November 2019

MEMO

To: Hospital Blood Bank Management Staff
    Transfusion Medical Directors

From: Nancy Kelting, MT, MBA
      VP Business Development

Recently we learned that the Centers for Medicare and Medicaid Services (CMS) has issued the 2020 Hospital Outpatient Prospective Payment System final rule. The rule addresses payment to hospital outpatient departments and ambulatory surgical centers (ASCs), including payment rates for blood components.

Of primary importance, the rule exempts blood centers from the Medicare laboratory Date of Service policy, clarifying that blood centers do not have to bill Medicare directly for molecular tests performed on patient samples. CMS had previously exercised enforcement discretion of the policy until January 2, 2020. Specifically, the Final Rule states:

Response: For the reasons discussed in the CY 2020 OPPS/ASC proposed rule, and based on the support received from stakeholders, we are finalizing the revision to exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5). In addition, we agree with commenters that their suggested revised definition of blood banks and centers clearly defines the primary role of blood banks and centers and better distinguishes blood banks and centers from other types of laboratories. To effectuate this policy change, we are revising § 414.510(b)(5) to exclude molecular pathology tests when performed by a laboratory that is a blood bank or center. We are defining the term “blood bank or center” instead of “blood bank and center” to reflect that a molecular pathology test is excluded when performed by either a blood bank or blood center. We are also defining “blood bank or center” at § 414.502 as an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

We (CMS) clarify that this policy change categorically excludes molecular pathology testing performed by laboratories that are blood banks or blood centers from the laboratory DOS exception at § 414.510(b)(5). Under our final policy, molecular pathology testing performed by blood banks or centers on a specimen collected during a hospital outpatient encounter is never subject to the laboratory DOS exception at § 414.510(b)(5). We believe that the burden on hospitals will be mitigated with the policy we are finalizing.

Please contact me with any questions. Thank you!