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

MLN Matters Number: MM11574
Related Change Request (CR) Number: 11574
Related CR Release Date: December 20, 2019
Effective Date: January 1, 2020
Related CR Transmittal Number: R4481CP
Implementation Date: January 23, 2020

PROVIDER TYPES AFFECTED

This MLN Matters Article is for laboratories and other providers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11574 updates the Laboratory Date of Service (DOS) Policy in the Medicare Claims Processing Manual, Chapter 16, Section 40.8 . Make sure your billing staffs are aware of these updates.

BACKGROUND

Medicare requires a DOS 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 Section 414.510(b)(5) previously stated that, for a molecular pathology test or a test designated by the Centers for Medicare & Medicaid Services (CMS) as an Advanced Diagnostic Laboratory Test (ADLT) under paragraph (1) of the definition of an ADLT in Section 414.502, the DOS of the test 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

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- the results of the test do not guide treatment provided during the hospital outpatient encounter
- 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, Centers for Medicare Services (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).

Note: 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.

ADDITIONAL INFORMATION

The official instruction, CR11574, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/R4481CP.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
December 23, 2019	Initial article released.

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