ASCLS
The American Society for Clinical Laboratory Science

One Voice, One Vision

September 27, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
P.O. Box 8013
Baltimore, MD 21244-1850.

DELIVERED ELECTRONICALLY

On behalf of 8,000 clinical laboratory professionals, the American Society for Clinical Laboratory Science (ASCLS) is pleased to provide the following comments to the proposed rule by the Centers for Medicare & Medicaid Services on August 9, 2019.

Agency/Docket Number: CMS-1717-P

XIX. Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy

"We are particularly interested in comments regarding our position that when the results of molecular pathology testing and Criterion (A) ADLTs are intended to guide treatment during a future hospital outpatient encounter, the test is a hospital service."

This position is not medically logical and is an unreasonable expectation. In most cases, the laboratory has no knowledge as to what treatment might be initiated based on the test results and has no knowledge about where that treatment will be administered. In the current healthcare system, with many new and different patient care sites, there is no need to treat patients in a hospital setting if the patient's condition doesn't warrant.

In addition, given that decisions may be based on insurance coverage, the next steps of a patient's treatment can be very open-ended and unpredictable; the physician may not know if, when or where treatment will be initiated. It would depend entirely on the results.

Obtaining information about treatment from physicians will be difficult, if not impossible. What does CMS mean by "guiding treatment?" Does it include deciding not to treat, treating with a certain agent, and/or predicting response to treatment already administered?

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What is the purpose of this change? Many laboratories have been unable to comply with the current exceptions and laboratories that have systems in place to comply have made mistakes. The current system is very complicated, and this will make the exceptions even more so. The entire rule is administratively overburdensome. Requiring physicians to attest that the test would NOT determine future treatment would be almost impossible because, for many tests, future treatment would depend on the outcome of the test and whether the outcome determines treatment or just presents options.

For instance, genetic testing guides treatment: the presence of HER2/neu in breast cancer indicates that the tumor is likely to respond to treatment with trastuzumab; however, if the gene is not present, treatment will depend on a variety of other factors that may require further testing. Colon cancer tumors positive for the KRAS gene will likely not respond to tyrosine kinase inhibitor agents. As in the previous example, testing for the gene does not determine treatment in all patients; it will depend on the results, which no physician can predict before the testing is done.

Most Laboratory Information Systems (LIS) do not have access to completed demographics, insurance information, or diagnostic codes necessary to safely implement CMS's proposed approach. Laboratories cannot screen patients based on insurance and are, therefore, unable to secure the appropriate information for billing from the physician.

CMS appears to be under the assumption that all hospitals are doing their own molecular testing and it is only the ADLTs that are specific to one lab, but that assumption is not true.

We question the motivation for what will be an administratively burdensome requirement: is CMS trying to save money or restrict molecular testing? Neither benefit the patient. If the specimen was sent to a reference lab, these entities do not receive enough information, in many cases, to know why the test was ordered so they can ask/remind physician to attest to use of the test. Laboratories at academic medical centers only bill the client (i.e. the laboratory that sent the test). These new rules create the potential that some laboratory tests would be unbillable, severely restricting access.

"We also are interested in receiving public comments regarding the administrative aspects of requiring the ordering physician to determine when the test results are not intended to guide the treatment during a hospital outpatient encounter, as well as the process for the ordering physician to document this decision and provide notification to the hospital that collected the specimen for billing purposes."

If a pathologist ordered a test after biopsy, the treating physician might not know whether the test would guide treatment. The current science, especially in cancer genetics, is not definitive enough and still evolving.

Many laboratories do not currently have access to the data necessary to bill Medicare. For those laboratories billing directly now, this approach will work, but for many laboratories who do not have access to data, the hospital should be allowed to bill for the test. A modifier would be created when the hospital bills and the laboratory would have to pass date of performance back to hospital.

"We are requesting comments on potentially limiting the laboratory DOS exception policy at § 414.510(b)(5) to Criterion (A) ADLTs that have been granted ADLT status by CMS. We note that we would consider finalizing this approach as a result of the public comments received."

The development of ADLTs is advancing at an unprecedented rate as we learn more about the genetics of many disorders/pathologies. The science is overwhelming for the medical community to manage and federal agencies seem to have even more difficulty keeping up. What processes does CMS have in place to respond to updates in science and avoid limiting medically appropriate testing because of suddenly outdated billing mechanisms?

"We are requesting comments from hospitals, blood banks and centers, and other interested stakeholders regarding a potential revision to laboratory DOS policy that would exclude blood banks and centers from the laboratory DOS exception policy at § 414.510(b)(5). We also are requesting specific comments as to how a blood bank and blood center may be defined in the context of this provision, and particularly how to distinguish blood banks and centers from other laboratories"

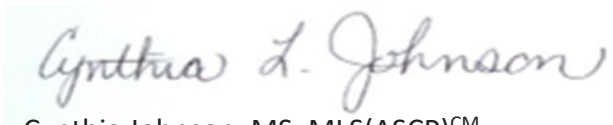
ASCLS assumes that the CMS definition of a blood bank or center is a free-standing entity. We believe that CMS should also acknowledge that blood centers also provide reference laboratory testing. Excluding blood banks from the DOS exception policy makes sense because the purpose for the test is to determine the appropriate transfusion – we agree that the service is so connected to the hospital visit that it should be billed by the hospital.

"Potential Revision to Laboratory Date of Service (DOS) Policy In section XIX. of this proposed rule, we are soliciting comments regarding potential revisions to the laboratory date of service (DOS) provisions at §414.510(b)(5) for a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ''advanced diagnostic laboratory test'' in §414.502. The laboratory DOS service policy does not impose any information collection

requirements. Consequently, review by the Office of Management and Budget under the authority of the PRA is not required."

ASCLS strenuously disagrees with the assumption that the date of service policy, as it relates to requiring the ordering physician to determine when the test results are not intended to guide treatment, will not impose any information collection requirements on laboratory providers. There will be a considerable amount of time spent tracking down the appropriate physician and a huge cost to implement a computerized process to gather physician attestations.

Sincerely,



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