

**Questions and Answers on the
6-Month Extension of the Enforcement Discretion Period for the
Laboratory Date of Service (DOS) Exception Policy Under the
Medicare Clinical Laboratory Fee Schedule (CLFS)**

On December 14, 2017, CMS finalized an additional exception to the current laboratory date of service (DOS) regulations in the CY 2018 Medicare hospital outpatient prospective payment system/Ambulatory Surgical Center final rule. Under the new regulation, the DOS for Advanced Diagnostic Laboratory Tests (ADLTs) and molecular pathology tests excluded from the Medicare hospital outpatient prospective payment system (OPPS) packaging policy is the date the test was performed (instead of the date of specimen collection) if certain conditions are met. Change Request 10419; Transmittal 4000 implements the revised laboratory DOS exception and updated the Medicare claims processing manual at Pub. 100-04; Chapter 16; Section 40.8. On July 3, 2018, CMS announced that it would 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).

Q1. When does the current enforcement discretion period for the laboratory DOS end?

A1. The current enforcement discretion period for the laboratory DOS policy (42 CFR 414.510(b)(5)) ends on January 1, 2019.

Q2. Is there a new enforcement discretion period?

A2. Yes. CMS announced today that it will exercise enforcement discretion for an additional six (6) months, effective January 2, 2019, with respect to the laboratory DOS exception policy.

Q3. Can the hospital bill instead of the performing laboratory during the extension of the enforcement discretion period?

A3. If a laboratory is still not able to comply with the DOS billing requirements, the hospital may continue to bill for Advanced Diagnostic Laboratory Tests (ADLTs) and molecular pathology tests that would otherwise be subject to the laboratory DOS exception during the extension of the enforcement discretion period. In such cases the laboratory would seek payment for the test from the hospital.

Q4. Does this mean that providers and suppliers have until July 1, 2019 to implement the laboratory DOS exception at 42 CFR 414.510(b)(5)?

A4. 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 laboratory DOS exception at 42 CFR 414.510(b)(5) until July 1, 2019.

Q5. Who is affected by the 6-month extension of the enforcement discretion period?

A5. The 6-month extension of the enforcement discretion period 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.

Q6. Why did CMS choose to exercise its authority to extend the enforcement discretion period for the new laboratory DOS exception policy for six months?

A6. In recent communications with representatives of providers and suppliers that are affected by the policy, we learned there are still many entities who will not be able to implement the laboratory DOS exception by the deadline and will need additional time to come into compliance.

Q7. Will hospitals and laboratories be expected to bill for laboratory tests subject to the new laboratory DOS exception policy when the enforcement discretion period ends?

A7. Hospitals and laboratories that are prepared to comply with the new laboratory DOS exception policy should do so, and those that are not yet ready should make every effort to comply with the requirements as soon as possible during this enforcement discretion period.

Q8. What if a performing laboratory is able to bill Medicare directly before the end of the enforcement discretion period?

A8. The enforcement discretion period does not prevent performing laboratories prepared to bill Medicare directly for ADLTs and molecular pathology tests subject to the laboratory DOS exception from doing so before July 2, 2019. However, in no case should both the hospital and the performing laboratory bill for the same test for the same beneficiary.

Q9. Where can hospitals and laboratories find more information on the new laboratory DOS exception policy at 42 CFR 414.510(b)(5)?

A9. For additional information on the laboratory DOS exception policy at 42 CFR 414.510(b)(5) and the list of specific laboratory HCPCS codes subject to the DOS exception, please visit the CLFS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html>.