CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1655	**Date: December 31, 2008**
	Change Request 6245

Subject: End Stage Renal Dialysis (ESRD) Medicare Claims Processing Manual Clarification

I. SUMMARY OF CHANGES: This instruction clarifies existing laboratory billing policies in Pub. 100-04, chapters 8 and 16.

Clarification
Effective Date: January 1, 2009
Implementation Date: February 2, 2009

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	16/30.3/ Method of Payment for Clinical Laboratory Tests ý Place of Service Variation
R	16/40.6.2/ Claims Processing for Separately Billable Tests for ESRD Beneficiaries
R	16/40.6.2.1/ Separately Billable ESRD Laboratory Tests
R	16/40.6.2.2/ Reserved
R	16/40.6.2.3/ Skilled Nursing Facility (SNF) Consolidated Billing (CB) Editing and Separately Billed ESRD Laboratory Test Furnished to Patients of Renal Dialysis Facilities
R	16/60.1.3/ Specimen Drawing for Dialysis Patients

III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:
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):
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: 1655	Date: December 31, 2008	Change Request: 6245

SUBJECT: End Stage Renal Dialysis (ESRD) Medicare Claims Processing Manual Clarification

Effective Date: January 1, 2009

Implementation Date: February 2, 2009

I. GENERAL INFORMATION

A. Background: This change request (CR) clarifies existing policy located in Publication 100-04, Chapters 8 and 16 regarding billing for ESRD related laboratory services.

B. Policy: This is a clarification of existing policy related to laboratory billing procedures for laboratory services furnished to hospital-based and independent dialysis facility patients.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

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	
6245.1	The contractor shall refer to Pub. 100-04, chapter 16 §40.3 for details on Part B hospital billing procedures for laboratory services furnished to ESRD beneficiaries.	X		X	X						
6245.2	The contractor shall refer to Pub. 100-04, chapter 16 §40.6 for details on billing ESRD related laboratory tests.	X		X	X						
6245.3	The contractor shall refer to Pub. 100-04, chapter 16 §40.6.2.1 for clarification on how independent laboratories and hospital based laboratories can bill for separately billable ESRD laboratory services.	X		X	X						
6245.4	The contractor shall note that the instruction in Pub. 100-04, chapter 16 §40.6.2.2 has been removed and consolidated into §40.6.2.1.	X		X	X						
6245.5	The contractor shall refer to Pub. 100-04, chapter 16 §40.6.2.3 for details on billing ESRD laboratory services ordered by an ESRD facility, when the beneficiary is a SNF resident in a Part A stay.	X		X	X						
6245.6	The contractor shall note that laboratory billing instructions located in Pub. 100-04, chapter 16 §60.1.3 has been removed and relocated in §40.6.2.1.	X		X	X						
6245.7	Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.	X		X	X						

III. PROVIDER EDUCATION 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	
6245.8	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site 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 your 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	X		X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Michelle Cruse at 410-786-7540 or michelle.cruse@cms.hhs.gov

Post-Implementation Contact(s): Michelle Cruse at 410-786-7540 or michelle.cruse@cms.hhs.gov

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs) and Carriers:*
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)*, use 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.

60.1 - Lab Services

(Rev.1655, Issued: 12-31-08, Effective: 01-01-09, Implementation: 02-02-09)

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* and are paid in accordance with the *hospital* outpatient lab*oratory* 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 the ICD-9-CM coding system.

Medicare Claims Processing Manual
Chapter 16 - Laboratory Services

Table of Contents
(Rev. 1655, 12-31-08)

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

(Rev.1655, Issued: 12-31-08, Effective: 01-01-09, Implementation: 02-02-09)

The following apply in determining the amount of Part B payment for clinical laboratory tests, including those furnished under method II for ESRD beneficiaries:

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.

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 CAHs and 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) and 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. 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 CAH, payment is made on a reasonable cost basis.

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. This also may apply to hospitals in States granted approval for alternative payment methods for paying for hospital outpatient services under §1886(c) of the Act. 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 based on current methodology.

Critical Access Hospital - For a CAH being reimbursed under the "Standard Method" of reimbursement (See Chapter 4), payment for clinical laboratory services furnished as an outpatient service is made on a reasonable cost basis. Critical Access Hospitals choosing the "Standard Method" are paid under the fee schedule for services for a non-patient laboratory specimen (bill type 14X). 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 based on current methodology.

CAHs choosing the "Optional Method" of reimbursement (see Chapter 4) are reimbursed at reasonable cost for outpatient (bill type 85X) non-professional clinical laboratory services and at 115 percent of the fee schedule for professional clinical laboratory services. 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 based on current methodology.

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

Dialysis facility - Payment to a hospital-based or independent dialysis facility for laboratory tests included under the ESRD composite rate payment and performed for a patient of that facility, is included in the facility's composite rate payment for these tests and is subject to the Part B deductible and coinsurance. Laboratory tests that are not included under the ESRD composite rate payment; and are performed by an independent laboratory or a *hospital*-based laboratory for dialysis patients of independent dialysis facilities or *hospital*-based facilities; are paid in addition to the composite rate payment and are subject to the fee schedule limits. This also applies to all laboratory tests furnished to home dialysis patients who have selected Payment Method II. *(See §40.3 for details on Part B hospital billing rules for laboratory services and §40.6 for details on ESRD billing.)*

Rural health clinic - Payment to a rural health clinic (RHC) for laboratory tests performed for a patient of that clinic is not included in the all-inclusive rate and may be billed separately by the laboratory (including a laboratory that is part of a hospital that hosts a hospital based RHC). Payment for the laboratory service is not subject to Part B deductible and coinsurance. (See §40.4 for details on RHC 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.

40.6.2 - Claims Processing for Separately Billable Tests for ESRD Beneficiaries

(Rev.1655, Issued: 12-31-08, Effective: 01-01-09, Implementation: 02-02-09)

Clinical laboratory tests can be performed individually or in predetermined groups on automated profile equipment. If a test profile is performed see §40.6.1. If a clinical laboratory test is performed individually, see §40.6.2.1**.** However the tests are performed in the laboratory setting, the services must be billed individually, and must not be billed in a group as an organ or disease panel.

40.6.2.1 - Separately Billable ESRD Laboratory Tests

(Rev.1655, Issued: 12-31-08, Effective: 01-01-09, Implementation: 02-02-09)

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 §40.3 for details on Part B hospital billing rules for laboratory services.)

Hospital-based laboratories providing separately billable laboratory services to dialysis patients of the hospital's dialysis facility or any other dialysis facility bill and 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 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/or 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.

40.6.2.2 – *Reserved*

(Rev.1655, Issued: 12-31-08, Effective: 01-01-09, Implementation: 02-02-09)

40.6.2.3 – Skilled Nursing Facility (SNF) Consolidated Billing (CB) Editing and Separately Billed ESRD Laboratory Test Furnished to Patients of Renal Dialysis Facilities

(Rev.1655, Issued: 12-31-08, Effective: 01-01-09, Implementation: 02-02-09)

Effective April 1, 2003, for DOS on or after April 1, 2001, CWF will not apply the SNF CB edits to line items that contain the CB modifier. A provider or supplier may use the "CB" modifier only when it has determined that: (a) the beneficiary has ESRD

entitlement, (b) the test is related to the dialysis treatment for ESRD, (c) the test is ordered by a doctor providing care to patients in the dialysis facility, and (d) the test is not included in the dialysis facility's composite rate payment.

Those diagnostic tests that are presumptively considered to be dialysis-related and, therefore, appropriate for submission with the " CB" modifier are identified in Exhibit 3. This list was not designed as an all- inclusive list of Medicare covered diagnostic services. Additional diagnostic services related to the beneficiary's ESRD treatment/care may be considered dialysis-related. However, if these services are not included in our listing, the *contractor* may require supporting medical documentation.

When a hospital laboratory is billing for laboratory services ordered by an ESRD facility and the patient (beneficiary) is a SNF resident under a Part A stay, the hospital laboratory must use the "CB" modifier for those services excluded from consolidated billing.

Beneficiaries in a SNF Part A stay are eligible for a broad range of diagnostic services as part of the SNF Part A benefit. Physicians ordering medically necessary diagnostic test that are not directly related to the beneficiary's ESRD are subject to the SNF consolidated billing requirements. Physicians may bill the *contractor* for the professional component of these diagnostic tests. In most cases, however, the technical component of diagnostic tests is included in the SNF PPS rate and is not separately billable to the *contractor*. Physicians should coordinate with the SNF in ordering such tests since the SNF will be responsible for bearing the cost of the technical component.

60.1.3 - Specimen Drawing for Dialysis Patients

(Rev.1655, Issued: 12-31-08, Effective: 01-01-09, Implementation: 02-02-09)

See the Medicare Benefit Policy Manual, Chapter 11, for a description of laboratory services included in the composite 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 y patients dialyzed in the facility or for patients dialyzed at home under reimbursement Method I. Payment for this service is included under the ESRD composite rate, regardless of whether the laboratory test itself is included in the composite rate or is separately billable.

Fees for taking specimens from home dialysis patients, who have elected reimbursement Method II may be paid separately, provided all other criteria for payment are met. Also, 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.