Laboratory Services Regulations Carry HIM Implications

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This is Part 1 of a two-part article on national coverage and policies for clinical diagnostic laboratory services payable under medicare Part B. Part 1 concentrates on the administrative policies. Part 2, which will appear in the October issue of the Journal, *will focus on the national coverage policies developed for individual clinical diagnostic laboratory tests. For additional information regarding the new administrative policies, see the Centers for Medicare & Medicaid Services (CMS) Program Memorandum AB-02-030, which was issued to all Medicare contractors on March 5, 2002.*

A final rule establishing national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B was published in the November 23, 2001, *Federal Register*. Are you familiar with the specific elements of these regulations? And are you aware of their implications for HIM practices?

These regulations apply to all entities that perform diagnostic laboratory tests, including hospitals, clinics, independent laboratories, and physicians' offices. They also apply to all healthcare practitioners who order laboratory tests. They are binding on all Medicare contractors and quality improvement organizations. This article will look at the administrative policies of the final rule and what they mean for HIM.

What Is Covered

The Social Security Act stipulates that all clinical diagnostic laboratory tests must be ordered by a physician or qualified nonphysician practitioner (this category includes clinical nurse specialists, clinical psychologists, clinical social workers, nurse midwives, nurse practitioners, and physician assistants who furnish services that would be physician services if furnished by a physician and who work within the scope of their authority under state law and within the scope of the Medicare statutory benefit).

Other than in the case of certain explicit statutory exceptions, the act provides that no Medicare payment may be made for expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Medicare coverage excludes expenses for services for routine physical checkups, eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed during the course of an eye examination to determine the refractive state of the eyes, hearing aid examination, or immunizations except as otherwise allowed under specific sections of the act.

Congress granted the secretary of Health and Human Services the authority to decide which specific expenses incurred for items or services in the covered categories are covered by Medicare. Most Medicare coverage and policy decisions are made locally by Medicare contractors, but CMS also has authority to develop coverage policies that apply nationwide, known as national coverage decisions. Frequently, contractors publish local medical review policies (LMRPs) to provide guidance to the public and medical community that they serve.

The Balanced Budget Act of 1997 (BBA) mandated the use of a negotiated rule-making committee to develop national coverage and administrative policies for clinical diagnostic laboratory services. The BBA required that these national coverage policies be designed to promote program integrity, national uniformity, and administrative simplification requirements in connection with:

- beneficiary information required to be submitted with each claim or order for laboratory services

- medical conditions for which a laboratory test is reasonable and necessary
- appropriate use of procedure codes in billing for a laboratory test, including the unbundling of laboratory services
- medical documentation that is required by a Medicare contractor at the time a claim is submitted for a laboratory test
- record-keeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding these requirements
- procedures for filing claims and for providing remittances by electronic media
- limitations on frequency of coverage for the same services performed on the same individual

Final Regulations Include Seven Provisions

The final regulations addressing administrative and coverage policies for clinical diagnostic laboratory tests include the following provisions:

1. The physician or qualified nonphysician practitioner who orders the diagnostic laboratory service is required to **maintain documentation of medical necessity** in the beneficiary's medical record.
2. The laboratory service provider is required to **maintain the following documentation**:

    - documentation that it receives from the ordering physician
    - documentation that the information that it submitted with the laboratory claim accurately reflects the information it received from the ordering physician

3. The laboratory service provider may request **additional diagnostic and other information** from the ordering physician to document that the services it bills are reasonable and necessary. Only material relevant to the medical necessity of the specific test(s) may be requested, taking into consideration current rules and regulations. The laboratory must, upon request, provide to CMS:

    - **documentation of the physician's order** for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician)
    - **documentation showing accurate processing** of the order and submission of the claim
    - any **diagnostic or other medical information** supplied to the laboratory by the ordering physician, including any ICD-9-CM code or narrative description supplied by the ordering physician. Laboratory service providers that submit electronic claims must report ICD-9-CM diagnosis codes rather than narrative diagnoses. Laboratory service providers that submit paper claims may report narrative diagnoses. The diagnostic information provided by the ordering physician should be coded to the highest degree of specificity, both in terms of valid digit assignment and clinical knowledge of the patient's medical condition. If no definitive diagnosis has been established, it is appropriate to report the ICD-9-CM code(s) for sign(s) and symptom(s), as this represents the highest degree of certainty known at that time.

    If the documentation provided to CMS by the laboratory service provider does not adequately support medical necessity, CMS will request that the ordering physician provide it with a copy of the pertinent sections of the beneficiary's medical record. If the ordering physician does not supply the requested documentation, CMS will notify the laboratory service provider that the necessary documentation has not been provided and the claim will be denied.

4. The **date of service** reported on a Medicare claim for clinical diagnostic laboratory services is defined as the date the specimen was collected.
5. Claims for laboratory services should not be denied because a **frequency threshold** had been exceeded, unless the Medicare contractor or CMS has published an indication of the frequency of performing the test that is generally considered reasonable. Medicare contractors can establish frequency limits for tests that have national coverage decisions as long as the national coverage decision does not indicate a different limitation on frequency. When establishing frequency limitations for a particular laboratory test, Medicare contractors must consult with appropriate advisors, including medical specialty and other organizations, before developing and publishing frequency information for a clinical diagnostic laboratory test.
6. When a claim exceeds **utilization parameters** (i.e., frequency screens), Medicare will review all relevant documentation submitted with the claim before denying the claim (e.g., justifications prepared by providers, secondary diagnoses, copies of medical records).

7. Claims may be **automatically denied** when there is a national coverage decision or LMRP that specifies the circumstances under which the service is denied (and these circumstances apply to the claim in question), the service is statutorily excluded from Medicare coverage, or the specific provider has engaged in egregious overuse of the service and the claim is for that service. National coverage decisions were developed for 23 clinical diagnostic laboratory tests.

What the Doctor Ordered?

It is important to note that when diagnostic information is required for claims payment, such as when there is a national coverage decision or LMPR, physicians and qualified nonphysician practitioners are required to provide diagnostic information at the time the test is ordered.

Some members of the public, as well as members of the negotiated rule-making committee, expressed concern regarding the lack of a regulatory requirement for physicians to provide diagnostic information necessary to support medical necessity in every case. Providing information to support the reason for the encounter would be useful in evaluating patient outcomes and quality of care and would ensure consistency and simplicity.

CMS felt, however, that such a requirement would be unduly burdensome on some physicians at this time. CMS encourages physicians to voluntarily provide diagnostic information with every order, and they also encourage laboratory service providers to submit this information on the claim when it is received from the ordering physician.

Physicians: Sign Here

The regulations also addressed common misconceptions concerning CMS' requirements for physician signatures on requisitions for diagnostic laboratory services. CMS clarified that it does not require requisitions for diagnostic tests to be signed by the ordering physician. Per federal regulations, diagnostic radiology, laboratory, and other diagnostic tests must be ordered by the physician who is treating the Medicare patient for a specific medical problem and who uses the results in the management of the patient's medical problem. CMS noted that while a signature is one way of documenting that the treating physician ordered the test, it is not the only permissible way. For example, the physician may document the ordering of diagnostic tests in the patient's medical record.

Because some Medicare contractors were requiring physician signatures on requisitions, CMS agreed to publish an instruction to Medicare contractors clarifying that the signature of the ordering physician is not required for Medicare purposes on a requisition for a clinical diagnostic laboratory test. However, this does not change the fact that there must be some form of documentation indicating that the treating physician ordered the test. So, if a healthcare organization chooses not to require physicians to sign the requisitions for diagnostic tests, there must be another process in place for ensuring there is documentation that the patient's physician ordered the test.

Clarifications of ICD-9-CM Diagnosis Code Reporting Requirements

Ordering physicians are not required to provide ICD-9-CM codes to the laboratory service provider. If a laboratory service provider receives a requisition with a narrative diagnosis rather than an ICD-9-CM code, that entity may translate the narrative to the appropriate ICD-9-CM code. The laboratory service provider must maintain the requisition containing the narrative diagnosis and submit a copy to Medicare upon request.

CMS clarified that the narrative diagnosis provided by the ordering physician does not have to exactly match the narrative description of the ICD-9-CM code assigned, as long as it is the appropriate diagnosis code for the provided diagnosis. This clarification is intended to address the problem of some Medicare contractors denying claims because the physician's documented diagnosis did not match the ICD-9-CM code description word-for-word (for example, unstable angina is classified to code 411.1, which has a description of "intermediate coronary syndrome").

If the ordering physician submits an ICD-9-CM diagnosis code on the laboratory requisition, the laboratory service provider must use that code unless there is a reason to query the physician about the code. For example, the code may be invalid, unrelated to the services rendered, or inconsistent with other diagnostic information.

The laboratory service provider must receive and maintain the documentation to alter the claim when it is necessary to change the code originally provided by the ordering physician. This documentation may be written information from the ordering physician or a written note documenting the telephone call with the ordering physician. A faxed copy of the documentation is acceptable. The laboratory must be able to submit a copy of this documentation to Medicare upon request.

CMS clarified that until standards permitting eight ICD-9-CM diagnosis codes are implemented, Medicare contractors with information systems that accept fewer than eight ICD-9-CM codes in the diagnoses field would permit laboratory service providers to submit additional codes in the narrative field.

Claims should not be denied solely because there is no matching of diagnosis and procedure codes on the claim form.

Modifier -59 vs. Modifier -91

Modifier -59, Distinct procedural service, should be used to report multiple service submissions by a clinical laboratory for the same beneficiary on the same day. For laboratory services, these situations usually involve microbiology where samples or cultures are taken from a patient from different anatomical sites or different wounds using the same CPT code and then are tested the same day.

Modifier -91, Repeat clinical diagnostic laboratory test, is more frequently applicable for laboratory services than modifier -59. If an ordering physician requests a laboratory test that requires that several of the same services (reported by the same CPT code) be performed for the same patient on the same day, the laboratory service provider should use modifier -91 to indicate that multiple clinical diagnostic laboratory tests were performed on the same day.

"Screening" CPT Codes

The term "screening" or "screen" in CPT code descriptions does not necessarily have the same meaning as when this term is used in the context of diagnostic screening, which indicates that the test was performed in the absence of signs or symptoms of an illness, disease, or medical condition.

Regulatory Effective Date

Elements of the regulations that are not likely to require systems changes or extensive education became effective February 21, 2002. These elements consist of clarifications of pre-existing requirements. All other provisions of the regulations, including the definition of date of service, documentation, and recordkeeping requirements to support medical necessity, and the national coverage decisions developed for 23 clinical diagnostic laboratory tests, will become effective November 25, 2002.

References

"Medicare Program: Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services." 42 CFR Part 410. *Federal Register* 66, no. 226 (November 23, 2001). Available at http://cms.hhs.gov/regulations/regnotices.asp

Medicare Transmittal AB-02-030 is available at the CMS Web site at www.cms.hhs.gov/manuals/pm_trans/AB02030.pdf.

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Article citation:
Prophet, Sue. "Laboratory Services Regulations Carry HIM Implications." *Journal of AHIMA* 73, no.8 (2002): 20,22,24.