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Medicare OPPS Lab 'Packaging' Policy Raises Bundle of Issues [Ober|Kaler]

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April 02, 2014

In previous *Payment Matters* articles, we described a policy included in the 2014 hospital outpatient prospective payment system (OPPS) final rule that would "package" certain clinical laboratory tests into OPPS, and CMS instructions regarding the new policy's implementation. We commented that the new "packaging" policy was not described in the regulations themselves, or even in revisions to CMS interpretive manuals that would remain easily available to hospitals.

CMS has continued to revise policies related to packaging of clinical laboratory tests in informal issuances, most recently in a Medicare Learning Network (MLN) Matters® article, "Update to 2014 Hospital Outpatient Clinical Diagnostic Laboratory Test Payment and Billing," SE1412 (MLN Update). MLN Matters articles can be issued quickly and can provide useful guidance in a convenient format, but they may not receive the same level of attention as more formal agency pronouncements or include all of the information necessary to fully understand the relevant issues.

As discussed below, certain statements included in the MLN Update are potentially inconsistent with those included in the previously issued CMS instructions. Others may be subject to misinterpretation. Finally, the MLN Update does not address the more fundamental Medicare rule requiring hospitals to submit claims for non-physician services furnished to hospital outpatients. This is an issue which is likely to receive increased attention as a result of the new packaging policy.

In the MLN Update, CMS states the following:

- In describing the exception to the packaging requirement generally permitting individual billing of lab tests when no other hospital services were provided, CMS states that individual payment for lab tests can be claimed if "a hospital collects specimen and furnishes only the outpatient labs *on a given date of service*." Previously issued agency instructions, however, had used terms included in OPPS regulations. They provided that lab tests could be individually billed when the hospital only provided lab tests to the patient and he or she did not "also receive other hospital outpatient services during that same *encounter*." Similarly, in addressing individual lab payment claims when other hospital services were clinically unrelated to the lab tests, the MLN Update refers to "other hospital outpatient services *furnished the same day*." CMS instructions had referred to tests provided during the same *encounter* as the other services. The differences in terminology could, in some instances, lead to a different result.
- Effective for claims submitted on or after July 1, 2014, payment claims for laboratory tests that are not required to be packaged – either because they were the only hospital services furnished on the particular date of service or were clinically unrelated to any other such services – should be submitted as a 13x Type of Bill (TOB) with a new modifier. This would replace the current procedure requiring use of a TOB 14x bill in these two situations. CMS states that a provider using the new modifier is "attesting" that the test is not required to be packaged for one of the two reasons stated above. According to CMS, there will be no change to the procedure used to claim payment for lab services billed individually because the test was performed on a "non-patient (referred) specimen."

- "[I]t is optional for OPPS hospitals to seek separate payment under the CLFS [clinical laboratory fee schedule] for a given outpatient lab test." CMS indicates that a hospital may claim payment for lab tests that are unrelated to other hospital services – for which separate payment is available under the CLFS – in order to "receive packaged payment under the OPPS." The agency's explanation indicates actually that hospitals have the option to *not* seek separate payment under the CLFS for an outpatient lab test for which such payment is available. Hospitals are not afforded, however, the option of disregarding the packaging requirements where applicable and claiming separate payment for lab tests under the CLFS.
- The current method of claiming payment for lab tests that are not packaged does not fully compensate certain sole community hospitals (SCHs) that qualify for payments based on a fee schedule providing for greater payments than those made to other hospitals. CMS' "solution" is to permit such SCHs to wait until the new reporting methodology goes into effect on July 1, 2014 to submit claims for payment.
- CMS will review claims data "for potential inappropriate unbundling of laboratory services under the new OPPS packaging policy." The agency warns hospitals that they "may not establish new scheduling patterns in order to provide laboratory services on separate dates of service from other hospital services for the purpose of receiving separate payment under the CLFS."

CMS provides several billing scenarios to demonstrate appropriate use of the new modifier on or after July 1, 2014. In each instance, CMS describes the scenario and then states whether particular laboratory tests performed as part of the scenario can be billed individually. Unfortunately, however, the agency does not specify the basis for its conclusion.

As part of one such scenario, a patient receives a presurgical exam in a provider-based clinic for outpatient surgery that is to be performed two weeks later, and receives related lab tests from the hospital on the same day as the exam. CMS states that the hospital would not be entitled to separate payment for the lab tests under the CLFS, presumably because the lab tests were related to other hospital outpatient services that were furnished on the same day.

Based on its comments related to change in scheduling patterns to obtain separate payment for lab tests, CMS would presumably find it inappropriate (and potentially unlawful) if the provider-based clinic modified its policies so that the lab tests would be performed on a different day than the presurgical exam.

Under a modified version of this scenario, the patient receives a presurgical exam in a free-standing physician office, but then has to return to work, so the tests are not performed by the hospital until two days later. In contrast to the original scenario, CMS states that the hospital could seek separate payment for the lab tests. Presumably, the agency was attempting to demonstrate that lab tests that were not performed on the same day as other hospital services could be billed separately. There is, however, another possible explanation. Unlike in the original scenario, the presurgical exam occurred in a free-standing physician office, so the individual for whom the tests were performed was not a hospital outpatient when the tests were ordered. As a result, if the patient did not physically present at the hospital for collection of the specimen, the test could also be considered a "non-patient (referred) specimen," exempt from packaging requirements.

Ober|Kaler's Comments

For more than ten years, clinical laboratory tests have been subject to Medicare outpatient "rebundling" rules. These principles govern when clinical laboratory tests are considered outpatient services that must be billed by a hospital. Such tests can include tests ordered in a provider-based clinic or performed for a hospital outpatient

by a reference laboratory. The packaging rule may refocus attention on Medicare outpatient rebundling requirements because Medicare may now pay different amounts for a lab test depending upon whether the hospital or another provider claims payment for the service.

Related pronouncements may also impact application of Medicare rebundling requirements, irrespective of whether this was the agency's intent. Hospitals that participate in arrangements under which another entity claims payment for hospital outpatient lab tests that are required to be billed by the hospital are subject to civil monetary penalties and exclusion. Accordingly, hospitals should make appropriate efforts to insure that they are billing for all tests for which Medicare will pay only the hospital, and to make certain that payment is not being claimed for those services by another entity, such as a lab that may have performed outpatient reference tests.