New CMS Regulations Regarding Molecular Pathology

Date: June 11, 2019

On July 1, 2019, the Centers for Medicare & Medicaid Services (CMS) will begin enforcing the laboratory date of service (DOS) exception policy under the Medicare Clinical Laboratory Fee Schedule (CLFS) (See 42 CFR 414.510(b)(5)) (the "14 Day Rule"). This applies to providers and suppliers with regard to advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests subject to the new laboratory DOS exception policy, as adopted in the CY 2018 Medicare Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule published on December 14, 2017 (See 82 FR 59393).

Per the new DOS exception policy enacted by CMS, performing laboratories are now required to directly bill Medicare for hospital outpatient services involving clinical molecular pathology tests. Also, under the new policy the DOS of the applicable tests must now be the date the test was performed, ***not*** the collect date.

If your organization refers ***outpatient*** testing to the University of Rochester Medical Center (URMC) for molecular pathology tests, the performing laboratory will be required to bill Medicare directly for tests that meet the specific requirements outlined below. This new exception to the laboratory DOS policy will ***not*** apply to molecular pathology tests performed on a specimen collected from a hospital ***inpatient***.

If the following conditions are met in regards to a molecular pathology test or an ADLT the performing lab must bill Medicare directly and the DOS must be the date the test was performed:

(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 § 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.

URMC is requesting your organization inform us of the appropriate patient orders that meet the Medicare criteria as we do not have access to the patient records needed to identify hospital outpatients with Medicare coverage. Additional patient demographic information will also be required in order for MML to file claims to Medicare.

Completed patient demographics, date of collection, insurance information, applicable diagnosis codes, ordering physician signature, and any other information required by CMS must be provided.