

# Enforcement of CLIA and Billing Regulations

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As most laboratorians are painfully aware, the laboratory is already a highly regulated healthcare service, and is becoming increasingly so. While we support regulation that ensures that we provide high quality services and keeps our patients safe, we may also be challenged by the time demands of the details that compliance requires.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) were intended to ensure that patients receive accurate, reliable test results regardless of the setting in which their tests are performed. The Center for Medicare and Medicaid Services (CMS) has responsibility for administering the CLIA regulations. The Office of Inspector General (OIG) looks for areas of non-compliance and has the authority to take enforcement action. Each year the OIG publishes a "work plan" that lists areas of concern that they expect to focus on in the coming year. The work plan is lengthy and covers many areas of healthcare. In this article we will discuss those from the 2004 work plan that are of most direct interest to the laboratory.

- Laboratory Proficiency Testing: OIG will assess laboratory compliance with CLIA requirements to participate in proficiency testing. Proficiency testing is a statutorily mandated condition of participation in which laboratories are graded for their accuracy in analyzing clinical specimens. It is one of the primary mechanisms for ensuring quality testing. Medicare pays over \$4 billion annually for clinical laboratory services, all of which must meet CLIA requirements.

Laboratories performing moderate and high complexity testing (CLIA categories) are required to participate in proficiency testing for all analytes they perform. If external proficiency testing is not available, the laboratory must find some

other way to verify accuracy of results (such as exchanging samples with another laboratory, or sending samples to a reference laboratory.) Proficiency testing results for those analytes classified as "regulated" under CLIA must be reported to CMS.

Presumably, OIG will be looking to ensure that laboratories are performing proficiency testing for all analytes for which they are billing (other than tests sent to reference laboratories). They may also tighten up scrutiny of PT results, since poorly performing laboratories are subject to exclusion from participation in the Medicare program.

- Clinical Laboratory Testing Outside Certified Specialties: OIG will determine the extent to which Medicare paid for any testing outside the scope of a laboratory's CLIA certification. Laboratories must be certified for each specialty in which testing is conducted; however, certifying additional specialties can raise the cost of certification. Medicare currently does not compare billed testing with CLIA specialty certification before paying claims. OIG will compare claims with certification records to quantify any improper payments and lost CLIA certification fees, as well as evaluate existing programmatic controls.

In this work plan element, OIG is quite specific about what they intend to do to examine laboratories' certification compared with their billing.

Since 2001, CMS has been surveying a sample of laboratories performing waived testing. Waived laboratories are not subject to inspection under the CLIA regulations, unless there is some suspicion of quality problems. When educational visits to a small number of waived laboratories turned up a number of quality problems, CMS expanded the visits to more laboratories in more states. The types of quality problems found were detailed in Washington Beat in the Winter 2001 issue of *Clinical Laboratory Science*.

The other common problem that CMS has found in these visits is that almost 25% of laboratories are performing testing beyond the scope of their CLIA certificate, that is, waived laboratories may be performing moderate complexity or even

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high complexity testing. It is also possible that hospital laboratories, which typically are classified as high complexity, may add an area of testing and overlook the need to add that specialty to their CLIA certificate. Or, as a result of mergers, laboratories may reduce their scope of testing and neglect to remove the affected specialties from their certificate.

- **Hospital Laboratory Services:** OIG will evaluate whether hospitals separately billed Medicare for laboratory services that were already included in their ESRD (End Stage Renal Disease) composite rate. Under Medicare's composite rate reimbursement system, ESRD facilities are reimbursed at 100% of their costs. Because laboratory services are paid for under the composite rate, hospitals should not separately bill for those services.

The regulations for billing samples on patients covered by the ESRD program are too complex to delineate here. Close collaboration among the dialysis center, the laboratory, and the billing office is required to ensure that regulations are not violated.

Another item on the work plan not specifically targeted at the laboratory may have impact nonetheless:

- **Use of Modifiers with National Correct Coding Initiative Edits:** OIG will determine whether claims were paid appro-

priately when modifiers were used to bypass National Correct Coding Initiative Edits. The initiative, one of CMS's tools for detecting and correcting improper billing, is designed to provide Medicare Part B carriers with code pair edits for use in reviewing claims. A provider may include a modifier to allow payment for both services within the code pair under certain circumstances. In 2001, Medicare paid \$565 million to providers who included the modifier with code pairs within the National Correct Coding Initiative. OIG will determine whether modifiers were used appropriately.

Laboratories that work closely with their billing departments to resolve claims problems, either retrospectively or prospectively, may have noted an increasing need to use modifiers in order to be paid for all services. One example is common in hospital laboratories that serve a same-day surgery service, where a patient may have a hemogram pre-operatively, and a hemoglobin post-operatively, or perhaps a basic metabolic panel early and a potassium later in the same day. The CCI edits will reject these as duplicate charges on the same date of service, and the addition of a modifier is necessary in order to be paid for both tests. OIG intends to look at the use of modifiers, making laboratories susceptible to audits in this process. Proper use of modifiers should be easily defensible.

OIG also proposed a modified regulation on pricing for laboratory services in the September 15, 2003 Federal Register. That will be the topic of a future article.

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