| CMS Manual System | **Department of Health & Human Services (DHHS)** |
|---|---|
| Pub 100-04 Medicare Claims Processing | **Centers for Medicare & Medicaid Services (CMS)** |
| **Transmittal 1729** | **Date: MAY 8, 2009** |
| | **Change Request 6395** |

**This transmittal rescinds and replaces transmittal 1712 because it is no longer sensitive and the word "other" was removed from the Policy section. In the IOM, the reference to CAH based SNF was removed and the word "other" in Chapter 4, §250.6 and Chapter 16, §30.3. All other information remains the same.**

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

**I. SUMMARY OF CHANGES:** This Change Request (CR) provides billing instructions based on the new criteria for determining a patient's outpatient status for a CAH or an entity provider-based to the CAH, per Section 148 of MIPPA.

**New / Revised Material**
**Effective Date: July 1, 2009**
**Implementation Date: July 6, 2009**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | Chapter / Section / Subsection / Title |
|---|---|
| R | 4/250.6/Clinical Diagnostic Laboratory Tests Furnished by CAHs |
| R | 13/20.2.1/Hospital and Skilled Nursing Facility (SNF) Patients |
| R | 16/10.2/General Explanation of Payment |
| R | 30/30.3/30.3 - Method of Payment for Clinical Laboratory Tests - Place of Service Variation |
| R | 16/40.3/Hospital Billing Under Part B |
| R | 16/40.3.1/Critical Access Hospital (CAH) Outpatient Laboratory Service |

**III. FUNDING:**

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

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

**IV. ATTACHMENTS:**

**Business Requirements**

**Manual Instruction**

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

# Attachment - Business Requirements

| Pub. 100-04 | Transmittal: 1729 | Date: May 8, 2009 | Change Request: 6395 |
|---|---|---|---|

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

**Effective Date:** July 1, 2009

**Implementation Date:** July 6, 2009

## I. GENERAL INFORMATION

**A. Background:** Change Request (CR) 3835 (issued on October 28, 2005), redefined the Type of Bill (TOB) 14X to be used for non-patient laboratory specimens, effective October 1, 2004. The CR also ensured that Critical Access Hospitals (CAHs) billing a 14X TOB would be reimbursed under the Clinical Laboratory Fee Schedule rather than reasonable cost. Soon after the issuance of CR 3835, CR 4208 was issued on December 30, 2005 to update all applicable references within the Internet-Only Manual.

**B. Policy:** Effective for services furnished on or after July 1, 2009 a CAH will be paid 101 percent of reasonable costs for outpatient clinical diagnostic laboratory tests, and 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 an entity that is provider-based to the CAH.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement.*

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 6395.1 | Effective for dates of service on or after July 1, 2009, contractors shall be aware of new criteria for determining a patient's outpatient status for a CAH or an entity provider-based to the CAH, per Section 148 of MIPPA. | X | | X | | | | | | | |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 6395.2 | A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.<br>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | | X | | | | | | | |

## IV. SUPPORTING INFORMATION

**Section A: For all recommendations and supporting information associated with listed requirements:**
*"Should" denotes a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|
| | |

**Section B: For all other recommendations and supporting information:**

## V. CONTACTS

**Pre-Implementation Contacts:**
**Policy:**
Renate Rockwell at 410-786-4645 or renate.rockwell@cms.hhs.gov
Taimyra Jones at 410-786-1562 or taimyra.jones@cms.hhs.gov
Linda McKenna at 410-786-4537 or linda.mckenna@cms.hhs.gov

**Claims Processing:**
Joe Bryson at 410-786-2986 or joseph.bryson@cms.hhs.gov
Valeri Ritter at 410-786-8652 or valeri.ritter@cms.hhs.gov

**Post-Implementation Contact:** Regional Office

## VI. FUNDING

**Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Intermediaries (RHHIs)*:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**Section B:** ***For Medicare Administrative Contractors (MACs)*****:**

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

# Medicare Claims Processing Manual
## Chapter 4 - Part B Hospital
## (Including Inpatient Hospital Part B and OPPS)

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### 250.6 - Clinical Diagnostic Laboratory Tests Furnished by CAHs

***(Rev. 1729; Issued: 05-08-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)***

Medicare beneficiaries are not liable for any coinsurance, deductible, copayment, or other cost sharing amount for clinical diagnostic laboratory services furnished as a CAH outpatient service.

*For dates of service prior to July 1, 2009, payment* for clinical diagnostic laboratory tests furnished by a CAH is made *at 101 percent of* reasonable cost only if the patient is an outpatient of the CAH and is physically present in the CAH at the time the specimen is collected - (Type of Bill (TOB), 85x).

*For dates of service on or after July 1, 2009, an 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.*

Tests for non-patients are billed on TOB 14x, and are paid under the lab fee schedule.

# Medicare Claims Processing Manual
## Chapter 13 - Radiology Services and Other Diagnostic Procedures

### 20.2.1 - Hospital and Skilled Nursing Facility (SNF) Patients

***(Rev. 1729; Issued: 05-08-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)***

Carriers may not pay for the technical component (TC) of radiology services furnished to hospital patients. Payment for physicians' radiological services to the hospital, e.g., administrative or supervisory services, and for provider services needed to produce the radiology service, is made by the fiscal intermediary (FI)*/AB MAC to the hospital* as a provider service.

FI*s/AB MACs* include the TC of radiology services for hospital inpatients, except Critical Access Hospitals (CAH*s*), in the prospective payment system (PPS) payment to hospitals.

Hospital bundling rules exclude payment to suppliers of the TC of a radiology service for beneficiaries in a hospital inpatient stay. CWF performs reject edits to incoming claims from suppliers of radiology services.

Upon receipt of a hospital inpatient claim at the CWF, CWF searches paid claim history and compares the period between the hospital inpatient admission and discharge dates to the line item service date on a line item TC of a radiology service billed by a supplier. The CWF will generate an unsolicited response when the line item service date falls within the admission and discharge dates of the hospital inpatient claim.

Upon receipt of an unsolicited response, the carrier will adjust the TC of the radiology service and recoup the payment.

For CAHs, payment *to the CAH for inpatients* is made *at 101 percent of* reasonable cost.

Radiology and other diagnostic services furnished to hospital outpatients are paid under the Outpatient Prospective Payment System (OPPS) to the hospital. This applies to bill types 12X and 13X that are submitted to the FI*/AB MAC*. Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for radiology services.

As a result of SNF Consolidated Billing (Section 4432(b) of the Balanced Budget Act (BBA) of 1997), carriers may not pay for the TC of radiology services furnished to Skilled Nursing Facility (SNF) inpatients during a Part A covered stay. The SNF must bill radiology services furnished its inpatients in a Part A covered stay and payment is included in the SNF Prospective Payment System (PPS).

Radiology services furnished to outpatients of SNFs may be billed by the supplier performing the service or by the SNF under arrangements with the supplier. If billed by

the SNF, *Medicare* pay*s* according to the Medicare Physician Fee Schedule. SNFs submit claims to the FI*/AB MAC* with type of bill 22X or 23X.

# Medicare Claims Processing Manual

## Chapter 16 - Laboratory Services

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### 10.2 - General Explanation of Payment

***(Rev. 1729; Issued: 05-08-09; 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.”

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

***(Rev. 1729; Issued: 05-08-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)***

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

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

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

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

**Non-Patient Laboratory Specimen**-Laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule for a non-patient laboratory specimen (bill type 14X) is the lesser of the actual charge, the fee schedule amount, or the NLA (including 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** - Payment to a hospital-based or independent dialysis facility for laboratory tests included under the ESRD composite rate payment and performed for a patient of that facility, is included in the facility's composite rate payment for these tests and is subject to the Part B deductible and coinsurance. Laboratory tests that are not included under the ESRD composite rate payment; and are performed by an independent laboratory or a provider-based laboratory for dialysis patients of independent dialysis facilities or provider based facilities; are paid in addition to the composite rate payment and are subject to the fee schedule limits. This also applies to all laboratory tests furnished to home dialysis patients who have selected Payment Method II. These limits are 60 percent for all tests unless performed by a qualified hospital laboratory in a sole community hospital; in which case the 62 percent rate applies. The laboratory performing the tests must bill.

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

**Enrolled in Managed Care** - Payment to a participating health maintenance organization (HMO) or health care prepayment plan (HCPP) for laboratory tests provided

to a Medicare beneficiary who is an enrolled member is included in the monthly capitation amount.

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

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

## 40.3 - Hospital Billing Under Part B

***(Rev. 1729; Issued: 05-08-09; 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. 1729; Issued: 05-08-09; 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.