PUBLICATION

CMS Provides Guidance Regarding OPPS 'Packaging' of Clinical Laboratory Tests [Ober|Kaler]

Authors: Robert E. Mazer
February 06, 2014

In a previous *Payment Matters* article, we described a new CMS policy under which, effective January 1, 2014, hospitals would no longer be permitted to bill Medicare separately for clinical laboratory tests for hospital outpatients. Instead, these tests would be "packaged" into the Medicare outpatient prospective payment system (OPPS). In the final rule adopting this policy, CMS stated that it planned to issue revised contractor instructions for billing for laboratory tests for hospital outpatients.

These instructions were included in Transmittal 2485, "SUBJECT: January 2014 Update of the Hospital Outpatient Prospective Payment System (OOPS)," issued on December 27, 2013. CMS's instructions further define those laboratory tests that would be exempt from the "packaging" requirement. Tests performed under the following three scenarios would not be "packaged," but instead would continue to be paid under the Medicare clinical laboratory fee schedule (CLFS):

1. The test is a "non-patient" laboratory test;
2. The patient *does not* receive any hospital outpatient services other than laboratory tests as part of the same "encounter;" or
3. The patient *does* receive hospital outpatient services in addition to laboratory tests during the same "encounter," but the tests are "clinically unrelated" to the other hospital services, and the laboratory tests were ordered by a different practitioner than the practitioner who ordered the other services.

The instructions specify that the same "packaging" principles apply whether the hospital actually performed the laboratory tests or they were provided "under arrangement," that is, the tests were performed by another laboratory that had agreed to accept payment from the hospital as full compensation for the test.

CMS instructs that when a laboratory test is not required to be "packaged" with another outpatient service for the same patient, the laboratory test should be billed on a 14x claim; the other hospital outpatient service should be billed on a 13x claim.

The new instructions state that a "non-patient" – whose clinical laboratory tests would not be "packaged" – continues to be defined as a Medicare beneficiary who is not a hospital inpatient or outpatient, but whose specimen is submitted to the hospital for analysis and the beneficiary is not physically present at the hospital.

The instructions do not address specifically when a laboratory test will be considered to have been provided during the "same encounter" as other hospital outpatient services. The longstanding definition of an "encounter" is a direct personal contact between a patient and a physician or other person authorized to order or furnish hospital services for the diagnosis or treatment of a patient. The agency has recognized previously that when a patient leaves a hospital and obtains a diagnostic test from another provider, the test is not considered to have been furnished to a hospital outpatient during an encounter. The determination regarding when one encounter ends and another begins may be more difficult when only a single provider is involved in the patient's care.

Ober|Kaler's Comments

CMS regulations, as revised to reflect the new laboratory “packaging” policy, will state only that “[c]ertain clinical diagnostic laboratory tests” are paid as part of payment rates for outpatient services under OPPS. 42 C.F.R. § 419.2(b)(17). They will not include a detailed explanation of the principles to be used in determining whether a clinical laboratory test must be “packaged” or whether separate payment for the test can be claimed under the CLFS. Similarly, the CMS transmittal that included related contractor instructions did not revise language in the CMS manuals to reflect the new laboratory “packaging” policy. Accordingly, pre-existing language in certain agency manuals could lead a hospital or clinical laboratory to an incorrect result. In addition, other CMS interpretations have used different language in distinguishing a “non-patient” from a hospital inpatient or outpatient; those definitions may not be directly applicable to the determination as to whether tests can be billed separately or must be “packaged” into OPPS, but they could result in confusion. Hospitals should retain a copy of the transmittal for future reference, at least until the policy is incorporated into CMS manuals.