CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3116	**Date: November 6, 2014**
	Change Request 8957

SUBJECT: Elimination of the 50/50 Payment Rule for Laboratory Services on End Stage Renal Disease (ESRD) Claims

I. SUMMARY OF CHANGES: This Change Request updates billing requirements for ESRD facilities and claims processing requirements for Original Medicare systems to no longer apply the 50/50 payment rule for Automated Multi-Channel Chemistry laboratory tests.

EFFECTIVE DATE: April 1, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 6, 2015

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	8/60.1/Lab Services
R	16/40.6.1/Automated Multi-Channel Chemistry (AMCC) Tests for ESRD Beneficiaries

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 obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 3116	Date: November 6, 2014	Change Request: 8957

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I. GENERAL INFORMATION

A. Background: The Medicare ESRD benefit previously paid for dialysis and some dialysis related services under a per treatment composite rate. Separate payment for Automated Multi-Channel Chemistry (AMCC) laboratory tests was determined according to the 50/50 rule. Separate payment for the laboratory services was subject to whether 50 percent or more of the tests performed were in excess of the composite rate. ESRD facilities were required to report modifier CD, to indicate if the laboratory test was included in the composite rate, modifier CE, to indicate the laboratory tests exceeded the frequency of the composite rate or modifier CF, to indicate the laboratory test was not included in the composite rate. In addition, ESRD facilities were required to itemize on the claim the individual laboratory CPT codes rather than reporting disease panel codes.

B. Policy: ESRD laboratory services are no longer paid in accordance with the 50/50 rule with the implementation of the ESRD Prospective Payment System (PPS). The ESRD PPS requires that all renal dialysis laboratory services be paid in the ESRD facility bundled payment and therefore, may only be billed by the ESRD facility.

For ESRD claims with dates of service on or after April 1, 2015, ESRD facilities will no longer be required to submit the 50/50 rule modifiers CD, CE and CF. In addition, facilities may report panel codes (i.e., CPT codes 80047, 80048, 80051, 80053, 80061, 80069, and 80076) when performed for an ESRD beneficiary.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8957.1	The contractor shall no longer require modifiers CD, CE or CF to be present when a HCPCS code for an Automated Multi-Channel Chemistry test is billed on Type of Bill 072x.					X				
8957.2	The contractor shall no longer require a HCPCS code for an Automated Multi-Channel Chemistry test to be					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	present when a modifier CD, CE or CF is reported on Type of Bill 072x.									
8957.3	The contractor shall allow the reporting of CPT codes for laboratory tests which are organ or disease-oriented panels (CPT codes 80047, 80048, 80051, 80053, 80061, 80069, and 80076) on Type of Bill 072x.	X				X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8957.4	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X				

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
8957.3	This is currently enforced by FISS reason code 36147.
8957.1	This is currently enforced by FISS reason code 36138.
8957.2	This is currently enforced by FISS reason codes 36139 through 36142.

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

V. CONTACTS

Pre-Implementation Contact(s): Wil Gehne, wilfried.gehne@cms.hhs.gov, Wendy Tucker, wendy.tucker@cms.hhs.gov

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

VI. 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

60.1 - Lab Services

(Rev.3116, Issued: 11-06-14, Effective; 04-01-15, Implementation: 04-06-15)

See the Medicare Benefit Policy Manual, Chapter 11, for a description of lab services included in the composite rate.

Independent laboratories and independent dialysis facilities with the appropriate clinical laboratory certification in accordance with CLIA may be paid for ESRD clinical laboratory tests that are separately billable. The laboratories and independent dialysis facilities are paid for separately billable clinical laboratory tests according to the Medicare laboratory fee schedule for independent laboratories. (See Chapter 16, section 40.3 for details on Part B hospital billing rules for laboratory services and Chapter 16, section 40.6 for details on ESRD billing.)

Hospital-based laboratories providing separately billable laboratory services to dialysis patients of the hospital's dialysis facility or another dialysis facility bill are paid in accordance with the hospital outpatient laboratory provisions in Chapter 16, section 40.3. If the ESRD patient also receives other hospital outpatient services on the same day as a specimen collection and/or laboratory test, then the patient is considered to be a registered hospital outpatient and cannot be considered to be a non-patient on that day for purposes of the specimen collection and laboratory test. When the patient does not also receive hospital outpatient services on the same day as the specimen collection and/or laboratory test, then the hospital may choose to register the beneficiary as an outpatient for the specimen collection or bill for these services as non-patient on the 14x bill type.

Clinical laboratory tests are performed individually. Automated profiles and application of the "50 percent rule" can be found in Chapter 16 of this manual.

A specimen collection fee determined by CMS (as of this writing, up to $3.00) will be allowed for ESRD Method II billing 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.

Laboratory tests for Hemodialysis, Intermittent Peritoneal Dialysis (IPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Hemofiltration (as specified in the Medicare Benefit Policy Manual Pub. 100-02, Chapter 11, Section 30.2) are usually performed for dialysis patients and are routinely covered at the frequency specified in the absence of indications to the contrary, i.e., no documentation of medical necessity is required other than knowledge of the patient's status as an ESRD beneficiary. When any of these tests is performed at a frequency greater than that specified, the additional tests are separately billable and are covered only if they are medically justified by accompanying documentation. A diagnosis of ESRD alone is not sufficient medical evidence to warrant coverage of the additional tests. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of the test(s) must be present on the claim. Such information must be furnished using ICD diagnosis codes.

Renal dialysis facilities must bill all lab tests provided for the treatment of ESRD. This is true whether the tests were provided directly or under arrangements with an independent lab and whether or not the lab test was separately payable prior to the ESRD PPS. When lab *tests* are billed by providers other than the ESRD facility and the lab *test is provided for the treatment of ESRD*, the claim will be rejected or denied. In the event that a lab *test usually provided for the treatment of ESRD* 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.

ESRD facilities should only bill for lab *tests* related to the treatment of ESRD or *other* lab *tests* performed by the dialysis facility (i.e. CLIA waived lab tests). Lab tests that are not for the treatment of ESRD and *are* not performed by the ESRD facility are not to be reported on the ESRD facility claim.

Medicare Claims Processing Manual
Chapter 16 - Laboratory Services

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(Rev.3116, Issued: 11-06-14)

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

Rev.3116, Issued: 11-06-14, Effective; 04-01-15, Implementation: 04-06-15)

Instructions for Services Provided on and After January 1, 2011

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 *on the CMS website* 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 *no longer required* for independent laboratories effective for dates of service on and after January 1, 2011. However, *for services provided between January 1, 2011 and March 31, 2015,* 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). *For services provided on or after April 1, 2015, the 50/50 rule modifiers are no longer required for use by ESRD facilities.*

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. The aforementioned organ disease panel codes *were* added to the list of bundled ESRD PPS laboratory tests in January 2012.

Effective for dates of service on and after April 1, 2015, contractors shall allow organ disease panel codes (i.e., HCPCS codes 80047, 80048, 80051, 80053, 80061, 80069, and 80076) to be billed by ESRD facilities for AMCC panel tests furnished to ESRD eligible beneficiaries if:

- *These codes best describe the laboratory services provided to the beneficiary, which are paid under the ESRD PPS, or*
- *The test is not related to the treatment of ESRD, in which case the ESRD facility would append modifier "AY" and the service may be paid separately from the ESRD PPS.*

Instructions for Services Provided Prior to January 1, 2011

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

Requirement Number	Requirements	Responsibility
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	Standard Systems

	ATP 22 rate.	

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.