| CMS Manual System | Department of Health & Human Services (DHHS) |
|---|---|
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| **Transmittal 2581** | **Date: November 2, 2012** |
| | **Change Request 8025** |

**NOTE: This Transmittal is no longer sensitive and was re-communicated on April 19, 2013. This CR is being re-issued to change the attachment title from One-Time-Notification to Business Requirements. The Transmittal Number, date of Transmittal and all other information remain the same. This instruction may now be posted to the Internet.**

**SUBJECT: Outpatient Laboratory Services Rendered in a Critical Access Hospital (CAH)**

**I. SUMMARY OF CHANGES:** This instruction implements the necessary system changes to apply beneficiary cost sharing for non clinical-diagnostic laboratory services rendered in an outpatient CAH setting.

**EFFECTIVE DATE: April 1, 2013**
**IMPLEMENTATION DATE: April 1, 2013**

***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 | 04/250.1/Standard Method - Cost-Based Facility Services, With Billing of Carrier for Professional Services |
| R | 16/10.2/General Explanation of Payment |
| R | 16/30.2/Deductible and Coinsurance Application for Laboratory Tests |
| R | 16/40.3/Hospital Billing Under Part B |
| R | 16/40.3.1/Critical Access Hospital (CAH) Outpatient Laboratory Service |

**III. FUNDING:**
**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs):**
No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

**For Medicare Administrative Contractors (MACs):**
The Medicare Administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized

by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

## IV. ATTACHMENTS:

**Business Requirements**
**Manual Instruction**
***Unless otherwise specified, the effective date is the date of service**.

# Attachment – Business Requirements

| **Pub. 100-04** | **Transmittal: 2581** | **Date: November 2, 2012** | **Change Request: 8025** |
|---|---|---|---|

**NOTE: This Transmittal is no longer sensitive and was re-communicated on April 19, 2013. This CR is being re-issued to change the attachment title from One-Time-Notification to Business Requirements. The Transmittal Number, date of Transmittal and all other information remain the same. This instruction may now be posted to the Internet.**

**SUBJECT: Outpatient Laboratory Services Rendered in a Critical Access Hospital (CAH)**

**EFFECTIVE DATE: April 1, 2013**
**IMPLEMENTATION DATE: April 1, 2013**

## I. GENERAL INFORMATION

**A. Background:** Currently, all outpatient laboratory services, other than the clinical diagnostic laboratory services, are not applying the appropriate coinsurance and/or deductible. Medicare beneficiaries are not liable for any coinsurance, deductible, copayment, or other cost sharing amounts for outpatient clinical diagnostic laboratory services. However, there are non-clinical diagnostic laboratory services that coinsurance and deductible should be applicable.

This instruction implements the necessary system changes to apply beneficiary cost sharing for non clinical-diagnostic laboratory services rendered in an outpatient CAH setting.

**B. Policy:** 413.70(b)(3)(iii), Payment to a CAH, other than for clinical diagnostic laboratory tests, is subject to the Part B deductible and coinsurance amounts as determined under §§ 410.152(k), 410.160, and 410.161.

## II. BUSINESS REQUIREMENTS TABLE

*Use "Shall" to denote a mandatory requirement.*

| **Number** | **Requirement** | **Responsibility** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | Other |
| | | Part A | Part B | | | | | FISS | MCS | VMS | CWF | |
| 8025.1 | Contractors shall update the revenue code table to require HCPCS codes for TOB 85X with REV codes 0300-0319 | X | | | X | | | | | | | |
| 8025.2 | Contractors shall apply or not apply the correct coinsurance and deductible based on the HCPCS file. | | | | | | | X | | | | |
| 8025.3 | Contractors shall apply the logic currently used for | | | | | | | X | | | | |

| Number | Requirement | Responsibility | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | Other |
| | | Part A | Part B | | | | | FISS | MCS | VMS | CWF | |
| | outpatient hospitals (TOB 13x) regarding deductible and coinsurance for all laboratory services to CAH outpatient hospitals (TOB 85x) | | | | | | | | | | | |
| 8025.4 | Contractors shall continue to allow 101 percent of reasonable cost for CAH's. | | | | | | | X | | | | |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | DME MAC | FI | CARRIER | RHHI | Other |
| | | Part A | Part B | | | | | |
| 8025.5 | MLN Article: A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | | | X | | | |

## IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**
*Use "Should" to denote a recommendation.*

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

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

## V. CONTACTS

**Pre-Implementation Contact(s):** Cindy Pitts, 410-786-2222 or Cindy.Pitts@cms.hhs.gov,
Jason Kerr, 410-786-2123 or Jason.Kerr@cms.hhs.gov

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

## VI. FUNDING

**Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs):**
No additional funding will be provided by CMS; Contractors activities are to be carried out with 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 do 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.

### 250.1 - Standard Method - Cost-Based Facility Services, With Billing of Carrier for Professional Services

*(Rev. 2581, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)*

Effective for cost reporting periods beginning on or after January 1, 2004, payment for outpatient CAH services under this method will be made for the lesser of: 1) 80 percent of 101 percent of the reasonable cost of the CAH in furnishing those services, or 2) 101 percent of the reasonable cost of the CAH in furnishing those services, less applicable Part B deductible and coinsurance amounts.

Payment for professional medical services furnished in a CAH to CAH outpatients is made by the carrier on a fee schedule, charge, or other fee basis, as would apply if the services had been furnished in a hospital outpatient department. For purposes of CAH payment, professional medical services are defined as services provided by a physician or other practitioner, e.g., a physician assistant that could be billed directly to a carrier under Part B of Medicare or a nurse practitioner that could be billed directly to a carrier under Part B of Medicare.

In general, payment for professional medical services, under the cost-based CAH payment plus professional services billed to the carrier method should be made on the same basis as would apply if the services had been furnished in the outpatient department of a hospital.

Bill type 85X is used for all outpatient services including services approved as ASC services. Non-patient laboratory specimens (those not meeting the criteria for reasonable cost payment in §250.6) will be billed on a 14X type of bill.

(See Section 2*5*0.6 – Clinical Diagnostic Laboratory Tests Furnished by CAHs.)

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

### 10.2 - General Explanation of Payment
*(Rev. 2581, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)*

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. 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."

### 30.2 - Deductible and Coinsurance Application for Laboratory Tests
*(Rev. 2581, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)*

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.

## 40.3 - Hospital Billing Under Part B

***(Rev. 2581, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)***

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.

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. 2581, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)***

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.

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