

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1515	Date: May 23, 2008
	Change Request 6018

Subject: Date of Service (DOS) for Clinical Laboratory and Pathology Specimens

I. SUMMARY OF CHANGES: This Change Request (CR) implements revisions to the DOS policy for tests performed on laboratory specimens. The technical component (TC) of physician pathology services have been added to this policy, in accordance with updates to 42 CFR§414.50.

New / Revised Material

Effective Date: January 1, 2009

Implementation Date: January 5, 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	16/40/40.8/ DOS for Clinical Laboratory and Pathology Specimens

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: 1515	Date: May 23, 2008	Change Request: 6018
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SUBJECT: Date of Service (DOS) for Clinical Laboratory and Pathology Specimens

Effective Date: January 1, 2009

Implementation Date: January 5, 2009

I. GENERAL INFORMATION

A. Background:

In the final physician fee schedule regulation published in the *Federal Register* on November 27, 2007, the Centers for Medicare and Medicaid Services (CMS) revised the DOS policy for clinical laboratory test and added the technical component of physician pathology service effective January 1, 2009 (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 either a clinical laboratory test or the technical component of physician pathology service is as follows:

General Rule: The DOS of the test/service 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 either a clinical laboratory test or the technical component of physician pathology service:

A. DOS for Tests/Services Performed on Stored Specimens:

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

- The test/service 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/service do not guide treatment provided during the hospital stay; and
- The test/service 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/service must be the date the specimen was obtained from storage.

B. DOS for Chemotherapy Sensitivity Tests/Services Performed on Live Tissue:

In the case of a chemotherapy sensitivity test/service performed on live tissue, the DOS of the test/service must be the date the test/service 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/service do not guide treatment provided during the hospital stay; and
- The test/service 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 M A C	D M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6018.1	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 either a clinical laboratory test or technical component of physician pathology service.	X		X	X						
6018.2	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 M A C	D M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6018.3	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLN MattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	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.										

IV. SUPPORTING INFORMATION

Section 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:
	None.

Section 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

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

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

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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

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

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(Rev. 1515, Issued: 05-23-08, Effective: 01-01-09, Implementation: 01-05-09)

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