CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2487	**Date: June 8, 2012**
	Change Request 7749

Note to contractors: Transmittal 2475, dated May 18, 2012 is being rescinded and replaced by Transmittal 2487, dated June 8, 2012, to transmit the correct implementation date on the Business Requirements. The correct date is June 19, 2012. All other information remains the same.

SUBJECT: Internet Only Manual (IOM) Update for Laboratory Services and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Claims Processed under the End Stage Renal Disease Prospective Payment System (ESRD PPS)

I. SUMMARY OF CHANGES: This CR will bring the Internet Only Manual (IOM) up to date on End Stage Renal Disease Prospective Payment System (ESRD PPS) claims processing as it relates to laboratory services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

EFFECTIVE DATE: January 1, 2011
IMPLEMENTATION DATE: June 19, 2012

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	1/10.1/Carrier Jurisdiction of Requests for Payments
R	1/10.1.5.1/Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies, Parental and Enteral Nutrition (PEN)
R	1/30.3.1/ Mandatory Assignment on Carrier Claims
R	1/30.3.8/ Mandatory Assignment and Other Requirements for Home Dialysis Supplies and Equipment Paid Under Method II on Claims Submitted to Carriers
R	16/30.3/ Method of Payment for Clinical Laboratory Tests - Place of Service Variation
R	16/40.6/ Billing for End Stage Renal Disease (ESRD) Related Laboratory Tests
R	16/40.6.1/ Automated Multi-Channel Chemistry (AMCC) Tests for ESRD Beneficiaries
R	16/60.1.3/ Specimen Drawing for Dialysis Patients
R	16/100.6/ Pricing Modifiers
R	20/Table of Contents
R	20/30.8/ Payment for Home Dialysis Supplies and Equipment
R	20/30.8.1/ DMERC, Carrier and FI Determination of ESRD Method Selection
R	20/30.8.2/Installation and Delivery Charges for ESRD Equipment
N	20/30.8.3/Elimination of Method II Home Dialysis

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

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not 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

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 2487	Date: June 8, 2012	Change Request: 7749

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SUBJECT: Internet Only Manual (IOM) Update for Laboratory Services and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Claims Processed under the End Stage Renal Disease Prospective Payment System (ESRD PPS)

Effective Date: **January 1, 2011**
Implementation Date: June 19, 2012

I. GENERAL INFORMATION

A. Background:

Effective for dates of service on and after January 1, 2011, Section 153b of the Medicare Improvement for Patients and Providers Act (MIPPA) required the implementation of an End Stage Renal Disease bundled prospective payment system (ESRD PPS).

B. Policy:

This change request will update claims processing portion of the Internet Only Manual (IOM) to reflect the new ESRD PPS policies as they relate to laboratory services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7749.1	Contractors shall note the revisions to the laboratory and DMEPOS sections of the claims processing IOM to reflect the ESRD PPS policy that became effective for dates of service on and after January 1, 2011.	X	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)						
		A/B	DME	FI	CAR	RHH	Shared-System Maintainers	OTHER

		MAC	MAC		RIER	I	FISS	MCS	VMS	CWF	
	None.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

X-Ref Requirement Number	Recommendations or other supporting information:
	None.

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s):
Felicia Rowe at Felicia.Rowe@cms.hhs.gov

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

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers,* use only one of the following statements:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs),* include the following statement:

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.

Medicare Claims Processing Manual
Chapter 1 - General Billing Requirements

10.1 - Carrier Jurisdiction of Requests for Payment

(Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12)

B3-3100

Carriers have jurisdiction for all claims from the following:
• Physicians;
• Other individual practitioners;
• Groups of physicians or practitioners;
• Labs not part of a hospital;
• Ambulance claims submitted by ambulance companies under their own Medicare number (hospitals may operate ambulances as part of the hospital and bill the intermediary (FI));
• Ambulatory surgical centers (ASCs); and
• Independent diagnostic testing facilities (IDTFs).

Durable *Medical Equipment Medicare Administrative Contractors (DME MACs)* have jurisdiction for claims from the following:

• Nonimplantable durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) (including home use);

• Suppliers of enteral and parenteral products other than to inpatients covered under Part A;

• Oral drugs billed by pharmacies; and

• Method II home dialysis *(for dates of service prior to January 1, 2011)*. ***Note:*** *Please refer to Section 30.3.8 for information regarding the elimination of Method II home dialysis for dates of service on and after January 1, 2011.*

The CMS maintains a list of which HCPCS codes are under *DME MAC* jurisdiction and which are area carrier jurisdiction, and issues updates to *DME MACs* and carriers as needed.
There are four *DME MACs* each of which is assigned specific States.

Medicare area carriers typically process Part B fee-for-service claims for services furnished in specific geographic areas (e.g., a State). However a single carrier processes all physician/supplier claims for railroad retirement beneficiaries. (See §10.1.3 for claims for Part B medical services performed outside the U.S. for individuals who reside in the U.S.).

The rules for determining jurisdiction are the same whether a claim is assigned or nonassigned (see §30.3 for assignment rules).

Further information on carriers for specific geographic areas is available on the CMS Web site at http://www.cms.hhs/contacts/incardir.asp.
Most skilled nursing facilities submit claims to the FI. However, a nonparticipating skilled nursing facility (SNF) is considered a supplier and its claims are submitted to the appropriate carrier under its own Medicare supplier number.

10.1.5.1 - Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies, Parental and Enteral Nutrition (PEN)

(*Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12*)

B3-3116, B-3102

Claims for DMEPOS submitted by suppliers for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) are handled by *Durable Medical Equipment Medicare Administrative Contractors (DME MACs).*

To determine which services are processed by *DME MACs* vs. local carriers, CMS maintains and updates a table of services by HCPCS code that indicates who to bill for which services. The CMS updates this list by a special One-Time Special Notification as needed. In general, claims for DMEPOS, other than implanted durable medical equipment and implanted prosthetic devices, are processed by the appropriate *DME MAC.* The appropriate *A/B MAC* processes claims for implanted durable medical equipment and implanted prosthetic devices, as well as DMEPOS items incident to a physician's service.

Note that **surgical procedures** for implantable DME or for prosthetic devices, performed in an inpatient or outpatient hospital setting include the cost of the device in the Diagnosis Related Group (DRG) or Ambulatory Payment Classification (APC) rate. However, there are some implantable devices that are eligible for separate pass through under Outpatient Prospective Payment System (OPPS). *DME MACs* do not process claims for DMEPOS items that are subject to consolidated billing or bundled payment under Prospective Payment System (PPS) or in a DRG.

Claims from parenteral and enteral nutrition (PEN) suppliers are processed by the *DME MAC.*

Method II ESRD claims *for dates of service prior to January 1, 2011,* are also processed by the *DME MAC. For dates of service on and after January 1, 2011, refer to Section 30.3.8 for information regarding the elimination of Method II home dialysis.*

The claims processing jurisdiction among *DME MACs* is determined by the beneficiary's permanent address. A beneficiary's permanent address is determined by where the beneficiary resides for more than six months of a year. See the CMS Web site at http://www.cms.hhs.gov/contacts/incardir.asp for a list of State jurisdictions by *DME MAC.*

30.3.1 - Mandatory Assignment on Carrier Claims

(Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12)

The following practitioners who provide services under the Medicare program are required to accept assignment for all Medicare claims for their services. This means that they must accept the Medicare allowed amount as payment in full for their practitioner services. The beneficiary's liability is limited to any applicable deductible plus the 20 percent coinsurance.

Assignment is mandated for the following claims:
• Clinical diagnostic laboratory services and physician lab services;
• Physician services to individuals dually entitled to Medicare and Medicaid;

Services of physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, certified registered nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians/nutritionists, anesthesiologist assistants, and mass immunization roster billers.

NOTE: The provider type Mass Immunization Roster Biller can only bill for influenza and pneumococcal vaccinations and administrations. These services are **not** subject to the deductible or the 20 percent coinsurance.

• Ambulatory surgical center services; (No deductible and 25% coinsurance for colorectal cancer screening colonoscopies {G0105 and G0121) and effective for dates of service on or after January 1, 2008 G0104 also applies);

• Home dialysis supplies and equipment paid under Method II *for dates of service prior to January 1, 2011. Refer to Section 30.3.8 for information regarding the elimination of Method II home dialysis for dates of service on and after January 1, 2011.;*

• Drugs and biologicals; and,

• Ambulance services

When these claims are inadvertently submitted as unassigned, carriers process them as assigned. Note that, unlike physicians, practitioners, or suppliers bound by a participation agreement, practitioners/entities providing the services/supplies identified above are required to accept assignment only with respect to these services/supplies (unless they have signed participation agreements which blanket the full range of their services).

The carrier system must be able to identify (and update) the codes for those services subject to the assignment mandate.

For the practitioner services of physicians and independently practicing physical and occupational therapists, the acceptance of assignment is not mandatory. Nor is the acceptance of assignment mandatory for the suppliers of radiology services or diagnostic tests. However, these practitioners and suppliers may nevertheless voluntarily agree to participate to take advantage of the higher

payment rate, in which case the participation status makes assignment mandatory for the term of the agreement. Such an agreement is known as the Medicare Participating Physician or Supplier Agreement. (See §30.3.12.2 Carrier Participation Agreement.) Physicians, practitioners, and suppliers who sign this agreement to participate are agreeing to accept assignment on all Medicare claims. The Medicare Participation Agreement and general instructions are on the CMS Web site.

Future updates to this section will be communicated in a Recurring Update Notification.

30.3.8 - Mandatory Assignment and Other Requirements for Home Dialysis Supplies and Equipment Paid Under Method II on Claims Submitted to Carriers

(*Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12*)

B3-3045.7

For services furnished prior to January 1, 2011, the DME MACs pay only on an assignment basis for home dialysis supplies and equipment furnished *to* a beneficiary who ha*d* selected Method II.

Effective for dates of service on and after January 1, 2011, Section 153b of the Medicare Improvements for Patients and Providers Act (MIPPA) eliminated Method II home dialysis claims. All home dialysis claims must be billed by an ESRD facility and paid to the ESRD facility under the ESRD PPS.

Refer to chapter 8 and chapter 20 for more information.

Medicare Claims Processing Manual
Chapter 16 – Laboratory Services

30.3 - Method of Payment for Clinical Laboratory Tests - Place of Service Variation

(Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12)

The following apply in determining the amount of Part B payment for clinical laboratory tests:

Independent laboratory or a physician or medical group - Payment to an independent laboratory or a physician or medical group is the lesser of the actual charge, the fee schedule amount or the national limitation amount. Part B deductible and coinsurance do not apply.

Reference laboratory - For tests performed by a reference laboratory, the payment is the lesser of the actual charge by the billing laboratory, the fee schedule amount, or the national limitation amount (NLA). (See §50.5 for carrier jurisdiction details.) Part B deductible and coinsurance do not apply.

Outpatient of the hospital - Payment to a hospital for laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule, furnished to an outpatient of the hospital, is the lesser of the actual charge, fee schedule amount, or the NLA. Part B deductible and coinsurance do not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS.

Exception: Reasonable cost reimbursement has been provided for outpatient clinical laboratory tests furnished by hospitals with fewer than 50 beds in qualified rural areas for cost reporting periods beginning on July 1, 2004 through 2008 (per the following legislation: Section 416 of the Medicare Modernization Act (MMA) of 2003, Section 105 of the Tax Relief and Health Care Act (TRHCA) of 2006, and Section 107 of the Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) Extension Act of 2007). Section 3122 of the Patient Protection and Affordable Care Act re-institutes the above reasonable cost provisions for cost reporting periods beginning on or after July 1, 2010, through June 30, 2011. Section 109 of the Medicare and Medicaid Extenders Act extends the above reasonable cost provisions for cost reporting periods beginning on or after July 1, 2011, through June 30, 2012.

Non-Patient Laboratory Specimen-Laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule for a non-patient laboratory specimen (bill type 14X) is the lesser of the actual charge, the fee schedule amount, or the NLA (including MD Waiver hospitals). Part B deductible and coinsurance do

not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) or the current methodology for hospitals not subject to OPPS.

Inpatient without Part A - Payment to a hospital for laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule, is the lesser of the actual charge, fee schedule amount, or the NLA. Part B deductible and coinsurance do not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS. Payment to a SNF inpatient without Part A coverage is made under the laboratory fee schedule.

Inpatient or SNF patient with Part A - Payment to a hospital for laboratory tests furnished to an inpatient, whose stay is covered under Part A, is included in the PPS rate for PPS facilities or is made on a reasonable cost basis for non-PPS hospitals and is made at 101 percent of reasonable cost for CAHs. Payments for lab services for beneficiaries in a Part A stay in a SNF, other than a swing bed in a CAH are included in the SNF PPS rate. For such services provided in a swing bed of a CAH, payment is made at 101 percent of reasonable cost.

Sole community hospital - Payment to a sole community hospital for tests furnished for an outpatient of that hospital is the least of the actual charge, the 62 percent fee schedule amount, or the 62 percent NLA. The Part B deductible and coinsurance do not apply.

Waived Hospitals - Payment for outpatient (bill type13X), to a hospital which has been granted a waiver of Medicare payment principles for outpatient services is subject to Part B deductible and coinsurance unless otherwise waived as part of an approved waiver. Specifically, laboratory fee schedules do not apply to laboratory tests furnished by hospitals in States or areas that have been granted demonstration waivers of Medicare reimbursement principles for outpatient services. The State of Maryland has been granted such demonstration waivers. Payment for non-patient laboratory specimens (bill type14X) is based on the fee schedule**.** Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be paid based on current methodology.

Critical Access Hospital - When the CAH bills a 14X bill type as a non-patient laboratory specimen, it is paid on the laboratory fee schedule.

Beneficiaries are not liable for any coinsurance, deductible, co-payment, or other cost sharing amount with respect to CAH clinical laboratory services.

<u>Section 148 of The Medicare Improvements for Patients and Providers Act (MIPPA)</u>

A CAH will be paid 101 percent of reasonable cost for outpatient clinical diagnostic laboratory tests. Effective for services furnished on or after July 1, 2009, the individual is no longer required to be physically present in a CAH at the time the specimen is collected. However, the individual must be an outpatient of the CAH, as defined at 42 CFR §410.2 and be receiving services directly from the CAH. In order for the individual to be receiving services directly from the CAH, the individual must either be

receiving outpatient services in the CAH on the same day the specimen is collected, or the specimen must be collected by an employee of the CAH or of a facility provider-based to the CAH.

Dialysis facility - *Effective for items and services furnished on or after January 1, 2011 Section 153b of the Medicare Improvements for Patients and Providers Act (MIPPA) requires that all ESRD-related laboratory tests be reported by the ESRD facility whether provided directly or under arrangements with an independent laboratory. When laboratory services are billed by a laboratory other than the ESRD facility and the laboratory service furnished is designated as a laboratory test that is included in the ESRD PPS (i.e., ESRD-related), the claim will be rejected or denied. . The list of items and services subject to consolidated billing located at* http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage *includes the list of ESRD-related laboratory tests that are routinely performed for the treatment of ESRD. In the event that an ESRD-related laboratory service was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the supplier may submit a claim for separate payment using modifier "AY". See Publication 100-04, Chapter 8 for more information regarding Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims.*

Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC) - Payment to a RHC/FQHC for laboratory tests performed for a patient of that clinic/center is not included in the all-inclusive rate and may be billed separately by either the base provider for a provider-based RHC/FQHC, or by the physician for an independent or free-standing RHC/FQHC. Payment for the laboratory service is not subject to Part B deductible and coinsurance. If the RHC/FQHC is provider-based, payment for lab tests is to the base provider (i.e., hospital). If the RHC/FQHC is independent or freestanding, payment for lab tests is made to the practitioner (physician) via the clinical lab fee schedule. (See Sections 30.1.1 and 40.5 for details on RHC/FQHC billing.)

Enrolled in Managed Care - Payment to a participating health maintenance organization (HMO) or health care prepayment plan (HCPP) for laboratory tests provided to a Medicare beneficiary who is an enrolled member is included in the monthly capitation amount.

Non-enrolled Managed Care - Payment to a participating HMO or HCPP for laboratory tests performed for a patient who is not a member is the lesser of the actual charge, or the fee schedule, or the NLA. The Part B deductible and coinsurance do not apply.

Hospice - Payment to a hospice for laboratory tests performed by the hospice is included in the hospice rate.

40.6 - Billing for End Stage Renal Disease (ESRD) Related Laboratory Tests

(*Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12*)

With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate and must be reported by the ESRD facility and are not separately paid. For instructions on ESRD facility billing under ESRD PPS, see Publication 100-04, Chapter 8. The list of items and services subject to consolidated billing located at http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage *includes the list of ESRD-related laboratory tests that are routinely performed for the treatment of ESRD.*

Laboratory services that are not related to the treatment of ESRD are separately billable under the ESRD PPS and may be billed by either the ESRD facility or the independent laboratory. If the ESRD facility or independent laboratory bills a laboratory service that was not related to the treatment of ESRD, the bill must include the modifier AY. The AY modifier serves as an attestation that the item or service is medically necessary for the dialysis patient but is not being used for the treatment of ESRD.

40.6.1 – Automated Multi-Channel Chemistry (AMCC) Tests for ESRD Beneficiaries

(*Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12*)

Section 153b of the MIPPA requires that all ESRD-related laboratory tests must be reported by the ESRD facility whether provided directly or under arrangements with an independent laboratory. When laboratory services are billed by providers other than the ESRD facility and the laboratory test furnished is designated as a laboratory test that is included in the ESRD PPS (ESRD-related), the claim will be rejected or denied. In the event that an ESRD-related laboratory test was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the provider may submit a claim for separate payment using modifier AY. The AY modifier serves as an attestation that the item or service is medically necessary for the dialysis patient but is not being used for the treatment of ESRD. The items and services subject to consolidated billing located at http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage *includes the list of ESRD-related laboratory tests that are routinely performed for the treatment of ESRD.*

For services provided on or after January 1, 2011, the 50/50 rule no longer applies to independent laboratory claims for AMCC tests furnished to ESRD beneficiaries. The 50/50 rule modifiers (CD, CE, and CF) are sunsetted for independent laboratories effective for dates of service on and after January 1, 2011. However, the 50/50 rule modifiers are still required for use by ESRD facilities that are receiving the transitional blended payment amount (the transition ends in CY 2014). Information regarding the ESRD PPS transition can be found in Publication 100-04, Chapter 8, §20.1.

Effective for dates of service on and after January 1, 2012, contractors shall allow organ disease panel codes (i.e., HCPCS codes 80047, 80048, 80051, 80053, 80061, 80069, and 80076) to be billed by independent laboratories for AMCC panel tests furnished to ESRD eligible beneficiaries if:

- *The beneficiary is not receiving dialysis treatment for any reason (e.g., post-transplant beneficiaries), or*
- *The test is not related to the treatment of ESRD, in which case the supplier would append modifier "AY".*

Contractors shall make payment for organ disease panels according to the Clinical Laboratory Fee Schedule and shall apply the normal ESRD PPS editing rules for independent laboratory claims described in Transmittal 2134, issued January 14, 2011. The aforementioned organ disease panel codes will be added to the list of bundled ESRD PPS laboratory tests in January 2012.

Prior to January 1, 2011

A-03-033

For claims with dates of service prior to January 1, 2011, Medicare will apply the following rules to Automated Multi-Channel Chemistry (AMCC) tests for ESRD beneficiaries:

- Payment is at the lowest rate for tests performed by the same provider, for the same beneficiary, for the same date of service.

- The facility/laboratory must identify, for a particular date of service, the AMCC tests ordered that are included in the composite rate and those that are not included. See Publication 100-02, Chapter 11, Section 30.2.2 for the chart detailing the composite rate tests for Hemodialysis, Intermittent Peritoneal Dialysis (IPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Hemofiltration as well as a second chart detailing the composite rate tests for Continuous Ambulatory Peritoneal Dialysis (CAPD).

- If 50 percent or more of the covered tests are included under the composite rate payment, then all submitted tests are included within the composite payment. In this case, no separate payment in addition to the composite rate is made for any of the separately billable tests.

- If less than 50 percent of the covered tests are composite rate tests, all AMCC tests submitted for that Date of Service (DOS) for that beneficiary are separately payable.

- A noncomposite rate test is defined as any test separately payable outside of the composite rate or beyond the normal frequency covered under the composite rate that is reasonable and necessary.

- For carrier processed claims, all chemistries ordered for beneficiaries with chronic dialysis for ESRD must be billed individually and must be rejected when billed as a panel.

(See §100.6 for details regarding pricing modifiers.)

Implementation of this Policy:

ESRD facilities when ordering an ESRD-related AMCC must specify for each test within the AMCC whether the test:

a. Is part of the composite rate and not separately payable;

b. Is a composite rate test but is, on the date of the order, beyond the frequency covered under the composite rate and thus separately payable; or

c. Is not part of the ESRD composite rate and thus separately payable.

Laboratories must:

a. Identify which tests, if any, are not included within the ESRD facility composite rate payment

b. Identify which tests ordered for chronic dialysis for ESRD as follows:

1) Modifier CD: AMCC Test has been ordered by an ESRD facility or MCP physician that is part of the composite rate and is not separately billable.

2) Modifier CE: AMCC Test has been ordered by an ESRD facility or MCP physician that is a composite rate test but is beyond the normal frequency covered under the rate and is separately reimbursable based on medical necessity.

3) Modifier CF: AMCC Test has been ordered by an ESRD facility or MCP physician that is not part of the composite rate and is separately billable.

c. Bill all tests ordered for a chronic dialysis ESRD beneficiary individually and not as a panel.

The shared system must calculate the number of AMCC tests provided for any given date of service. Sum all AMCC tests with a CD modifier and divide the sum of all tests with a CD, CE, and CF modifier for the same beneficiary and provider for any given date of service.

If the result of the calculation for a date of service is 50 percent or greater, do not pay for the tests.

If the result of the calculation for a date of service is less than 50 percent, pay for all of the tests.

For FI processed claims, all tests for a date of service must be billed on the monthly ESRD bill. Providers that submit claims to a FI must send in an adjustment if they identify additional tests that have not been billed.

Carrier standard systems shall adjust the previous claim when the incoming claim for a date of service is compared to a claim on history and the action is adjust payment. Carrier standard systems shall spread the payment amount over each line item on both claims (the claim on history and the incoming claim).

The organ and disease oriented panels (80048, 80051, 80053, and 80076) are subject to the 50 percent rule. However, clinical diagnostic laboratories shall not bill these services as panels, they must be billed individually. Laboratory tests that are not covered under the composite rate and that are furnished to

CAPD end stage renal disease (ESRD) patients dialyzing at home are billed in the same way as any other test furnished home patients.

FI Business Requirements for ESRD Reimbursement of AMCC Tests:

Requirement Number	Requirements	Responsibility
1.1	The FI shared system must RTP a claim for AMCC tests when a claim for that date of service has already been submitted.	Shared system
1.2	Based upon the presence of the CD, CE and CF payment modifiers, identify the AMCC tests ordered that are included and not included in the composite rate payment.	Shared System
1.3	Based upon the determination of requirement 1.2, if 50 percent or more of the covered tests are included under the composite rate, no separate payment is made.	Shared System
1.4	Based upon the determination of requirement 1.2, if less than 50 percent are covered tests included under the composite rate, all AMCC tests for that date of service are payable.	Shared System
1.5	Effective for claims with dates of service on or after January 1, 2006, include any line items with a modifier 91 used in conjunction with the "CD," "CE," or "CF" modifier in the calculation of the 50/50 rule.	Shared System
1.6	FIs must return any claims for additional tests for any date of service within the billing period when the provider has already submitted a claim. Instruct the provider to adjust the first claim.	FI or Shared System
1.7	After the calculation of the 50/50 rule, services used to determine the payment amount may never exceed 22. Effective for claims with dates of service on or after January 1, 2006, accept all valid line items submitted for the date of service and pay a maximum of the ATP 22 rate.	Shared System

Carrier Business Requirements for ESRD Reimbursement of AMCC Tests:

Requirement #	Requirements	Responsibility
1	The standard systems shall calculate payment at the lowest rate for these automated tests even if reported on separate claims for services performed by the same provider, for the same beneficiary, for the same date of service.	Standard Systems

2	Standard Systems shall identify the AMCC tests ordered that are included and are not included in the composite rate payment based upon the presence of the "CD," "CE" and "CF" modifiers.	Standard Systems
3	Based upon the determination of requirement 2 if 50 percent or more of the covered services are included under the composite rate payment, Standard Systems shall indicate that no separate payment is provided for the services submitted for that date of service.	Standard Systems
4	Based upon the determination of requirement 2 if less than 50 percent are covered services included under the composite rate, Standard Systems shall indicate that all AMCC tests for that date of service are payable under the 50/50 rule.	Standard Systems
5	Effective for claims with dates of service on or after January 1, 2006, include any line items with a modifier 91 used in conjunction with the "CD," "CE," or "CF" modifier in the calculation of the 50/50 rule.	Standard Systems
6	Standard Systems shall adjust the previous claim when the incoming claim is compared to the claim on history and the action is to deny the previous claim. Spread the payment amount over each line item on both claims (the adjusted claim and the incoming claim).	Standard Systems
7	Standard Systems shall spread the adjustment across the incoming claim unless the adjusted amount would exceed the submitted amount of the services on the claim.	Standard System
8	After the calculation of the 50/50 rule, services used to determine the payment amount may never exceed 22. Accept all valid line items for the date of service and pay a maximum of the ATP 22 rate.	Standard Systems

Examples of the Application of the 50/50 Rule

The following examples are to illustrate how claims should be paid. The percentages in the action section represent the number of composite rate tests over the total tests. If this percentage is 50 percent or greater, no payment should be made for the claim.

Example 1:

Provider Name: Jones Hospital

DOS 2/1/02

Claim/Services 82040 Mod CD

82310 Mod CD

82374 Mod CD

82435 Mod CD

82947 Mod CF

84295 Mod CF

82040 Mod CD (Returned as duplicate)

84075 Mod CE

82310 Mod CE

84155 Mod CE

ACTION: 9 services total, 2 non-composite rate tests, 3 composite rate tests beyond the frequency, 4 composite rate tests; 4/9 = 44.4%<50% pay at ATP 09

Example 2:

Provider Name: Bon Secours Renal Facility

DOS 2/15/02

Claim/Services 82040 Mod CE and Mod 91

84450 Mod CE

82310 Mod CE

82247 Mod CF

82465 No modifier present

82565 Mod CE

84550 Mod CF

82040 Mod CD

84075 Mod CE

82435 Mod CE

82550 Mod CF

82947 Mod CF

82977 Mod CF

ACTION: 12 services total, 5 non-composite rate tests, 6 composite rate tests beyond the frequency, 1 composite rate test; 1/12 = 8.3%<50% pay at ATP 12

Example 3:

Provider Name: Sinai Hospital Renal Facility

DOS 4/02/02

Claim/Services 82565 Mod CD

83615 Mod CD

82247 Mod CF

82248 Mod CF

82040 Mod CD

84450 Mod CD

82565 Mod CE

84550 Mod CF

82248 Mod CF (Duplicate

ACTION: 8 services total, 3 non-composite rate tests, 4 composite rate tests, 1 composite rate test beyond the frequency; 4/8 = 50%, therefore no payment is made.

Example 4:

Provider Name: Dr. Andrew Ross

DOS 6/01/02

Claim/Services 84460 Mod CF

82247 Mod CF

82248 Mod CF

82040 Mod CD

84075 Mod CD

84450 Mod CD

ACTION: 6 services total, 3 non-composite rate tests and 3 composite rate tests; 3/6 = 50%, therefore no payment.

Example 5: (Carrier Processing Example Only)

Payment for first claim, second creates a no payment for either claim

Provider Name: Dr. Andrew Ross

DOS 6/01/06 84460 Mod CF

82247 Mod CF

82248 Mod CF

ACTION: 3 services total, 3 non-composite rate tests, 0 composite rate tests beyond the frequency, and 0 composite rate tests, 0/3 = 0%, therefore ATP 03

Second Claim: No payment.

Provider Name: Dr. Andrew Ross

DOS 6/01/06 82040 Mod CD

84075 Mod CD

84450 Mod CD

ACTION: An additional 3 services are billed, 0 non-composite rate tests, 8 composite rate test beyond the frequency, 3 composite rate tests. For both claims there are 6 services total, 3 non-composite rate tests and 3 composite rate tests; 3/6 = 50% $\geq$ 50%, therefore no payment. An overpayment should be recovered for the ATP 03 payment.

60.1.3 - Specimen Drawing for Dialysis Patients

(Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12)

See the Medicare Benefit Policy Manual, Chapter 11, for a description of laboratory services included in the composite rate. *With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate.*

Clinical laboratory tests can be performed individually or in predetermined groups on automated profile equipment. A specimen collection fee determined by CMS (as of this writing, up to $3.00) will be allowed only in the following circumstances:

- Drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with a syringe or vacutainer to draw the specimen).

- Collecting a urine sample by catheterization.

Special rules apply when such services are furnished to dialysis patients. The specimen collection fee is not separately payable for patients dialyzed in the facility or for patients dialyzed at home under reimbursement Method I. *A specimen collection fee is also not separately payable when an ESRD facility is collecting a specimen for transplant eligibility or other transplant requirements.* Payment for specimen collection is included under the ESRD *PPS*, regardless of whether the laboratory test itself is included in the *ESRD PPS* or is separately billable *with the AY modifier (see §40.6 of this Chapter).*

Fees for taking specimens in the hospital setting, but outside of the dialysis unit, for use in performing laboratory tests not included in the ESRD composite rate may be paid separately.

100.6 - Pricing Modifiers

(Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12)

PM A-03-033

Prior to January 1, 2011

Three pricing modifiers discretely identify the different payment situations for ESRD Automated Multi-Channel Chemistry (AMCC) tests. The physician that orders the tests is responsible for identifying the appropriate modifier when ordering the tests. The modifiers are in the following listing:

- CD - AMCC test has been ordered by an ESRD facility or MCP physician that is part of the composite rate and is not separately billable
- CE - AMCC test has been ordered by an ESRD facility or MCP physician that is a composite rate test but is beyond the normal frequency covered under the rate and is separately reimbursable based on medical necessity
- CF - AMCC test has been ordered by an ESRD facility or MCP physician that is not part of the composite rate and is separately billable

The ESRD clinical laboratory tests identified with modifiers "CD," "CE," or "CF" may not be billed as organ or disease panels. Effective October 1, 2003, all ESRD clinical laboratory tests must be billed individually.

Effective January 1, 2011

With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate. If the ESRD facility needs to report a lab service that was not related to the treatment of ESRD, they must include the modifier AY to indicate the item or service is not for the treatment of ESRD. Modifiers CD, CE, and CF (also known as the 50/50 rule modifiers) are no longer valid for use on independent laboratory claims.

Effective January 1, 2012, contractors shall allow organ disease panel codes (i.e., HCPCS codes 80047, 80048, 80051, 80053, 80061, 80069, and 80076) to be billed by independent laboratories for AMCC panel tests furnished to ESRD eligible beneficiaries.

For more information regarding billing of AMCC tests for ESRD beneficiaries, see Section 40.6.1 of this manual.

Medicare Claims Processing Manual
Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

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30.8 - Payment for Home Dialysis Supplies and Equipment

(*Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12*)

B3-4272, B3-4272.1 partial, A3-3644, B3-3045.7

*For dates of service prior to January 1, 2011, t*here are two methods of payment for home dialysis equipment and supplies: Method I and Method II.

Under Method I, benefits are paid by a Medicare FI on the basis of a prospective payment, the composite rate. (See Chapters 8 and 12. for more information on establishing the composite rate). Under Method II, the *DME MAC* pays for supplies and services other than physician services. Physician services are paid at a monthly capitation rate by the local carrier. See Chapters 8 and 12 for more information on payment under Method II.

For dates of service on and after January 1, 2011, please refer to Section 30.8.3 for information on the elimination of Method II home dialysis.

30.8.1 – *DME MAC and A/B MAC* Determination of ESRD Method Selection

(*Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12*)

AB-01-61
A. Method Selection and Form CMS-382

*For services furnished prior to January 1, 2011, t*he beneficiary *was required to* complete Form CMS-382 to choose either Method I or Method II dialysis. Method I dialysis patients receive their home dialysis equipment and supplies from a dialysis facility. Method II patients chose to deal with a home dialysis supplier that is not a dialysis facility. Once a beneficiary made a method selection choice, the beneficiary or dialysis facility *submitted* the Form CMS-382 to the appropriate FI. The FI then *processed* information from the form to CWF. Chapter 8 *provided the* instructions *for completing* the form.

*For dates of service prior to January 1, 2011, t*he *DME MACs* deny Method II claims where there is no method selection or the method selection has a value of '1' on file at CWF.

For dates of service on and after January 1, 2011, please refer to Section 30.8.3 for information on the elimination of Method II home dialysis.

B. Changes in Method Selection
*Prior to the implementation of the ESRD PPS, for dates of service prior to January 1, 2011, i*f a beneficiary decide*d* to change his or her choice of method selection, he or she fill*ed* out a new Form CMS-382 to indicate the change. The beneficiary *could have* fill*ed* out a new method selection form at any time, but in most circumstances, the change *did* not take effect until January 1 of the following calendar year. If a beneficiary request*ed* an exception to the January 1 implementation date in writing

from the FI, the FI *could have chosen* to grant his or her request. See Chapter 8 for related requirements.
The *DME MAC* systems must be able to interpret the CWF trailer record that contains the method effective date.

For dates of service on and after January 1, 2011, please refer to Section 30.8.3 for information on the elimination of Method II home dialysis.

30.8.2 - Installation and Delivery Charges for ESRD Equipment

(*Rev.2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12*)

3-5105.1

ESRD facilities are responsible for all reasonable and necessary expenses incurred in the initial installation of home dialysis equipment, but not those expenses attributable to items that are basically for the purpose of improving the patient's home, e.g., plumbing or electrical work beyond that necessary to tie in with existing power or water lines.
The delivery and installation of renal dialysis equipment, unlike that involved when a hospital bed is delivered and set up, requires testing and assurance of equipment performance. Therefore, if the supplier of home dialysis equipment customarily charges for delivery and service, and this is a common practice among other suppliers as well, this is payable.

30.8.3- Elimination of Method II Home Dialysis

Effective for dates of service on and after January 1, 2011, Section 153b of the Medicare Improvements for Patients and Providers Act (MIPPA) eliminated Method II home dialysis claims. Specifically, Method II home dialysis is no longer recognized as a beneficiary option for dates of services beginning January 1, 2011, therefore, all ESRD patients that previously selected Method II are covered under Method I. All home dialysis claims must be billed by an ESRD facility and paid under the ESRD PPS. As a result, the submission of the CMS-382 form to the Medicare contractors is no longer required for home dialysis patients on or after January 1, 2011.

Method II claims will not be accepted for dates of service on or after January 1, 2011. Method II claims for dates of service prior to January 1, 2011 will continue to be processed within normal timely filing limitations. For more information on timely filing, see Pub. 100-04, Chapter 1, Sections 70 through 70.8.6.

For dates of service on or after January 1, 2011, contractors shall continue to allow separate billing for certain ESRD supply HCPCS codes subject to the ESRD PPS consolidated billing requirements when submitted by suppliers for services not related to the beneficiary's ESRD dialysis treatment and billed with the modifier AY. Contractors shall pay for ESRD supplies subject to ESRD CB when billed on a CMS-1500 or electronic equivalent if the ESRD supply claims contain modifier AY. A list of equipment and supplies eligible for separate payment when billed with modifier AY can be found in the first table (DME ESRD Supply HCPCS for ESRD PPS Consolidated Billing Edits) of the document titled "Items and Services Subject to Consolidated Billing for the ESRD PPS" located at the ESRD Payment website:
http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage.

Some equipment and supplies are ESRD-related but are not used in other provider settings and will, therefore, never be used for reasons other than for the treatment of ESRD. These equipment and supplies can be found listed in the second table (DME ESRD Supply HCPCS Not Payable to DME Suppliers) of the document titled "Items and Services Subject to Consolidated Billing for the ESRD PPS" located at the ESRD Payment website: http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage. DME suppliers will not be capable of billing and being paid for any of the supplies on this list using the AY modifier.