G-2 Compliance Report

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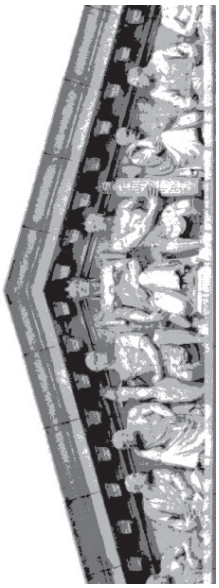
For Hospitals, Laboratories and Physician Practices



FDA To Allow Experimental Tests Without Consent

Effective June 7, the Food and Drug Administration (FDA) began allowing healthcare workers to use investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in the event of a public health emergency.

Under the interim final rule, published in the June 7 *Federal Register*, healthcare workers can conduct experimental tests on blood or other samples from individuals who become ill after a bioterrorist attack, suspected pandemic flu outbreak, natural disaster, or other potentially life-threatening public health emergencies. Laboratories that perform the experimental tests must determine when a public health emergency occurs.

According to the FDA, the rule is necessary to ensure that public health officials can identify chemical, biological, radiological, or nuclear agents or infectious diseases in the event of a terrorist attack or emerging pandemic. Generally, informed consent must be obtained before an investigational in vitro diagnostic device may be used unless an exception applies. ➥ *p. 2*

Labs To Be Excluded From Phase I Of MUEs

The Centers for Medicare and Medicaid Services (CMS) plans to significantly scale back its planned implementation of medically unbelievable edits (MUEs), according to an agency official.

Kimberly Brandt, director of CMS's Program Integrity Group, told representatives of the American Clinical Laboratory Association (ACLA) during a May 25 meeting that the revised MUEs will be much less restrictive than the current proposal, noting that the unit-of-service edits during the initial phase-in will focus largely on anatomic anomalies and obvious typographical errors.

According to ACLA's understanding, no laboratory or pathology codes will be included in the Phase I edits that will be implemented in January 2007. Instead, CMS will establish a separate process and timeline for defining which laboratory and pathology codes should be subject to MUEs, working with the appropriate communities in defining criteria. This more narrowly defined set of pathology and laboratory MUEs would not be effective until mid- to late 2007, according to ACLA.➥ *p. 9*

Inside this issue

Comments on the interim final rule will be considered if submitted by Aug. 7, 2006.

FDA To Allow Experimental Tests, *from p. 1*

The agency posits a scenario in which a terrorist event is not suspected until a public health laboratory cultures an unusual or rare organism. When a patient presents to a healthcare facility symptoms suggesting a systemic microbial infection, blood and other specimens are typically collected to determine the identity of the causative organism, the FDA explains.

In this case, the clinical laboratory would determine that the specimens contain an unusual organism that cannot be identified by the tests available in that laboratory. Because many clinical laboratories do not have the capability or resources to identify unusual organisms or those to which humans are rarely exposed naturally, the organism or collected specimen would be referred to a public health laboratory. The public health lab would use in vitro diagnostic devices, including those that are investigational, to try to identify the cultured organism or detect its presence directly in the specimen.

In this scenario, the referring laboratory would not have obtained informed consent when the specimen was collected because the person directing the specimen collection would not have known at the time that the infecting organism could be reliably identified only by using an investigational device, the agency explains in its notice. To obtain informed consent would require a number of steps and introduce unacceptable delays, it says.

Other Examples

The scenario described is just one example and is not the only set of circumstances in which this exception to informed consent might apply, according to the FDA. The new exception would also apply if the event were not terrorism-related but was another type of potential public health emergency, such as sporadic outbreaks resulting from the spread of an emerging infectious agent that has the potential to cause a life-threatening situation.

This rule would not apply in a situation that is not life threatening or where there is a cleared or approved available alternative method of diagnosis that provides an equal or greater likelihood of saving the life of the subject, such as the in vitro diagnostic devices for identifying agents causing certain known sexually transmitted diseases, such as *Chlamydia trachomatis, Neisseria gonorrhoeae*, human papillomavirus, and HIV.

The emergency nature of the event may or may not be suspected at the time the specimen is collected. Even if the nature of the event is suspected, the person collecting the specimen may not know the investigational status of the in vitro diagnostic device and thus would not know that informed consent should be obtained from the patient.

Privacy advocates believe the rule is unnecessary and might lead to conflict of interest or abuses. "This sounds like they're taking for themselves the right to test individuals every time they declare a public health emergency," Deborah Peel, chair of the Patient Privacy Rights Foundation, told the *Minneapolis Star Tribune*. "There is no way getting consent would delay testing."

Resources

- Interim final rule, June 7, 2006, *Federal Register: www.gpoaccess.gov/fr/index.html*

In Vitro Diagnostic Devices

Most in vitro diagnostic devices used to identify chemical, biological, radiological, or nuclear agents used in terrorism have been developed by the Centers for Disease Control and Prevention and the Department of Defense. Some nongovernmental entities are also developing such devices.

Many of these devices have not yet been approved or cleared by the FDA because clinical studies involving devices used for the identification of such agents frequently cannot be conducted, says the FDA. Studies may not be possible because natural exposure to these agents is rare or never occurs, and there may not be enough exposed subjects to enroll in a study.

Studies also may not be possible because it is not ethical to expose healthy human volunteers to a life-threatening toxic substance or organism to determine the ability of the unapproved device to correctly identify the agent. While these unapproved devices may not have been evaluated on specimens collected from human subjects, testing validation and other analytical studies generally have been conducted (or are being conducted) by the sponsors.

National Labs Subpoenaed Over Medi-Cal Billing

Three large national clinical laboratories—Quest Diagnostics (Lyndhurst, NJ), Laboratory Corporation of America (Burlington, NC), and AmeriPath (Palm Beach Garden, FL)—announced in May that they had received subpoenas from the California attorney general, seeking documents related to billings to Medi-Cal, the state's Medicaid program.

The labs announced the subpoenas in filings with the Securities and Exchange Commission. According to the filings, the subpoenas seek documents from various time frames ranging from three to 10 years. All three companies say they will cooperate with the California attorney general's office.

Little is known about what the attorney general, Bill Lockyer, is seeking. A spokesman for his office said he would "neither confirm nor deny" reports that the office is investigating the lab companies.

Michael Arnold, a consultant to the California Clinical Laboratory Association, declined to speculate about what the attorney general is after although he noted that this could be an important issue for the association. "We have been working hard over the years to make sure that reimbursement rates under the Medi-Cal program are sufficient to ensure high-quality laboratory services, and if the outcome of these activities makes that job more difficult, I'll be unhappy."

Gary Samuels, a spokesman for Quest, confirmed that the company had been served with a subpoena but could not comment further, other than to say that Quest is cooperating with the state AG's office.

Resource
Securities and Exchange Commission filings: *www.sec.gov*

Diagnostic Testing Execs Indicted In Fraud Scheme

Two former executives and a current employee of a Chicago diagnostic testing company were indicted on federal fraud charges for allegedly swindling thousands of investors out of millions of dollars, according to law enforcement authorities.

A federal grand jury on May 17 returned a 50-count indictment against the one-time executives of Buffalo Grove-based Efoora Inc., which with two subsidiaries, purported to be in the business of designing, manufacturing, and marketing rapid diagnostic tests for HIV, diabetes, mad cow disease, and chronic wasting disease in mules, deer, and elk.

As part of the alleged fraud schedule, the defendants gave staged tours of Efoora's facilities to potential investors and customers that included stacking, labeling, and arranging empty boxes for shipping, using temporary works, operating machinery that was not ordinarily in use, and assembling and packaging fake test kits in an attempt to show that the company was more productive and successful than it actually was.

Efoora issued and sold more than 100 million shares of stock ranging in price from 10 cents to $2.50 per share, raising more than $30 million from more than 3,000 investors, according to the indictment.

The defendants—David Grosky, Craig Rappin, and Melvin Dokich—were each charged with participating in a fraud scheme to deceive prospective and actual investors between the summer of 1999 and March 2006, said Patrick Fitzgerald, U.S. Attorney for the Northern District of Illinois. All three defendants will be arraigned at a later date in U.S. District

Court in Chicago.

The indictment also seeks forfeiture of alleged proceeds of at least $1.5 million from all three defendants and their residences as substitute assets. It also seeks an additional $478,548 from Grosky and Dokich, and an additional $311,000 from Dokich alone.

According to the indictment, Efoora attempted to develop diagnostic tests for commercial distribution in the United States. The HIV and diabetes tests required approval from the U.S. Food and Drug Administration (FDA) before they could be sold in the United States. Efoora was not able to obtain FDA approval to market the HIV test commercially and never submitted an application to the FDA for the glucose test.

The mad cow disease test and the chronic wasting disease test required approval from the U.S. Department of Agriculture (USDA) before they could be sold in the United States. Efoora never received USDA approval for the mad cow disease test, and although it did receive USDA approval for the wasting disease test in approximately March 2004, Efoora was not successful in marketing or selling that test.

The defendants allegedly schemed to fraudulently obtain money from prospective and actual investors by making false presentations and promises. In connection with the scheme, the defendants each personally obtained financial benefits from Efoora, including receiving millions of shares of Efoora stock.

If convicted, the mail and wire fraud counts each carry a maximum penalty of 20 years in prison and a $250,000 fine; some of the money laundering counts carry a maximum penalty of 20 years in prison, while others carry a maximum of 10 years and a $250,000 fine; and the structuring counts each carry a maximum of five years in prison and a $250,000 fine. As an alternative, the court may impose a maximum fine equal to twice the loss to any victim or twice the gain to any defendant, whichever is greater.

Resources

- U.S. Attorney for the North District of Illinois: 312-353-5300

HHS Relying On Voluntary Compliance To Enforce HIPAA

The Department of Health and Human Services (HHS) has received more than 19,000 grievances regarding alleged violations of medical privacy provisions in the Health Insurance Portability and Accountability Act (HIPAA), but the agency has levied no civil fines and prosecuted just two criminal cases, the *Washington Post* reports.

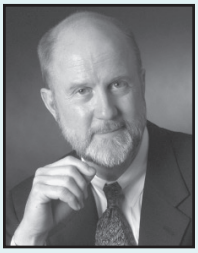
Since its implementation in 2003, HIPAA has guaranteed a uniform federal law for ensuring the privacy of medical records. HHS has the authority to impose fines for civil violations ranging from $100 to $25,000, and officials can refer possible criminal violations to the Department of Justice (DOJ).

The government has closed more than 14,000 of the 19,420 filed grievances, either ruling that a violation did not occur or allowing healthcare providers and insurers to correct violations voluntarily without issuing a penalty, according to the *Post*. At least 309 cases have been referred to the DOJ.

The most common allegations involve improper disclosures of medical records, inadequate security for records, failure to obtain authorization to disclose records, or difficulty for patients seeking to obtain their own records. An HHS spokesperson says the agency has conducted a "handful" of compliance reviews.

COMPLIANCE PERSPECTIVES

An Overview Of Federal Regulation Of Genetic Testing



James Wieland, Esq., is a principal in the health law group of Ober/Kaler (Baltimore, MD).

In the face of the developments of recent decades, the concept of "genetic testing" has drawn the attention of the public, the legislature, and the regulators alike. There are genetic tests available for, literally, hundreds of diseases. While there is no uniform definition, the federal government has defined a "genetic test" as "the analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect disease-related genotypes or mutations."

Tests for metabolites fall within the definition of genetic tests when an excess of deficiency of the metabolites indicates the presence of a mutation or mutations. Due to its perceived predictive power, genetic testing holds out a possibility of detecting, at the earliest opportunity, the possibility of disease.

Therein, of course, lies the issue that has attracted the attention of the public and the regulators: What are the permissible uses of such potentially powerful and intimate information about an individual? In addition—less from the public perspective but certainly from the regulatory perspective—is the question of how the quality of genetic testing should be addressed so that the results can be relied upon.

Fragmented Oversight

Federal regulation of this important subject is fragmented, at best. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) cover laboratories that offer genetic testing, requiring compliance with the personnel, quality control, and other recognized requirements to obtain CLIA certification. However, genetic testing is only recognized as a "specialty area," subject to additional standards for certification, in the area of clinical cytogenetics, the microscopic analysis of chromosomal abnormalities. Other than that, a laboratory offering genetic testing is at present subject only to CLIA's general standards.

The Food and Drug Administration (FDA) generally regulates genetic tests marketed as kits, such as in vitro diagnostic test kits. However, the majority of genetic tests performed by laboratories are so-called "home brew" tests (i.e., tests based on individual components/reagents assembled by the testing laboratory). Thus, while the components of the genetic test may be regulated by the FDA, the manner in which the components are assembled by the laboratory to actually perform the genetic test is not.

In 2000, President Bush signed Executive Order 13145, which prohibits discrimination in federal employment based on "protected genetic information"; information about an individual's genetic tests; the genetic tests of members of the individual's family members; or information about the occurrence of a disease, medical condition, or disorder in family members of the individual.

The Executive Order reflects one of the two overriding concerns about the use of genetic information in a discriminatory manner—that it will be used to make employment decisions about an individual, or more pointedly, that an individual will be denied employment or employment advancement because of the possibility of future disease disclosed by

genetic testing. The other potential area of discrimination is, of course, that genetic information will be used to deny individuals health, life, or disability insurance because genetic testing reveals a predisposition to a disease.

The Executive Order prohibits the federal government from discharging, failing or refusing to hire, or otherwise discriminating against any employee with respect to compensation, terms, conditions, or privileges of employment based on protected genetic information and from limiting, segregating, or classifying in any way that would adversely affect employment status because of genetic information.

Privacy Concerns

There is no comprehensive federal legislation addressing the more global concerns about privacy and use of the results of genetic tests. In 2003, the comprehensive federal law providing for privacy of individuals' medical information in the hands of most healthcare providers or insurers, the Privacy Rule promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), became generally effective.

The Department of Health and Human Services has specifically stated that "genetic information" is considered to be "protected health information" and covered under the Privacy Rule so long as the genetic information created or received by a HIPAA-covered entity, such as a healthcare provider or health plan, relates to the past, present, or future health of an individual or the provision of healthcare to an individual. Thus, such genetic information is subject to the use and disclosure protections and limitations of the Privacy Rule and subject to the various individual rights of access and notice of certain uses and disclosures.

However, a number of healthcare industry entities that might possess genetic information are not within the jurisdictional ambit of HIPAA, including employers and life insurance companies. In addition, the Privacy Rule expressly permits covered entities, such as healthcare insurers, to use protected health information for "underwriting" as a part of a covered entity's "healthcare operations," an apparent loophole for healthcare insurers that are otherwise covered under HIPAA.

Despite bipartisan support, Congress has been unable to pass comprehensive federal legislation specifically directed at genetic information. In 2003, the Senate passed the "Genetic Information Nondiscrimination Act"; however, the House version stalled. In 2005, the Senate again took up consideration of the bill. As presented to the Senate in 2005, the law would define "genetic information" as "genetic tests of an individual or family member or the occurrence of a disease or disorder in family members," and "genetic services" are defined as "tests, counseling, or education."

The proposed law broadly prohibits insurance companies that offer coverage in the group or individual markets from discrimination on the basis of genetic information or services. In addition, the law would declare it an unlawful employment practice for an employer, employment agency, labor organization, or training program to discriminate against an individual or deprive an individual of employment opportunities because of genetic information. Finally, the law would specifically ban the use, disclosure, or collection of genetic information for purposes of underwriting or the requesting, requiring, or purchasing of genetic information prior to enrollment.

Definition Of A Genetic Test

Genetic test: The analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn, and carrier screening, as well as testing in high-risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes.

Source: National Institute's of Health Genetic Testing Report, *Promoting Safe and Effective Genetic Testing in the United States*

In its February 2006 report, "Coverage and Reimbursement of Genetic Tests and Services," the Advisory Committee on Genetics, Health, and Society of the Secretary of Health and Human Services addressed the general need for public and private insurance coverage for genetic testing and genetic counseling through a series of nine recommendations. Noteworthy for clinical laboratories, the committee recommended that when the current freeze on laboratory payment rates ends in 2009, Medicare payment schedules should be revised "to reflect the true cost of a genetic test."

Reasons For Genetic Testing

Predictive testing identifies people who are at risk of getting a disease before any symptoms appear. Predictive tests include those that screen for some inherited predispositions to certain forms of cancer, such as colon and breast cancer.

Carrier testing can tell individuals if they are carriers of an inherited disorder that they may pass on to their children. A person who has only one abnormal copy of a gene for a recessive condition is known as a carrier. Carriers won't get the disease, but can pass on the defective gene to their children.

Prenatal testing is available to people at risk for having children with a chromosomal abnormality or an inherited genetic condition. Two procedures are commonly used in prenatal testing. Amniocentesis involves analyzing a sample of amniotic fluid from the womb. CVS (chorionic villus sampling) involves taking a tiny tissue sample from outside the sac where the fetus develops.

Newborn screening, the most widespread type of genetic testing, tests infant blood samples for abnormal or missing gene products.

While the committee's report did not address privacy or use concerns related to genetic information, it did address quality issues. One of its recommendations was the establishment of an appropriate government agency to determine which healthcare professions are qualified to provide genetic counseling services and which should be able to practice without physician supervision and, thereby, bill payers directly for their services. The report stated that the credentialing standards of " . . . a number of professional societies, such as the American Board of Genetic Counseling and the Genetic Nursing Credentialing Commission, could be used as a reference point."

State Laws

While beyond the scope of this article, it should be noted that a number of states have enacted their own laws relating to genetic testing. For example, in Florida, an individual's informed consent is required for the performance of DNA analysis. The results, whether in the hands of a public or a private entity, are the exclusive property of the person whose DNA was tested and are confidential.

Disclosure of the results of a DNA test requires the consent of the subject. If the test information is used to deny insurance or for any other purpose, the individual who was the subject of the test must be notified, the test must be repeated to verify its accuracy, and the insurance denial must be reviewed if the retest raises a question as to the accuracy of the initial test.

In California, among several laws applicable to genetic testing, an individual is given a statutory right to sue an HMO and certain other forms of health insurance plans for actual damages, including damages for economic, bodily, or emotional harm, if the plan discloses the results of a test for a genetic characteristic that is contained in the individual's medical records, unless the individual has consented to the disclosure in writing.

In addition, a person who improperly discloses the results of a genetic test is subject to civil penalties ranging from a maximum penalty of $1,000 for negligent disclosures up to $10,000 for disclosures that result in economic, bodily, or emotional harm.

Given the level of public concern about genetic tests, it seems inevitable that further legislation, at the state if not the federal level, will be enacted. Whether this legislation is comprehensive and at the federal level or is simply a continuation of the present patchwork will largely dictate how clinical laboratories and other healthcare providers involved in genetic testing must respond.

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A Brief Primer On Genetic Testing

The following is excerpted from a talk given by Francis S. Collins, M.D., Ph.D., director, National Human Genome Research Institute, at the World Economic Forum on Jan. 24, 2003.

What are the current indications for genetic tests and for whom are they appropriate?
Genetic tests can be done to confirm a suspected diagnosis, to predict the possibility of future illness, to detect the presence of a carrier state in unaffected individuals (whose children may be at risk), and to predict response to therapy. Genetic tests may be carried out in the prenatal arena, either through pre-implantation genetic diagnosis (where the diagnosis is made of an individual embryo before implantation), chorionic villus sampling (CVS), or amniocentesis. Most newborns in industrialized countries are tested at birth for a few genetic disorders that require immediate treatment. Genetic tests may be carried out on children (to confirm a diagnosis, but generally not to predict adult-onset disorders unless an intervention in childhood is essential).

What kinds of genetic tests are available?
About 900 genetic tests are now offered by diagnostic laboratories (see *www.genetests.org* for a wealth of information on the specifics). Some genetic tests look at whether the number of chromosomes is correct and whether there is any evidence of a chromosome rearrangement or other abnormality. This kind of test, for instance, would detect Down syndrome (an extra chromosome 21). Most genetic problems are more subtle than this, so tests able to detect them must look at the actual DNA sequence of a particular gene. To detect a carrier of Huntington's disease, for instance, the test must discover a particular expanded repeated sequence of a gene on chromosome 4. If this repeat of CAGCAGCAG… is very long, there is a high likelihood of the future onset of illness.

For many genes, however, there are multiple different ways that the gene can be misspelled; in that situation, an effective test may need to detect many possible misspellings (usually referred to as mutations). A standard test for cystic fibrosis, for instance, looks for 32 different mutations in the so-called CFTR gene, but will still miss rare ones. Other types of genetic tests do not look at DNA at all, but look at RNA (the messenger that is transcribed from the gene), or at the actual protein product of the gene. Carrier detection for Tay-Sachs disease, for instance, actually measures the enzyme activity of the protein product.

What kinds of tests are available now for predicting disease susceptibility?
The number of tests is growing, but most of these are currently applied only in families where there is a strong history of the disorder. For instance, BRCA1 and BRCA2 testing are only offered to individuals with a strong family history of breast and ovarian cancer. Similar situations exist for diseases such as colon cancer or Huntington's Disease. But in the next few years, it is expected that a much longer list of susceptibility tests will become available and may be offered to anyone interested in the information.

What will happen to genetic testing over the next decade?
It is likely that the major genetic factors involved in susceptibility to common diseases like diabetes, heart disease, Alzheimer's disease, cancer, and mental illness will be uncovered in the course of the next five to seven years. For many of these conditions, altering diet, lifestyle, or medical surveillance could be beneficial for high-risk individuals. That will open the door to wider availability of genetic tests to identify predispositions to future illness, potentially for virtually anyone. If applied properly, this could usher in a new era of individualized preventive medicine that could have considerable health benefits. It will be important to remember, however, that most of these tests will not be "yes or no" but rather will predict relative risk. For this paradigm to succeed, it will also be essential that predictive genetic information is used to benefit individuals, rather than to injure them by discriminatory misuse.

Phase I Of MUEs, *from p. 1*

During the May 25 meeting, ACLA officials pointed out that clinical laboratory and pathology codes differ from codes for other specialties in that they are far more numerous (more than 1,500 different CPT codes) and do not relate to a particular part of the body or anatomy. Thus, while it is only possible to do one appendectomy on a person, it is practically impossible to define the number of surgical pathologies, molecular probes, and chemistry analytes beyond which would be considered "unbelievable."

The Practicing Physicians Advisory Council (PPAC) also has weighed in on the MUEs. At its May 22 meeting in Washington, DC, the council made three recommendations on the edits:

- CMS should remove the term "unbelievable." Suggested replacements include "unlikely," "unusual," etc.
- CMS should allow modifiers for services that may be clinical outliers and develop an appeals process for claims denied under the MUE program.
- When CMS publishes its proposal for a MUE subset to be implemented in January 2007, it should provide information on the rationale for the edits and specific data on the estimated percentage of errors CMS hopes to address.

Resources

- ACLA: *www.clinical-labs.org*
- PPAC meeting transcript: *www.cms.hhs.gov/FAC03_ppac.asp#TopOfPage*

OIG To Work With Science Committee On Research Guidance

The Department of Health and Human Services Office of Inspector General (OIG) has accepted an offer from the National Science and Technology Council (NSTC) to expand upon the OIG's initial efforts to provide voluntary compliance guidance to recipients of federal research funding.

The NSTC's Committee on Science (COS) will establish an interagency initiative to develop voluntary compliance guidelines for recipients for federal research funding from all agencies across the federal government. The OIG published draft compliance guidance for recipients of public health services research awards on Nov. 28, 2005, and requested public comment (*GCR*, Feb. 2006, p. 1).

"The COS offer will further the goals of our draft compliance program guidance by providing voluntary guidance to all recipients of federal research funding as they address the prudent management and stewardship of research funds," said Inspector General Daniel Levinson in a statement.

Dr. John Marburger III, director of the White House Office of Science and Technology Policy (OSTP), says the project is ideally suited to the COS's Research Business Models Subcommittee, which promotes common policies and procedures among federal research agencies.

"The idea is not only to enhance their efficiency but also to reduce bureaucratic impacts on their constituents," Dr. Marburger says. "This topic has become more important as compliance requirements have increased substantially in recent years."

OIG's draft guidance was developed to provide recipients of research awards from HHS agencies with a framework for developing and implementing effective compliance programs that prevent and reduce fraud, waste, and abuse, as well as promote adherence to federal rules and regulations. The guidance provides information on the benefits and suggested components of a comprehensive, well-managed compliance program.

CMS Issues Alert On HIV Testing

The Centers for Medicare and Medicaid Services (CMS) has issued an alert addressing the potential for erroneous results associated with operator technique and a well-known pipetting system used to deliver a micro sample of specimen for an HIV-1 test kit.

According to the alert, one laboratory was identified where an operator incorrectly used the pipetting system with a Food and Drug Administration (FDA)-approved test kit that requires a micro sample of specimen. "This combination, as well as poor pipetting technique, caused questionable test results," says CMS. "This laboratory used root cause analysis to identify its own problem and has subsequently resolved it; however, we felt that this problem could reoccur in other laboratories under similar circumstances."

This potential problem is not a result of a malfunction of these products, notes CMS. It recommends that labs using this combination of test kit requiring a micro sample and dilution consider enhancing their existing quality control protocol to check the system. This should be in addition to the laboratory's existing pipette checks, staff training, competency assessments, and quality assurance.

The Joint Commission on Accreditation of Healthcare Resources (JCAHO) also recommends that labs include at least one low-level positive control in every run of patient testing, in addition to the positive and negative already required.

Laboratories should report any errors and accidents associated with in vitro diagnostics to the FDA's Center for Biologics Evaluation and Research. Reporting forms and information are available at *www.fda.gov/cber/biodev/biodev.htm* or by calling the FDA's MedWatch program at 800-FDA-1088.

Resource

CMS alert: *www.cms.hhs.gov/CLIA/downloads/HIV.alert.pdf*

Senators Ask For OIG Review Of Pharmacy Issues

Senate Finance Committee leaders have asked the Health and Human Services Office of Inspector General (OIG) to review the adequacy of Medicare Part D pharmacy networks in rural areas and reimbursements to participating pharmacies.

Their June 6 letter to Inspector General Daniel Levinson also requests a review of supposed "heavy-handed contracting strategies" in which plans may have required pharmacies to participate in the Medicare Rx network as a condition of the participation for other lines of business.

The letter is signed by 33 senators from both parties, including Finance Committee Chairman Charles Grassley (R-IA) and ranking minority member Max Baucus (D-MT). The senators said they were concerned that some beneficiaries in rural areas did not have access to a conveniently located pharmacy in their plan networks, even though the Centers for Medicare and Medicaid Services (CMS) had reviewed pharmacy networks submitted by drug plan sponsors.

In addition, the letter raises issues concerning payments to pharmacies by plan sponsors and whether such reimbursements, including rebates, were adequately covering pharmacies costs to acquire and dispense prescription drugs.

"Pharmacies have informed us that, in many cases, reimbursements fall well below their costs, which will undermine the long-term viability of local pharmacies and the MMA [Medicare Moderniza-

tion Act] goal of ensuring beneficiaries' access to them," the letter stated.

Regarding contract matters, the lawmakers said that, in addition to analyzing plans' contracting strategies, they hoped the OIG would review community pharmacies' use of third-party contractors to help negotiate Part D network contracts.

"We have heard that some pharmacies sometimes relied on a third-party to contract on their behalf and, as a result, had a limited understanding of the contract terms," the letter stated.

Groups Push For Delay In Switching To ICD-10 Codes

Health groups, including those representing clinical laboratories, say they need until 2012 to prepare for and make the transition to the ICD-10 billing code standard, a date three years later than contained in one version of legislation pending in the House.

A provision mandating replacement of the current ICD-9 diagnosis and procedure coding system with ICD-10 by 2009 was dropped from the health information technology bill (H.R. 4157) that the House Energy & Commerce Health Subcommittee approved June 8. However, the controversial proposal is contained in the version of H.R. 4157 that originated in and passed the House Ways and Means Health Subcommittee May 24.

Complex Transition

The shift to ICD-10 entails going from 13,000 diagnosis codes and 11,000 procedure codes under ICD-9, in use in this country since 1979, to approximately 120,000 diagnosis codes and 87,000 procedure codes. Compounding the complexity of the changeover is the fact that ICD-9 data sets cannot be converted into ICD-10 data sets or vice versa, so the shift would require a major overhaul of coding and billing systems/software.

The American Clinical Laboratory Association (ACLA) is part of the coalition lobbying Congress on the proposed changeover. The coalition argues that the proposed implementation date of 2009 is too soon and more time is needed to accomplish it smoothly, with the fewest possible glitches.

In a study commissioned by the America's Health Insurance Plans (AHIP), IBM managing consultant Kenneth Fody said health plans need about three years to assess their needs, change systems and processes, and test new billing systems.

The Blue Cross Blue Shield Association along with attorney D. McCarty Thornton, with Sonnenschein Nath & Rosenthal LLP (Washington, DC), argue that an overly hasty transition to ICD-10 would leave Medicare and other federal programs vulnerable to fraud and abuse. Thornton is former chief counsel for the Health and Human Services Office of Inspector General.

Chief among problems with an early deadline, Thornton says, is that payers would not have enough time to retool system edits and anti-fraud software designed to detect aberrant billing patterns using ICD-9 codes. He notes that the Medicare payment error rate has dropped from 13.8% in 1996 to 5.2% in 2005 and that it is inevitable it will rise again after migration to ICD-10 coding.

"It isn't if it goes up, but how much?" he asks, adding that if the implementation were forced too soon, Medicare could return to double-digit payment error rates.

Thornton also said the shift to ICD-10 should be delayed until the Centers for Medicare and Medicaid Services has completed the shift from separate Part A and Part B billing contractors to the consolidated 15 Medicare Administrative Contractors (MACs), expected to be complete in 2009.

Tenet Case Dismissed: The U.S. Attorney for the Southern District of California, Carol Lam, has filed a notice to dismiss charges against a Tenet Healthcare Corp. hospital in San Diego and its former chief executive officer, ending years of legal wrangling over allegations the defendants paid kickbacks to physicians in return for patient referrals, a spokeswoman for Lam said June 2. Lam agreed to drop the charges in exchange for Tenet's agreement to pay the government $21 million and to either dispose of or sell Alvarado Hospital Medical Center, the facility at the heart of the case. Tenet, based in Dallas, reportedly is holding conversations with several possible bidders for Alvarado.

TAP Settlement: Wisconsin Attorney General Peggy Lautenschlager said May 25 that TAP Pharmaceuticals Products Inc. will pay the state $798,000 to settle charges it defrauded Medicare patients by artificially inflating the price of its cancer drug, Lupron. The state alleged that TAP illegally influenced doctors to prescribe Lupron by using free samples, rebates, discounts, bribes, lavish trips, and other inducements, she said. The latest settlement money comes out of a nationwide class-action lawsuit filed in federal court in Massachusetts. Previously, Wisconsin recovered an additional $1.4 million from TAP on behalf of Wisconsin's Medicaid program in connection with illegal marketing of Lupron.

JCAHO Questioned: Three federal lawmakers have questioned the Joint Commission on Accreditation of Healthcare Organization's ability to accredit hospitals independently while its own consulting subsidiary profits from the sale of products and services that aid hospitals in meeting accreditation standards. In a May 19 letter to JCAHO President Dennis O'Leary, Sen. Charles Grassley (R-IA), Sen. Max Baucus (D-MT), and Rep. Fortney (Pete) Stark (D-CA) argued that the commission's claims to be a not-for-profit organization that maintains state-of-the-art standards could not be "further from the truth." In a May 22 statement, JCAHO said it welcomes a congressional review of its accreditation process, expecting such a review to inform public policymakers of the benefits JCAHO provides.