

MLN Matters Number: MM4156

Related Change Request (CR) #: 4156

Related CR Release Date: December 30, 2005

Effective Date: April 3, 2006

Related CR Transmittal #: R800CP

Implementation Date: April 3, 2006

Clinical Diagnostic Laboratory Date of Service (DOS) for Archived Specimens

Note: This article was updated on February 21, 2013, to reflect current Web addresses. All other information remains unchanged.

Provider Types Affected

Suppliers and providers billing Medicare carriers and/or fiscal intermediaries (FIs) for clinical diagnostic laboratory services

Provider Action Needed

This article is based on Change Request (CR) 4156, which is being issued to define the DOS policy for laboratory tests on archived specimens, to clarify what is/ or is not an archived specimen, and to revise the policy regarding a laboratory test that requires a specimen obtained from storage.

Background

The Centers for Medicare & Medicaid Services published a proposed rule on November 23, 2001 in the Federal Register (66 FR 58792, http://www.access.gpo.gov/su_docs/fedreg/a011123c.htm) that clarified the date of service (DOS) for clinical diagnostic laboratory services, and CR 2383 (Transmittal AB-02-134, dated October 4, 2002) was issued but did not define archived specimens.

Note: CR 2383 (Transmittal AB-02-134, dated October 4, 2002, subject: Questions and Answers Related to Implementation of National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services) can be found at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/AB02134.pdf> on the CMS website.

CMS has since developed a definition of an archived specimen through its rulemaking process and issued a revised DOS policy in the Federal Register

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notice dated February 25, 2005 (70 FR 9357, which can be viewed at http://www.access.gpo.gov/su_docs/fedreg/a050225c.htm).

CR4156 implements this revised DOS policy for laboratory tests, and it clarifies what is/or is not an archived specimen. As a general rule, the DOS of a test is the date the specimen was collected, except as shown in the following table:

Specimen Description	Date of Service (DOS)
Specimen collected over a period spanning two calendar days (unless collected from archive).	Date the specimen collection ended.
Specimen stored for more than 30 calendar days before testing, (otherwise known as "an archived specimen").	Date the specimen was obtained from storage.

Additional Information

For complete details, please see the official instruction issued to your carrier/intermediary regarding this change. That instruction may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R800CP.pdf> on the CMS website.

If you have any questions, please contact your carrier/intermediary at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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