitable for *kidney* transplantation. If the patient is a suitable *kidney* transplant candidate, a living donor transplant is considered first because of the high success rate in comparison to a *deceased donor* transplant. Whether one or multiple potential donors are available, the following sections provide a general description of the usual course of events in preparation for a liv*ing* donor *kidney* transplant.

140.2 - Identifying Suitable Liv*ing Kidney* Donors

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A3-3178.2, RDF-231

Those who are willing and medically able to donate a kidney are tested to determine whether they are of the same blood type as the recipient. After blood typing, the recipient and the donors are tissue typed. Only those candidates with blood and tissue types similar to the recipient are considered further.

After tissue typing, those medically suitable donors are evaluated on physical, psychological, and social factors. Potential donors who remain after the above testing may be hospitalized for about two days for further evaluation using procedures not appropriately performed on outpatients. These procedures may include intravenous urography and renal arteriography.

If the results of the above tests identify several suitable donors, the most suitable donor is selected, and arrangements are made for the transplant. At such time, the donor and recipient will enter the hospital to undergo the excision and transplantation, respectively.

When tests do not identify an acceptable living donor, the patient is considered for a *kidney transplant using a deceased donor* and placed on hemo- or peritoneal dialysis, if this has not already proved necessary. If the ultimate goal is transplantation, the patient is registered with a *registry for a* kidney transplant.

140.3 - Pre-transplant Outpatient Services

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A3-3178.3

All hospital outpatient services provided to liv*ing* donors and recipients in anticipation of a transplant during the pre-entitlement period and after entitlement, but prior to admission to the hospital for transplantation, are covered. Such services would include kidney recipient registration fees *(see 42 CFR § 413.402(b)(6) for additional requirements related to registry fees)*, laboratory tests (including tissue typing of recipient and donors), and general medical evaluations of the recipient and the donor(s). Pretransplant physicians' services are also covered.

140.4 - Pre-transplant Inpatient Services

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A3-3178.4

The following rules apply to kidney transplant inpatient medical evaluations when the kidney recipient has Medicare entitlement or is in the pre-entitlement period. The pre-entitlement period is that period prior to the patient's actual Medicare entitlement, during which services are furnished in anticipation of a transplant, after the patient has been diagnosed to have end stage renal disease. If the potential kidney recipient does not have *Medicare* entitlement, or is not in the pre-entitlement period, *Medicare will not cover* services rendered to the *potential* kidney recipient or to the living donor for medical evaluations.

140.5 - Living *Kidney* Donor Evaluation, Patient Has Entitlement or is in Pre-entitlement Period

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A3-3178.5, RDF-233.1

When a living donor is admitted to a hospital (before admission for excising the donor kidney) for a medical evaluation in anticipation of a kidney donation, all hospital and physicians' services costs applicable to medical evaluation are considered kidney acquisition service costs. As such, the hospital statistics (charges, patient days, etc.) and the physicians' charges should be treated in accordance with all other kidney acquisition service statistics, and the related costs are included in *the Medicare hospital cost report for kidney acquisition*.

When the liv*ing* donor subsequently enters the hospital for the actual excision, the hospital costs of services rendered to the donor will continue to be treated as kidney acquisition costs under Part A. However, at that point physician services are no longer considered kidney acquisition *costs* and are not reimbursable under Part A. Instead, during the *living* donor's inpatient stay for the excision surgery and during any subsequent *living* donor inpatient stays resulting from a direct complication of the kidney donation, physician services are billed under Part B. They are billed in the normal manner but on the account of the *Medicare transplant* recipient at 100 percent of the fee schedule. Note that services furnished to *living* kidney donors are covered under the *Medicare Beneficiary Identifier* of the *Medicare transplant* recipient.

Services listed in the following sections are also covered. However, they are not billed as such but become a part of the kidney acquisition costs *and are included in the kidney acquisition cost center on the Medicare hospital cost report*.

140.6 - Kidney Recipient Admitted for Transplant Evaluation

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A3-3178.6, RDF-233, RDF-233.2

When a potential *kidney* recipient is admitted to a hospital (before admission for the actual transplant) solely for a medical evaluation for an anticipated kidney transplant, all hospital and physicians' services costs applicable to the anticipated transplant are considered kidney acquisition costs.

140.7 - Kidney Recipient Evaluated for Transplant During Inpatient Stay

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A3-3178.7, RDF-233.3

When a *potential kidney* recipient is admitted to a hospital for a medical reason other than in anticipation of a transplant, but during the stay, a medical evaluation for an anticipated kidney transplant is performed, all hospital and physicians' services costs applicable to the medical evaluation are considered kidney acquisition costs. Accordingly, those services will be treated the same as the services *described in section 140.6*. However, all hospital and physicians' services applicable to the nontransplant related services (i.e., related to the medical services for which the patient was actually admitted) must not be included with kidney acquisition costs; instead *the costs of* such services must be billed in the same manner as any other inpatient service on the account of the recipient. These latter services may be billed to the Medicare program only if the recipient has actual Medicare entitlement.

140.8 - Kidney Recipient Admitted for Transplantation and Evaluation

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A3-3178.8, RDF-233.4

When the medical evaluation for a transplant is performed on the recipient or the living donor during the same inpatient stay in which the actual transplant occurs, all such services will be billed, and the costs will be accumulated in the normal manner. For example, all hospital services rendered to the donor will be considered kidney acquisition *costs*. However, all physicians' services rendered to the living donor and all hospital and physicians' services rendered to the recipient will be billed in the same manner as any other inpatient services on the account of the recipient.

140.9 - Post-transplant Services Provided to Liv*ing Kidney* Donor

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The term Medicare Beneficiary Identifier (M*BI*) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) for certain business areas that will continue to use the HICN as part of their processes.

The donor of a *kidney* for a Medicare beneficiary *transplant recipient* is covered for an unlimited number of days of care in connection with the *kidney* removal operation. Days of inpatient hospital care used by the donor in connection with the *kidney* removal operation shall not be charged against either party's utilization record. However, the program's assumption of liability is limited to those donor expenses that are incurred directly in connection with the *kidney* donation.

Coverage of *kidney* donor services includes postoperative recovery services directly related to the *kidney* donation. For routine follow-up care, the period of postoperative recovery ceases when the donor no longer exhibits symptoms related to the kidney donation. Claims for services rendered more than 3 months after donation surgery will be reviewed. However, follow-up examinations may be covered up to 6 months after the donation to monitor for possible complications. The requirement that additional payment cannot be made for services included in the donor's *kidney* removal charge still applies.

Regarding donor follow-up:

Expenses incurred by the transplant *hospital* for routine donor follow-up care are included in the transplant *hospital*'s *kidney* acquisition cost center.

Follow-up services performed by the operating physician are included in the 90-day global payment for the surgery. Beyond the 90-day global payment period, follow-up services are billed *to Part B* using the recipient's *MBI*.

Routine follow-up services billed *to Medicare* by a physician other than the operating physician for up to 3 months following donation surgery should be billed under the recipient's *MBI*.

Regarding donor complications:

Expenses incurred for complications that arise with respect to the donor are covered only if they are directly attributable to the donation surgery. Complications that arise after the date of the donor's discharge will be billed under the *transplant* recipient's *MBI*. This is true of both facility cost and physician services. *The Medicare Administrative Contractor reviews costs for kidney donor complications billed under the transplant recipient's MBI*.

In all of these situations, the *kidney* donor is not responsible for co-insurance or deductible.

140.10 - Coverage After *Kidney* Recipient Has Exhausted Part A

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A3-3178.11

If the *transplant* recipient has exhausted Part A benefits while the *kidney* donor still requires and receives inpatient hospital care, the program continues to pay for such donor care under Part A at 100 percent reimbursement.

140.11 - *Deceased Donor* Kidney *Acquisition Costs*

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A3-3178.12

Costs incurred by the *transplant hospital* in connection with the acquisition of a *deceased donor* kidney are reimbursable by the program through the kidney acquisition cost center *on the hospital's Medicare cost report*. *Acquisition* costs involved in *procuring* the *deceased donor's* kidney *are set forth in 42 CFR § 413.402(b) and include:*

(1) Tissue typing, including tissue typing furnished by independent laboratories.
(2) Donor and beneficiary evaluation.
(3) Other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or deceased donor.
(4) Operating room and other inpatient ancillary services applicable to the living or deceased donor.
(5) Organ preservation and perfusion costs.
(6) Organ Procurement and Transplantation Network registration fees, and the reasonable and necessary cost of other fees, such as the registration fees for a kidney paired exchange, to register candidates for organ transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature.
(7) Surgeons' fees for excising deceased organs (currently limited to $1,250 for kidneys).
(8) Transportation of the: (i) Excised organ to the transplant hospital; and (ii) Deceased donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs.
(9) Costs of organs acquired from other hospitals or organ procurement organizations.
(10) Hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to inpatient admission).
(11) Costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs.
(12) All pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and the costs of physicians' services.

140.12 - Services Involved

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A3-3178.13, RDF-232

When there is no suitable living donor, a patient with renal failure may be considered for a *deceased donor* transplant. In such cases, the services provided to recipients of "liv*ing* donor" kidneys (i.e., tissue typing and other related tests) are also provided to potential recipients *of deceased donor* kidneys. However, because a kidney may not be available for a long period of time, additional services may be provided in the form of direct physician care for the patient's renal condition, and certain tests may be performed on a regular basis to allow the physician to have current information regarding the status of the patient and their suitability for transplant. In addition, the number of mixed lymphocyte cultures which are prepared whenever a kidney is procured that may suit the recipient depends on the number of kidneys which become available for transplant.

140.13 - Tissue Typing Services for *Deceased Donor* Kidney

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A3-3178.14

See section 140.17

140.14 – Kidneys *Procured En Bloc*

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A3-3178.15

When two kidneys are obtained from a *deceased donor*, and both kidneys are shipped to the same transplant hospital or *OPO*, the hospital should adjust its normal charges to reflect any increased perfusion, preservation, and shipping costs due to the additional kidney. On the other hand, when the kidneys are sent to separate organizations or transplant hospitals, the excising hospital should prorate its charges to the receiving organizations so that the total charges do not exceed the amount that would have been billed if one transplant hospital or *OPO* had received both kidneys.

Under 42 CFR § 413.412(c), for Medicare cost allocation purposes, OPOs and THs count
(1) En bloc kidneys procured and transplanted en bloc (two kidneys transplanted as one unit) as one total usable kidney. En bloc kidneys transplanted into a Medicare beneficiary count as one Medicare usable kidney.
(2) En bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable kidneys. For each kidney transplanted into a Medicare beneficiary, count each as one Medicare usable kidney.

140.15 - Provider Costs Related to *Deceased Donor* Kidney Excisions

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A3-3178.16

Typical provider costs involved in excising a *deceased donor* kidney whether or not it is eventually transplanted include:

- Intensive care costs;
- Surgeon's services, anesthetist services, operating room, preservation supplies (perfusion materials and equipment), preservation technician's services, donor evaluation and support, pathology, central exchange costs (transportation and packaging), and *reasonable* administration costs (overhead items).

140.16 – Non-covered Transplant Related Items and Services

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A3-3178.17

*Pursuant to 42 CFR § 413.402(d), t*he following represents some transplant related items and services *that* are not covered and for which no program payment can be made:

(1) Items or services that are not related or reasonable to acquire a kidney for transplantation, non-allowable administrative and general costs, or costs that are not related to patient care, are not considered kidney acquisition costs.

(2) Examples of items or services that are not kidney acquisition costs include, but are not limited to the following:

- *Kidney donor burial and funeral expenses;*
- *Transportation costs of the deceased donor after kidney procurement for funeral services or for burial;*
- *Transportation costs for a living kidney donor (including travel, room, and board expenses incurred by a living donor;*
- *Fees or in-center payments for kidney donor referrals;*
- *Costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at § 486.326(b));*
- *Unreasonable costs incurred for administrator's duties associated with professional organizations;*
- Travel, room, and board expenses (to any transplant center) incurred by the recipient; and
- Reimbursement for the kidney itself when the liv*ing* donor or the *deceased* donor's next of kin sells the kidney.

140.17 - Other Covered Services

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A3-3178.18

A. Tissue Typing

Tissue typing of the recipient, as well as tissue typing and tests to determine the suitability of a living donor or a *deceased donor* kidney, are covered as medical expenses, necessary for the treatment of an eligible recipient. The costs of these services are covered under the hospital insurance or medical insurance programs (Part B coverage after recipient has exhausted Part A), and are reflected in the kidney acquisition costs.

B. Preservation Laboratories

The services performed by preservation laboratories are medically necessary for the treatment of a beneficiary's illness. A participating hospital is reimbursed for the reasonable cost of such services which its own laboratory performs or which the hospital purchases from a freestanding preservation laboratory or *OPO*.

C. Registration Fees

A participating hospital which expects to perform a kidney transplant will be reimbursed *the reasonable cost* for *OPTN registration fees, and the reasonable and necessary cost of other fees, such as the registration fees for a kidney paired exchange, to register candidates for organ transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature. (42 CFR § 413.402(b)(6)). T*he reasonable cost incurred *is attributable to* listing the patient and the patient's blood characteristics with a professionally recognized organization that maintains a registry of potential transplant candidates, and which provides a regular listing of such patients to hospitals engaged in kidney procurement.

140.18 - Hospitals that Excise but Do Not Transplant Kidneys

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A3-3178.19

The excising hospital plays an important part in the national organ procurement effort. Most of these hospitals are community hospitals and neither excise kidneys on a regular basis nor perform transplants. A hospital that excises but does not transplant kidneys must be certified to participate in the Medicare program. Where the hospital is not participating in the Medicare program, organs may be accepted from it only if they cannot be obtained from any other source.