

Frequently Asked Questions Revised Laboratory Date of Service Exception Policy

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. A compilation of frequently asked questions (FAQs) and the CMS responses are provided below.

Q1. When is the new laboratory DOS exception policy effective?

A1. The new exception to the laboratory DOS policy is effective with dates of service on or after January 1, 2018.

Q2. When is the implementation date for the new laboratory DOS exception policy?

A2. The exception to laboratory DOS policy for ADLTs and molecular pathology tests excluded from the Medicare hospital outpatient prospective payment system (OPPS) packaging policy was implemented beginning July 2, 2018.

Q3. What is the date of service (DOS)?

A3: The date of service (DOS) is a required field 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.

Q4. What was the previous DOS policy for laboratory tests?

A4. 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 CFR 414.510(b). For instance, if the physician orders the test at least 14 days following a patient's discharge from the hospital, the DOS is the date the test is performed (instead of the date the specimen was collected).

Q5. Why was the previous DOS policy a potential problem for some laboratories?

A5. Under the previous DOS policy, if the test was not ordered at least 14 days following the date of the patient's discharge from an outpatient hospital procedure, there is no way that the laboratory performing a molecular pathology laboratory test or ADLT (which are separately payable under the Clinical Laboratory Fee Schedule) can avoid having to seek payment from the

hospital. If the test is ordered less than 14 days from the date the patient was released from the hospital outpatient department, the laboratory cannot bill Medicare directly for the test.

Q6. Did CMS solicit comments on potential revisions to laboratory DOS policy?

A6. Yes. Certain laboratory stakeholders informed CMS that the laboratory DOS policy creates unintentional operational consequences for hospitals and laboratories who perform molecular pathology tests and ADLTs. To better understand the potential impact of the current DOS policy on billing for ADLT and molecular pathology tests excluded from OPSS packaging policy (which are separately paid at the CLFS rate) we solicited public comments on specific potential revisions to the current laboratory DOS policy that would allow the laboratory to bill Medicare directly for these laboratory tests instead of seeking payment from the hospital outpatient department.

Q7. What revisions did CMS make to the laboratory DOS policy?

A7. After considering the comments received, CMS added an additional exception to the laboratory DOS regulations so that the DOS for ADLTs and molecular pathology tests excluded from OPSS packaging policy is the date the test was performed if certain conditions are met.

In the case of a molecular pathology test or an ADLT that meets the criteria of section 1834A(d)(5)(A) of the Act, the date of service must be the date the test was performed only if the following conditions are met: (1) The test is performed following the date of a hospital outpatient's discharge from the hospital outpatient department; (2) The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 CFR 410.2); (3) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) The results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) The test was reasonable and medically necessary for the treatment of an illness.

Q8. Is the performing laboratory required to bill Medicare for the test if all conditions of the new laboratory DOS exception are met?

A8. Yes. If all of the conditions for the new laboratory DOS exception are met, the performing laboratory is required to bill Medicare directly for those tests, instead of seeking payment from the hospital outpatient department.

Q9. Does the hospital still have the option to bill Medicare for the test if all of the conditions for the new laboratory DOS exception are met?

A9. Revising the laboratory DOS policy for ADLTs and molecular pathology tests that are excluded from OPSS packaging policy effectively disconnects the laboratory test away from the hospital outpatient encounter so the "under arrangements" provisions do not apply. Given that the "under arrangements" rules would not apply to ADLTs and molecular pathology testing performed following the patient's discharge from the hospital outpatient department, the

laboratory must bill for the test. The hospital would no longer bill for these tests unless the hospital laboratory actually performed the test. That is, if the hospital laboratory performed the ADLT or molecular pathology test, then the hospital laboratory could bill Medicare for the test.

Q10. Can the hospital bill for referred laboratory services?

A10. As discussed in the Medicare Claims Processing Manual, Publication 100-04, Chapter 16, § 40.1.1, claims for referred laboratory services may be made only by suppliers having specialty code 69, i.e., independent clinical laboratories. Claims for referred laboratory services made by other entities will be returned as unprocessable. Hospitals may not submit claims for reference laboratory services. As previously discussed, if the laboratory DOS exception applies, the performing laboratory must bill for the test.

Q11. If a test takes many dates to complete, what date would be the performed date? Would it be the date the testing began or the date the testing concluded?

A11. Laboratories should consult with their local Medicare Part B contractor regarding the date of performance for the specific laboratory test in question. Note that if testing is started following a hospital outpatient's discharge from the hospital outpatient department, then the requirement that the test was performed following a hospital outpatient's discharge from the hospital outpatient department would be met.

Q12. Does the new laboratory DOS exception apply when the specimen was collected from a non-patient?

A12. As discussed previously, in order for the new laboratory DOS exception to apply (among other criteria) the specimen must be collected from a registered hospital outpatient during a hospital outpatient encounter. If a molecular pathology test was performed on a specimen that was collected from a "non-patient" (e.g. a patient that is not a registered hospital outpatient) then the new laboratory DOS exception does not apply.

Q13. Is there a list of specific laboratory test codes subject to the new laboratory DOS exception?

A13. Yes. CMS published a list of specific HCPCS codes that are subject to the new laboratory DOS exception on the CLFS website. This list is updated quarterly as appropriate.

Q14. Where can I find information about the laboratory DOS exception?

A14. Information on the laboratory DOS exception is available on the CLFS website: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html>.