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Federal Compliance Blitz: Enforcement Challenges Ahead for Labs and Pathologists

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Given the federal government's recent efforts to step up its fraud enforcement, now is a good time for all health care providers, including clinical laboratories and pathologists, to review policies and procedures to ensure they are in compliance with all applicable laws and regulations, advises Hope Foster, an attorney with Mintz Levin in Washington, D.C.

Foster addressed the challenges ahead during Washington G-2 Reports' 28th Annual Lab Institute, held in Arlington, Va., Oct. 13-15.

In the past 18 months, lawmakers have passed a number of laws giving the feds increased enforcement authority, including the Fraud Enforcement and Recovery Act of 2009 (FERA) and the Patient Protection and Affordable Care Act (PPACA). In May 2009 the departments of Justice and Health and Human Services announced a new interagency initiative to combat Medicare fraud—the Health Care Fraud Prevention and Enforcement Action Team (HEAT).

In fall 2009, President Obama announced a new interagency financial fraud enforcement task force and proposed a budget of $1.7 billion for the Health Care Fraud and Abuse Control Program (HCFACP). And in March 2010, the president issued a memorandum regarding finding and recapturing improper payments, which effectively expanded the use of payment recapture audits.

"Follow the money," notes Foster. "If you want to see what the government cares about, see where it's spending its money. And if it's spending more money on enforcement, it means there will be more enforcement."

These new initiatives, taken together with laws and regulations already in place, amount to one of the toughest health care fraud enforcement climates in a number of years, says Foster. Among key changes:

The anti-kickback intent standard has been revised. Under the new standard, a person need not have actual knowledge of the law or specific intent to commit a violation. Essentially this lowers the level of intent required to provide a violation.

PPACA adds language linking anti-kickback violations to the False Claims Act. PPACA also makes changes to the FCA, which under

certain circumstances, bars qui tam cases based on "publicly disclosed" allegations unless the individual bringing the suit was the "original source" of the information. Under PPACA, the government can oppose dismissal of such a qui tam case. In addition, the law further defines "public" as being at the federal level.

PPACA changes the threshold for qualifying as an original source under the FCA, modifies the requirements that the relator has "direct and independent knowledge," and mandates that for prefiling disclosures, the relator must have knowledge of the information that is "independent of" and that "materially adds to" the previously disclosed information about the allegations or transaction.

CMS has tried to address some of the problems related to the Stark prohibition on self-referrals, including highly detailed rules, strict liability, mandatory compliance with exceptions, link to FCA, and potentially ruinous penalties for de minimis violations. In March 2009, the HHS Office of Inspector General announced that there would be no Stark law self-disclosure under its self-disclosure protocol unless there was a "colorable anti-kickback violation." As a result, CMS on Sept. 23 published its own voluntary self-disclosure protocol to address violations of the Stark law (*see related article on p. 4*).

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PPACA provides a new exception under the Stark law for "[R]emuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs." This applies to items and services related to the medical care of the patient, when there is a good-faith determination that the patient is in financial need.

PPACA requires that Medicare and Medicaid overpayments must be reported, explained, and returned to the appropriate entity within 60 days after identification or on the date any corresponding cost report is due, whichever is later.

PPACA expands the types of conduct subject to CMPs to include failing to provide the OIG timely access for audits, investigations, or certain other statutory functions; knowingly making, using, or causing to be made or used a false record or statement material to a false claim for payment for items or services; knowingly making a false statement, omission, or misrepresentation on an enrollment application, bid, or contract; and ordering or prescribing items or services (including lab tests) during any period when the person ordering or prescribing has been excluded.

PPACA also requires establishment of a compliance program as a condition of enrollment under the Medicare and other federal health programs, eliminates limitations on prepayment review, and expands the Recovery Audit Contractor program to cover Medicaid and Medicare Parts C and D.

Laboratory Compliance Issues

All of the enforcement changes made in the past year and a half have the potential to affect laboratories and pathologists, notes Foster. In fact, laboratory-related compliance issues reach all aspects of laboratory operations, including sales and marketing, relationships with referrers and those who arrange for and recommend referrals, test ordering, test performance, test reporting, and billing.

Labs should carefully consider relationships with referral sources, says Foster, noting that this is a fertile area for enforcement. "I spend a lot of time looking at relationships because there has been a significant uptick in enforcement in this

area," she says, adding that both the AKS and the Stark law are implicated. Recent laws have expanded the definition of "inducement," the definition of "remuneration," and enforcement of "arranging for" or "recommending" prohibitions.

In terms of test ordering, labs must consider the identity of the test orderer, clarity of the test order, need for individualized test orders, provision of complete information (including diagnosis information), procedures for obtaining missing information, provision for memorializing the receipt of missing information, add-on requests, and retention of information.

Test performance issues include compliance with CLIA or other applicable performance standards, compliance with manufacturer's label or with CLIA validation requirements if procedure is modified, compliance with CLIA validation requirements for laboratory-developed tests, compliance with requirements applicable to proficiency testing, and licensure of test-performing personnel.

Questions that labs must answer when determining compliance with test reporting requirements include: To whom is the report sent? Can reports be sent to patients? How do you respond to requests for copies of reports? What does the report say? Can the verbiage be construed to be the unauthorized practice of medicine? Have all tests for which results are reported been ordered?

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Potential trouble spots in billing include identification of the proper party to bill, billing an inappropriate party, billing for tests not performed, billing for tests not ordered or improperly ordered, and use of improper CPT codes. In addition, labs must avoid diagnosis code steering or jamming, billing for services ordered pursuant to an inappropriate or unlawful referral, knowingly billing for uncovered services, and billing for medically unnecessary services and tests of inadequate quality.

"These are real issues that labs have problems with," stresses Foster. "I have defended labs in all of these areas. They are not to be taken lightly."

Ms. Foster is a member of Mintz Levin's Health Law Practice, serves on the firm's Policy Committee and chairs the firm's Health Care Enforcement Defense Group