

MLN Matters® Number: MM5573 **Revised**

Related Change Request (CR) #: 5573

Related CR Release Date: August 17, 2007

Effective Date: January 1, 2007

Related CR Transmittal #: R1319CP

Implementation Date: January 1, 2008

Date of Service (DOS) for Laboratory Specimens

Note: This article was updated on September 10, 2012, to reflect current Web addresses. This article was also revised on May 19, 2009, to delete a Web address from page 2 that was no longer available. All other information remains the same.

Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare carriers, Fiscal Intermediaries (FIs), or Part A/B Medicare Administrative Contractors (A/B MACs), for services provided to Medicare beneficiaries related to tests performed on laboratory specimens.

Provider Action Needed

This article is based on Change Request (CR) 5573 which implements revisions to the date of service (DOS) policy for tests performed on laboratory specimens, in accordance with updates to 42CFR414.510 that were published in the Federal Register on December 1, 2006. **Remember when submitting claims that the general rule is that the date of service is the date the specimen is collected. Where a specimen is collected over a period that spans two calendar days, the date of service is the date the collection period ended.**

Background

The general rule for the date of service (DOS) of a test performed on a laboratory specimen is the date that the specimen is collected. If a specimen is collected over a period that spans two calendar days, then the DOS must be the date that the collection period ended.

The current DOS policy allows an exception to the general rule for tests performed on an archived specimen. If a specimen was stored for more than 30 calendar

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days before testing (otherwise known as “an archived specimen”), the DOS of the test must be the date that the specimen was obtained from storage.

In the final physician fee schedule regulation published in the Federal Register on December 1, 2006

(http://www.access.gpo.gov/su_docs/fedreg/a061201c.html), the Centers for Medicare & Medicaid Services (CMS) revised the DOS policy for laboratory specimens to allow additional exceptions to the general rule and the DOS rule for tests performed on an archived specimen.

CR 5573 implements the revisions to the DOS policy for tests performed on laboratory specimens specified in the final rule, in accordance with the updates to 42 CFR Section 414.510.

As already mentioned, under the revised DOS policy for laboratory specimens, the **General Rule** is that the DOS of the test must be the date the specimen was collected. However, there is a **variation**: If a specimen is collected over a period that spans two calendar days, then the DOS must be the date the collection ended.

The following exceptions apply to the DOS policy for laboratory tests:

DOS for Tests Performed on Stored Specimens:

In the case of a test 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 must be the date the test was performed only if:**

- The test 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 do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for treatment of an illness.

Note: 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 must be the date the specimen was obtained from storage.

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DOS for Chemotherapy Sensitivity Tests Performed on Live Tissue:

In the case of a chemotherapy sensitivity test performed on live tissue, the DOS of the test must be the date the test 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 do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for treatment of an illness.

Note: 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.

Additional Information

The official instruction, CR5573, issued to your carrier, FI, and A/B MAC regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1319CP.pdf> on the CMS website.

If you have any questions, please contact your Medicare carrier, FI, or A/B MAC 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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