COMPLIANCE PERSPECTIVES

Laboratory Compliance Hot Button Issues

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Government enforcement efforts in the 1990s focused criminal and civil investigations on national clinical laboratories for billing and marketing practices that caused the submission of false claims or violations of the federal anti-kickback statute. Some of the allegations involved tests not performed, tests not actually ordered, unbundled test billings, routine standing orders, and add-on tests that were medically unnecessary. Many of the large national laboratories companies settled laboratory false claims billing allegations under the civil False Claims Act and entered into Office of Inspector General (OIG) corporate integrity agreements (CIAs).

In 1998, the OIG issued compliance guidance for clinical laboratories that identified billing and marketing practices that may result in administrative, civil, or criminal sanctions. Some of the practices that were identified included free products or services to physicians or hospitals, misleading marketing that failed to inform the physician, hospital, or patient of all the tests included in panels or profiles, overreliance on standing orders that were not necessary for the condition of the patient, and failing to properly process specimens.

Many of the abuses in the laboratory industry as they relate to billing and coding issues have diminished as a result of government investigations and the industry's response in compliance safeguards.

More recently, however, there has been a renewed focus on laboratory billings and laboratory quality assurance standards at independent laboratories as well as hospital laboratories. There is also an increasing recognition by the government and other enforcement agencies that the compliance efforts of the 1990s do not ensure that the industry is cured of all compliance issues, and there is a greater emphasis on evaluating "effective" compliance programs and strategies.

Recent Laboratory Prosecutions

The government has continued to predominantly use the False Claims Act and its multiplier damages to address laboratory compliance issues related to nursing home services, hospitals, and other healthcare providers.

Since 2003 there have been several False Claims Act settlements involving laboratory practices. In March 2004, Quest Diagnostics settled False Claims Act allegations, paying over $11 million to resolve allegations that it defrauded the United States by billing Medicare for medically unnecessary tests. The medically unnecessary tests included apolipoproteins, which are part of profiles in panels relating to coronary testing, urine microscopy exams, and calcium tests. The government alleged that Quest automatically calculated "free" thyroid test panel indexes that should have been included as part of disease test panels.

In April 2004, Health Line Clinical Laboratories paid $10 million to settle allegations that its billing practices defrauded Medicare and Medicaid from 1996 to 2003 (*see related article, pg. 1*). The allegations were made by two former sales representatives who brought whistleblower suits under the civil False Claims Act. The allegations involved unnecessary blood tests added to blood-test panels and profiles ordered by physicians.

Genesis Clinical Laboratory, owned by MacNeal Health Services, was a subject of a whistleblower suit under the False Claims Act relating to allegations that its laboratory requi-

sition forms improperly bundled tests, encouraging physicians to order tests that were not medically necessary.

Abington Memorial Hospital, near Philadelphia, settled a False Claims Act suit that alleged it submitted over 70,000 false claims related to outpatient clinical laboratory tests. The hospital allegedly submitted claims that unbundled or duplicated charges for blood chemistry tests and more than 10,000 claims for blood tests for auditing iron binding capacity that were not medically necessary as add-on tests. The government alleged there was double billing of platelet counts and hematology profiles and unbundling of two hematology procedure codes. The Abington settlement is significant because the government alleged the hospital failed to respond to internal compliance questions about hospital laboratory operations by self-auditing its outpatient laboratory billings to Medicare and failed to undertake any sample review of individual laboratory complaints.

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OIG 2004 Work Plan

Laboratory compliance issues have frequently been viewed as billing issues, but, increasingly, quality of care issues have received notice. There have been False Claims Act whistleblower suits alleging substandard or poor quality laboratory testing, which is actionable under the False Claims Act as a "worthless service." Medicare pays over $4 billion annually for clinical laboratory services, all of which must meet condition-of-participation requirements.

The OIG 2004 work plan indicates that it will undertake a study to determine whether Medicare pays for any testing outside the scope of a laboratory's Clinical Laboratory Improvement Act (CLIA) certification. Laboratories are required to certify for each specialty in which testing is conducted. Some laboratories have been certifying additional specialties, which raise the cost of certification. Currently, Medicare does not reconcile billed testing with CLIA specialty certification before paying claims and, therefore, may be overpaying certain laboratory claims. The OIG will compare claims of certification records to quantify whether there is any improper payment or any loss CLIA certification fees.

The OIG will also evaluate laboratory compliance with the CLIA 1988 requirements to participate in proficiency testing. Proficiency testing is required as a condition of participation in which laboratories are graded for their accuracy in analyzing clinical specimens. The OIG is not simply concerned with independent clinical laboratories. The 2004 OIG work plan will evaluate whether hospitals separately bill Medicare for laboratory services that are already included in their end-stage renal disease composite rate (ESRD). Under Medicare's composite-rate reimbursement system, the ESRD facilities are reimbursed for 100% of their cost. Hospitals that separately bill laboratory services relating to ESRD services are in effect double billing the Medicare program.

The OIG will also undertake a review to determine the extent and nature of any medically unnecessary or excessive imaging and laboratory services provided to nursing home residents. Medicare pays more than $200 million a year for imaging and laboratory services in nursing homes, and it will undertake a sample of services and utilization patterns for nursing facilities. This is an area where routine standing orders have been in place and may be subject to scrutiny.

Increased Scrutiny

The concern regarding laboratory test quality is not limited to the OIG or federal prosecutors in the U.S. attorneys' offices. CMS has indicated that it will conduct on-site inspections of laboratories, particularly laboratories with waivers that allow them to perform routine testing without regular federal review. As a part of reviews undertaken in Ohio and Colorado in 2002, CMS identified a pilot program that would expand CLIA in-

spections to eight states because of concerns regarding significant quality and certification problems.

Even the Environmental Protection Agency has focused its enforcement eye on New England facilities after finding numerous environmental violations at hospital laboratories.

Maryland General Hospital: Laboratory Compliance Gone Awry

Laboratory quality problems uncovered recently at Maryland General Hospital (Baltimore) provide a powerful illustration of the kind of mistakes that could provoke criminal and civil investigations, not to mention a public health crisis. Maryland General Hospital is a 245-bed facility affiliated with the University of Maryland Health System. Over a two-year period, numerous laboratory technicians advised supervisors that the laboratory blood analyzer machine was malfunctioning and providing questionable results. They also reported concerns regarding lab-billing practices. The laboratory quality issues were a source of considerable internal controversy at the hospital before being brought to the attention of hospital management and to the Maryland Office of Health Quality, which is responsible for state oversight of hospital operations.

What happened at Maryland General Hospital may have national repercussions for hospital laboratories

The lab technicians reporting the laboratory testing deficiencies were not taken seriously, and no corrective action was undertaken in response to their concerns. It is reported that a climate of intimidation existed in which hospital employees felt that they would lose their jobs if they pursued the allegations. Additionally, during this time, state surveys of the hospital lab were conducted but found no serious deficiencies. The accrediting agency also undertook a review that found no serious deficiencies.

However, in March 2004, Maryland Hospital revealed that over 340 HIV tests were conducted improperly, and said that patients would have to be notified of inaccurate results. Other testing deficiencies became public thereafter. It is reported that state inspectors have subsequently found that test data may have been manipulated or eliminated and that manufacturing standards may not have been followed.

What happened at Maryland General Hospital has become a public health scandal, one that could have been avoided had the hospital listened to its laboratory technicians. The incident may have national repercussions for hospital laboratories. Recriminations aside, an effective compliance program could have resulted in a more timely and appropriate response to the testing deficiencies and avoided a public health crisis in the Baltimore area. It is reported that the hospital is now under criminal investigation by the Maryland Medicaid Fraud Control Unit, as well as other state and federal enforcement agencies. Congressman Elijah Cummings (D-MD) has commenced congressional hearings on the efficacy of the state inspection process and the reliance on outside accrediting bodies to detect and report quality assurance issues. During the two-year period that the hospital employees were reporting laboratory overbilling and quality-assurance concerns, the accrediting agency was rating the hospital laboratory as in good standing.

There is a growing concern among state and federal regulators that laboratory quality assurance issues are a big problem. This concern will capture the attention of government prosecutors and whistleblowers and launch False Claims Act investigations against independent and hospital laboratories. It is a good bet that laboratory billing and quality-assurance issues will be a focus of future government enforcement efforts. Laboratories that have compliance programs should consider a meaningful evaluation of the effectiveness of their compliance activities in light of recent enforcement developments.

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