G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

FDA Issues Draft Guidance On Blood Products

The Food and Drug Administration on January 16 issued draft guidance recommending a streamlined path to licensure for establishments that manufacture cord blood for certain medical conditions.

Placental/umbilical cord blood is a rich source of precursor cells capable of differentiating into mature blood cells. These precursor cells are known as hematopoietic stem/progenitor cells and can be used to replenish the bone marrow in patients with blood-based malignancies, such as leukemia.

The draft guidance describes FDA's regulatory approach to the regulation of cord blood hematopoietic stem/progenitor cells that are:

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Inside this issue

CMS Offers Advice On Protecting Remote EPHI

Noting that there have been a number of security incidents related to the use of laptops and other portable devices that store or are used to access electronic protected health information (EPHI), the Centers for Medicare and Medicaid Services has issued additional guidance on how to protect such information.

In a document posted online Dec. 28, 2006, CMS offers strategies that it says may be reasonable and appropriate for entities covered under the Health Insurance Portability and Accountability Act (HIPAA) Security Rule to follow for offsite use of, or access to, EPHI.

The kinds of devices and tools about which there is growing concern because of their vulnerability include the following: laptops; home-based personal computers; PDAs and smart phones; hotel, library, or other public workstations and Wireless Access Points (WAPs); USB flash drives and memory cards; floppy disks; CDs; DVDs, backup media; e-mail; smart cards; and remote access devices (including security hardware).

"In general, covered entities should be extremely cautious about allowing the offsite use of, or access to, EPHI," states CMS. "There may be situations that warrant such offsite use or access, e.g., when it is clearly determined necessary through the entity's business case(s), and then only where great rigor has been taken to ensure that policies,

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FDA Issues Draft, *from page 1*

- Minimally manipulated (processing does not alter the original characteristics of the cells);
- Used to replenish the bone marrow in patients with blood-related malignancies; and
- Used in recipients unrelated to the donor of the stem cells.

"Cord blood hematopoietic stem/progenitor cells offer the potential for tremendous therapeutic benefit," said Jesse Goodman, MD, MPH, director of FDA's Center for Biologics Evaluation and Research (CBER). "In this draft guidance, FDA provides recommendations on a streamlined path to licensure for these promising products that also ensures their safety and effectiveness."

The new draft guidance offers cord blood banks a less burdensome path to licensure. Rather than having to submit their own clinical data, they may cite existing data in the docket.

Tiered Approach

FDA first proposed a new regulatory framework for human cells, tissues, and cellular and tissue-based products (HCT/P), including cord blood, in 1997. This tiered approach, fully implemented in May of 2005, requires that establishments register with FDA and list their products, ensure quality control by adhering to the agency's current good tissue practices, and follow the agency's rules on donor eligibility. Under this framework, cord blood hematopoietic stem/progenitor cells from unrelated donors are regulated as both HCT/P and as biologic drugs subject to licensure."

In 1998, when cord blood transplants were still relatively uncommon, FDA sought input from scientists and industry to develop product standards, establishment controls, and processing controls that would clear the way for biologics license applications ensuring the safety and effectiveness of placental/umbilical cord blood from unrelated donors that is used to replenish a patient's bone marrow.

To provide a scientific basis for the proposed standards, FDA requested the submission of clinical and nonclinical laboratory data to a public site created for this purpose.

In 2003, the agency convened its Biological Response Modifiers Advisory Committee to discuss the current clinical data, safety, and effectiveness issues surrounding placental/umbilical cord blood transplantation, and possible quality measures. At that time, cord blood was being used in increasing numbers, and members of the interested public voiced their opinion that licensure of cord blood products would increase confidence in the safety and effectiveness of these products, according to FDA officials.

Less Burdensome Path

FDA has since determined that cord blood hematopoietic stem/progenitor cells are safe and effective for certain indications based on the data submitted to the public docket and the large body of published literature.

Therefore, the new draft guidance offers cord blood banks a less burdensome path to licensure. Rather than having to submit their own clinical data, they may cite existing data in the docket.

The draft guidance also provides manufacturers with recommendations on the content and format of information to be submitted with an application, discusses the manufacture of cord blood hematopoietic stem/progenitor cells, and elaborates on how to comply with applicable regulatory requirements.

Resource

- FDA guidance: *www.fda.gov/cber/gdlns/cordbld.pdf*.

COLA Receives Renewed Approval To Accredit Labs

COLA, a Maryland-based accrediting organization, said January 3 that it has received renewed approval from the Centers for Medicare and Medicaid Services to accredit laboratories.

Formerly known as the Commission on Office Laboratory Accreditation, COLA said it is the first accrediting organization to be renewed since the increased government scrutiny of survey organizations, driven by a 2006 government investigation into laboratory errors.

"The accreditation renewal comes at a time when there have been many changes in the industry and in federal requirements," says Maxfield Williams, director of policy and external affairs for COLA. "We have always had stringent requirements in place, and employing trained surveyors allows our organization to perform consistent surveys, which benefits the labs we accredit."

COLA's new accreditation process is closely aligned with quality systems methodology and has demonstrated equivalency to the CLIA 2003 requirements, the organization said in a statement. COLA will incorporate new standard program requirements that coincide with updated CLIA requirements and will demonstrate a closer alignment with COLA's Quality Management Systems (QMS) accreditation program.

Some of the new program features for laboratories in 2007 include:

- Revised quality control requirements;
- Increased attention to laboratory information systems;
- New focus on quality assessment activities that span all phases of laboratory testing; and
- Incorporation of quality systems methodologies to cytology and histopathology specialties.

A Government Accountability Office report in June 2006 said that CMS's inspections process was inadequate to ensure that labs were meeting federal quality standards (*GCR*, Sept. 06, p. 1).

CMS does not undertake survey and certification of labs, but oversees several deeming organizations that have responsibility for ensuring that labs meet requirements. These include the College of American Pathologists (CAP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), as well as COLA.

Resource

- COLA: *www.cola.org*.

JCAHO Has Adequate 'Firewall' Between Consulting, Accreditation Divisions, Says GAO

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has created a substantial firewall between it and its independent consulting subsidiary, JCR, and must continue to do so to ensure the independence of the accreditation process, according to a Government Accountability Office (GAO) report released January 16.

Concerns about the relationship between the two entities lie in their respective missions, according to the report prepared for Sen. Charles Grassley (R-IA) and Rep. Fortney "Pete" Stark (D-CA).

JCAHO is a nonprofit corporation responsible for setting standards that hospitals must meet to receive their accreditation. JCR is a nonprofit, controlled affiliate of

JCAHO that provides healthcare facilities with consultative and educational assistance. Essentially, as the Joint Commission is accrediting hospitals, JCR is advising them on how to get and stay accredited.

Despite JCAHO's control over JCR, the two organizations have taken steps to protect facility-specific information, including creating a firewall in 1987 that was designed to establish a barrier between the organization to prevent improper sharing of this information, according to the report. Both organizations took further steps in 2003 intended to strengthen the oversight of the implementation of, and compliance with, the firewall and related policies.

The two organizations, according to the report, have acknowledged the need to ensure that JCR's consultative services do not affect, and are perceived not to affect, the independence of the Joint Commission's accreditation process, either through the improper sharing of information about facilities using JCR's services with Joint Commission accreditation staff or through any implication that using JCR's services will provide an undue advantage in the Joint Commission process.

Resource

❖ GAO report, "Hospital Accreditation: Joint Commission on Accreditation of Healthcare Organizations' Relationship with Its Affiliate," (GAO-07-79), *www.gao.gov/new.items/d0779.pdf*.

RTI Issues Draft Anti-Fraud Guidelines For EHRs

RTI International, a contractor for the Department of Health and Human Services (HHS), has released draft anti-fraud guidelines for electronic health systems.

The draft recommendations are intended to prevent claim errors and safeguard public and private health insurers against fraudulent claims generated using electronic health records (EHRs).

Among RTI's recommendations is the development of standardized audit logs to track actions taken in an EHR and who is taking the action. In addition, the draft recommends requiring that EHR systems demonstrate the ability to use the National Provider Identifier in audit logs to reduce fraud losses through improper use of NPIs to submit false claims.

Other recommendations include requiring the ability to view an audit version of each encounter note within an EHR, which would allow a fraud and abuse investigator to determine whether certain automated functions were used to inappropriately generate claims.

RTI further recommends that EHR systems be required to generate document tracking numbers each time a copy of an EHR is printed or electronically transmitted. The proposed recommendations also include allowing patients to access their own completed records.

The research team is working with the National Healthcare Antifraud Association (NHCAA), healthcare providers, health insurers, federal agencies, and the Health Information Technology Standards Panel (HITSP) to develop model claims efficiency standards for EHRs that will prevent, detect, and support the prosecution of healthcare fraud, as well as minimize opportunities for error or fraud.

"Currently, most billing errors or fraud is detected after payment is made, which makes dealing with the claims very inefficient for both the provider and the payer," said Colleen McCue, Ph.D., a senior research scientist at RTI and project manager. "EHR systems will allow for the opportunity to correctly bill from the very beginning, which will help physicians to receive accurate payments and ultimately will reduce fraud."

Resource

❖ The draft is available at *ehrantifrauddev.rti.org*.

COMPLIANCE PERSPECTIVES

The Merging Of Radiology & Lab Medicine: An Idea Whose Time Has Come?

The merging of radiology and pathology/laboratory medicine under a unified umbrella, once considered impractical and unlikely, appears to be gaining some traction, largely driven by growth of molecular diagnostics.

While the Veterans Administration (VA) in 1997 began taking the lead in bringing the specialties together under a single Diagnostic Medicine Service Line in some of its regions, for the most part diagnostic imaging and laboratory medicine have remained two very distinct and separate service areas within healthcare.

Within the past couple of years, however, two of the largest diagnostic imaging companies have begun expanding their businesses to focus not only on in-vivo diagnostics but also on in-vitro diagnostics. This change is largely driven by a belief that molecular medicine—of all forms—will play an essential role in the future of diagnosing and treating diseases.

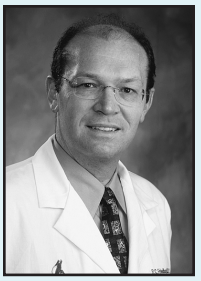
"It's like the three legs of a stool—imaging, in-vitro diagnostics, and clinical informatics, and none of them can stand on their own. Together, they are the future of diagnostic medicine,"
—Bruce Friedman, M.D.

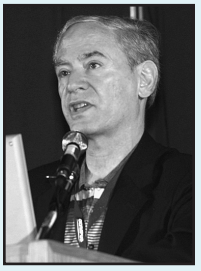
In 2006, Siemens Medical Solutions purchased Bayer Diagnostics and Diagnostics Product Corp. (DPC), merging them into a single business unit called "Siemens Medical Solutions Diagnostics." The new business, say company officials, will be a leader in the worldwide immunodiagnostics market. "Bringing together the entire medical imaging, laboratory diagnostics, and clinical IT value chain under one roof puts Siemens in a unique position to leverage trendsetting technologies for an improved quality of patient care at reduced costs," says the company in a press release issued January 3.

GE Healthcare also is pursuing research and development in both in-vitro and in-vivo medicine. In 2004, the company established a molecular diagnostics division, appointing a former vice president of Abbott Laboratories to head it. The company currently is investigating types of biomarkers that are indicative of several different disease states, including Alzheimer's, cardiovascular disease, novel MRI contrast agents, and antibody technology.

Once a biomarker has been discovered and validated, biochemists design "smart" molecules that can seek out and attach themselves to the presence of these specific biomarkers in the body. The molecules are designed to "light up" under an imaging device such as an MRI or PET scanner and report back on the presence and quantity of the biomarker. This process allows physicians to determine if, where, and how much of a disease exists in the body—all before the onset of traditional symptoms.

In addition to diagnosing disease, these molecular diagnostics can be used to track the effectiveness of therapies. Doctors can use molecular diagnostics to


Richard Friedberg, M.D


Bruce Friedman, M.D.

"see" the diseased cells they are trying to fix. In addition, genetic information could be used to design a treatment that is tailored to an individual's molecular makeup.

Diagnostic Testing Centers

At the VA Atlanta Healthcare Network, radiology, nuclear medicine, and pathology have been combined under one Diagnostic Medicine Service Line since 1997.

"We started with a capital procurement group for radiology and pathology, and as we looked for synergies across the network, it became clear that running the laboratory and radiology services on a much larger scale would give us economies of scale and allow for more streamlining," says Richard Friedberg, M.D., Ph.D., chairman of the Department of Pathology at Baystate Health (Springfield, MA), medical director of Baystate Reference Laboratories, and a professor at Tufts University School of Medicine. Dr. Friedberg worked at the VA in 1997 and helped develop the service line.

"We found that radiologists and pathologists have much more in common than they ever realized," he explains. "They both interact with the healthcare system in the same way—performing and interpreting tests and reporting the results. When we put them together, we found that it worked very well."

While the merger of imaging and lab medicine has not gained widespread acceptance outside of the VA, Dr. Friedberg believes that is about to change. As Siemens and GE continue to break down barriers between the two specialties, corporate America is likely to take notice, he says.

Dr. Friedberg believes that a company like Quest Diagnostics or LabCorp may explore development of diagnostic testing centers that offer both lab and diagnostic imaging tests. The benefit to patients would be tremendous since it would reduce the burden of traveling to separate facilities for tests. Referring physicians would benefit from the consolidation of test results. And the company developing the diagnostic testing center would benefit through increased market share, he says.

Bruce Friedman, M.D., active emeritus professor, Department of Pathology, at the University of Michigan Medical School (Ann Arbor, MI), agrees that radiology and laboratory medicine will one day become integrated, starting with molecular diagnostics.

"Siemens talks about the diagnostics value chain, and I think they are right on target," says Dr. Friedman, who is a strong proponent of the merger of the specialties and writes about this topic, among others, on his blog at *www.labsoftnews.com*.

"It's like the three legs of a stool—imaging, in-vitro diagnostics, and clinical informatics, and none of them can stand on their own. Together, they are the future of diagnostic medicine," he tells *GCR*.

Dr. Friedman predicts that the pre-eminent clinician of the future will be what he calls a "molecularist." This clinician will "order mega-panels (100-300 biomarkers) from the clinical lab to diagnose diseases based on their molecular character, he writes on his blog. "He will extend his diagnostic reach by ordering imaging studies to locate lesions and even use molecular imaging . . . to achieve more specificity about the location and natural history of diagnosed lesions. And he will eradicate diseases with a cocktail of bioengineered molecules that will attack the abnormal cells and ignore the normal ones."

While the integration of radiology and laboratory medicine won't happen overnight, both Dr. Friedberg and Dr. Friedman believe that the merger is inevitable. "We are certainly headed in that direction," says Dr. Friedberg. "It's just a matter of time."

10 Reasons For Merging Pathology/Lab Medicine With Radiology

1 Substantial overlap between the missions of the two specialties—diagnosis of disease through images and the analysis of biomarkers—already exists. A merger would serve to reinforce and provide greater impetus to a trend that is already occurring.

2 Enhanced clinical and research value of the merged, LIS, RIS, and PACS databases. We have not yet begun to fully understand the value of querying image databases, particularly when correlated with complex genomic and proteomic results.

3 The integrated reports of pathologists and radiologists working collaboratively would achieve higher levels of quality. Although there is some knowledge currently shared between radiologists, pathologists, and lab scientists, it would not equal what could be accomplished through coordinated activities in the same department.

4 The merger of medical imaging, molecular imaging, and molecular diagnostics is already taking place on a very active basis in multinational corporations (for example Siemens and GE Medical). Large companies such as these have already established their strategic goals, and they involve placing large bets on the future of diagnostic medicine.

5 The science and research agendas of molecular imaging and molecular diagnostics already demonstrate extensive overlap.

6 Although the specialty of radiology has made great progress with interventional radiology, clinical specialists—such as cardiologists—are extending their imaging and therapeutic reach to the vascular system. Diagnostic medicine encompassing medical imaging, molecular imaging, molecular diagnostics, nuclear medicine, and histologic tissue diagnosis would form the basis for a cohesive and logistical specialty focus.

7 Economic and political change in the healthcare industry is driven by trainees who have recently finished their residencies and fellowships. The new specialty of diagnostic medicine would benefit from a critical mass of such trainees who would launch their careers and work within the hospital and health system committee structure to carve out a professional identity.

8 Much of the core technologies used in surgical pathology are badly outdated and would benefit from an infusion of the new science and technology currently being explored in medical imaging and molecular imaging.

9 Pathology and lab medicine need a greater influx of capital investment in the form of corporate R&D funds analogous to that supporting molecular imaging. A merged specialty of diagnostic medicine would have a legitimate claim on some portion of this investment in research.

10 The future of radiology, pathology, and lab medicine are all similarly dependent on information technology, molecular diagnostics, and imaging technology. Pooling resources and strategic goals in these three areas of inquiry will have a powerful multiplier effect on the merged specialty.

Source: Bruce Friedman, M.D., *www.labsoftnews.com*.

Protecting Remote EPHI, *from page 1*

procedures, and work-force training have been effectively deployed, and access is provided consistent with the applicable requirements of the HIPAA privacy rule."

Some examples of appropriate business cases might include:

- A home health nurse collecting and accessing patient data using a PDA or laptop during a home health visit;
- A physician accessing an e-prescribing application on a PDA, while out of the office, to respond to patient requests for refills; and
- A health plan employee transporting backup enrollee data on a media storage device to an offsite facility.

There may be additional business cases that will require the offsite use of, or access to, EPHI, acknowledges CMS, noting that the guidance is not intended to provide a comprehensive list of applicable business cases, nor does it attempt to identify all covered entity compliance scenarios. A covered entity must evaluate its own need for offsite use of, or access to, EPHI, and when deciding which security strategies to use, must consider those factors set forth in the Security Rule:

1. The size, complexity, and capabilities of the covered entity;
2. The covered entity's technical infrastructure, hardware, and software security capabilities;
3. The costs of security measures; and
4. The probability and criticality of potential risks to EPHI.

Specifically, with respect to remote access to or use of EPHI, covered entities should place significant emphasis and attention on their:

- Risk analysis and risk management strategies;
- Policies and procedures for safeguarding EPHI; and
- Security awareness and training on the policies and procedures for safeguarding EPHI.

Possible Risk Management Strategies

The CMS document includes tables that list risks applicable to specific categories,

RISKS	POSSIBLE RISK MANAGEMENT SOLUTIONS
Log-on/password information is lost or stolen, resulting in potential unauthorized or improper access to or inappropriate viewing or modification of EPHI.	❑ Implement two-factor authentication for granting remote access to systems that contain EPHI. This process requires factors beyond general user names and passwords to gain access to systems (e.g., requiring users to answer a security question such as "Favorite Pet's Name"); and ❑ Implement a technical process for creating unique user names and performing authentication when granting remote access to a work-force member. This may be done using Remote Authentication Dial-In User Service (RADIUS) or other similar tools.
Laptop or other portable device is lost or stolen, resulting in potential unauthorized or improper access to or modification of EPHI housed or accessible through the device.	❑ Identify the types of hardware and electronic media that must be tracked, such as hard drives, magnetic tapes or disks, optical disks or digital memory cards, and security equipment and develop inventory control systems; ❑ Implement process for maintaining a record of the movements of, and person(s) responsible for, or permitted to use hardware and electronic media containing EPHI; ❑ Require use of lock-down or other locking mechanisms for unattended laptops; ❑ Password protect files; ❑ Password protect all portable or remote devices that store EPHI; ❑ Require that all portable or remote devices that store EPHI employ encryption technologies of the appropriate strength; ❑ Develop processes to ensure appropriate security updates are deployed to portable devices such as Smart Phones and PDAs; and ❑ Consider the use of biometrics, such as fingerprint readers, on portable devices.

Source: CMS

such as access, storage, and transmission, paired with risk management strategies (see below). Where applicable, the strategies column suggests basic solutions first, followed by solutions that may be more complex and, therefore, possibly more appropriate for organizations with advanced technical capabilities.

This is a sample of risks and strategies. The full document, including additional tables, is available at *www.cms.hhs.gov/EducationMaterials*.

Providers Criticize CMS Interpretation Of False Claims Act Provision

Medicaid providers on January 11 criticized the Centers for Medicare & Medicaid Services (CMS) for an overly broad interpretation of, and not enough guidance on, a Deficit Reduction Act (DRA) provision that requires certain Medicaid entities to establish written policies for educating all employees, contractors, and agents on the federal False Claims Act.

The providers were among 800 callers participating in a phone briefing on the provision, during which CMS's Medicaid Program Integrity Group Acting Director Robb Miller defended the agency's interpretation of the law and guidance to the Medicaid community.

However, Miller also said his group was still reviewing certain aspects of the provision and would provide additional guidance to states and providers at a later date—guidance that he indicated could reverse earlier CMS thinking in some areas.

DRA mandates that state Medicaid programs require entities that make or receive $5 million or more in annual Medicaid payments adopt written policies to educate all employees, contractors, and agents on the federal False Claims Act.

However, Miller said CMS has interpreted the law to apply directly to providers, meaning even if states have not yet drafted requirements, Medicaid providers were liable for complying with the DRA provision as of the January 1 effective date.

One caller criticized the agency for that approach, saying it was impossible for providers to comply with state requirements that were not yet available.

Miller responded that CMS did not have the authority to change the effective date of the provision and that he believed providers were required to respond to the DRA mandate regardless of where their state programs were in drafting state-based regulations.

State Implementation Requirements

In December 2006, CMS wrote in a memo to state Medicaid directors that the employee education requirement must be implemented by January 1 and that states must develop methods by which to determine compliance among affected Medicaid providers. States must also amend no later than March 31 their state plans—filed with CMS—to reflect the requirement, the memo stated.

Miller said CMS has not, nor will it, mandate the method in which states must enforce the DRA provision, nor will the agency give providers any bright-line guidance.

Nevertheless, he said that CMS is working with the Department of Health and Human Services Office of Inspector General and the Department of Justice to obtain a uniform description of the federal FCA so that providers and states are not at risk of incorrectly interpreting the statute.

Owners Of Imaging Labs Plead Guilty To Fraud

Several owners of California digital imaging laboratories have pleaded guilty to charges of billing Medicare $1.1 million for exams and ultrasound tests not performed or not needed, the U.S. attorney's office for the Northern District of California announced January 10.

Five defendants were named September 2005 in a 61-count indictment alleging healthcare fraud, aiding and abetting, and conspiracy following a two-year investigation by the FBI and the Department of Health and Human Services.

Between October 2003 and May 2004, the indictment alleged, Milpitas Medical Clinical in Milpitas, California, billed Medicare $1,109,000 for exams not performed or not performed by the physicians listed and for ultrasound tests not ordered.

The owners of four digital imaging services, who formed the Milpitas clinic, and physician Armond Tollette II obtained $909,000 in reimbursements for which they were not entitled, the indictment said. Tollette pleaded guilty to conspiracy to commit healthcare fraud.

Alexander Dzhuga, the owner of Direct Vision AD Inc.; Leonid Dzhuga, owner of National Diagnostic Inc.; Vladimir Semenov, owner of Pulse Diagnostic Services Inc.; and Natalia Stadnik, the owner of Prolink Diagnostic Inc., pleaded guilty to 60 counts of aiding and abetting healthcare fraud, authorities said. All defendants agreed to pay restitution of the funds they received from Medicare for their illegitimate claims.

U.S. District Judge Jeremy Fogel scheduled sentencing April 18 for Alexander and Leonid Dzhuga, Semenov, and Stadnik. Tollette is scheduled for sentencing on May 8.

Resource

- U.S. Attorney Kevin Ryan, Northern District of California: 415-436-7200

GE Medical Agrees To Injunction Of X-ray Systems

GE OEC Medical Systems Inc., its parent company, GE Healthcare, and two top executives have signed a consent degree of permanent injunction related to X-ray surgical imaging systems manufactured by the company, the Food and Drug Administration (FDA) announced January 12.

The consent decree prohibits the manufacturing and distribution of specified GE X-ray surgical imaging systems at facilities in Salt Lake City, Utah, and Lawrence, Massachusetts, until the devices and facilities have been shown to be in compliance with FDA's current good manufacturing practice (CGMP) requirements as set forth in the Quality System (QS) regulation for devices.

The decree was filed January 12 in the U.S. District Court for the District of Utah and is subject to court approval. The systems subject to the decree include the 9900 Elite C-Arm System, 9900 Elite NAV C-Arm System, 9800 C-Arm System, 2800 UroView System, as well as their components and accessories.

GE Healthcare agrees not to resume manufacturing and distribution of these products in the United States until it completes certain steps, which principally include:

- Obtaining FDA approval of GE Healthcare's plan to resolve issues with certain products. Installed OEC surgical imaging systems can continue to be used consistent with their intended uses and labeling;

- Having an independent third-party auditor undertake a review of GE OEC Medical Systems' Salt Lake City and Lawrence facilities and certify compliance with the FDA's QSR regulations and reporting requirements; and
- Establishing, to FDA's satisfaction, that GE OEC process, facilities, and controls are in compliance with these requirements.

The consent decree arises out of several FDA Inspections in November 2004 and August, November, and December 2006, in which the FDA investigators made a number of observations relating to nonconformities in GE OEC Medical Systems' Quality System practices and reporting activities. GE voluntarily ceased shipments of products until the company's processes have been re-evaluated to ensure compliance with FDA requirements.

Resources

- FDA announcement: *www.fda.gov*, 888-INFO-FDA
- GE Healthcare: *www.gehealthcare.com*, 262-544-3937

Recent Enforcement Actions By HHS OIG

The Health and Human Services Office of Inspector General (OIG) recently announced enforcement actions for the month of December:

- **In New York, a dentist was sentenced to 18 months in jail and ordered to forfeit $5 million in assets as a result of being found guilty of defrauding the Medicaid program.** The dentist, who became excluded from participating in the Medicaid program in 1995, devised a scheme to maintain his practice, comprised of 95% Medicaid patients. So he could continue treating his Medicaid patients, he hired junior dentists with valid Medicaid provider numbers to perform basic procedures and paid them on a per diem basis. The excluded dentist provided the more complex procedures and billed Medicaid for all the services performed in the practice under the provider numbers of the junior dentists. In an attempt to cover up his scheme, the dentist created management companies so he could deposit the Medicaid funds received that were in the names of the junior dentists.
- **In Pennsylvania, a radiologic technologist was sentenced to 577 hours of community service and ordered to pay $22,000 in restitution for false statements relating to healthcare matters.** The technologist performed mammograms provided at a clinic without first performing required daily and weekly quality control tests on mammography machines. As required by federal law, quality-control tests are to be performed to ensure machines are operating within acceptable limits. The investigation revealed that to conceal the fraud, the technologist created false records during a 24-week period. As a result, mammograms performed on 577 women could not be considered reliable, and the women had to undergo repeat screenings.
- **In Florida, a durable medical equipment (DME) company owner was sentenced to 10 months in prison and ordered to pay $11,000 in restitution for conspiracy to violate the anti-kickback statute.** In 2002, the DME company owner entered into an improper relationship with an owner of a pharmacy. The investigation revealed that the DME company owner received illegal kickback payments in exchange for each patient referral.

Resource

HHS Office of Inspector General: *www.oig.hhs.gov*.

New Tips on Video

Check out our new "Tips on Video," which replaces the quarterly "Tips on Disc" supplement to G2 Compliance Report. This month, senior editor Kimberly Scott interviews Thomas Hirsch, co-founder and president of Laboratory Billing Solutions about common problems in lab accounting and billing. To view the video, go to *www.g2reports.com*, click on *G2 Compliance Report* and log-in with your user name and password.

Clinic Operator Convicted: A federal jury in December convicted a former physical therapy clinic operator from Massachusetts of mail fraud, healthcare fraud, and conspiracy to commit money laundering in connection with false billings to automobile insurance companies for medical tests (*United States v. Moyseyev*). Severin Yelaun, who operated Global Tech Diagnostics in Chelsea, Massachusetts, and Lynn Diagnostics in Lynn, Massachusetts, was one of four men—two doctors and two clinic operators—indicted in January 2005 and charged with operating a scheme to submit false bills to insurers. Yelaun's sentencing is set for March 10. He faces up to 20 years' imprisonment on all of the counts of conviction, except for conspiracy, which carries a maximum of five years in prison.

State Whistleblower Laws: Few state false claims laws reviewed recently by the Department of Health and Human Services Office of Inspector General meet requirements in the Deficit Reduction Act of 2005 (DRA) to receive increases in their share of Medicaid fraud recoveries, according to the OIG. Of the 10 state laws that the OIG has evaluated since it released the review guidelines in August 2006, just three—Illinois, Massachusetts, and Tennessee—were approved for the DRA incentive bonus. Under the DRA, if states enact false claims laws that mirror closely the federal False Claims Act, they become eligible for a 10% increase in their share of money recovered under state action brought under the law.

Stark, FCA Settlement: SCCI Health Services Corp. (Austin, TX) and its hospital subsidiary paid the United States $7.5 million to settle allegations they violated the Stark self-referral statute and the False Claims Act, the Department of Justice said January 5. SCCI and its nationwide long-term acute-care facilities were acquired in 2005 by Houston-based Triumph Healthcare Corp. The government had alleged that SCCI violated the Stark statute by making illegal payments to three physicians from November 1996 through 1999. Over the same period, SCCI was responsible for submission of false claims to the Medicare program in violation of the False Claims Act, the Justice Department said.

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