

Subject: 6-Month Extension of Enforcement Discretion Period Announced for Date of Service Exception

CMS Announces Extension of Enforcement Discretion Period for Laboratory Date of Service Exception Policy Under the Medicare Clinical Laboratory Fee Schedule Until January 2, 2020

Today, the Centers for Medicare & Medicaid Services (CMS) announced that it will exercise enforcement discretion for an additional six (6) months, until January 2, 2020, with respect to the laboratory date of service (DOS) exception policy at 42 CFR 414.510(b)(5) under the Medicare Clinical Laboratory Fee Schedule (CLFS). During the enforcement discretion period, hospitals may continue to bill for advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests that would otherwise be subject to the laboratory DOS exception. This enforcement discretion applies to providers and suppliers with regard to ADLTs and molecular pathology tests subject to the 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 (82 FR 59393) and implemented by Change Request 10419, Transmittal 4000.

On July 3, 2018, CMS announced a 6-month enforcement discretion period with respect to the laboratory DOS exception at 42 CFR 414.510(b)(5). We stated that stakeholder feedback suggested many providers and suppliers would not be able to implement the laboratory DOS exception by the July 2, 2018 implementation date established by Change Request 10419, Transmittal 4000, and that such entities required additional time to develop the systems changes necessary to enable the performing laboratory to bill for tests subject to the laboratory DOS exception. On December 26, 2018, we announced an extension of the enforcement discretion period for 6 more months, until July 1, 2019. In recent communications with representatives of providers and suppliers that are affected by the policy, we have learned there are still many entities who are not able to implement the laboratory DOS exception and will need additional time to come into compliance. Based on information provided by these entities, we are extending the enforcement discretion period for an additional 6 months, until January 2, 2020.

During this enforcement discretion period, laboratories that are prepared to bill Medicare directly for ADLTs and molecular pathology tests subject to the laboratory DOS exception at 42 CFR 414.510(b)(5) should do so, and those that are not yet ready should make every effort to comply with the requirements as soon as possible. We remind hospitals and performing laboratories that in no case should both the hospital and the performing laboratory bill for the same test for the same beneficiary.

CMS is committed to the successful implementation of the laboratory DOS exception policy at 42 CFR 414.510(b)(5) and will provide guidance as necessary. For additional information on the laboratory DOS exception policy and the specific laboratory test codes subject to the exception, please visit the CLFS website:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html>.