

# Regulations Regarding Reflexive Testing and Narrative Interpretations in Laboratory Medicine

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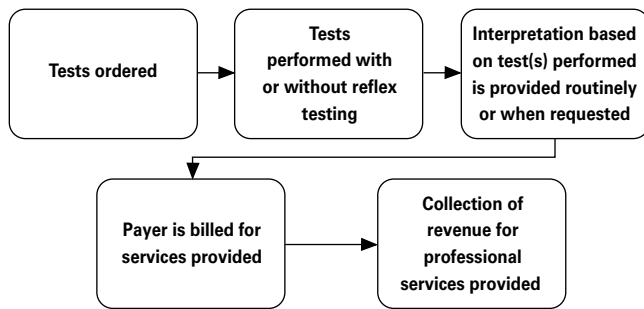
## Abstract

*The use of reflexive test selection and patient-specific narrative interpretations in laboratory medicine is associated with a host of compliance issues and government regulations. Reflexive testing is associated with many advantages for patients and their physicians, but if not adequately organized it has the potential for inefficient test ordering and abuse by physicians and laboratories. Patient-specific narrative interpretations in laboratory medicine, much more than fixed comments generated by a computer with a specific test result, also provide clinical and financial benefit when done effectively. Regulations exist to ensure that the physician-provided information has clinical value. This report describes the compliance and billing regulations regarding reflex testing and narrative interpretations. The codes used for narrative interpretations in laboratory medicine are also presented, as well as the use of those codes to obtain payment for the interpretation provided.*

During the past decade, there has been a dramatic increase in the number of available laboratory tests, including many expensive genetic analyses. As the number of test options and the demand for cost containment increase, the need for advice on test selection and interpretation expands.<sup>1,2</sup> Reflexive testing permits physicians to obtain relevant laboratory results without having to order individual tests to arrive at a definitive diagnosis. Reflex testing and a comprehensive, patient-specific interpretation of the test results can substantially improve the quality of care and reduce the cost per case<sup>3</sup> by decreasing the time to diagnosis, the number of tests ordered, and the number of patient visits.<sup>4</sup> In addition, interpretations provide a new source of professional revenue for the expert physician.

The results from the clinical laboratories help clinicians determine diagnoses, therapies, and future clinical studies needed. If the laboratories are used inappropriately or run inefficiently, poor case management and increased cost per patient can result.<sup>5</sup> Therefore, it is important to augment the current laboratory services by providing valuable information about test selection and result interpretation to the physicians ordering the tests.

The objectives of this article are to present (1) the regulations related to reflexive testing in the clinical laboratories, (2) the components of narrative interpretations that are necessary for billing, (3) the policies to maximize the billing potential for clinical laboratory interpretations, and (4) the elements of a valuable and informative narrative interpretation of laboratory test results. **Figure 1** depicts the sequence of events in a clinical laboratory service. The sequence is more fully described in the following sections.



**Figure 1** Series of events from test ordering for clinical laboratory assays.

## Test Performed With or Without Reflex Testing

The laboratory tests are ordered, and the clinical laboratory performs them with or without the use of a reflex algorithm, depending on the request by the ordering physician, who can select either option. There are 2 types of reflex testing. The most common type is the “standard of care” or “universally applied” series of reflex tests. One example of this is the standard bacterial culture, in which an initial routine culture is performed, and if clinically significant organisms are found, reflexive testing occurs for antibiotic susceptibility without a second request from a physician. Another example is an automated WBC differential with a preprogrammed instrument flag, which reflexes to a manual WBC differential.

The second type of reflex testing is “institutional” or “locally applied.” This type is developed within a specific institution based on its individual standards of clinical practice. There are several examples of local reflex tests in our institution. One is used for an evaluation of a prolonged partial thromboplastin time (PTT). This workup begins with the PTT, followed by a PTT mixing study, and then by factor assays or inhibitor assays. The PTT mixing study determines whether there is a factor deficiency or an inhibitor, and the results of the factor and inhibitor assays usually identify the cause of the prolonged PTT. Another example of locally applied reflex testing involves the thyroid stimulating hormone assay.<sup>6</sup> A high value leads to reflexive testing for thyroxine ( $T_4$ ) and a thyroid hormone binding index. The medical policy committee of the institution must approve these locally applied reflexive testing protocols and establish that they are based on medical necessity and clinical manifestations.

There are 2 compliance issues related to reflexive testing: (1) The physician should be aware before ordering the algorithm(s) which tests are included in the algorithm and the criteria for reflex. This information can be available through the policy committee, on the requisition, or in the order entry

system. (2) The physician should have the option of ordering the secondary tests independent of the reflexive protocol.<sup>7</sup>

If locally applied reflexive testing is not approved in the institution, only the tests ordered may be performed. Therefore, if there is an abnormal or unexpected finding, the patient must return for follow-up tests, and the clinician must order exactly the correct tests. This challenges a clinician, with the immense burden of time, cost, and knowledge limits about the available tests, to know which tests are most cost-effective and provide the most valuable clinical information in the shortest time. Returning to the example of the prolonged PTT, if reflexive testing is not used, at least 3 blood specimens most likely would be required from the patient at separate times, and the clinician might need to order as many as 9 tests to diagnose a simple factor deficiency. Reflexive testing would require 1 specimen from the patient and many fewer tests to arrive at the same diagnosis.

Test selection is difficult to govern, but it is a behavior that can be changed. A meta-analysis found that to limit the number of tests ordered, an intervention that addressed multiple behavioral issues, such as identifying specific guidelines for test selection through a group of expert physicians at the institution and educating physicians on proper test selection, could change the behavior of the ordering physician.<sup>8,9</sup>

## Interpretation Based on Test(s) Performed Is Provided Routinely or on Request

An anatomic pathologist automatically provides a patient-specific diagnostic interpretation of a histologic preparation of a biopsy for a surgeon. An expert interpretation of a computed tomography scan showing a lung mass is provided automatically by a radiologist. However, nearly all clinical laboratories provide primary care physicians with only numbers and yes-no type answers for complex batteries of tests without a patient-specific narrative interpretation by an expert physician. This places the responsibility of test selection and interpretation on the primary care physician for more than 1,000 tests in all areas of medicine. (See the article by Dighe et al, page 123, for examples of narrative interpretations in a variety of areas in laboratory medicine.)

Recognizing the importance of interpretive information from a pathologist for laboratory results, Medicare approved a number of *Current Procedural Terminology* (CPT) codes. When billed with the -26 modifier, the codes allow physicians to bill for their interpretations. The list of these laboratory codes is shown in **Table 1**.<sup>10</sup> Billing and reimbursement for interpretations is a separate function from the technical component.

As with the technical component, documentation of the physician interpretation must be included in the patient's record and meet current billing compliance rules. The key elements of an interpretation for clinical laboratory test results that make it billable are as follows: it is patient specific, the test results are correlated with a clinical condition, a diagnosis and/or a recommendation demonstrating clinical judgment or expertise is provided to the ordering physician, the interpretation is signed by the physician either by hand or electronically, and the interpretation is filed in the patient's medical record.

Based on these criteria, it is important to note that generic information, such as an excerpt from a package insert, does not qualify as a narrative interpretation, and the pathologist cannot bill for such an interpretation. If a -26 modified CPT code exists for the laboratory test results, the medical policy committee at the institution must provide approval for a standing order to bill for these services. If a standing order exists, the ordering physician does not need to request an interpretation to permit use of one of the -26 modified CPT codes for billing. If no -26 modified CPT code exists and the desired interpretation is not associated with another specific code, then an interpretation may be provided and billed through the limited clinical pathology consultation (code 80500) or the comprehensive clinical pathology consultation (code 80502), depending on which is more appropriate. The choice is determined by the level of pathologist activity on the case. When these codes are used, the physician's request must be documented, and there cannot be a standing order for this type of consultation. At our hospital, an interpretation often is provided without a -26 modifier in the field of toxicology when addicted women are pregnant, and a neonatal toxicology evaluation is ordered.<sup>10</sup>

### Payer Is Billed for Services Provided

A qualified laboratory physician must provide the narrative interpretation. Even though a resident can be involved in the generation of the narrative report, the resident cannot sign out the interpretation. Interpretations provided by a technologist or a clinical laboratory scientist with a PhD cannot be billed. As with all billing activity, payers require specific information associated with the case and the professional before they will reimburse the practice organization. These include the patient's name; the ordering physician's name; the name of the physician performing the interpretation; the date of service; the CPT code for interpretation, which could be a -26 modified code; and the diagnosis code from the *International Classification of Diseases, 9th Revision*.

Reimbursement for the interpretation is based on prevailing fee schedules published by payers, analogous to the

**Table 11**  
**Clinical Laboratory Interpretation Codes**  
**With the -26 Modifier<sup>10</sup>**

Code	Description
86320-26	Immunoelectrophoresis, serum
86325-26	Immunoelectrophoresis, other fluids
86327-26	Immunoelectrophoresis, 2-dimensional
86334-26	Immunofixation electrophoresis
87162-26	Darkfield examination, any source
87207-26	Smear, primary source, for inclusion bodies/parasites
88371-26	Protein analysis by Western blot, interpretation
88372-26	Protein analysis by Western blot, with probe, interpretation
89060-26	Crystal identification by light microscopy
83020-26	Hemoglobin, electrophoresis
83912-26	Nucleic acid probe, each with examination and report
84165-26	Protein, electrophoretic fraction and quantitation
84181-26	Western blot interpretation
84182-26	Western blot interpretation, immunological probe for band identification, each
85390-26	Fibrinolysis or coagulopathy screen interpretation and report
85576-26	Platelet aggregation (in vitro), each agent
86255-26	Fluorescent antibody, screen, each antibody
86256-26	Fluorescent antibody, titer, each antibody

billing for technical laboratory components. Medicare has assigned relative value units (RVUs) for each of the CPT codes acceptable with a -26 modifier. The RVUs were established with the same method used to establish RVUs for all professional services. They are generally based on the practice expense and malpractice expense and are adjusted for local variances. Medicare's reimbursement is determined by the unit payment per RVU and is published in its fee schedule.<sup>11</sup>

Before billing for narrative interpretations in laboratory medicine, the attending physician must establish himself or herself as a billing entity within the institution, with the understanding that additional credentials may be necessary. It is also important for the physician to understand the mechanics of the billing system, including the internal billing system of the institution and the billing agency, to comprehend hidden complexities, streamline the process, maximize revenue, and avoid common mistakes. It is equally important for physicians to receive compliance training to avoid mistakes in coding and billing. The ideal provider of such training is the compliance officer at the institution.

Other compliance recommendations include the avoidance of "up-coding."<sup>7</sup> This practice involves the use of a code that is less specific to the case but is associated with a higher payment. Also, as might be expected, it is essential to avoid interpretations that seem unnecessary and do not enhance the referring physician's ability to treat the patient. The value of this type of interpretation may be questioned during an audit, and any payments received for the service may be reviewed by the payer. Therefore, it is better to interpret only the cases in which clear clinical value is provided.

The internal compliance officer at the institution should review and accept billing protocols that include the appropriate information and correct CPT code. Billing for computer-generated comments without physician review of the case is an important item to avoid, as noted earlier, as physician reviewers are essential to meet compliance recommendation. Only the physician performing the interpretation can bill for it.

## Collection of Revenue for Professional Services Provided

Among the recommendations for maximizing collection of revenue, it is important to track the rejections for payment and identify the cause for the rejection. In tracking the rejections, it is helpful to sort them by payer and by CPT code. One strategy for tracking rejections is to identify the highest dollar value cases in which the payer did not reimburse for the services provided and identify the reason for the rejection. If the rejection is based on payer-specific reimbursement rules, a discussion about the rules for reimbursement and opportunities to adjust the rules based on current practice should occur. The payer may be willing to rectify the problem for that particular case and to recommend strategies to avoid these mistakes in the future for cases that follow a similar pattern.

Common causes of payment rejections include missing or invalid information, such as a missing -26 modifier, an invalid diagnosis code, and exceeding the filing limit for posting the charge. Even if a CPT code is documented in a fee schedule, it does not guarantee that an institution will receive payment by the payer. Payments also can be rejected if patients have reached the maximum coverage of their benefit plans; the location in which the services were provided is not recognized as a suitable site (this is especially important with transfusions in an outpatient hospital setting, which is usually not covered by Medicare, as opposed to a clinic, which is covered by Medicare); and the diagnosis code is not appropriate for the services provided, according to the payer.

## Conclusion

Most clinical laboratories perform a number of tests that can be billed under the CPT -26 modified codes. Most notably these include hemoglobin electrophoresis, antinuclear antibody screening and titer evaluations, WBC differentials, and serum protein electrophoresis. In these cases, payment can be received for reports that interpret bands, images, or cells that are present. Interpretive services for

complex laboratory test results, independent of special requests from clinicians, provide substantial visibility to pathologists and value to the ordering physician. The interpretation, if it is concise and beyond the knowledge of the ordering physician, makes the clinical pathologist essential for achieving optimal patient care.

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## References

1. Burke MD. Laboratory medicine in the 21st century. *Am J Clin Pathol.* 2000;114:841-846.
2. Burke MD. Clinical laboratory consultation. *Clin Chem.* 1995;41:1237-1240.
3. Laposata M. Providing value-added services. *Advance for Administrators of the Laboratory.* 2000;9:14-15.
4. Smith BJ, McNeely MDD. The influence of an expert system for test ordering and interpretation on laboratory investigations. *Clin Chem.* 1999;45(8 pt 1):1168-1175.
5. van Walraven C, Naylor CD. Do we know what inappropriate laboratory utilization is? a systematic review of laboratory clinical audits. *JAMA.* 1998;280:550-558.
6. Nurdyke RA, Reppun TS, Madanay LD, et al. Alternative sequences of thyrotropin and free thyroxine assays for routine thyroid function testing. *Arch Intern Med.* 1998;158:266-272.
7. College of American Pathologists. *Compliance Guidelines for Pathologists.* Northfield, IL: College of American Pathologists; 1998;14-15, 47.
8. Solomon DH, Hashimoto H, Daltroy L, et al. Techniques to improve physicians' use of diagnostic tests: a new conceptual framework. *JAMA.* 1998;280:2020-2027.
9. Lundberg GD. Changing physician behavior in ordering diagnostic tests [editorial]. *JAMA.* 1998;280:2036.
10. Health Care Financing Administration. *Carrier's Manual Part 3.* Chapter XV, Section 15020. Available at <http://www.hcfa.gov>. Accessed August 6, 2001.
11. Health Care Financing Administration. *Carrier's Manual Part 3.* Chapter XV, Section 15006. Available at <http://www.hcfa.gov>. Accessed August 6, 2001.