

**Questions and Answers**  
**6-Month Enforcement Discretion Period Announced for Laboratory Date of Service  
Exception Policy Under the Medicare Clinical Laboratory Fee Schedule**

***Q1. What is CMS doing today?***

A1. CMS announced that it will exercise enforcement discretion until January 2, 2019, 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).

***Q2. Can the hospital bill instead of the performing laboratory during the enforcement discretion period?***

A2. Yes. 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 new laboratory DOS exception. In such cases the laboratory would seek payment for the test from the hospital.

***Q3. Does this mean that providers and suppliers have until January 2, 2019 to implement the new laboratory DOS policy?***

A3. This means that CMS will not enforce the requirement that the performing laboratory must bill for ADLTs and molecular pathology tests excluded from hospital outpatient prospective payment system (OPPS) packaging policy that are subject to the new laboratory DOS exception until January 2, 2019.

***Q4. Who is affected by the 6-month enforcement discretion period?***

A4. The 6-month enforcement discretion period applies to providers and suppliers with regard to ADLTs and molecular pathology tests subject to the new laboratory date of service 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).

***Q5. Why did CMS choose to exercise its authority to announce a 6-month enforcement discretion period for the new laboratory DOS exception policy?***

A5. Industry feedback suggests that many hospital and laboratories will not be able to implement the new laboratory DOS exception by the July 2, 2018 implementation date established by Change Request 10419, Transmittal 4000 and that such entities require additional time to develop the systems changes necessary to enable the performing laboratory to bill for tests subject to the new laboratory date of service exception.

***Q6. Why did CMS select a 6-month enforcement discretion period?***

A6. The duration of the enforcement discretion is consistent with the 6-month implementation delay established through Change Request 10419 (that is, the claims processing instruction implementing the laboratory DOS exception).

***Q7. What if a performing laboratory is able to bill Medicare directly before the end of the enforcement discretion period?***

A7. This enforcement discretion period does not prevent performing laboratories prepared to bill Medicare directly for ADLTs and molecular pathology tests subject to the new laboratory DOS exception from doing so before January 2, 2019. However, in no case should both the hospital and the performing laboratory bill for the same test for the same beneficiary.

***Q8. Where can hospitals and laboratories find more information on the new laboratory DOS exception policy?***

A8. For additional information on the new laboratory DOS exception policy and the list of specific laboratory HCPCS codes subject to the new DOS exception, please visit the CLFS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html>.