



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

6120 Executive Blvd., Suite 700, Rockville, MD 20852

Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

September 27, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
P.O. Box 8016
Baltimore, MD 21244-8013

RE: CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1717-P)

Dear Administrator Verma:

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide comments on the CY 2020 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry.

We applaud CMS for recognizing the billing and payment challenges and complexities laboratories face. We look forward to working with CMS as this proposed rule moves toward implementation and offer the following comments regarding the proposed changes to the Clinical Laboratory Fee Schedule.

Clinical Laboratory Fee Schedule: Proposed Revisions to the Laboratory Date of Service Policy

AMP appreciates that CMS is seeking comments on three potential changes to the laboratory date of service (DOS) exception. In order to reduce additional regulatory burdens for providers and hospitals, we recommend that the agency refrain from changing the test results requirement or limiting the DOS exception to advanced diagnostic laboratory tests (ADLT).

Background

In the CY 2018 Final Rule, CMS acknowledged the concerns raised by multiple stakeholders about burdens imposed on clinical laboratories, hospitals, treating physicians, and Medicare beneficiaries by the DOS rule and to address these concerns, CMS implemented a new exception to the Laboratory DOS rule for molecular pathology tests and ADLT tests by CMS. Under this new exception, the date of service for the test would be the date the test was performed if the following criteria were met:

- (1) Test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- (2) Specimen was collected from a hospital outpatient during an encounter (as both are defined in §410.2);
- (3) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- (4) Results of the test do not guide treatment provided during the hospital outpatient encounter; and
- (5) Test was reasonable and medically necessary for the treatment of an illness.

The result of implementing this DOS exception enabled laboratories performing ADLTs and molecular pathology tests to be excluded from the OPPS packaging policy to bill Medicare directly for those tests, instead of requiring them to seek payment from the hospital outpatient department.

Changing the Test Results Requirement

CMS requested comments on whether a test should be considered a hospital service and excluded from the DOS policy if the ordering physician determines the results of a molecular pathology test or ADLT will guide treatment during the current outpatient encounter as well as a future hospital outpatient encounter(s). Under current policy, the DOS is the date of test performance if certain criteria are met including that the test does not guide treatment during the outpatient encounter at which the specimen was collected.

AMP recognizes that CMS is seeking ways to determine concretely whether or not the test guides treatment during the outpatient encounter at which the specimen is collected and proposes that the ordering physician make this determination. We applaud CMS for recognizing role of the professional to identify the role a test serves in a patient's care. However, AMP is concerned this potential revision is unworkable as proposed and may create additional burdens for hospital administration, which could lead to a negative impact on access to timely molecular pathology testing. We urge CMS not to implement this policy at this time and find another, less burdensome way to accomplish this.

While in theory this proposed revision could put the decision back in the hands of the care teams, in practice it would be difficult to implement due to the variability and intricacies of patient care. The ability of the ordering physician to make a prediction as to whether the test results will or will not guide treatment management will vary widely based on the type of physician, the type of test, the treatment options available to the patient, as well as other factors. For example, the provider doing a biopsy is often not the same provider who would be using the biopsy to guide treatment. Further complications could arise when a patient also has to see an oncologist after the biopsy sampling to get the testing "ordered" by the physician. In instances when the care team is fragmented, it may be difficult to assign responsibility for making the determination of whether or not the testing should be separated from the outpatient encounter.

Moreover, CMS is seeking to implement a policy that would require the ordering physician to determine how the test will relate to not only the current encounter, but also future encounters. Neither the ordering physician nor the performing physician, if they are not the same physician, will be able to predict whether the test results will guide future treatment. The proposal would be difficult to manage within the hospital setting, require hospitals to change their systems and create additional administrative burden on providers that may result in a delay in testing.

Limiting the DOS Exception at 42 CFR 414.510(b)(5) to ADLT

CMS is requesting comments on limiting the laboratory DOS provisions in Social Security Act § 414.510(b)(5) to tests designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502. The agency is no longer convinced that molecular pathology tests present the same concerns of delayed access to medically necessary care as ADLTs. AMP strongly opposes the agency's proposal to limit the laboratory DOS exception to tests designated as ADLTs as this change would limit patient access to clinically appropriate molecular testing and the treatment decisions that result from it.

To protect patient access to molecular testing and the treatment decisions that it dictates, CMS should not distinguish between ADLTs and molecular testing as ADLTs are a type of molecular pathology testing. Molecular pathology testing, including ADLTs, is performed in a wide-variety of laboratory settings including academic and community hospitals, independent and commercial reference laboratories, and sole source laboratories. Both types of testing require significant investment and technical expertise to perform. The distinction between ADLTs and other molecular tests was made by the Protecting Access to Medicare Act (PAMA) and was not intended to differentiate ADLTs from other molecular pathology testing in terms of how they inform a patient's longitudinal care. Under PAMA, ADLTs are provided by a single laboratory which furnishes the test, and that may also design, offer, or sell the test. ADLTs are required to meet one of the following criteria:

- (A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result;
- (B) The test is cleared or approved by the Food and Drug Administration; or
- (C) The test meets other similar criteria established by the Secretary¹."

Molecular pathology tests may also meet all of the same criteria as an ADLT except they are offered by more than one laboratory. The rationale that may exist for differential pricing processes for a test provided by a single laboratory is not a sufficient reason to distinguish ADLTs from other molecular pathology tests regarding patterns of clinical use for the purposes of the DOS rule.

Any changes CMS makes to the DOS rule should promote timely patient access to molecular testing providers in all settings. AMP cannot support a policy change that will potentially delay a test result and patient access to therapies. We are concerned that this policy will increase operational complexity without a corresponding benefit to patient care. Many hospitals, particularly those in rural areas, send a test out to be performed regardless of whether it is an ADLT or another molecular test. Thus, the designation of ADLT status for a molecular test does not differentiate it from other molecular tests for the purposes of the DOS rule.

AMP offers the following example of ADLTs and molecular tests that answer the same clinical question and have the same clinical utility. For example, FoundationOne[®], an ADLT, and a comparable multi-gene panel test provided by a laboratory in an academic medical center have similar clinical utility in that they are both performed to comprehensively assess mutations in a patient's tumor.

To support this proposal, CMS asserts that many molecular pathology tests are becoming available as kits and thus can be performed by hospitals, negating the need to create an exception for send-out molecular pathology tests. This is inaccurate and hospitals capabilities and availability of skilled laboratorians to complete this testing vary widely. A significant portion of molecular pathology tests are performed by the laboratory even though test kits may be available. Moreover, some hospitals, especially those in rural areas, do not have in-house

¹ Section 216(d)(5) of Public Law 113-93. April 1, 2014. (128 Stat. 1057).

laboratories and must send out testing for their patients.

CMS finalized changes to the DOS policy for 2018 because independent laboratories were unable to bill for tests and hospitals were required to bill for them. Practice patterns have not changed in the intervening time. The agency changed the DOS policy for these tests when they meet certain criteria in order to allow the performing lab to be able to bill and seek payment directly from CMS. This change was effective January 1, 2018, but CMS has instead chosen to exercise its enforcement discretion, leaving laboratories in limbo. Hospitals have incurred significant cost to implement this change and in a few areas desire to implement the change, however, due to the delay, some performing laboratories refuse to implement the change forcing hospitals to have different billing practices depending on the laboratory. This has created additional administrative burden running counter to this administration's efforts to reduce operational burden. AMP requests that CMS finally implement the policy effective January 1, 2018 so that hospitals can proceed and that performing labs can also proceed to implement this change.

For the reasons stated above, AMP cannot support the proposed policy that distinguishes ADLTs from other molecular tests under a revised DOS policy.

Conclusion

Notwithstanding the comments and concerns outlined above, AMP recognizes that CMS is working to improve the billing and payment processes for laboratory services to better patient care. However, AMP urges CMS not to make any of the changes discussed above to the DOS policy at this time. Instead, the agency should convene stakeholders to discuss how the DOS policy can further be refined to ensure it is not limiting patient access to important care options. AMP welcomes the opportunity to work with CMS to ensure patients have access to appropriate molecular testing under the DOS policy.

Thank you for the opportunity to submit recommendations for CMS to consider while revising the DOS policy. We are happy to answer any questions about our recommendations and provide further information. Please direct your correspondence to Tara Burke, PhD, AMP Senior Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Victoria M. Pratt, PhD, FACMG
President, Association for Molecular Pathology