CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1319	**Date: AUGUST 17, 2007**
	Change Request 5573

Subject: Date of Service for Laboratory Specimens

I. SUMMARY OF CHANGES: This change request (CR) implements revisions to the date of service (DOS) policy for tests performed on laboratory specimens, in accordance with updates to 42 CFR (Section) 414.510.

New / Revised Material
Effective Date: January 1, 2007
Implementation Date: January 1, 2008

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	16/40.8/Laboratory DOS for Specimens

III. FUNDING:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2008 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1319	Date: August 17, 2007	Change Request: 5573

SUBJECT: Date of Service for Laboratory Specimens

Effective Date: January 1, 2007

Implementation Date: January 1, 2008

I. GENERAL INFORMATION

A. Background: In the final physician fee schedule regulation published in the *Federal Register* on December 1, 2006, the Centers for Medicare and Medicaid Services (CMS) revised the DOS policy for laboratory effective January 1, 2007 (42 CFR § 414.510). This transmittal provides additional instructions to the contractors concerning the DOS policy.

B. Policy: The DOS policy as specified in 42 CFR § 414.510 for laboratory specimens is as follows:

General Rule: The DOS of the test 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 laboratory tests:

A. 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.

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.

B. 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.

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.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5573.1	Contractors shall ensure that providers, physicians and suppliers comply with the revised instructions in Publication 100-04, Medicare Claims Processing Manual, Chapter 16, § 40.8, by providing effective provider education on the revised DOS policy for laboratory specimens.	X		X	X							
5573.2	Contractors shall not search for claims adjudicated between the effective and implementation dates but shall reprocess any such claims that are brought to the contractor's attention.	X		X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5573.3	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	X		X	X							

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		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	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.											

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wendy Knarr at Wendy.Knarr@cms.hhs.gov or dial Relay at #711 then have agent call (410) 786-0843.

Post-Implementation Contact(s): Contact the appropriate Regional Office.

VI. FUNDING

A. ***For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC)*****:**
No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2008 operating budgets.

B. ***For Medicare Administrative Contractors (MAC)*****:**

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in

excess of the amounts alloted 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 16 - Laboratory Services

Table of Contents
(Rev.1319, 08-17-07)

40.8 - *Date of Service (DOS) for Laboratory Specimens*

(Rev. 1319, Issued: 08-17-07, Effective: 01-01-07, Implementation: 01-01-08)

The date of service policy for laboratory tests is as follows:

General Rule: The DOS of the test shall be the date the specimen was collected.

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

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

A. DOS for Tests Performed on Stored Specimens:

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- *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.*

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.

B. 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.*

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.