# Medicare Claims Processing Manual
## Chapter 16 - Laboratory Services

**Table of Contents**
*(Rev. 2487, 06-08-12)*


**Transmittals for Chapter 16**

10 - Background

10.1 - Definitions

10.2 - General Explanation of Payment

20 - Calculation of Payment Rates - Clinical Laboratory Test Fee Schedules

20.1 - Initial Development of Laboratory Fee Schedules

20.2 - Annual Fee Schedule Updates

30 - Special Payment Considerations

30.1 - Mandatory Assignment for Laboratory Tests

30.1.1 - Rural Health Clinics

30.2 - Deductible and Coinsurance Application for Laboratory Tests

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

30.4 - Payment for Review of Laboratory Test Results by Physician

40 - Billing for Clinical Laboratory Tests

40.1 - Laboratories Billing for Referred Tests

40.1.1 - Claims Information and Claims Forms and Formats

40.1.1.1 - Paper Claim Submission to Carriers/B MAC

40.1.1.2 - Electronic Claim Submission to Carriers/B MAC

40.2 - Payment Limit for Purchased Services

40.3 - Hospital Billing Under Part B

40.3.1 - Critical Access Hospital (CAH) Outpatient Laboratory Service

40.4 - Special Skilled Nursing Facility (SNF) Billing Exceptions for Laboratory Tests

40.4.1 - Which Contractor to Bill for Laboratory Services Furnished to a Medicare Beneficiary in a Skilled Nursing Facility (SNF)

40.5 - Rural Health Clinic (RHC) Billing

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

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

40.6.2 - Claims Processing for Separately Billable Tests for ESRD Beneficiaries

40.6.2.1 - Separately Billable ESRD Laboratory Tests Furnished by Hospital-Based Facilities

40.6.2.2 - Reserved

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

40.7 - Billing for Noncovered Clinical Laboratory Tests

40.8 - Date of Service (DOS) for Clinical Laboratory and Pathology Specimens

50 – Carrier Claims Processing

50.1 - Referring Laboratories

50.2 - Physicians

50.2.1 - Assignment Required

50.3 - Hospitals

50.3.1 - Hospital-Leased Laboratories

50.3.2 - Hospital Laboratory Services Furnished to Nonhospital Patients

50.4 - Reporting of Pricing Localities for Clinical Laboratory Services

50.5 - Jurisdiction of Laboratory Claims

50.5.1 - Jurisdiction of Referral Laboratory Services

50.5.2 - Examples of Independent Laboratory Jurisdiction

60 - Specimen Collection Fee and Travel Allowance

60.1 - Specimen Collection Fee

60.1.1 - Physician Specimen Drawing

60.1.2 - Independent Laboratory Specimen Drawing

60.1.3 - Specimen Drawing for Dialysis Patients

60.1.4 - Coding Requirements for Specimen Collection

60.2 - Travel Allowance

70 - Clinical Laboratory Improvement Amendments (CLIA) Requirements

70.1 - Background

70.2 - Billing

70.3 - Verifying CLIA Certification

70.4 - CLIA Numbers

70.5 - CLIA Categories and Subcategories

70.6 - Certificate for Provider-Performed Microscopy Procedures

70.7 - Deleted - Held for Expansion

70.8 - Certificate of Waiver

70.9 - HCPCS Subject To and Excluded From CLIA Edits

70.10 - CLIA Number Submitted on Form CMS-1500

70.10.1 - Physician Notification of Denials

70.11 - Reasons for Denial - Physician Office Laboratories Out-of-Compliance

80 - Issues Related to Specific Tests

80.1 - Screening Services

80.2 - Anatomic Pathology Services

80.2.1 - Technical Component (TC) of Physician Pathology Services to Hospital Patients

80.3 - National Minimum Payment Amounts for Cervical or Vaginal Smear Clinical Laboratory Tests

80.4 - Oximetry

90 - Automated Profile Tests and Organ/Disease Oriented Panels

90.1 - Laboratory Tests Utilizing Automated Equipment

90.1.1 - Automated Test Listing

90.2 - Organ or Disease Oriented Panels

90.3 - Claims Processing Requirements for Panel and Profile Tests

90.3.1 - History Display

90.3.2 - Medicare Secondary Payer

90.4 - Evaluating the Medical Necessity for Laboratory Panel CPT Codes

90.5 - Special Processing Considerations

100 - CPT Codes Subject to and Not Subject to the Clinical Laboratory Fee Schedule

100.1 - Deleted - Held for Expansion

100.2 - Laboratory Tests Never Subject to the Fee Schedule

100.3 - Procedures Not Subject to Fee Schedule When Billed With Blood Products

100.4 - Not Otherwise Classified Clinical Laboratory Tests

100.5 - Other Coding Issues

100.5.1 - Tests Performed More Than Once on the Same Day

100.6 - Pricing Modifiers

110 - Coordination Between Carriers and Other Entities

110.1 - Coordination Between Carriers and FIs/RRB

110.2 - Coordination With Medicaid

110.3 - Coordination With FIs and Providers

110.4 - Carrier Contacts With Independent Clinical Laboratories

120- Clinical Laboratory Services Based on the Negotiated Rulemaking

120.1 - Negotiated Rulemaking Implementation

120.2 – Implementation and Updates of Negotiated National Coverage Determinations (NCDs) or Clinical Diagnostic Laboratory Services

Exhibit 1- List of Diagnostic Tests that are Considered End Stage Renal Disease (ESRD)

## 10 - Background
**(Rev. 1, 10-01-03)**
**B3-2070, B3-2070.1, B3-4110.3, B3-5114**

Diagnostic X-ray, laboratory, and other diagnostic tests, including materials and the services of technicians, are covered under the Medicare program. Some clinical laboratory procedures or tests require Food and Drug Administration (FDA) approval before coverage is provided.

A diagnostic laboratory test is considered a laboratory service for billing purposes, regardless of whether it is performed in:

- A physician's office, by an independent laboratory;
- By a hospital laboratory for its outpatients or nonpatients;
- In a rural health clinic; or
- In an HMO or Health Care Prepayment Plan (HCPP) for a patient who is not a member.

When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory, and still bills the fiscal intermediary (FI). Also, when physicians and laboratories perform the same test, whether manually or with automated equipment, the services are deemed similar.

Laboratory services furnished by an independent laboratory are covered under SMI if the laboratory is an approved Independent Clinical Laboratory. However, as is the case of all diagnostic services, in order to be covered these services must be related to a patient's illness or injury (or symptom or complaint) and ordered by a physician. A small number of laboratory tests can be covered as a preventive screening service.

See the Medicare Benefit Policy Manual, Chapter 15, for detailed coverage requirements.

See the Medicare Program Integrity Manual, Chapter 10, for laboratory/supplier enrollment guidelines.

See the Medicare State Operations Manual for laboratory/supplier certification requirements.

## 10.1 – Definitions
**(Rev. 85, 02-06-04)**
**B3-2070.1, B3-2070.1.B, RHC-406.4**

**"Independent Laboratory" -** An independent laboratory is one that is independent both of an attending or consulting physician's office and of a hospital that meets at least the requirements to qualify as an emergency hospital as defined in §1861(e) of the Social

Security Act (the Act.) (See the Medicare Benefits Policy Manual, Chapter 15, for detailed discussion.)

**"Physician Office Laboratory"** – A physician office laboratory is a laboratory maintained by a physician or group of physicians for performing diagnostic tests in connection with the physician practice.

**"Clinical Laboratory" -** See the Medicare Benefits Policy Manual, Chapter 15.

**"Qualified Hospital Laboratory" -** A qualified hospital laboratory is one that provides some clinical laboratory tests 24 hours a day, 7 days a week, to serve a hospital's emergency room that is also available to provide services 24 hours a day, 7 days a week. For the qualified hospital laboratory to meet this requirement, the hospital must have physicians physically present or available within 30 minutes through a medical staff call roster to handle emergencies 24 hours a day, 7 days a week; and hospital laboratory technologists must be on duty or on call at all times to provide testing for the emergency room.

**"Hospital Outpatient" -** See the Medicare Benefit Policy Manual, Chapter 2.

**"Referring laboratory" -** A Medicare-approved laboratory that receives a specimen to be tested and that refers the specimen to another laboratory for performance of the laboratory test.

**"Reference laboratory"** - A Medicare-enrolled laboratory that receives a specimen from another, referring laboratory for testing and that actually performs the test.

**"Billing laboratory"** - The laboratory that submits a bill or claim to Medicare.

**"Service"** - A clinical diagnostic laboratory test. Service and test are synonymous.

**"Test" -** A clinical diagnostic laboratory service. Service and test are synonymous.

**"CLIA"** - The Clinical Laboratory Improvement Act and CMS implementing regulations and processes.

**"Certification"** - A laboratory that has met the standards specified in the CLIA.

**"Draw Station' -** A place where a specimen is collected but no Medicare-covered clinical laboratory testing is performed on the drawn specimen.

**"Medicare-approved laboratory -** A laboratory that meets all of the enrollment standards as a Medicare provider including the certification by a CLIA certifying authority.

## 10.2 - General Explanation of Payment

**(Rev. 1782; Issued: 07-30-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)**

Outpatient laboratory services can be paid in different ways:

- Physician Fee Schedule;
- 101 percent of reasonable cost (critical access hospitals (CAH) only);

  **NOTE:** When the CAH bills a 14X bill type for a non-patient laboratory specimen, the CAH is paid under the fee schedule.

- Laboratory Fee Schedule;
- Outpatient Prospective Payment System, (OPPS) except for most hospitals in the State of Maryland that are subject to a waiver; or
- Reasonable Charge

Annually, CMS distributes a list of codes and indicates the payment method. Carriers, FIs, and A/B MACs pay as directed by this list. Neither deductible nor coinsurance applies to HCPCS codes paid under the laboratory fee schedule; further, deductible and coinsurance do not apply to HCPCS laboratory codes paid via 101 percent of reasonable cost to CAHs. The majority of outpatient laboratory services are paid under the laboratory fee schedule or the OPPS.

Carriers, FIs and A/B MACs are responsible for applying the correct fee schedule for payment of clinical laboratory tests. FIs/AB MACs must determine which hospitals meet the criteria for payment at the 62 percent fee schedule. Only sole community hospitals with qualified hospital laboratories are eligible for payment under the 62 percent fee schedule. Generally, payment for diagnostic laboratory tests that are not subject to the clinical laboratory fee schedule is made in accordance with the reasonable charge or physician fee schedule methodologies (or at 101 percent of reasonable cost for CAHs).

For Clinical Diagnostic Laboratory services denied due to frequency edits contractors must use standard health care adjustment reason code 151 - “Payment adjusted because the payer deems the information submitted does not support this many services.”

## 20 - Calculation of Payment Rates - Clinical Laboratory Test Fee Schedules

**(Rev. 1, 10-01-03)**
**HO-437, A3-3628, PM AB-98-7, B3-5114.1**

Under Part B, for services rendered on or after July 1, 1984, clinical laboratory tests performed in a physician’s office, by an independent laboratory, or by a hospital laboratory for its outpatients are reimbursed on the basis of fee schedules. Current exceptions to this rule are CAH laboratory services as described in §10, and services provided by hospitals in the State of Maryland.

Medicare pays the lesser of:

- Actual charges;

- The fee schedule amount for the State or a local geographic area; or

- A national limitation amount (NLA) for the HCPCS code as provided by §1834(h) of the Act.

Annually, CMS furnishes to carriers and FIs the proper amount to pay for each HCPCS code for each local geographic area. This includes a calculation of whether a national limitation amount or the local fee schedule amount is to be used.

This information is available to the public on the CMS Web site in public use files.

## 20.1 - Initial Development of Laboratory Fee Schedules

**(Rev. 1, 10-01-03)**
**HO-437, A3-3628, B3-5114.1.C**

Initially, each carrier established the fee schedules on a carrier-wide basis (not to exceed a statewide basis). If a carrier's area includes more than one State, the carrier established a separate fee schedule for each State. The carrier determined the fee schedule amount based on prevailing charges for laboratory billings by physicians and independent laboratories billing the carrier. Carriers set the fees at 60 percent of prevailing charges. FIs used the same fee schedules to pay outpatient hospital laboratory services. They set the fee at 62 percent of carrier prevailing charges. Subsequently, except for sole community hospitals, which continue to be paid at the 62 percent rate, FIs changed payments to hospital laboratories to the "60 percent fee schedule."

In 1994, CMS took over the annual update and distribution of clinical laboratory fee schedules. The CMS updates the fee schedule amounts annually to reflect changes in the Consumer Price Index (CPI) for all Urban Consumers (U.S. city average), or as otherwise specified by legislation.

Effective for hospital outpatient tests furnished by a hospital on or after April 1, 1988, to receive the 62 percent fee the hospital must be a sole community hospital. Otherwise, the fee is the "60 percent fee schedule." If a hospital is uncertain whether it meets the qualifications of a sole community hospital it can seek assistance from the FI or the RO.

For tests to hospital nonpatients, the fee is 60 percent of the carrier prevailing charge. If a hospital laboratory acts as an independent laboratory, i.e., performs tests for persons who are nonhospital patients; or if the hospital laboratory is not a qualified hospital laboratory, the services are reimbursed using the 60 percent fee schedule or the adjusted fee schedule, as appropriate.

See §10.1 for the definition of a hospital outpatient.

## 20.2 - Annual Fee Schedule Updates

**(Rev. 2106, Issued: 11-24-10, Effective: 01-01-11, Implementation: 01-03-11)**

The CMS adjusts the fee schedule amounts annually to reflect changes in the Consumer Price Index for all urban consumers (CPI-U) (U.S. city average) and the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity, unless alternative updates are specified by legislation. The CMS communicates this information via an annual recurring update notification (RUN). The CMS also determines, publishes for contractor use, and places on its web site, coding and pricing changes. This information is updated on an annual basis.

## 30 - Special Payment Considerations
**(Rev. 1, 10-01-03)**

## 30.1 - Mandatory Assignment for Laboratory Tests
**(Rev. 1, 10-01-03)**
**B3-5114.1**

Unless a laboratory, physician, or medical group accepts assignment, the carrier makes no Part B payment for laboratory tests paid on the laboratory fee schedule. Laboratories, physicians, or medical groups that have entered into a participation agreement must accept assignment. Sanctions of double the violation charges, civil money penalties (up to $2,000 per violation), and/or exclusion from the program for a period of up to five years may be imposed on physicians and laboratories, with the exception of rural health clinic laboratories, that knowingly, willfully, and repeatedly bill patients on an unassigned basis. However, sole community physicians and physicians who are the sole source of an essential specialty in a community are not excluded from the program. Whenever a carrier is notified of a sanction action for this reason, the carrier does not pay for any laboratory services unless the services were furnished within 15 days after the date on the exclusion or suspension notice to the practitioner, and:

- It is the first claim filed for services rendered to that beneficiary after the date on the notice of suspension or exclusion; or

- It is filed with respect to services furnished within 15 days of the date on the first notice of denial of claims to the beneficiary. (Fifteen days are allowed for the notice to reach the beneficiary.)

Carriers refer questions on payment procedures to the Sanctions Coordinator in the RO.

Carriers process laboratory claims inadvertently submitted as unassigned as if they were assigned. (See §50.)

For purposes of this section, the term assignment includes assignment in the strict sense of the term as well as the procedure under which payment is made, after the death of the beneficiary, to the person or entity that furnished the service, on the basis of that person's or entity's agreement to accept the Medicare payment as the full charge or fee for the service.

## 30.1.1 - Rural Health Clinics
**(Rev. 1, 10-01-03)**

**PM A-99-8, Rev. 810, CR 1133, PM A-00-30**

Rural Health Clinics (RHCs) must furnish the following laboratory services to be approved as an RHC. However, these and other laboratory services that may be furnished are not included in the encounter rate and must be billed separately:

- Chemical examinations of urine by stick or tablet method or both;
- Hemoglobin or hematocrit;
- Blood sugar;
- Examination of stool specimens for occult blood;
- Pregnancy tests; and
- Primary culturing for transmittal to a certified laboratory (No CPT code available).

Effective January 1, 2001, freestanding RHCs/Federally Qualified Health Centers (FQHCs) bill all laboratory services to the carrier, and provider based RHCs/FQHCS bill all laboratory tests to the FI under the host provider's bill type. In either case payment is made under the fee schedule. HCPCS codes are required for laboratory services. (See §40.4 for details on RHC billing.)

## 30.2 - Deductible and Coinsurance Application for Laboratory Tests

**(Rev. 1, 10-01-03)**
**B3-2462, B3-5114.1, A3-3215, HHA-160**

Neither the annual cash deductible nor the 20 percent coinsurance apply to:

- Clinical laboratory tests performed by a physician, laboratory, or other entity paid on an assigned basis;

- Specimen collection fees; or

- Travel allowance related to laboratory tests (e.g., collecting specimen).

Codes on the physician fee schedule are generally subject to the Part B deductible and coinsurance, although exceptions may be noted for a given code in the MPFS or through formal Medicare instructions such as temporary instructions and requirements for specific services noted in this manual.

Any laboratory code paid at reasonable charge is subject to the Part B deductible and coinsurance, unless otherwise specified in the description of coverage and payment rules. Neither deductible nor coinsurance is applied to payment for codes on the laboratory fee schedule that are made to CAHs.

## 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.

Section 148 of The Medicare Improvements for Patients and Providers Act (MIPPA)

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.

## 30.4 - Payment for Review of Laboratory Test Results by Physician

**(Rev. 1, 10-01-03)**
**B3-5114.2**

Reviewing results of laboratory tests, phoning results to patients, filing such results, etc., are Medicare covered services. Payment is included in the physician fee schedule payment for the evaluation and management (E and M) services to the patient. Visit services entail a wide range of components and activities that may vary somewhat from patient to patient. The CPT lists different levels of E and M services for both new and established patients and describes services that are included as E and M services. Such activities include obtaining, reviewing, and analyzing appropriate diagnostic tests.

## 40 - Billing for Clinical Laboratory Tests

**(Rev. 1, 10-01-03)**

## 40.1 - Laboratories Billing for Referred Tests

**(Rev. 85, 02-06-04)**
**B3-5114.1.E,**

Section 1833(h)(5)(A) of the Act provides that a referring laboratory may bill for clinical laboratory diagnostic tests on the clinical laboratory fee schedule for Medicare beneficiaries performed by a reference laboratory only if the referring laboratory meets

certain conditions. Payment may be made to the referring laboratory but only if one of the following conditions is met:

- the referring laboratory is located in, or is part of, a rural hospital;

- the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity; or

- the referring laboratory does not refer more than 30 percent of the clinical laboratory tests for which it receives requests for testing during the year (not counting referrals made under the wholly-owned condition described above).

In the case of a clinical laboratory test provided under an arrangement (as defined in §1861(w)(1)) made by a hospital, CAH or SNF, payment is made to the hospital or SNF.

**Examples of 30 Percent Exception:**

(1) - A laboratory receives requests for 200 tests, performs 139 tests, and refers 61 tests to a non-related laboratory. All tests referred to a non-related laboratory are counted. Thus, 30.5 percent (61/200) of the tests are considered tests referred to a non-related laboratory and, since this exceeds the 30 percent standard, the referring laboratory may not bill for any Medicare beneficiary laboratory tests referred to a non-related laboratory.

(2) - A laboratory receives requests for 200 tests, performs 139 tests and refers 15 to a related laboratory and 46 to a non-related laboratory. Only 23 percent of the tests were referred to non-related laboratories. Since this is less than 30 percent, the referring laboratory may bill for all tests.

If it is later found that a referring laboratory does not, in fact, meet an exception criterion, the carrier should recoup payment for the referred tests improperly billed. The RO shall take whatever action is necessary to correct the problem.

**NOTE:** This provision of §6111(b) of OBRA of 1989 has no effect on hospitals that are paid under §1833(h)(5)(A)(iii).

**NOTE:** Laboratory services provided to a SNF inpatient under Part A are billed by the SNF, not the laboratory, due to consolidated billing for SNFs.

Only one laboratory may bill for a referred laboratory service. It is the responsibility of the referring laboratory to ensure that the reference laboratory does not bill Medicare for the referred service when the referring laboratory does so (or intends to do so). In the event the reference laboratory bills or intends to bill Medicare, the referring laboratory may not do so.

## 40.1.1 - Claims Information and Claims Forms and Formats
**(Rev. 85, 02-06-04)**

Claims for referred laboratory services may be made only by suppliers having specialty code 69, i.e., independent clinical laboratories. Claims for referred laboratory services made by other entities will be returned as unprocessable.

Independent laboratories shall use modifier 90 to identify all referred laboratory services. A claim for a referred laboratory service that does not contain the modifier 90 is returned as unprocessable if the claim can otherwise be identified as being for a referred service.

The name, address, and CLIA number of both the referring laboratory and the reference laboratory shall be reported on the claim.

## 40.1.1.1 - Paper Claim Submission To Carriers/B MAC

**(Rev. 1690; Issued: 02-27-09; Effective/Implementation Date: 03-27-09)**

An independent clinical laboratory that elects to file a paper claim form shall file Form CMS-1500 for a referred laboratory service (as it would any laboratory service). The line item services must be submitted with a modifier 90.

An independent clinical laboratory that submits claims in paper format) may not combine non-referred (i.e., self-performed) and referred services on the same CMS 1500 claim form. When the referring laboratory bills for both non-referred and referred tests, it shall submit two separate claims, one claim for non-referred tests, the other for referred tests. If billing for services that have been referred to more than one laboratory, the referring laboratory shall submit a separate claim for each laboratory to which services were referred (unless one or more of the reference laboratories are separately billing Medicare). A paper claim that contains both non-referred and referred tests is returned as unprocessable. When the referring laboratory is the billing laboratory, the reference laboratory's name, address, and ZIP Code shall be reported in item 32 on the CMS-1500 claim form to show where the service (test) was actually performed. The NPI shall be reported in item 32a. Also, the CLIA number of the reference laboratory shall be reported in item 23 on the CMS-1500 claim form. A paper claim that does not have the name, address, and ZIP Code of the reference laboratory in item 32 and NPI in 32a or the CLIA number of the reference laboratory in item 23 is returned as unprocessable.

**EXAMPLE:** A physician has ordered the ABC Laboratory to perform carcinoembryonic antigen (CEA) and hemoglobin testing for a patient. Since the ABC Laboratory is approved to perform tests only within the hematology LC level (which includes the hemoglobin test), it refers the CEA testing (which is a routine chemistry LC) to the XYZ laboratory.

Result: The ABC laboratory submits a claim for the hemoglobin test and reports its CLIA number in item 23 on the CMS-1500 form. Since the ABC laboratory referred the CEA test to the XYZ laboratory to perform, the ABC laboratory (billing laboratory) submits a second claim for the CEA testing, reporting XYZ's CLIA number in item 23 on the CMS-1500 form. The XYZ laboratory's name, address, and ZIP Code are also reported in item 32 and the NPI is reported in item 32a on Form CMS-1500 to show where the service (test) was actually rendered.

**NOTE:** When the reference laboratory is not located in the same billing jurisdiction as the referring laboratory, the referring (billing) laboratory shall use their own NPI for reporting purposes.

When a diagnostic service is billed as a purchased service and the service is purchased from another billing jurisdiction, the billing provider must submit their own NPI in Item 32a with the name, address, and ZIP Code of the performing provider in Item 32. The billing provider should keep a record of the performing provider's NPI in the clinical records for auditing purposes.

## 40.1.1.2 - Electronic Claim Submission to Carriers/B MAC

**(Rev. 1690; Issued: 02-27-09; Effective/Implementation Date: 03-27-09)**

**Electronic Claim Submission**

American National Standards Institute (ANSI) X12N 837 (HIPAA version) format electronic claims:

CLIA number:

An ANSI claim for laboratory testing will require the presence of the performing (and billing) laboratory's CLIA number; if tests are referred to another laboratory, the CLIA number of the laboratory where the testing is rendered must also be on the claim. An ANSI electronic claim for laboratory testing must be submitted using the following format:

ANSI Electronic claim: the billing laboratory performs all laboratory testing.

The independent laboratory submits a single claim for CLIA-covered laboratory tests and reports the billing laboratory's number in:

X12N 837 (HIPAA version) loop 2300, REF02. REF01 = X4

ANSI Electronic claim: billing laboratory performs some laboratory testing; some testing is referred to another laboratory.

The ANSI electronic claim will not be split; CLIA numbers from both the billing and reference laboratories must be submitted on the same claim. The presence of the '90' modifier at the line item service identifies the referral tests. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69.

The billing laboratory submits, on the same claim, tests referred to another (referral/rendered) laboratory, with modifier 90 reported on the line item and reports the referral laboratory's CLIA number in:

X12N 837 (HIPAA version) loop 2400, REF02. REF01 = F4

**EXAMPLE:** A physician has ordered the DEF independent laboratory to perform glucose testing and tissue typing for a patient. Since the DEF Laboratory is approved to

perform only at the routine chemistry LC level (which includes glucose testing), it refers the tissue-typing test to the GHI laboratory.

The DEF laboratory submits a single claim for the glucose and tissue typing tests; the line item service for the glucose test is submitted without a '90' modifier since the DEF laboratory performed this test. The CLIA number for the DEF laboratory is entered in the electronic claim in:

X12N 837 (HIPAA version) loop 2300, REF02. REF01 = X4

On the same claim, the line item service for the tissue typing test is submitted with a '90' modifier and the referral/rendering GHI laboratory's CLIA number is entered on the electronic claim in:

X12N 837 (HIPAA version) loop 2400, REF02. REF01 = F4

Reference Laboratory's Address:

An electronic claim for laboratory testing requires the presence of the performing and billing laboratory's, name and address. The performing laboratory for a service with a line item CPT 90 modifier requires provider information for the appropriate 837 loop.

**NOTE:** When the reference laboratory is not located in the same billing jurisdiction as the referring laboratory, the referring (billing) laboratory shall use their own NPI for reporting purposes.

When a diagnostic service is billed as a purchased service and the service is purchased from another billing jurisdiction, the billing provider must submit their own NPI with the name, address, and ZIP Code of the performing provider in the appropriate data field. The billing provider should keep a record of the performing provider's NPI in the clinical records for auditing purposes.

## 40.2 - Payment Limit for Purchased Services
**(Rev. 16, 10-31-03)**

For payment instructions for Physician purchased diagnostic tests refer to the Claims Processing Manual 100-04, Chapter 1, §30.2.9, Chapter 13 §20.2.4ff.

When an Independent Laboratory (IL) bills for the technical component (TC) of a physician pathology service purchased from a separate physician or supplier, the payment amount for the TC is based on the lower of the billed charge or the Medicare Physician Fee Schedule. The purchase diagnostic test payment provision does not apply, thus, the purchase service information shall not be entered on the claim.

All purchased diagnostic services are based on the Medicare Physician Fee Schedule and are subject to the jurisdiction rules for that fee schedule.

The IL must perform at least one of the component services. If they purchase both the PC and the TC services, only the physician or supplier that performed those services may bill.

## 40.3 - Hospital Billing Under Part B

**(Rev. 1782; Issued: 07-30-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)**

Hospital laboratories, billing for either outpatient or non-patient claims, bill the FI/AB MAC.

Neither deductible nor coinsurance applies to laboratory tests paid under the fee schedule (or for any laboratory tests billed by a CAH).

Hospitals must follow requirements for submission of the ANSI X12N 837 I or the hardcopy Form CMS-1450 (see Chapter 25 for billing requirements).

When the hospital obtains laboratory tests for outpatients under arrangements with clinical laboratories or other hospital laboratories, only the hospital can bill for the arranged services.

If the hospital is a sole community hospital identified in the PPS Provider Specific File with a qualified hospital laboratory identified on the hospital's certification; tests for outpatients are reimbursable at 62 percent.

If the hospital bills claims for both hospital outpatient and non-patient laboratory tests on different dates of service, it should prepare two bills: one for the outpatient (13X type of bill) laboratory test and the other for the non-patient laboratory specimen (14X type of bill) tests. The hospital includes laboratory tests provided to hospital outpatients on the same bill with other hospital outpatient services to the same beneficiary, unless it is billing for non-patient laboratory specimen tests provided on a different day from the other hospital outpatient services, in which case it submits a separate bill for the non-patient laboratory specimen tests.

For all hospitals (including CAHs) except Maryland waiver hospitals, if a patient receives 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 laboratory test. However if any hospital other than a CAH or a Maryland waiver hospital only collects or draws a specimen from the patient and the patient does not also receive hospital outpatient services on that day, the hospital may choose to register the patient as an outpatient for the specimen collection or bill for these services as non- patient on the 14x bill type.

For CAHs, payment for clinical diagnostic laboratory tests is made at 101 percent of reasonable cost only if the individuals are outpatients of the CAH (85X type of bill), as defined in 42 CFR 410.2, and are physically present in the CAH at the time the specimens are collected, for dates of service prior to July 1, 2009. However, for dates of service on or after July 1, 2009, the individuals do not have to be physically present in the

CAH at the time the specimen is collected as long as certain criteria are met, per Section 148 of the MIPPA (see Section 30.3 above, Critical Access Hospital). Clinical diagnostic laboratory tests performed for persons who are not physically present at the CAH when the specimens are collected by a non-CAH employee or who are not receiving other outpatient services in the CAH on the same day the specimen is collected, are paid in accordance with the provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Social Security Act. See also 42 CFR 413.70(b)(iii). Similarly, for Maryland waiver hospitals, the waiver is limited to services to inpatients and registered outpatients as defined in 42 CFR 410.2. Therefore payment for non-patients (specimen only, TOB 14X) who are not registered outpatients at the time of specimen collection will be made on the clinical diagnostic laboratory fee schedule.

Hospitals should not submit separate bills for laboratory tests performed in different departments on the same day.

Section 416 of the Medicare Prescription, Drug, Improvement, and Modernization Act (MMA) of 2003 also eliminates the application of the clinical laboratory fee schedule for hospital outpatient laboratory testing by a hospital laboratory with fewer than 50 beds in a qualified rural area for cost reporting periods beginning during the 2-year period beginning on July 1, 2004. Payment for these hospital outpatient laboratory tests will be reasonable costs without coinsurance and deductibles during the applicable time period. A qualified rural area is one with a population density in the lowest quartile of all rural county populations.

The reasonable costs are determined using the ratio of costs to charges for the laboratory cost center multiplied by the PS&R's billed charges for outpatient laboratory services for cost reporting periods beginning on or after July 1, 2004 but before July 1, 2006.

In determining whether clinical laboratory services are furnished as part of outpatient services of a hospital, the same rules that are used to determine whether clinical laboratory services are furnished as an outpatient critical access hospital service will apply.

## 40.3.1 - Critical Access Hospital (CAH) Outpatient Laboratory Service

**(Rev. 1782; Issued: 07-30-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)**

Effective for services furnished on or after the enactment of Balanced Budget Refinement Act of 1999 (BBRA), Medicare beneficiaries are not liable for any coinsurance, deductible, co-payment, or other cost sharing amount with respect to clinical laboratory services furnished as a CAH outpatient service. This change is effective for claims with dates of service on or after November 29, 1999, that were received July 1, 2001 or later.

For CAH bill type 85X, the laboratory fees are paid at 101 percent of cost with no cost-sharing.

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

## 40.4 - Special Skilled Nursing Facility (SNF) Billing Exceptions for Laboratory Tests

**(Rev. 1, 10-01-03)**
**SNF 541, A3-3137.1, HO-437, B3-5114.1**

When a SNF furnishes laboratory services directly, it must have a Clinical Laboratory Improvement Act (CLIA) number or a CLIA certificate of waiver, and the laboratory itself must be in the portion of the facility so certified. Normally the FI makes payment under Part B for clinical laboratory tests only to the entity that performed the test. However, the law permits SNFs to submit a Part B claim to the FI for laboratory tests that it makes arrangements for another entity to perform on the SNF's behalf. Section 1833(h)(5) of the Act (as enacted by The Deficit Reduction Act of 1984, P.L. 98-369) requires the establishment of a fee schedule for clinical laboratory tests paid under Part B and also requires that, with certain exceptions, only the entity that performed the test may be paid.

The fee schedule applies to all SNF clinical laboratory services.

Where a SNF operates a laboratory that provides laboratory services to patients other than its own patients, it is functioning as a clinical laboratory. The billing for these laboratory services depends upon the HCPCS code as defined in the CMS annual fee schedule releases (laboratory and MPFS), and the arrangements made for payment with the referring entity (e.g., does the SNF or the referring entity bill under the agreement between the two). The SNF is responsible for ascertaining the necessary information for billing the FI. Any questions must be referred to the FI.

### 40.4.1 - Which Contractor to Bill for Laboratory Services Furnished to a Medicare Beneficiary in a Skilled Nursing Facility (SNF)

**(Rev. 1, 10-01-03)**

**Inpatient Part A beneficiary** - SNF bills the FI under Part A. The service is included in SNF PPS payment.

**Inpatient Part B beneficiary (benefits exhausted or no Part A entitlement)** - SNFs may provide the service and bill the FI, may obtain the service under arrangement and bill the FI under Part B, or may have agreement with a reference laboratory for the reference laboratory to provide the service and have the reference laboratory bill the carrier under Part B. Regardless of who bills, CMS policy requires that the service be paid under the fee schedule, whether or not the beneficiary is in a Medicare certified bed.

**Outpatient Part B** - See inpatient Part B beneficiary (benefits exhausted or no Part A entitlement), immediately above.

## 40.5 - Rural Health Clinic (RHC) Billing

**(Rev. 1, 10-01-03)**
**B3-3628**

For independent RHCs, laboratory services provided in the RHC's laboratory are not included in the all-inclusive rate payment to the RHC and may be billed separately to the carrier. This includes the six basic laboratory tests required for certification as well as any other laboratory tests provided in the RHC laboratory.

**Note:** If the RHC sends laboratory services to an outside laboratory, the outside laboratory bills the Part B carrier for the tests.

If the RHC laboratory becomes certified as a clinical laboratory, it bills all laboratory tests performed in its laboratory to the laboratory's Part B carrier. Laboratory tests are not included as RHC costs nor as part of the RHC all-inclusive rate payment.

For provider based RHCs the rules in the preceding paragraph apply with the following exception. The provider bills tests provided in its laboratory to the FI.

## 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 - FIs

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

***Effective 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 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***

*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 |

| Requirement Number | Requirements | Responsibility |
|---|---|---|
| 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.

## 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 Furnished by Hospital-Based Facilities

**(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. 1769, Issued: 07-10-09, Effective/Implementation: 07-31-09)**

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 1. 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.

## 40.7 - Billing for Noncovered Clinical Laboratory Tests
**(Rev. 1, 10-01-03)**
**B3-5114.1**

Ordinarily, neither a physician nor a laboratory bills the Medicare Program for noncovered tests. However, if the beneficiary (or his/her representative) contends that a clinical laboratory test which a physician or laboratory believes is noncovered may be covered, the physician or laboratory must file a claim that includes the test to effectuate the beneficiary's right to a Medicare determination. The physician or laboratory annotates the claim that he/she believes that the test is noncovered and is submitting it at the beneficiary's insistence. Before furnishing a beneficiary a test which the physician or laboratory believes is excluded from coverage as not reasonable and necessary (rather than excluded from coverage as part of a routine physical check-up), the physician or laboratory must obtain a signed Advanced Beneficiary Notice (ABN) from the beneficiary (or representative) that the physician or laboratory has informed him/her of the noncoverage of the test and that there will be a charge for the test. This protects the physician or laboratory against possible liability for the test under the limitation of liability provision.

See Chapter 30, regarding Advance Beneficiary Notices (ABN) and demand bills.

## 40.8 - Date of Service (DOS) for Clinical Laboratory and Pathology Specimens
**(Rev. 1515, Issued: 05-23-08, Effective: 01-01-09, Implementation: 01-05-09)**

The DOS policy for either a clinical laboratory test or the technical component of physician pathology service is as follows:

General Rule: The DOS of the test/service must be the date the specimen was collected.

Variation: If a specimen is collected over a period that spans two calendar days, then the DOS must be the date the collection ended.

Exceptions: The following two exceptions apply to the DOS policy for either a clinical laboratory test or the technical component of physician pathology service:

A. DOS for Tests/Services Performed on Stored Specimens:

In the case of a test/service performed on a stored specimen, if a specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test/service must be the date the test/service was performed only if:

- The test/service is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

- The specimen was collected while the patient was undergoing a hospital surgical procedure;

- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

- The results of the test/service do not guide treatment provided during the hospital stay; and

- The test/service was reasonable and medically necessary for treatment of an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived and the DOS of the test/service must be the date the specimen was obtained from storage.

B. DOS for Chemotherapy Sensitivity Tests/Services Performed on Live Tissue:

In the case of a chemotherapy sensitivity test/service performed on live tissue, the DOS of the test/service must be the date the test/service was performed only if:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

- The specimen was collected while the patient was undergoing a hospital surgical procedure;

- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

- The results of the test/service do not guide treatment provided during the hospital stay; and

- The test/service was reasonable and medically necessary for treatment of an illness.

For purposes of applying the above exception, a "chemotherapy sensitivity test" is defined as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. CMS identifies such tests through program instructions issued to the Medicare contractors.

## 50 – Carrier Claims Processing
**(Rev. 1, 10-01-03)**

## 50.1 - Referring Laboratories
**(Rev. 85, 02-06-04)**
**B3-5114.1**

Medicare recognizes that specimens drawn or collected by one laboratory are sometimes referred to another laboratory for testing. Payment for a Medicare-covered, referred laboratory service may be made under the rules established in Chapter 15 §40.1.

The rules specified Chapter 15 §40.1 do not apply to services performed in a physician office laboratory or a qualified hospital laboratory. Both circumstances are entirely outside the scope of all sections concerning referral laboratory services.

Every carrier shall process a claim for a referred laboratory service if submitted by an independent clinical laboratory with a physical presence within the carrier's jurisdiction, notwithstanding that the referred laboratory service may have been performed outside of its jurisdiction.

Every carrier shall maintain the clinical laboratory fee schedules for each carrier jurisdiction and be able to process claims using those fee schedules.

Every carrier shall base payment for a referred service on the fee schedule for the jurisdiction in which the service was performed, i.e., where the test was performed. An exception to this rule allows a payment for a service that is carrier-priced to be based upon the price developed by the carrier processing the claim.

Every carrier that has previously assigned "reference use only" PINs to out-of-jurisdiction laboratories for the purpose of their billing referred services shall cancel such "reference-use-only" PINs.

Carriers must use the numerical locality codes specified in 50.4 to identify the appropriate clinical diagnostic laboratory fee schedule for use in pricing a referred laboratory service.

## 50.2 - Physicians

**(Rev. 1, 10-01-03)**
**B3-4110.2**

If a physician or medical group furnishes laboratory tests in an office setting and it is appropriate for them to be performed in the physician's office, no further development of the source of the laboratory tests is required.

If a claim or physician's bill raises a question as to the source of a laboratory test and it cannot be resolved from available information, carriers must request the source of the laboratory service from the physician.

If the clinical laboratory test is subject to the laboratory fee schedule, carriers must pay only the person or entity that performed or supervised the performance of the test. However, carriers may also pay one physician for tests performed or supervised by another physician with whom he/she shares a practice, i.e., the two physicians are members of a medical group whose physicians submit claims in their own names rather than in the name of the group. Where the medical group submits claims in the name of the group for the services of the physician who performed or supervised the performance

of these tests, carriers must pay the group. Regardless of who submits the claim, assignment is required for payment. See §50.2.1 below.

## 50.2.1 - Assignment Required

**(Rev. 1, 10-01-03)**
**B3-4110.2**

Carriers must:

- Pay for clinical laboratory services provided in the physician's office only on an assignment basis.

- Treat as assigned any claims for clinical laboratory services provided in the physician's office even if the claimant submits the claim on a non-assigned basis or if the assignment option is not designated.

- Deny claims where it is apparent from the claims form or from other evidence that the beneficiary or provider refuses to assign. Use MSN notice 16.41 or 16.6 and remittance Remark code PR106 or CO111, as appropriate.

## 50.3 - Hospitals

**(Rev. 1, 10-01-03)**

## 50.3.1 - Hospital-Leased Laboratories

**(Rev. 1, 10-01-03)**
**B3-4110.1**

Carriers process claims from hospital laboratories that are leased by physicians and independent laboratories.

Before processing claims for services furnished by a hospital laboratory department operated on a lease or concession basis by a pathologist or by a nonphysician specialist such as a biochemist (with a visiting pathologist or outside independent laboratory doing the hospital's tissue work), carriers must ascertain if the laboratory has been approved by the RO.

Services furnished by a laboratory that does not meet the hospital laboratory conditions of participation and is operated under a lease arrangement in a domestic emergency hospital are covered only if they are emergency inpatient services payable under Part A.

Additional information concerning nonparticipating emergency hospital services is found in Chapter 3.

## 50.3.2 - Hospital Laboratory Services Furnished to Nonhospital Patients

**(Rev. 734; Issued: 10-28-05; Effective Date: 10-01-04; Implementation Date: 04-03-06)**

When a hospital laboratory performs a laboratory service for a non-hospital patient, (i.e., for neither an inpatient nor an outpatient), the hospital bills its FI on the ANSI X-12 837I

or on the hard copy form, CMS-1450. If a carrier receives such claims, the carrier should deny them. When the lab services are provided in Maryland, services to a hospital's own outpatients are paid under the State cost containment system. A Maryland hospital cannot seek payment based on a percent of charges for tests provided to individuals in locations such as a rural health clinic (RHC), a provider-based HHA, the individual's home or a physician's office). Individuals in these locations are non-patients of the Maryland hospital and their lab tests would be categorized as "non-patient specimen only lab tests" (TOB 14x), and **are** paid under the lab fee schedule.

When a hospital-leased laboratory performs a service for a non-hospital patient, it must bill the carrier.

## 50.4 - Reporting of Pricing Localities for Clinical Laboratory Services

**(Rev. 85, 02-06-04)**
**PM-B-97-12**

Carriers shall report to the common working file (CWF) new State pricing localities (positions 58 and 59 on the carrier record) indicated on the Clinical Diagnostic Laboratory fee schedule for any reference laboratory service billed with a HCPCS 90 modifier. If the laboratory test billed is not a reference laboratory service, the Carrier Locality (location 11-12) on the Clinical Diagnostic Laboratory fee schedule should be forwarded to the CWF. For dates of service on or after April 1, 2004, CWF will not edit clinical laboratory pricing locality.

The carrier and intermediary record layouts, plus the State pricing locations are as follows:

CARRIER RECORD LAYOUT FOR DATA FILE

CLINICAL LABORATORY FEE SCHEDULE

| Data Element Name | Picture | Location | Comment |
|---|---|---|---|
| HCPCS Code | X(05) | 1-5 | |
| Carrier Number | X(05) | 6-10 | |
| Carrier Locality | X(02) | 11-12 | 00--Single State Carrier<br>01--North Dakota<br>02--South Dakota<br>20--Puerto Rico |
| 60% Local Fee | 9(05)V99 | 13-19 | |
| 62% Local Fee | 9(05)V99 | 20-26 | |
| 60% Natl Limit Amt | 9(05)V99 | 27-33 | |
| 62% Natl Limit Amt | 9(05)V99 | 34-40 | |
| 60% Pricing Amt | 9(05)V99 | 41-47 | |
| 62% Pricing Amt | 9(05)V99 | 48-54 | |
| Gap-Fill Indicator | X(01) | 55-55 | 0--No Gap-fill Required<br>1--Carrier Gap-fill<br>2--Special Instructions Apply |
| Modifier | X(02) | 56-57 | Where modifier is shown, QW denotes a CLIA waiver |

| | | | |
|---|---|---|---|
| | | | Test. |
| State Locality | X(02) | 58-59 | See attached |
| FILLER | X(01) | 60 | |

INTERMEDIARY RECORD LAYOUT FOR DATA FILE
CLINICAL LABORATORY FEE SCHEDULE

| **Data Element Name** | **Picture** | **Location** | **Comment** |
|---|---|---|---|
| HCPCS | X(05) | 1-5 | |
| Filler | X(04) | 6-9 | |
| 60% Pricing Amt | 9(05)V99 | 10-16 | |
| 62% Pricing Amt | 9(05)V99 | 17-23 | |
| Filler | X(07) | 24-30 | |
| Carrier Number | X(05) | 31-35 | |
| Carrier Locality | X(02) | 36-37 | 00--Single State Carrier<br>01--North Dakota<br>02--South Dakota<br>20--Puerto Rico |
| State Locality | X(02) | 38-39 | See Attached |
| FILLER | X(21) | 40-60 | |

**CarrierLocality/StateLocality Map**

Carrier/Loc 0051000=StateLoc 01 (ALABAMA)
Carrier/Loc 0051100=StateLoc 02 (GEORGIA)
Carrier/Loc 0051200=StateLoc 03 (MISSISSIPPI)
Carrier/Loc 0052000=StateLoc 04 (ARKANSAS)
Carrier/Loc 0052100=StateLoc 05 (NEW MEXICO)
Carrier/Loc 0052200=StateLoc 06 (OKLAHOMA)
Carrier/Loc 0052300=StateLoc 07 (MISSOURI GENERAL AMERICAN)
Carrier/Loc 0052800=StateLoc 08 (LOUISIANA)
Carrier/Loc 0059000=StateLoc 09 (FLORIDA)
Carrier/Loc 0059100=StateLoc 10 (CONNECTICUT)
Carrier/Loc 0063000=StateLoc 11 (INDIANA)
Carrier/Loc 0065000=StateLoc 12 (KANSAS)
Carrier/Loc 0065500=StateLoc 13 (NEBRASKA)
Carrier/Loc 0066000=StateLoc 14 (KENTUCKY)
Carrier/Loc 0074000=StateLoc 15 (MISSOURI)
Carrier/Loc 0075100=StateLoc 16 (MONTANA)
Carrier/Loc 0080100=StateLoc 17(WESTERN NEW YORK)
Carrier/Loc 0080300=StateLoc 18 (EMPIRE NEW YORK)
Carrier/Loc 0080500=StateLoc 19 (NEW JERSEY)
Carrier/Loc 0082001=StateLoc 20 (NORTH DAKOTA)
Carrier/Loc 0082002=StateLoc 21(SOUTH DAKOTA)
Carrier/Loc 0082400=StateLoc 22 (COLORADO)
Carrier/Loc 0082500=StateLoc 23 (WYOMING)
Carrier/Loc 0082600=StateLoc 24 (IOWA)

Carrier/Loc 0083100=StateLoc 25 (ALASKA)
Carrier/Loc 0083200=StateLoc 26 (ARIZONA)
Carrier/Loc 0083300=StateLoc 27 (HAWAII)
Carrier/Loc 0083400=StateLoc 28 (NEVADA)
Carrier/Loc 0083500=StateLoc 29 (OREGON)
Carrier/Loc 0083600=StateLoc 30 (WASHINGTON STATE)
Carrier/Loc 0086500=StateLoc 31 (PENNSYLVANIA)
Carrier/Loc 0087000=StateLoc 32 (RHODE ISLAND)
Carrier/Loc 0088000=StateLoc 33 (SOUTH CAROLINA)
Carrier/Loc 0088300=StateLoc 34 (OHIO)
Carrier/Loc 0088400=StateLoc 35 (WEST VIRGINIA)
Carrier/Loc 0090000=StateLoc 36 (TEXAS)
Carrier/Loc 0090100=StateLoc 37 (MARYLAND)
Carrier/Loc 0090200=StateLoc 38 (DELAWARE)
Carrier/Loc 0090300=StateLoc 39 (DISTRICT OF COLUMBIA)
Carrier/Loc 0090400=StateLoc 40 (VIRGINIA)
Carrier/Loc 0091000=StateLoc 41 (UTAH)
Carrier/Loc 0095100=StateLoc 42 (WISCONSIN)
Carrier/Loc 0095200=StateLoc 43 (ILLINOIS)
Carrier/Loc 0095300=StateLoc 44 (MICHIGAN)
Carrier/Loc 0095400=StateLoc 45 (MINNESOTA)
Carrier/Loc 0097320=StateLoc 46 (PUERTO RICO)
Carrier/Loc 0513000=StateLoc 47 (IDAHO)
Carrier/Loc 0544000=StateLoc 48 (TENNESSEE)
Carrier/Loc 0553500=StateLoc 49 (NORTH CAROLINA)
Carrier/Loc 1433000=StateLoc 50 (NEW YORK GHI)
Carrier/Loc 3114000=StateLoc 51 (NORTHERN CALIFORNIA)
Carrier/Loc 3114200=StateLoc 52 (MAINE)
Carrier/Loc 3114300=StateLoc 53 (MASSACHUSETTS)
Carrier/Loc 3114400=StateLoc 54 (NEW HAMPSHIRE)
Carrier/Loc 3114500=StateLoc 55 (VERMONT)
Carrier/Loc 3114600=StateLoc 56 (SOUTHERN CALIFORNIA OCCIDENTAL)

## 50.5 - Jurisdiction of Laboratory Claims

**(Rev. 1, 10-01-03)**
**B3-3102**

Jurisdiction of payment requests for laboratory services furnished by an independent laboratory, except where indicated in §50.5.1 and §50.5.2, lies with the carrier serving the area in which the laboratory test is performed. Jurisdiction is not affected by whether or not the independent laboratory uses a central billing office and whether or not the laboratory provides services to customers outside its carrier's service area.

## 50.5.1 - Jurisdiction Of Referral Laboratory Services

**(Rev. 85, 02-06-04)**

Regardless of whether the laboratory that bills Medicare is the referring or reference laboratory, the laboratory that does the billing may bill only the carrier that services the jurisdiction in which the billing laboratory is physically located. The location of the draw

station, when a separate draw station is employed, never determines claims filing jurisdiction.

## 50.5.2 - Examples of Reference Laboratory Jurisdiction Rules

**(Rev. 85, 02-06-04)**
**B3-3102**

**EXAMPLE 1:**

**Scenario 1:**

An independent laboratory located in Oregon performs laboratory services for physicians whose offices are located in several neighboring States. A physician from Nevada sends specimens to the Oregon laboratory.

Jurisdiction:

The carrier in Oregon has jurisdiction.

**EXAMPLE 2:**

**Scenario 2:**

American Laboratories, Inc., is an independent laboratory company with branch laboratories located in Philadelphia, PA and Wilmington, DE, as well as regional laboratories located in Millville, NJ and Boston, MA.

The Philadelphia laboratory receives a blood sample from a patient whose physician ordered a complete blood count, a basic metabolic panel and a B12 and folate. The Philadelphia laboratory performs the complete blood count, but the basic metabolic panel is performed at the Millville laboratory, while the B12 and folate is performed at the Boston Laboratory.

Jurisdiction:

The Pennsylvania carrier may retain jurisdiction for processing the claim for all of the services. The local carrier servicing Boston and/or Millville may have jurisdiction for processing their claims if those laboratories bill for the services they perform, but the Philadelphia laboratory is barred from billing for the services that Boston and Millville submit for payment.

**EXAMPLE 3:**

**Scenario 3:**

Same relationships as in Example 2. American Laboratories, Inc., is an independent laboratory company with branch laboratories located in Philadelphia, PA and Wilmington, DE, as well as regional laboratories located in Millville, NJ and Boston, MA.

This time the Wilmington laboratory draws a blood specimen from a patient whose physician has ordered a blood culture. The Wilmington laboratory then sends the specimen to the Boston laboratory, which performs the required test.

Jurisdiction:

The carrier processing claims for providers/suppliers located in Delaware may retain jurisdiction for processing the claim. If the laboratory in Boston chooses to bill for the service to the Massachusetts carrier, then the Wilmington laboratory may not bill for the service.

## 60 - Specimen Collection Fee and Travel Allowance

**(Rev. 1, 10-01-03)**
**B3-5114.1**

## 60.1 - Specimen Collection Fee

**(Rev. 1, 10-01-03)**
**B3-5114.1, A3-3628**

In addition to the amounts provided under the fee schedules, the Secretary shall provide for and establish a nominal fee to cover the appropriate costs of collecting the sample on which a clinical laboratory test was performed and for which payment is made with respect to samples collected in the same encounter.

A specimen collection fee is allowed in circumstances such as drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacutainer to draw the specimen) or collecting a urine sample by catheterization. A specimen collection fee is not allowed for blood samples where the cost of collecting the specimen is minimal (such as a throat culture or a routine capillary puncture for clotting or bleeding time). This fee will not be paid to anyone who has not extracted the specimen. Only one collection fee is allowed for each type of specimen for each patient encounter, regardless of the number of specimens drawn. When a series of specimens is required to complete a single test (e.g., glucose tolerance test), the series is treated as a single encounter.

## 60.1.1 - Physician Specimen Drawing

**(Rev. 1, 10-01-03)**
**HO-437, A3-3628, B3-5114.1**

Medicare allows a specimen collection fee for physicians only when (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen, and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen.

## 60.1.2 - Independent Laboratory Specimen Drawing

**(Rev. 1, 10-01-03)**
**B3-4110.4, HO-437, A3-3628**

Medicare allows separate charges made by laboratories for drawing or collecting specimens whether or not the specimens are referred to hospitals or independent laboratories. The laboratory does not bill for routine handling charges where a specimen is referred by one laboratory to another.

Medicare allows a specimen collection fee when it is medically necessary for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient. The technician must personally draw the specimen, e.g., venipuncture or urine sample by catheterization. Medicare does not allow a specimen collection fee to the visiting technician if a patient in a facility is (a) not confined to the facility, or (b) the facility has personnel on duty qualified to perform the specimen collection. Medical necessity for such services exists, for example, where a laboratory technician draws a blood specimen from a homebound or an institutionalized patient. A patient need not be bedridden to be homebound. However, where the specimen is a type that would require only the services of a messenger and would not require the skills of a laboratory technician, e.g., urine or sputum, a specimen pickup service would not be considered medically necessary. (See Chapters 7 and 15 of the Medicare Benefit Policy Manual for a discussion of "homebound" and a more complete definition of a medically necessary laboratory service to a homebound or an institutional patient.)

In addition to the usual information required on claim forms (including the name of the prescribing physician), all independent laboratory claims for such specimen drawing or EKG services prescribed by a physician should be appropriately annotated, e.g., "patient confined to home," "patient homebound," or "patient in nursing home, no qualified person on duty to draw specimen." Carriers must assure the validity of the annotation through scientific claims samples as well as through regular bill review techniques. (This could be done by use of the information in carrier files, and where necessary, contact with the prescribing physician.)

If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, the medical necessity criteria in Chapter 15 of the Medicare Benefit Policy Manual, an educational contact with the prescribing physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the carrier is assured that the physician prescribes such services only when the criteria are met.

## 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.

## 60.1.4 - Coding Requirements for Specimen Collection
**(Rev. 1, 10-01-03)**

The following HCPCS codes and terminology must be used:

- G0001 - Routine venipuncture for collection of specimen(s).
- P96l5 - Catheterization for collection of specimen(s).

The allowed amount for specimen collection in each of the above circumstances is included in the laboratory fee schedule distributed annually by CMS.

## 60.2 - Travel Allowance
**(Rev. 1584, Issued: 09-05-08, Effective: 07-01-08, Implementation: 10-06-08)**

In addition to a specimen collection fee allowed under §60.1, Medicare, under Part B, covers a specimen collection fee and travel allowance for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient under §1833(h)(3) of the Act and payment is made based on the clinical laboratory fee schedule. The travel allowance is intended to cover the estimated travel costs of collecting a specimen and to reflect the technician's salary and travel costs.

The additional allowance can be made only where a specimen collection fee is also payable, i.e., no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel. The travel allowance may not be paid to a physician unless the trip to the home, or to the nursing home was solely for the purpose of drawing a specimen. Otherwise travel costs are considered to be associated with the other purposes of the trip.

The travel allowance is not distributed by CMS. Instead, the carrier must calculate the travel allowance for each claim using the following rules for the particular Code. The following HCPCS codes are used for travel allowances:

**Per Mile Travel Allowance (P9603)**

- The minimum "per mile travel allowance" is $1.035. The per mile travel allowance is to be used in situations where the average trip to patients' homes is longer than 20 miles round trip, and is to be pro-rated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip. - one way, in connection with medically necessary laboratory specimen collection drawn from homebound or nursing home bound patient; prorated miles actually traveled (carrier allowance on per mile basis); or

- The per mile allowance was computed using the Federal mileage rate plus an additional 45 cents a mile to cover the technician's time and travel costs. Contractors have the option of establishing a higher per mile rate in excess of the minimum (1.035 cents a mile in CY 2008) if local conditions warrant it. The minimum mileage rate will be reviewed and updated in conjunction with the clinical lab fee schedule as needed. At no time will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.

**Example 1:** In CY 2008, a laboratory technician travels 60 miles round trip from a lab in a city to a remote rural location, and back to the lab to draw a single Medicare patient's blood. The total reimbursement would be $62.10 (60 miles x 1.035 cents a mile), plus the specimen collection fee.

**Example 2:** In CY 2008, a laboratory technician travels 40 miles from the lab to a Medicare patient's home to draw blood, and then travels an additional 10 miles to a non-Medicare patient's home and then travels 30 miles to return to the lab. The total miles traveled would be 80 miles. The claim submitted would be for one half of the miles traveled or $41.40 (40 x 1.035), plus the specimen collection fee.

**Flat Rate (P9604)**

The CMS will pay a minimum of $9.55 one way flat rate travel allowance. The flat rate travel allowance is to be used in areas where average trips are less than 20 miles round trip. The flat rate travel fee is to be pro-rated for more than one blood drawn at the same address, and for stops at the homes of Medicare and non-Medicare patients. The laboratory does the pro-ration when the claim is submitted based on the number of patients seen on that trip. The specimen collection fee will be paid for each patient encounter.

This rate is based on an assumption that a trip is an average of 15 minutes and up to 10 miles one way. It uses the Federal mileage rate and a laboratory technician's time of $17.66 an hour, including overhead. Contractors have the option of establishing a flat rate in excess of the minimum of $9.55, if local conditions warrant it. The minimum national flat rate will be reviewed and updated in conjunction with the clinical laboratory fee schedule, as necessitated by adjustments in the Federal travel allowance and salaries.

**The claimant identifies round trip travel by use of the LR modifier**

**Example 3**: A laboratory technician travels from the laboratory to a single Medicare patient's home and returns to the laboratory without making any other stops. The flat rate would be calculated as follows: 2 x $9.55 for a total trip reimbursement of $19.10, plus the specimen collection fee.

**Example 4**: A laboratory technician travels from the laboratory to the homes of five patients to draw blood, four of the patients are Medicare patients and one is not. An additional flat rate would be charged to cover the 5 stops and the return trip to the lab (6 x $9.55 = $57.30). Each of the claims submitted would be for $11.46 ($57.30 /5 = $11.46). Since one of the patients is non-Medicare, four claims would be submitted for $11.46 each, plus the specimen collection fee for each.

**Example 5**: A laboratory technician travels from a laboratory to a nursing home and draws blood from 5 patients and returns to the laboratory. Four of the patients are on Medicare and one is not. The $9.55 flat rate is multiplied by two to cover the return trip to the laboratory (2 x $9.55 = $19.10) and then divided by five (1/5 of $19.10 = $3.82). Since one of the patients is non-Medicare, four claims would be submitted for $3.82 each, plus the specimen collection fee.

If a carrier determines that it results in equitable payment, the carrier may extend the former payment allowances for additional travel (such as to a distant rural nursing home) to all circumstances where travel is required. This might be appropriate, for example, if the carrier's former payment allowance was on a per mile basis. Otherwise, it should establish an appropriate allowance and inform the suppliers in its service area. If a carrier decides to establish a new allowance, one method is to consider developing a travel allowance consisting of:

- The current Federal mileage allowance for operating personal automobiles, plus a personnel allowance per mile to cover personnel costs based upon an estimate of average hourly wages and average driving speed.

Carriers must prorate travel allowance amounts claimed by suppliers by the number of patients (including Medicare and non-Medicare patients) from whom specimens were drawn on a given trip.

The carrier may determine that payment in addition to the routine travel allowance determined under this section is appropriate if:

- The patient from whom the specimen must be collected is in a nursing home or is homebound; and

- The clinical laboratory tests are needed on an emergency basis outside the general business hours of the laboratory making the collection.

- Subsequent updated travel allowance amounts will be issued by CMS via Recurring Update Notification (RUN) on an annual basis.

# 70 - Clinical Laboratory Improvement Amendments (CLIA) Requirements

**(Rev. 1, 10-01-03)**
**A3-3628.2, RHC-640, ESRD 322, HO-306, HHA-465, SNF 541, HO-437.2, PM B-97-3**

## 70.1 - Background

**(Rev. 1, 10-01-03)**
**A3-3628.2, PM B-97-4**

The Clinical Laboratory Improvements Amendments of 1988 (CLIA), Public Law 100-578, amended §353 of the Public Health Service Act (PHSA) to extend jurisdiction of the Department of Health and Human Services to regulate all laboratories that examine human specimens to provide information to assess, diagnose, prevent, or treat any disease or impairment. The purpose of the CLIA program is to assure that laboratories testing specimens in interstate commerce consistently provide accurate procedures and services. As a result of CLIA, any laboratory soliciting or accepting specimens in interstate commerce for laboratory testing is required to hold a valid license or letter of exemption from licensure issued by the Secretary of HHS. The term "interstate commerce" means trade, traffic, commerce, transportation, or communication between any state, possession of the United States, the Commonwealth of Puerto Rico, or the District of Columbia, and any place outside thereof, or within the District of Columbia.

The CLIA mandates that virtually all laboratories, including physician office laboratories (POLs), meet applicable Federal requirements and have a CLIA certificate in order to receive reimbursement from Federal programs. CLIA also lists requirements for laboratories performing only certain tests to be eligible for a certificate of waiver or a certificate for Physician Performed Microscopy Procedures (PPMP). Since 1992, carriers have been instructed to deny clinical laboratory services billed by independent laboratories which did not meet the CLIA requirements. POLs were excluded from the 1992 instruction but included in 1997.

The CLIA number must be included on each Form CMS-1500 claim for laboratory services by any laboratory performing tests covered by CLIA.

## 70.2 - Billing

**(Rev. 1, 10-01-03)**

The CLIA number is required in field 23 of the paper Form CMS-1500. The electronic formats have a field reserved for a CLIA number. See Chapter 26 for specific reporting requirements.

## 70.3 - Verifying CLIA Certification

**(Rev. 865, Issued: 02-17-06; Effective: 01-01-06; Implementation: 07-03-06)**

CWF edits Carrier claims to ascertain that the laboratory identified by the CLIA number is certified to perform the test. (CWF uses data supplied from the certification process.) See Chapter 27 for related specifications.

Providers that bill FIs are responsible for verifying CLIA certification prior to ordering laboratory services under arrangement. The survey process validates that these providers have procedures in place to insure that laboratory services are provided by CLIA approved laboratories.

Refer to the Medicare State Operations Manual for information about CLIA license or the CLIA licensure exemptions.

## 70.4 - CLIA Numbers
**(Rev. 1, 10-01-03)**
**A3-3628.2.D**

The structure of the CLIA number follows:

> Positions 1 and 2 contain the State code (based on the laboratory's physical location at time of registration);
>
> Position 3 contains the letter "D"; and
>
> Positions 4-10 contain the unique CLIA system assigned number that identifies the laboratory. (No other laboratory in the country has this number.)

Initially, providers are issued a CLIA number when they apply to the CLIA program.

Independent dialysis facilities must obtain a CLIA certificate in order to perform clotting time tests.

## 70.5 - CLIA Categories and Subcategories
**(Rev. 1, 10-01-03)**

A laboratory may be licensed or exempted from licensure in several major categories of procedures. These major categories are:

| | |
|---|---|
| 010 | Histocompatibility |
| 100 | Microbiology |
| 110 | Bacteriology |
| 115 | Mycobacteriology |
| 120 | Mycology |
| 130 | Parasitology |
| 140 | Virology |
| 150 | Other Microbiology |

| | |
|---|---|
| 200 | Diagnostic Immunology |
| 210 | Syphilis Serology |
| 220 | General Immunology |
| 300 | Chemistry |
| 310 | Routine |
| 320 | Urinalysis |
| 330 | Endocrinology |
| 340 | Toxicology |
| 350 | Other |
| 400 | Hematology |
| 500 | Immuno-hematology |
| 510 | ABO Group and RH Type |
| 520 | Antibody Detection (Transfusion) |
| 530 | Antibody Detection (Non Transfusion) |
| 540 | Antibody Identification |
| 550 | Compatability Testing |
| 560 | Other |
| 600 | Pathology |
| 610 | Histopathology |
| 620 | Oral Pathology |
| 630 | Cytology |
| 800 | Radioassay |
| 900 | Clinical Cytogenics |

For a list of specific HCPCS codes see http://www.cms.hhs.gov/clia/default.asp

## 70.6 - Certificate for Provider-Performed Microscopy Procedures

**(Rev. 865, Issued: 02-17-06; Effective: 01-01-06; Implementation: 07-03-06)**

Effective January 19, 1993, a laboratory that holds a certificate for provider-performed microscopy procedures may perform only those tests specified as provider-performed microscopy procedures and waived tests, as described below, and no others.

| HCPCS Code | Test |
|---|---|
| Q0111 | Wet mounts, including preparations of vaginal, cervical or skin specimens |
| Q0112 | All potassium hydroxide (KOH) preparations |
| Q0113 | Pinworm examinations |
| Q0114 | Fern test |
| Q0115 | Post-coital direct, qualitative examinations of vaginal or cervical mucous |
| 81015 | Urinalysis; microscopic only |
| 81000 | Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy |
| 81001 | Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy (NOTE: May only be used when the lab is using an automated dipstick urinalysis instrument approved as waived.) |
| 81020 | Urinalysis; two or three glass test |
| 89055 | Fecal leukocyte examination |
| 89190 | Nasal smears for eosinophils |
| G0027 | Semen analysis; presence and/or motility of sperm excluding Huhner |

## 70.7 - Deleted - Held for Expansion
**(Rev. 1, 10-01-03)**

## 70.8 - Certificate of Waiver
**(Rev. 1652, Issued: 12-19-08, Effective: 01-01-09, Implementation: 01-05-09)**

Effective September 1, 1992, all laboratory testing sites (except as provided in 42 CFR 493.3(b)) must have either a CLIA certificate of waiver, certificate for provider-performed microscopy procedures, certificate of registration, certificate of compliance, or

certificate of accreditation to legally perform clinical laboratory testing on specimens from individuals in the United States.

The Food and Drug Administration approves CLIA waived tests on a flow basis. The CMS identifies CLIA waived tests by providing an updated list of waived tests to the Medicare contractors on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA waived tests have unique HCPCS procedure codes and some must have a QW modifier included with the HCPCS code.

For a list of specific HCPCS codes subject to CLIA see
http://www.cms.hhs.gov/CLIA/downloads/waivetbl.pdf

## 70.9 - HCPCS Subject To and Excluded From CLIA Edits
**(Rev. 865, Issued: 02-17-06; Effective: 01-01-06; Implementation: 07-03-06)**

At this time, all claims submitted for laboratory tests subject to CLIA are edited at the CLIA certificate level. However, the HCPCS codes that are considered a laboratory test under CLIA change each year. The CMS identifies the new HCPCS (non-waived, non-provider-performed procedure) codes, including any modifiers that are subject to CLIA edits by providing an updated listing of these tests to the Medicare contractors on an annual basis via a Recurring Update Notification. A facility that submits a claim for any test mentioned in the HCPCS codes that are subject to CLIA edits list must have either a valid, current CLIA certificate of registration (certificate type 9), a CLIA certificate of compliance (certificate type 1), or a CLIA certificate of accreditation (certificate type 3).

For a list of the specific HCPCS codes subject to CLIA edits refer to the following Internet site: http://www.cms.hhs.gov/CLIA/downloads/Subject.to.CLIA.pdf

In addition, the CMS identifies the new HCPCS codes in the 80000 series that are excluded from CLIA edits by providing an updated listing of these tests to the Medicare contractors on an annual basis via a Recurring Update Notification. No CLIA certificate is required for a claim submitted for any test mentioned in the HCPCS codes in the 80000 series that are excluded from CLIA edits list.

For a list of the specific HCPCS codes in the 80000 series that are excluded from CLIA edits refer to the following Internet site:
http://www.cms.hhs.gov/CLIA/downloads/cpt4exc.pdf

## 70.10 - CLIA Number Submitted on Form CMS-1500
**(Rev. 1, 10-01-03)**

Effective with services provided October 1, 1997, any independent laboratory performing tests covered by CLIA must submit the CLIA number on the Form CMS-1500 hardcopy or electronic claim form. The CLIA number is reported in:

- Field 23 of the paper CMS-1500,
- Record FAO, field 34 of the NSF,

- ASC X12 837 (3051) REF segment as REF02, with qualifier of “X4” in REF01
- ASC X12 837 (4010) REF segment as REF02, with qualifier of “X4” in REF01

The CLIA number is not required on UB 92 or its related data sets.

See chapter 26 for detailed format instructions.

Laboratory claims submitted without the CLIA number are returned as unprocessable. If the CLIA number is submitted on the claim, but is inconsistent with the CLIA format, the carrier returns the claim as unprocessable. If more than one CLIA number is submitted on the claim, except when a reference laboratory is on the same claim, the carrier returns the claim as unprocessable.

If the tests on one claim have been performed in more than one Physician Office Laboratory (POL) by the same physician, the appropriate CLIA number should be associated with the test that was performed in each laboratory. In such a case, the physician must submit a separate claim for each location (CLIA number) where a test was performed.

## 70.10.1 - Physician Notification of Denials
**(Rev. 1, 10-01-03)**

If there is no CLIA number on the claim, the carrier sends RA messages MA 120 and MA 130, which state:

> MA 120 - Did not complete or enter accurately the CLIA number.
>
> MA 130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim in unprocessable. Please submit the correct information to the appropriate FI or carrier.

## 70.11 - Reasons for Denial - Physician Office Laboratories Out-of-Compliance
**(Rev. 1, 10-01-03)**

Carriers use remittance advice (RA) message B7 to notify the provider of the reason for denial. The B7 message states: “This provider was not certified/eligible to be paid for this procedure/service on this date of service.”

Carriers use MSN message #14.1, which states:

> The laboratory is not approved for this type of test.

## 80 - Issues Related to Specific Tests
**(Rev. 1, 10-01-03)**

## 80.1 - Screening Services

**(Rev. 1, 10-01-03)**

See chapter 18 for payment, edit and MSN requirements for the following screening services.

- Screening Pap Smear and Pelvic Examination
- Screening Prostate Tests
- Colorectal Cancer Screening

## 80.2 - Anatomic Pathology Services

**(Rev. 1, 10-01-03)**
**A3-3628.1, SNF 541.1, HO-437.1, RHC-437, CIM 50.20.1, PM AB-98-7, AB-98-22, B-98-16, A-98-6, R103.CIM, A3-4603.1**

Clinical laboratory tests include some services described as anatomic pathology services in CPT (i.e., certain cervical, vaginal, or peripheral blood smears). The CPT code 85060 is used only when a physician interprets an abnormal peripheral blood smear for a hospital inpatient or a hospital outpatient, and the hospital is responsible for the technical component. When an independent laboratory bills a physician interpretation of an abnormal peripheral blood smear, the service is considered a complete or global service, and is not billed under the CPT code 85060. A physician interpretation of an abnormal peripheral blood smear performed by an independent laboratory is considered a routine part of the ordered hematology service (i.e., those tests that include a different white blood count).

The HCPCS code 88150 (cervical or vaginal smears) included both screening and interpretation in CPT 1986 terminology while the CPT 1987 terminology includes only screening. A new code, 88151, was added for those smears that require physician interpretation. Code 88151 is treated and priced in the same manner as code 88150 was previously treated and priced. Code 88151 with a "-26" modifier is paid when a physician performs an interpretation of an abnormal smear for a hospital inpatient or outpatient, and the hospital is responsible for the technical component. The "-26" modifier for code 88150 is no longer recognized. Code 88151(26) is priced as code 88150(26) would have been priced if the coding terminology had not been revised. Independent laboratories bill under code 88150 for normal smears and under code 88151 for abnormal smears. However, the fee schedule amount is equivalent.

## 80.2.1 - Technical Component (TC) of Physician Pathology Services to Hospital Patients

**(Rev. 1945; Issued: 04-09-10; Effective Date: 01-01-10; Implementation Date: 07-09-10)**

Section 542 of the Benefits Improvement and Protection Act of 2000 (BIPA) provides that the Medicare A/B MAC/carrier can continue to pay for the TC of physician pathology services when an independent laboratory furnishes this service to an inpatient or outpatient of a covered hospital. This provision applies to TC services furnished during the 2-year period beginning on January 1, 2001. Administrative extensions of this provision, and new provisions established under Section 732 of the Medicare

Modernization Act (MMA); Section 104 of the Tax Relief and Health Care Act (TRHCA) of 2006; Section 104 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA); Section 136 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA); and Section 3104 of the Patient Protection and Affordable Care Act (PPACA) allow the A/B MAC/carrier to continue to pay for this service through December 31, 2010.

For this provision, covered hospital means a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the TC of physician pathology services to fee-for-service Medicare beneficiaries who were hospital inpatients or outpatients and submitted claims for payment for the TC to a A/B MAC/carrier. The TC could have been submitted separately or combined with the professional component and reported as a combined service.

The term "fee-for-service Medicare beneficiary" means an individual who:

1. Is entitled to benefits under Part A or enrolled under Part B of title XVIII or both; and

2. Is not enrolled in any of the following:

    a. A Medicare + Choice plan under Part C of such title;

    b. A plan offered by an eligible organization under §1876 of the Act;

    c. A program of all-inclusive care for the elderly under §1894 of the Act; or

    d. A social health maintenance organization demonstration project established under §4108(b) of the Omnibus Budget Reconciliation Act of 1987.

The following examples illustrate the application of the statutory provision to arrangements between hospitals and independent laboratories.

In implementing BIPA §542; MMA §732; TRHCA §104; MMSEA §104; MIPPA §136; and PPACA § 3104, the A/B MAC/carriers should consider as independent laboratories those entities that it has previously recognized and paid as independent laboratories.

An independent laboratory that has acquired another independent laboratory that had an arrangement on July 22, 1999, with a covered hospital, can bill the TC of physician pathology services for that hospital's inpatients and outpatients under the physician fee schedule through December 31, 2010.

**EXAMPLE 1:**

Prior to July 22, 1999, independent laboratory A had an arrangement with a hospital in which this laboratory billed the carrier for the TC of physician pathology services. In July 2000, independent laboratory B acquires independent laboratory A. Independent laboratory B bills the carrier for the TC of physician pathology services for this hospital's patients in 2001 and 2002.

If a hospital is a covered hospital, any independent laboratory that furnishes the TC of physician pathology services to that hospital's inpatients or outpatients can bill the carrier for these services furnished in 2001 and 2002.

**EXAMPLE 2:**

As of July 22, 1999, the hospital had an arrangement with an independent laboratory, laboratory A, under which that laboratory billed the A/B MAC/carrier for the TC of physician pathology service to hospital inpatients or outpatients. In 2001, the hospital enters into an arrangement with a different independent laboratory, laboratory B, under which laboratory B wishes to bill its A/B MAC/carrier for the TC of physician pathology services to hospital inpatients or outpatients. Because the hospital is a "covered hospital," independent laboratory B can bill its A/B MAC/carrier for the TC of physician pathology services to hospital inpatients or outpatients.

If the arrangement between the independent laboratory and the covered hospital limited the provision of TC physician pathology services to certain situations or at particular times, then the independent laboratory can bill the A/B MAC/carrier only for these limited services.

An independent laboratory that furnishes the TC of physician pathology services to inpatients or outpatients of a hospital that is not a covered hospital may not bill the A/B MAC/carrier for TC of physician pathology services furnished to patients of that hospital.

An independent laboratory that has an arrangement with a covered hospital should forward a copy of this agreement or other documentation to its A/B MAC/carrier to confirm that an arrangement was in effect between the hospital and the independent laboratory as of July 22, 1999. This documentation should be furnished for each covered hospital the independent laboratory services. If the laboratory did not have an arrangement with the covered hospital as of July 22, 1999, but has subsequently entered into an arrangement, then it should obtain a copy of the arrangement between the predecessor laboratory and the covered hospital and furnish this to the A/B MAC/carrier. The A/B MAC/carrier maintains a hard copy of this documentation for postpayment reviews.

Effective on or after January 1, 2011, only the hospital may bill for the TC of a physician pathology service provided to an inpatient or outpatient. In addition, the hospital cannot bill under the OPPS for the TC of physician pathology services if the independent laboratory that services that hospital outpatient is receiving payment from its A/B MAC/carrier under the physician fee schedule.

## 80.3 - National Minimum Payment Amounts for Cervical or Vaginal Smear Clinical Laboratory Tests

**(Rev. 1, 10-01-03)**
**PM AB-99-84, AB-99-99**

For cervical or vaginal smear clinical laboratory tests, payment is the lesser of the local fee or the national limitation amount, but not less than the national minimum payment

amount (NMPA). However, in no case may payment for these tests exceed actual charges. The Part B deductible and coinsurance do not apply.

For tests performed on or after January 1, 2000, a NMPA of $14.60 is established and applies for cervical or vaginal smear clinical laboratory tests in accordance with §224 of the Balanced Budget Refinement Act (Public Law 106-113). The affected CPT laboratory test codes for the NMPA are 88142, 88143, 88144, 88145, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, G0123, G0143, G 0144, G0145, G0147, G0148, and P3000.

The NMPA will be reviewed and updated in conjunction with the clinical laboratory fee schedule, as required. Instructions for such updates will be sent to contractors through periodic temporary instructions.

## 80.4 - Oximetry

**(Rev. 1, 10-01-03)**
**B3-5114.1**

Certain blood gas levels are determined either by invasive means through use of a blood specimen for a clinical laboratory test or by noninvasive means through ear or pulse oximetry, which is not considered a clinical laboratory test. CPT code 82792 is used for invasive oximetry. HCPCS code M0592 is used for ear and pulse oximetry. Code M0592 is not subject to fee schedules.

## 90 - Automated Profile Tests and Organ/Disease Oriented Panels

**(Rev. 1, 10-01-03)**

The term “profile” or “panel” means a grouping of laboratory tests, which is usually performed automatically on a single piece of testing equipment.

## 90.1 - Laboratory Tests Utilizing Automated Equipment

**(Rev. 1, 10-01-03)**
**B3-5114, HO-437, A3-3628**

Clinical laboratory tests are covered under Medicare if they are reasonable and necessary for the diagnosis or treatment of an illness or injury. Because of the numerous technological advances and innovations in the clinical laboratory field and the increased availability of automated testing equipment, no distinction is generally made in determining payment for individual tests because of either (1) the sites where the service is performed, or (2) the method of the testing process used, whether manual or automated. Whether the test is actually performed manually or with automated equipment, the services are considered similar and the payment is the same.

However, where groups of tests that are billed individually may be done as a panel or profile, a determination must be made about whether payment should be made at the individual rate or at the panel or profile rate.

## 90.1.1 - Automated Test Listing

**(Rev. 1, 10-01-03)**
**B3-5114, HO-437, A3-3628, PMs AB-97-5, AB-97-7, AB-97-17**

Profiles are specific groupings of blood chemistries that enable physicians to more accurately diagnose their patients' medical problems. While the component tests in automated profiles may vary somewhat from one laboratory to another, or from one physician's office or clinic to another, in order to develop appropriate payment amounts, contractors group together those profile tests that can be performed at the same time on the same equipment. The carrier or FI must group together the individual tests in the profile when billed separately and consider the price of the related automated profile test. Payment cannot exceed the lower of the profile price or the totals of the prices of all the individual tests. (This rule is applicable also if the tests are done manually.) The profile HCPCS code and each individual test is priced at the lower of the billed charge or the fee amount; and payment is made at the lower of the profile/panel price or the total of the prices for all covered components.

Payment is made only for those tests in an automated profile that meet Medicare coverage rules. Where only some of the tests in a profile of tests are covered, payment cannot exceed the amount that would have been paid if only the covered tests had been ordered. For example, the use of the 12-channel serum chemistry test to determine the blood sugar level in a proven case of diabetes is unreasonable because the results of a blood sugar test performed separately provide the essential information. Normally, the payment allowance for a blood sugar test is lower than the payment allowance for the automated profile of tests. In no event, however, may payment for the covered tests exceed the payment allowance for the profile.

However, the carrier prices and pays the 1-22 automated multi-channel chemistry tests tested in §90.2 at the lowest possible amount in accordance with §90.3.

## 90.2 - Organ or Disease Oriented Panels

**(Rev. 1451; Issued: 02-15-08; Effective: 07-01-08; Implementation: 07-07-08)**

Organ or disease panels must be paid at the lower of the billed charge, the fee amount for the panel, or the sum of the fee amounts for all components. When panels contain one or more automated tests, the contractor determines the correct price for the panel by comparing the price for the automated profile laboratory tests with the sum of the fee amounts for individual tests. Payment for the total panel may not exceed the sum total of the fee amounts for individual covered tests. All Medicare coverage rules apply.

The Medicare standard systems must calculate the correct payment amount. The CMS furnishes fee prices for each code but the carrier system must compare individual codes billed with codes and prices for related individual tests. (With each HCPCS update, HCPCS codes are reviewed and the system is updated). Once the codes are identified, contractors publish panel codes to providers.

The only acceptable Medicare definition for the component tests included in the CPT codes for organ or disease oriented panels is the American Medical Association (AMA) definition of component tests. The CMS will not pay for the panel code unless all of the tests in the definition are performed. If the laboratory has a custom panel that includes

other tests, in addition to those in the defined CPT or HCPCS panels, the additional tests, whether on the list of automated tests or not, are billed separately in addition to the CPT or HCPCS panel code.

**NOTE:** If a laboratory chooses, it can bill each of the component tests of these panels individually, but payment will be based upon the above rules.

**TABLE OF CHEMISTRY PANELS**

| | | **Hepatic Function Panel 80076** | **Basic Metabolic Panel** (Calcium, ionized) **80047** | **Basic Metabolic Panel** (Calcium, total) **80048** | **Comprehensive Metabolic Panel 80053** | **Renal Function Panel 80069** | **Lipid[1] Panel 80061** | **Electrolyte Panel 80051** |
|---|---|---|---|---|---|---|---|---|
| **Chemistry** | **CPT** | | | | | | | |
| Albumin | 82040 | X | | | X | X | | |
| Alkaline phosphatase | 84075 | X | | | X | | | |
| ALT (SGPT) | 84460 | X | | | X | | | |
| AST (SGOT) | 84450 | X | | | X | | | |
| Bilirubin, total | 82247 | X | | | X | | | |
| Bilirubin, direct | 82248 | X | | | | | | |
| Calcium | 82310 | | | X | X | X | | |
| Calcium ionized | 82330 | | X | | | | | |
| Chloride | 82435 | | X | X | X | X | | X |
| Cholesterol | 82465 | | | | | | X | |
| CK, CPK | 82550 | | | | | | | |
| CO2 (bicarbonate) | 82374 | | X | X | X | X | | X |
| Creatinine | 82565 | | X | X | X | X | | |
| GGT | 82977 | | | | | | | |
| Glucose | 82947 | | X | X | X | X | | |
| LDH | 83615 | | | | | | | |
| Phosphorus | 84100 | | | | | X | | |
| Potassium | 84132 | | X | X | X | X | | X |
| Protein | 84155 | X | | | X | | | |
| Sodium | 84295 | | X | X | X | X | | X |
| Triglycerides | 84478 | | | | | | X | |
| Urea nitrogen (BUN) | 84520 | | X | X | X | X | | |
| Uric Acid | 84550 | | | | | | | |

## 90.3 - Claims Processing Requirements for Panel and Profile Tests
**(Rev. 372, Issued: 11-19-04, Effective: 04-01-05, Implementation: 04-04-05)**

All test codes should be processed and stored in history as they are submitted. That is, if tests are submitted as individual CPT codes together and paid as a panel (see §90), the

[1] CPT code 83718 is billed with Organ/Disease Panel 80061 but is not included in the AMCC bundling.

claim history data will reflect the individual codes and the panel used in pricing. All tests must maintain their identity as billed.

Prior to January 1, 1998, automated panel codes were adjudicated only on a line-by-line basis with application of the correct coding initiative (CCI) edits for duplicate detection.

Beginning with processing date January 1, 1998, when individual automated test codes are received, carriers and FIs do not combine them into panels for processing. The only instance in which they should be panel codes is when they are coded as such on the claim.

Panels must be processed line by line, and must be compared to other claims with automated test panels and/or single laboratory HCPCS codes in the current processing cycle, plus previous paid/processed claims. Therefore, any and all automated tests must be paid as a panel, but still retain their individual identity for duplicate detection and medical necessity review.

**Carriers and Fis**

**1. Deny Duplicates.** Deny duplicate services detected within the same processing cycle or stored in an automated history file. Consider claims that match on the following items as duplicates

a. The service was performed by the same provider,
b. For the same beneficiary, and
c. For the same date of service.

**2. Medical Necessity**. Determine medical necessity. This process permits the identification of CPT codes subject to local medical review policies.

**3. Process Claims.** The processes shown below (A-K) should be followed to price and pay claims for automated panels (as defined in HCPCS) and individual tests. This does not replace or abridge any current procedures in place concerning the adjudication of claim. This is a general procedure for combining these services to attain the lowest pricing outcome. This display is an example only. System maintainers have the flexibility to vary these procedures as long as they attain the same result.

A. Unbundle all panels to single lines representing individual automated multi-channel chemistry (AMCC) tests, and identify duplicate tests within the claim. On concurrently processed claims, determine the total amount payable based on the combination of all AMCC tests billed by the same laboratory, for the same beneficiary, and for the same date of service.

B. Check history for laboratory AMCC services provided by the same provider, to the same beneficiary, on the same day. Unbundle any panels. Identify duplicate services. Aggregate all nonduplicate services for pricing (include the submitted charge and paid amounts for both individually or paneled billed claims). If a single organ disease panel or a single chemistry panel contains the only AMCC test claims for that date of service, adjudicate as billed.

C. Compare each line's submitted charge to the fee schedule for that code (including automated tests retrieved from history).

D. Sum the comparisons of the line by line.

E. Obtain the fee for all AMCC tests as a panel including all services in history. If organ disease (OD) panels are involved, this amount will include fees for nonautomated tests included in the OD panel.

F. Carry forward the lesser of items D or E.

G. For steps A-C above, include the following calculations to price the claim by locality, using the fee schedule amount for each locality, when one or more test has been referred to another laboratory for processing:

Use the **total number of allowable AMCC tests** (both referred and nonreferred) to calculate the amount payable for each test. For example, if three tests are performed within the local carrier's jurisdiction, and two are referred to another laboratory for processing, first determine the amount payable for the five tests in each payment jurisdiction. Divide the total fee schedule amount for all tests being priced by the total number of allowable AMCC tests (in this example, five tests). The result is the unit price for each test. Multiply this result by the total number of AMCC tests performed within each pricing jurisdiction. (In this example, three tests were performed in jurisdiction 1 and two tests were performed in jurisdiction 2). Repeat this process for each pricing jurisdiction. In this example, there are two pricing jurisdictions. In jurisdiction 1, the amount payable is calculated by dividing the total fee schedule amount for jurisdiction 1 by five, and multiplying the result by three. Similarly, the amount payable for jurisdiction 2 is calculated by dividing the total fee schedule amount for jurisdiction 2 by five, and multiplying the result by two. Sum the two results (i.e., jurisdiction 1 amount + jurisdiction 2 amount). Compare this calculated amount to the submitted charges for the AMCC tests to determine the amount payable. (The amount payable is the lower of the fee schedule amount versus the submitted charges.)

H. Carry forward the lesser of the fee schedule amount versus the submitted charges, as determined in item G.

I. Subtract from item H any previous laboratory AMCC test (individual or paneled) or organ disease panel containing automated test payments. If nothing is payable on the claim, allow it with no payment.

J. The amount payable is the total payable based on the combination of current and previously processed claims, less the total amount paid on the previous claim(s).

K. If a claim is a CLIA reject from the CWF, Recycle that claim through the payment process to recalculate payment.

(**NOTE:** These calculations are provided as an example only. Carriers and standard system maintainers have the flexibility to vary these procedures as long as they attain the same result.)

If none of the AMCC tests have been referred to another laboratory for processing, carriers should exclude item G in calculating the amounts payable for individual AMCC tests and AMCC panels.

## 90.3.1 - History Display

**(Rev. 372, Issued: 11-19-04, Effective: 04-01-05, Implementation: 04-04-05)**

When displaying claims payment for each CPT code in history, contractors apply the following rules:

1. If all component tests of any panel are allowed because the individual line item comparison is less than the fee (as determined in item C above), record the panel codes as determined on the line-by-line comparison.

2. If all component tests are paid based on the panel price, allocate the current payment proportionate to the amount submitted for each CPT code.

3. If any panel tests will be denied or there are previously paid automated laboratory tests (as indicated by a check of beneficiary history), allocate the current payment amount by allowed line proportionate to what was submitted for the current claim being processed.

For administration of pricing requirements and/or invalid coding policies, contractors must establish a processing sequence for concurrently processed claims based on ascending order of internal control number (ICN). In the case of pricing, they must process the "first claim" (i.e., lower CN) based solely on the billed codes on that claim, process the "second" claim based on a combination of the billed codes on both claims and pay the balance due after subtracting the amount paid on the "first" claim. In the case of unacceptable code combinations, contractors must deny the "second" claim.

## 90.3.2 - Medicare Secondary Payer

**(Rev. 1, 10-01-03)**

When processing claims involving Medicare secondary payer (MSP), carriers should use the MSP payment formula as follows:

When Medicare is secondary, Medicare pays the lowest of:

- The actual charge less the primary payment;
- The amount Medicare would pay if primary; or
- The higher of the Medicare or primary allowable less the primary payment.

The two-step pricing comparison described above is required for calculating MSP amounts.

## 90.4 - Evaluating the Medical Necessity for Laboratory Panel CPT Codes

**(Rev. 1, 10-01-03)**
**PM-B-98-1**

The American Medical Association's (AMA) 1998 edition of the Current Procedural Terminology (CPT) establishes three new and one revised Organ or Disease Oriented laboratory panels. Since these panels are composed of clinically relevant groupings of automated multi-channel tests there is a general presumption of medical necessity. If contractors suspect abuse of the new panel codes, they should review such claims. Should a contractor determine the need to develop a LMRP for laboratory panel codes, the contractor should develop such a policy at the panel code level. As appropriate, a contractor may review the panel and deny component tests on a case-by-case basis or evaluate the need for the component level test.

## 90.5 - Special Processing Considerations

**(Rev. 1, 10-01-03)**
**PM AB-97-17**

To order any of the 22 automated tests, a physician may select individual tests or the panel. A physician may order a mix of panels and individual tests. The physician should review what tests are in each panel and not order individual tests that might duplicate tests in the panel. Medicare denies duplicate tests.

Specialists are not, based on their specialty, restricted to ordering certain panels or individual tests. The physician (general practitioner or specialist) should identify which tests he/she requires; and, if the tests match a grouping, order the appropriate panel. The claimant should file a separate claim for tests not included in a panel.

Claimants should use the QP modifier with the single ordering of tests or when a single code is available for groupings of tests. This modifier indicates that the claimant has documentation on file showing that the laboratory test(s) was ordered individually or ordered as a CPT-recognized panel other than automated profile codes 80002-80019, G0058, G0059, and G0060.

## 100 - CPT Codes Subject to and Not Subject to the Clinical Laboratory Fee Schedule

**(Rev. 1, 10-01-03)**
**HO-437, A3-3628, B3-5114.1**

For fee schedule purposes, clinical laboratory services include most laboratory tests listed in codes 80048-89399 of CPT-1996. The CMS issues an update to the laboratory fee schedule each year, with information about whether prices have been determined by CMS or whether the individual carrier must determine the allowable charge.

Codes not included are not paid under the laboratory fee schedule but may be paid under the MPFS if covered for Medicare.

## 100.1 - Deleted - Held for Expansion
**(Rev. 1, 10-01-03)**

## 100.2 - Laboratory Tests Never Subject to the Fee Schedule
**(Rev. 1, 10-01-03)**

Some CPT codes in the 80000 series are not clinical laboratory tests and are therefore never subject to fee schedule limitations. Some of these codes are exempted because they are not clinical laboratory services. They include codes for procedures, services, blood products and auto-transfusions. They include codes such as whole blood, various red blood cell products, platelets, plasma, and cryoprecipitate. Other codes for tests primarily associated with the provision of blood products are also not considered to be clinical tests. Such tests identify various characteristics of blood products, but are not diagnostic in nature. These include various blood cross matching techniques. If they are covered, Medicare pays exclusion codes under the MPFS, reasonable charges, reasonable costs, or OPPS as applicable.

## 100.3 - Procedures Not Subject to Fee Schedule When Billed With Blood Products
**(Rev. 1, 10-01-03)**

The following codes are not subject to fee schedule limitations when submitted for payment on the same bill with charges for blood products. Rather, assume they are to be used for blood matching and not for diagnostic purposes.

Codes: 86901, 86905, 86930-86932, 86920-86922, 86890, 86870, 86891, 86880-86886, 86971, and 86930.

If no blood product is provided and billed for on the same claim, assume the codes are diagnostic and subject to the clinical laboratory fee schedule.

The shared system provides for this processing.

## 100.4 - Not Otherwise Classified Clinical Laboratory Tests
**(Rev. 1, 10-01-03)**

The following codes for unlisted or not otherwise classified (NOC) clinical laboratory tests are not subject to the NLA:

81099 87999
84999 88299
85999 89399
86999

The NOC codes shall suspend for review and the carrier shall determine a price for them.

## 100.5 - Other Coding Issues
**(Rev. 1, 10-01-03)**

## 100.5.1 - Tests Performed More Than Once on the Same Day

**(Rev. 1, 10-01-03)**
**PM AB-98-7**

When it is necessary to obtain multiple results in the course of treatment, the modifiers 59 or 91 are used to indicate that a test was performed more than once on the same day for the same patient. The 91 modifier is used for laboratory tests paid under the clinical laboratory fee schedule.

These modifiers may be used to indicate that a test was performed more than once on the same day for the same patient, only when it is necessary to obtain multiple results in the course of treatment. These modifiers may not be used when tests are rerun to confirm initial results; due to testing problems with specimens and equipment; or for any other reason when a normal, one-time, reportable result is all that is required. These modifiers may not be used when there are standard HCPCS codes available that describe the series of results (e.g., glucose tolerance tests, evocative/suppression testing, etc.). These modifiers may be used only for laboratory tests paid under the clinical laboratory fee schedule.

Improper use of modifiers is likely to indicate a fraudulent or abusive circumstance. When informing laboratories of the availability of modifiers, carriers are to emphasize that these modifiers have very narrow application and that any evidence of excessive use will be referred to Carrier/FI Program Integrity Unit for further review.

## 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.*

## 110 - Coordination Between Carriers and Other Entities
**(Rev. 1, 10-01-03)**
**B3-5114.1**

## 110.1 - Coordination Between Carriers and FIs/RRB
**(Rev. 1, 10-01-03)**

The carrier furnishes copies of fees that are locally established under the fee schedules (price code = 22) to Medicare FIs and to the appropriate RRB carrier. The carrier must provide updates at least 30 days prior to the carrier's scheduled implementation of the update. The FIs add these fees to system fee schedule tables to use in paying for hospital laboratory tests performed for both outpatients of the hospital and persons who are not patients of the hospital. The RRB contractor uses the fee schedules in paying for outpatient clinical laboratory tests.

FIs and the RRB may consult with carriers on filling gaps in fee schedules for tests where the carrier may not have established an amount. If an FI or the RRB carrier has bills for payment on laboratory tests for which the carrier has not furnished amounts, it consults with the area carrier. If necessary the area carrier consults with other nearby carriers.

## 110.2 - Coordination With Medicaid
**(Rev. 1, 10-01-03)**

Carriers furnish copies of the fee schedules and the annual update (including NLAs where applicable) to State agencies (SAs). Carriers provide updates to SAs at least 30 days prior to the scheduled implementation. To obtain Federal matching funds for clinical laboratory services, State Medicaid agencies may not pay more than Medicare pays for the services and specimen collections.

Since the fee schedule provisions were implemented on a carrier wide basis, a State may have more than one carrier servicing Medicare beneficiaries residing in the State. A Medicaid agency for such a State may, if it deems necessary, use the fee schedules of

either one or both of the carriers to meet the Federal fund-matching requirement. State Medicaid agencies may consult with ROs concerning the fee schedule, the NLAs, and specimen collection provisions.

## 110.3 - Coordination With FIs and Providers

**(Rev. 1, 10-01-03)**
**HO-437, A3-3628**

There may be procedures hospitals bill for outpatients that are not included in the fee schedule. Where gaps occur, hospitals should work out procedures with the FI so that the hospital can secure the missing information promptly. Price Codes established by the carrier to fill gaps are valid until replaced by the earlier of permanent codes or the next annual update.

## 110.4 - Carrier Contacts With Independent Clinical Laboratories

**(Rev. 1, 10-01-03)**
**B3-2070.1.F**

An important role of the carrier is as a communicant of necessary information to independent clinical laboratories. Failure to inform independent laboratories of Medicare regulations and claims processing procedures may have an adverse effect on prosecution of laboratories suspected of fraudulent activities with respect to tests performed by, or billed on behalf of, independent laboratories. United States Attorneys often must prosecute under a handicap or may refuse to prosecute cases where there is no evidence that a laboratory has been specifically informed of Medicare regulations and claims processing procedures.

To assure that laboratories are aware of Medicare regulations and carrier's policy, notification must be sent to independent laboratories when any changes are made in coverage policy or claims processing procedures. Additionally, to completely document efforts to fully inform independent laboratories of Medicare policy and the laboratory's responsibilities, previously issued newsletters should be periodically re-issued to remind laboratories of existing requirements.

Some items which should be discussed are the requirements to have the same charges for Medicare and private patients, to document fully the medical necessity for collection of specimens from a skilled nursing facility or a beneficiary's home, and, in cases when a laboratory service is referred from one independent laboratory to another independent laboratory, to identify the laboratory actually performing the test.

Additionally, when carrier professional relations representatives make personal contacts with particular laboratories, they should prepare and retain reports of contact indicating dates, persons present, and issues discussed.

## 120 - Clinical Laboratory Services Based on the Negotiated Rulemaking

**(Rev. 1, 10-01-03)**
**PM AB-02-129**

Section 4554(b)(1) of the Balanced Budget Act (BBA), Public Law 105-33 mandated the use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical laboratory services payable under Part B of Medicare. The BBA required that these national policies be designed to promote program integrity and national uniformity; and to simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Part B.

These changes apply to every diagnostic clinical laboratory service that is payable under Medicare Part B. Neither the place where the service was performed, nor the type of contractor that will process the request for payment, has any effect on the applicability of these policies. A clinical laboratory service done in a hospital laboratory, independent laboratory, physician/practitioner office laboratory or other type of CLIA approved laboratory service is subject to these administrative policies.

The final rule did not affect the requirement that all physician claims must have a diagnosis. If a physician submits a claim for a service performed in a physician office laboratory, that claim is considered a physician claim and must meet the requirements for physician claims.

## 120.1 - Negotiated Rulemaking Implementation

**(Rev. 1769, Issued: 07-10-09, Effective/Implementation: 07-31-09)**

The following requirements apply to service providers:

- The date of service should be reported as the date of specimen collection.
- The person obtaining the specimen must furnish the date of collection for the specimen to the entity billing Medicare.
- For specimen collections that span more than a 24-hour period, the date of service should be reported as the date the collection began.
- For laboratory tests that require a specimen from stored collections, the date of service should be defined as the date the specimen was obtained from the archives.
- If a situation occurs that does not correspond to the two situations described, the contractor will submit the question to the RO with the appropriate documentation. The RO will contact the Division of Supplier Claims Processing in CMS, which will serve as the point of contact.

**Matching of Diagnosis to Procedure**

During claims processing and adjudication, the contractor adheres to the following:

- If there is a LMRP or NCD for one or more of the services included on the claim, the contractor reviews all of the diagnosis codes in making a determination regarding medical necessity of the service.

- Even though a claim matches diagnosis to procedure in accordance with an NCD, other rules of adjudication may apply, which could result in denial.

- Diagnoses are required on all claims.

**Physicians Reporting Diagnosis Codes When A Diagnostic Test Is Ordered**

Section 4317 of the Balanced Budget Act of 1997 provides, with respect to diagnostic laboratory and certain other services, that "if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the services to provide diagnostic or other medical information to the entity, the physician or practitioner ordering the service shall provide that information to the entity at the time the service is ordered by the physician or practitioner." A laboratory or other provider must report on a claim for Medicare payment the diagnostic code(s) furnished by the ordering physician. In the absence of such coding information, the laboratory or other provider may determine the appropriate diagnostic code based on the ordering physician's narrative diagnostic statement or seek diagnostic information from the ordering physician/practitioner. However, a laboratory or other provider may not report on a claim for Medicare payment a diagnosis code in the absence of physician-supplied diagnostic information supporting such code.

**Clarification of the Use of the Term "Screening" or "Screen"**

The final rule clarifies that effective February 21, 2002, the use of the term "screening" or "screen" in CPT code descriptor does not necessarily describe a test performed in the absence of signs and symptoms of illness, disease or condition. Contractors do not deny a service based solely on the presence of the term "screening" or "screen" in the descriptor.

Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described.

If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test. Contractors have discretionary authority to make reasonable and necessary scope of benefit determinations.

## 120.2 - Implementation and Updates of Negotiated National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services
**(Rev. 71, 01-23-04)**

Under a negotiated rulemaking process, the Center for Medicare & Medicaid Services (CMS) developed 23 NCDs for clinical diagnostic laboratory services. The NCDs are applicable to services billed under Part B regardless of the entity providing the services. Thus, they are binding on carriers and fiscal intermediaries in processing clinical diagnostic laboratory services on an outpatient basis.

In order to ensure uniformity in the implementation of the NCDs, CMS developed the NCDs utilizing three lists of ICD-9-CM diagnosis codes. Every ICD-9-CM diagnosis

code will fall into one the three lists. The lists included: ICD-9-CM Codes Covered by Medicare, ICD-9-CM Codes Denied, and ICD-9-CM Codes That Do Not Support Medical Necessity.

The CMS has contracted with Computer Sciences Corporation (CSC) to develop national uniform software to implement these negotiated NCDs. This software, called the laboratory edit module, was developed and incorporated in the shared systems so that laboratory claims subject to one of the 23 NCDs are processed uniformly throughout the nation effective January 1, 2003.

In addition, the NCDs are maintained through the NCD process that was announced in the "Federal Register" on September 26, 2003 (68 FR 55634). This process provides for public participation through a comment period at the beginning of the evaluation of the issue and includes a detailed decision document that outlines the rationale for the decision. These documents may be viewed on the Medicare coverage homepage at cms.hhs.gov/coverage.

On a quarterly basis, CMS will update the NCD edit module as necessary for ministerial coding changes and to implement the NCD decisions described above. NCD changes are transmitted to CSC. CSC modifies the edit module software and communicates the software to the shared system maintainers using connect:direct. The shared system maintainers install the revised edit module after testing and distribute it to the carriers and intermediaries (FIs) as part of their routine release. Carrier and FIs will conduct provider education to advise the laboratories of changes to the laboratory edit module quarterly.

## Exhibit 1 – List of Diagnostic Tests that are Considered End Stage Renal Disease (ESRD)

**(Rev. 1769, Issued: 07-10-09, Effective/Implementation: 07-31-09)**

**Refer to section 40.6.2.3 for guidance on the usage of this list.**

71010 Chest x-ray
71015 Chest x-ray
71020 Chest x-ray
71021 Chest x-ray
71022 Chest x-ray
71030 Chest x-ray
71035 Chest x-ray
73120 X-ray hand
75710 Artery x-rays, arm/leg
75716 Artery x-rays, arm/leg
75774 Artery x-rays, arms/legs
75790 Artery x-ray, each vessel
75820 Visualize A-V shunt
75822 Vein x-ray, arm/leg
75893 Vein x-ray, arms/legs
75894 Transcath therapy, embolization
75896 X-rays, transcath therapy
75898 X-rays, transcath therapy

75901 Mechanical removal of pericath obstructive material
75902 Mechanical removal of intraluminal obstructive material
75961 Transcath retrieval of intravascular foreign body
75962 Transcath balloon angioplasty
75964 Transcath balloon angioplasty, each additional
76070 Computed tomography, bone mineral density study, axial
76075 Dual energy DEXA, bone density study, axial
76080 Radiologic exam, abscess, fistual or sinus tract study
76092 Screening mammography bilateral
76778 Ultrasound, transplanted kidney
78070 Parathyroid nuclear imaging
78351 Bone density, dual photon absorptionmetry
80048 Basic metabolic panel
80051 Electrolyte panel
80053 Comprehensive Metabolic Panel
? 80061 Lipid panel
80069 Renal function panel
80074 Acute hepatitis panel
80076 Hepatic function panel
80197 Tacrolimus
80410 Calcitonin stim panel
81000 Urinalysis with microscopy
81001 Urinalysis, auto w/scope
81002 Urinalysis nonauto w/o scope
81003 Urinalysis, auto, w/o scope
81005 Urinalysis, qual or semi-quant
81007 Urine screen for bacteria, except by culture or dipstick
81015 Microscopic exam of urine
82009 Test for acetone/ketones,qual
82010 Acetone assay, quant
82017 Acylcarnitines, quant
82040 serum albumin
82042 albumin, urine quant or other source
82108 Assay of aluminum
82232 Beta2microglobulin (monitor large molecular weigh solute clearance by dial
82247 Bilirubin, total
82248 Bilirubin, direct
82306 Assay of vitamin D-3 (calcifediol)
82307 Assay of vitamin D (calciferol)
82308 Assay of calcitonin
82310 Assay of calcium
82330 Assay of calcium, ionized
82374 Bicarbonate (CO2)
82379 Assay of carnitine
82435 Chloride blood (needed to determine acid/base status)
82465 cholesterol, total serum
82550 CPK, total
82565 Assay of creatinine
82570 Assay of urine creatinine

82575 urine creatinine clearance test
82607 Vit B12
82728 ferritin
82746 serum folate
82747 RBC folate
82800 Blood Ggases, ppH onlyy
82803 Blood gases: pH, pO2 & pCO2
82805 Blood gases W/02 saturation
82810 Blood gases, O2 sat only
82945 Glucose other fluid
82947 Assay, glucose, blood quant
82948 Reagent strip/blood glucose
83540 Assay of iron
83550 Iron binding test
83735 magnesium (monitored to avoid hypermagnesium)
83937 Osteocalcin
83970 parathormone (PTH)
83986 Assay of body fluid acidity
84075 alkaline phosphatase
84100 Assay of phosphorus, inorganic
84105 urine phosphorus
84132 Assay of serum potassium
84133 urine potassium
84134 Assay of prealbumin
84155 Assay of protein
84160 serum protein by refractometry
84295 Assay of serum sodium
84315 Body fluid specific gravity
84450 Transferase (AST) (SGOT)
84460 Alanine amino (ALT) (SGPT)
84466 transferrin
84520 Urea nitrogen, quantitative
84540 Assay of urine/urea-n
84545 Urea-N clearance test
84630 zinc
85002 Bleeding time test
85004 Automated diff wbc count
85007 Bl smear w/diff wbc count
85008 Bl smear w/o diff wbc count
85009 Manual diff wbc count b-coat
85013 Spun microhematocrit
85014 Hematocrit
85018 Hemoglobin
85025 Complete CBC w/auto diff wbc
85027 Complete CBC, automated
85032 Manual cell count, each
85041 Automated RBC count
85044 Manual reticulocyte count
85045 Automated reticulocyte count

85046 Reticyte/hgb concentrate
85048 Automated leukocyte count
85049 Automated platelet count
85345 Coagulation time, Lee-White
85347 Coagulation time, activated
85348 Coagulation time, other methods
85520 Heparin assay
85610 Prothrombin time
85611 Prothrombin test,substitution
85651 sed rate
85652 automates sed rate
85730 thromboplastin time, partial (PTT)
85732 Thromboplastin time, partial, substitution
86590 Streptokinase, antibody
86644 CMV screen
86645 Cytomegalovirus antibody dfa (IgM)
86687 HTLV-I antibody
86688 HTLV-II antibody
86689 HTLV/HIV confirmatory test
86692 Hepatitis, delta agent
86701 HIV-1
86702 HIV-2
86703 HIV-1/HIV2, ,singgle assayy
86704 Hep B core antibody, total
86705 Hep b core antibody, IgM
86706 Hep B surface antibody
86707 Hep Be antibody
86709 Hep A, IgM antibody
86803 Hepatitis C ab test
86804 Hep C ab test, confirm
86812 HLA typing, A, B, or C
86813 HLA typing, A, B, or C, multiple antigens
86816 HLA typing, DR/DQ
86817 HLAy tpypigng, DR/DQ, multiple antigens
86900 Blood typing, ABO
86901 Rh typing
86903 Blood typing, antigen screen
86904 Blood typing, patient serum
86905 Blood typing, RBC antigens
86906 Blood typing, Rh phenotype
87040 culture, blood
87070 Culture, bacteria, other
87071 Culture bacteri aerobic other, quant
87073 Culture bacteria anaerobic, quant
87075 Culture bacteria anaerobic, any source w/ID
87076 Culture anaerobe ident, each
87077 Culture aerobic identify
87081 Culture screen only
87084 Culture w/ colony estimation

87086 Urine culture/quant colony count
87088 Urine bacteria culture, isolation & ID
87181 Microbe susceptible, diffuse
87184 Microbe susceptible, disk
87185 Microbe susceptible, enzyme
87186 Microbe susceptible, mic
87187 Microbe susceptible, mlc
87188 Microbe suscept, macrobroth
87190 Microbe suscept, mycobacteri
87197 Bactericidal level, serum
87205 Smear, gram stain
87271 CMV, DFA
87340 HepB surface antigen
87341 HepatitisB surface, ag, eia, neutralization
87350 HepatitisBe ag, eia
87380 Hepatitis delta ag, eia
87390 HIV-1 ag, eia
87391 HIV-2 ag, eia
87515 Hepatitis B, DNA, dir probe
87516 Hepatitis B, DNA, amp probe
87517 Hepatitis B, DNA, quant
87520 Hepatitis C, RNA, dir probe
87521 Hepatitis C, RNA, amp probe
87522 Hepatitis C, RN A, quant
87525 Hepatitis G, DNA, dir probe
87526 Hepatitis G, DNA, amp probe
87527 Hepatitis G, DNA, quant
89050 cell count, peritoneal fluid (no diff)
89051 cell count, peritoneal fluid with diff
93000 Echo exam of heart
93005 Electrocardiogram, tracing
93010 Electrocardiogram report
93040 Rhythm ECG with report
93041 Rhythm ECG, tracing
93042 Rhythm ECG with report
93307 Echo exam of heart
93308 Echo exam of heart, follow-up
93922 Extremity study
93923 Extremity study, multiple levels
93925 Lower extremity study - arterial
93926 Lower extremity study, limited- arterial
93930 Upper extremity study- arterial
93931 Upper extremity study, limited-arterial
93965 Extremity study-venous
93970 Extremity study-venous
93971 Extremity study, limited-venous
G0001 Routine venipuncture
G0202 Screening mammography, digital

## Transmittals Issued for this Chapter

| Rev # | Issue Date | Subject | Impl Date | CR# |
|---|---|---|---|---|
| R2487CP | 06/08/2012 | 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) | 06/19/2012 | 7749 |
| R2475CP | 05/18/2012 | 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) | 06/19/2012 | 7749 |
| R2136CP | 01/21/2011 | Medicare and Medicaid Extenders Act of 2010 (MMEA) Extension of Reasonable Cost Payment for Clinical Lab Tests Furnished to Hospitals with Fewer Than 50 Beds in Qualified Rural Areas | 07/05/2011 | 7294 |
| R2106CP | 11/24/2010 | Calendar Year (CY) 2011 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment | 01/03/2011 | 6991 |
| R1945CP | 04/09/2010 | New Legislation to Allow Independent Laboratory Billing for the Technical Component of Physician Pathology Services for Hospital Inpatients and Outpatients | 07/09/2010 | 6813 |
| R1940CP | 04/02/2010 | Extension of Reasonable cost Payment for Clinical lab Tests Furnished by Hospitals With Fewer Than 50 Beds in Qualified Rural Areas | 07/06/2010 | 6873 |
| R1884CP | 12/23/2009 | Calendar Year (CY) 2010 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment | 01/04/2010 | 6657 |
| R1782CP | 07/30/2009 | Section 148 of the Medicare Improvements for Patients and Providers Act (MIPPA) | 07/06/2009 | 6395 |

| Rev # | Issue Date | Subject | Impl Date | CR# |
|---|---|---|---|---|
| R1769CP | 07/10/2009 | ESRD: Placement of a List of Diagnostic Tests that are Considered End Stage Renal Disease (ESRD) | 07/31/2009 | 6515 |
| R1763CP | 07/02/2009 | ESRD: Placement of a List of Diagnostic Tests that are Considered End Stage Renal Disease (ESRD) – Rescinded and replaced by Transmittal 1769 | 07/02/2009 | 6515 |
| R1729CP | 05/08/2009 | Section 148 of the Medicare Improvements for Patients and Providers Act (MIPPA) - Rescinded and replaced by Transmittal 1782 | 07/06/2009 | 6395 |
| R1712CP | 04/17/2009 | Section 148 of the Medicare Improvements for Patients and Providers Act (MIPPA) - Rescinded and replaced by Transmittal 1729 | 07/06/2009 | 6395 |
| R1690CP | 02/27/2009 | Reporting the National Provider Identifier (NPI) on Claims for Reference Laboratory and Purchased Diagnostic Services Performed Outside the Billing Jurisdiction | 03/27/2009 | 6362 |
| R1655CP | 12/31/2008 | End Stage Renal Disease (ESRD) Medicare Claims Processing Manual Clarification | 02/02/2009 | 6245 |
| R1652CP | 12/19/2008 | New Waived Tests | 01/05/2009 | 6287 |
| R1584CP | 09/05/2008 | Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens | 10/06/2008 | 6195 |
| R1561CP | 07/25/2008 | Medicare Improvements for Patients and Providers Act of 2008- Legislative Change Concerning Independent Laboratory Billing for the Technical Component of Physician Pathology Services | 08/25/2008 | 6042 |
| R1524CP | 05/30/2008 | Clinical Laboratory Fee Schedule-Medicare Travel Allowance Fees for Collection of Specimens | 06/30/2008 | 5996 |
| R1515CP | 05/23/2008 | Date of Service (DOS) for Clinical Laboratory and Pathology Specimens | 01/05/2009 | 6018 |

| Rev # | Issue Date | Subject | Impl Date | CR# |
|---|---|---|---|---|
| R1472CP | 03/06/2008 | Update of Institutional Claims References | 04/07/2008 | 5893 |
| R1451CP | 02/15/2008 | Clinical Lab: New Automated Test for the AMCC Panel Payment Algorithm | 07/07/2008 | 5874 |
| R1445CP | 02/08/2008 | January 2008 Update of the Hospital Outpatient Prospective Payment System (OPPS)-Manualization | 03/10/2008 | 5946 |
| R1440CP | 02/07/2008 | Medicare, Medicaid, and SCHIP Extension Act of 2007 Changes to Independent Laboratory Billing for the Technical Component of Physician Pathology Services | 03/07/2008 | 5943 |
| R1421CP | 01/25/2008 | Update of Institutional Claims References - Rescinded and Replaced by Transmittal 1472 | 04/07/2008 | 5893 |
| R1319CP | 08/17/2007 | Date of Service for Laboratory Specimens | 01/01/2008 | 5573 |
| R1221CP | 04/18/2007 | Common Working File (CWF) Duplicate Claim Edit for the Technical Component (TC) of Radiology and Pathology Laboratory Services Provided to Hospital Patients | 04/02/2007 | 5347 |
| R1098CP | 11/03/2006 | Common Working File (CWF) Duplicate Claim Edit for the Technical Component (TC) of Radiology and Pathology Laboratory Services Provided to Hospital Patients Replace by Transmittal 1221 | 04/02/2007 | 5347 |
| R865CP | 02/17/2006 | Health Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits | 07/03/2006 | 4321 |
| R852CP | 02/10/2006 | Ambulance Fee Schedule – CY 2006 Update: Correction to CR 4061 | 02/24/2006 | 4362 |
| R800CP | 12/30/2005 | Clinical Diagnostic Laboratory Date of Service (DOS) for Archived Specimens | 04/03/2006 | 4156 |
| R795CP | 12/30/2005 | Redefined Type of Bill (TOB) 14X for Non-Patient Laboratory Specimens-CR 3835 | 04/03/2006 | 4208 |

| Rev # | Issue Date | Subject | Impl Date | CR# |
|---|---|---|---|---|
| | | Manualization | | |
| R744CP | 11/04/2005 | File Descriptions and Instructions for Retrieving the 2006 Fee Schedules and HCPCS through CMS's Mainframe Telecommunications System | 01/03/2006 | 4084 |
| R734CP | 10/28/2005 | Redefined Type of Bill (TOB), 14x, for Non-Patient Laboratory Specimens | 04/03/2006 | 3835 |
| R733CP | 10/28/2005 | Repeat Tests for Automated Multi-Channel Chemistries for End Stage Renal Disease Beneficiaries | 04/03/2006 | 4101 |
| R598CP | 06/27/2005 | Implementation of Carrier Guidelines for End Stage Renal Disease (ESRD) Reimbursement for Automated Multi-Channel Chemistry (AMCC) Tests | 01/01/2006 | 3890 |
| R595CP | 06/24/2005 | Implementation of Carrier Guidelines for End Stage Renal Disease (ESRD) Reimbursement for Automated Multi-Channel Chemistry (AMCC) Tests | 07/25/2005 | 3890 |
| R372CP | 11/19/2004 | Payment for Referred Laboratory Automated Multi-Channel Chemistry (AMCC) Tests | 04/04/2005 | 3483 |
| R289CP | 08/27/2004 | File Descriptions and Instructions for Retrieving 2004 Pricing Files | 01/03/2005 | 3428 |
| R198CP | 06/04/2004 | AMCC tests for ESRD-related lab services | 01/03/2005 | 2813 |
| R164CP | 04/30/2004 | Replaced by Rev 198CP | 06/04/2004 | 2813 |
| R102CP | 02/20/2004 | New waived tests approved by the Food and Drug Administration under Clinical Laboratory Improvement Amendments of 1988 | 04/05/2004 | 3061 |
| R100CP | 02/13/2004 | Outpatient Clinical Laboratory Tests Furnished by Hospitals with Fewer than 50 beds in Qualified Rural Areas for cost reporting periods beginning during the 2-year period beginning on July 1, 2004. | 07/06/2004 | 3130 |

| Rev # | Issue Date | Subject | Impl Date | CR# |
|---|---|---|---|---|
| R085CP | 02/06/2004 | Pricing payment for referred services based upon zip code of where the service was performed | 07/06/2004 | 3090 |
| R079CP | 02/06/2004 | ESRD Reimbursement for AMCC Tests | 07/06/2004 | 2813 |
| R071CP | 01/23/2004 | Quarterly updates for NCD edit module for clinical diagnostic lab services | 04/05/2004 | 3032 & 3072 |
| R069CP | 01/23/2004 | Deletion of requirement to validate that the ESRD beneficiary is in a SNF Part A stay | 02/23/2004 | 2906 |
| R023CP | 10/31/2003 | Pricing payment for referred services based upon zip code of where the service was performed | 4/5/2004 | 2193 |
| R016CP | 10/31/2003 | Fee schedule payment for independent laboratories for the technical component of a purchased diagnostic service | 04/05/2004 | 2919 |
| R012CP | 10/24/2003 | Claims for fecal leukocyte examinations | 01/01/2004 | 2924 |
| R001CP | 10/01/2003 | Initial Publication of Manual | NA | NA |

Back to top of Chapter