CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4481	**Date: December 20, 2019**
	Change Request 11574

SUBJECT: Internet Only Manual Update to Pub 100-04, Chapter 16, Section 40.8 – Laboratory Date of Service Policy

I. SUMMARY OF CHANGES: This Change Request (CR) updates the claims processing manual, Pub.100-04, Chapter 16, Section 40.8.

EFFECTIVE DATE: January 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 23, 2020

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

III. FUNDING:

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 4481	Date: December 20, 2019	Change Request: 11574

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I. GENERAL INFORMATION

A. Background: The date of service (DOS) is a required field on all Medicare claim types. A laboratory service may take place over a period of time. That is, for a given laboratory test, the date the physician orders the test, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date of the test, and the date results are produced may occur on different dates. In most cases, the DOS for a laboratory test is the date the specimen was collected, unless certain conditions are met as set forth in 42 CFR 414.510(b).The laboratory DOS exception at § 414.510(b)(5) previously stated that, for a molecular pathology test or a test designated by CMS as an Advanced Diagnostic Laboratory Test (ADLT) under paragraph (1) of the definition of an ADLT in § 414.502, the DOS of the test must be the date the test was performed only if: (i) the test was performed following a hospital outpatient's discharge from the hospital outpatient department; (ii) the specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2); (iii) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (iv) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (v) the test was reasonable and medically necessary for the treatment of an illness.

In the calendar year (CY) 2020 Medicare hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) proposed rule published on August 9, 2019, CMS sought comments on excluding blood banks and blood centers from the laboratory DOS exception at 42 CFR 414.510(b)(5). In response to comments, CMS finalized excluding blood banks or centers from the laboratory DOS exception at 42 CFR 414.510(b)(5) in the CY 2020 OPPS/ASC final rule published on November 12, 2019. CMS also adopted a definition of "blood bank or center" and clarified that this policy change categorically excludes molecular pathology testing performed by laboratories that are blood banks or blood centers from the laboratory DOS exception at 42 CFR 414.510(b)(5).

B. Policy: In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, or a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in 42 CFR 414.502, the date of service of the test must be the date the test was performed only if the following conditions are met: (1) The test is performed following a hospital outpatient's discharge from the hospital outpatient department; (2) The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 CFR 410.2); (3) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) The results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) The test was reasonable and medically necessary for the treatment of an illness.

Molecular pathology testing performed by laboratories that are blood banks or blood centers are categorically excluded from the laboratory DOS exception at 42 CFR 414.510(b)(5). That is, molecular pathology testing, when performed by blood banks or centers, are never subject to the laboratory DOS exception at 42 CFR 414.510(b)(5). For purposes of the laboratory DOS exception at 42 CFR 414.510(b)(5), a "blood bank or center" means an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for

transfusion and transplantation.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11574.1	Contractors shall be aware that molecular pathology testing performed by laboratories that are blood banks or centers are not subject to the laboratory DOS exception in Pub. 100-04, Chapter 16, Section 40.8.C of the Medicare claims processing manual.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11574.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes 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): Rasheeda Arthur, 410-786-3434 or rasheeda.arthur@cms.hhs.gov , Craig Dobyski, 410-786-4584 or craig.dobyski@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

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

(Rev. 4481; Issued: 12-20-19, Effective: 01-01-20, Implementation: 01-23-20)

The DOS policy 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 three 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 Administrative Contractors (MACs).

C. DOS for Advanced Diagnostic Laboratory Tests and Molecular Pathology Tests:

In the case of a molecular pathology test *performed by a laboratory other than a blood bank or center,* or a test designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in 42 CFR 414.502, the DOS must be the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;

- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);

- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

- The results of the test do not guide treatment provided during the hospital outpatient encounter; and

- The test was reasonable and medically necessary for the treatment of an illness.

For the purpose of section 40.8.C, a "blood bank or center" means an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.