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For Hospitals, Laboratories and Physician Practices

California Court to Rule on Injunction in Lab Competitive Bidding Suit

A California court is expected to decide on or around April 7 whether it will temporarily stop the Medicare competitive bidding demonstration for clinical laboratory services in San Diego from going forward.

After being rebuffed in February in their motion for a temporary restraining order to halt the demonstration, three labs—Sharp Healthcare, Scripps Health, and Internist Laboratory—on March 3 filed a request with the court seeking a preliminary injunction. The judge in the case has scheduled a hearing for April 7, according to the plaintiffs' attorney, Patric Hooper, a partner with Hooper, Lundy & Bookman in Los Angeles.

The court must first decide if it has jurisdiction to hear the case. If it determines that it does have jurisdiction, the court must then decide whether to enjoin—or halt—the demonstration, Hooper tells *GCR*.

"If the court enjoins the project, it will be a major victory for the laboratories," says Hooper. "We believe the labs are on the correct side of the law on this issue."

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OIG Cites High-Risk Areas, Management Challenges

Medicare payment errors, Medicaid program administration, and Part D oversight are among top management challenges and high-risk areas for the Department of Health and Human Services, as identified in a recent report by the HHS Office of Inspector General (OIG).

The OIG defined 10 areas of ongoing concern for HHS and assessed progress the department has made in addressing problem areas. The report, released February 20 by the OIG, was first contained in the *Fiscal Year 2007 HHS Agency Financial Report*, published in November 2007.

The OIG said oversight of the Part D program is among the top challenges for the agency. The Centers for Medicare & Medicaid Services (CMS) has "demonstrated progress" in protecting the prescription drug benefit from fraud abuse, the OIG said, but noted that additional safeguards are needed.

The report also identified Medicare payment integrity as a key management issue for HHS. The OIG said audits and evaluations of Medicare payments continued to show "serious internal control weaknesses in [Medicare's] financial systems and processes."

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Competitive Bidding Suit, *from page 1*

The demo, required by Congress in the Medicare Modernization Act of 2003, is intended to see if competitive bidding can be used to pay for Part B independent lab services at rates below the current lab fee schedule. CMS is expected to announce the winning bidders in the San Diego-Carlsbad-San Marcos area on April 11. The demo is due to start July 1.

"If the court enjoins the project, it will be a major victory for the laboratories." We believe the labs are on the correct side of the law on this issue." — Patric Hooper

Latest Volley

The request for an injunction is the latest volley in a battle to stop the competitive bidding demonstration before it begins. The three labs on January 29 filed a lawsuit in the U.S. District Court for the Southern District of California seeking an immediate halt to the demo, citing irreparable harm to their businesses and to thousands of Medicare fee-for-service beneficiaries. The suit also sought to require the government to follow public notice and comment on the demo in accord with the Administrative Procedures Act.

In his first ruling on the case, Judge Thomas Whelan on February 14 denied the plaintiff's motion for a temporary restraining order based on the government's contention that any challenge to the competitive bidding demonstration was premature. The government also argued that the court lacked jurisdiction to rule in the case.

Whelan gave the labs until February 29 to address the jurisdictional issues raised by the government. In papers filed February 28, the plaintiffs argue that they are not seeking to preemptively dispute the Health and Human Services secretary's determinations about what laboratories are winners and losers under the demonstration before he makes them.

"Rather, plaintiffs are attacking the entire process the secretary has used for developing the policies on which those determinations, among others, will be made," the attorneys argued. "In this regard, plaintiffs raise constitutional and other significant procedural and substantive challenges to the secretary's policies for the ongoing implementation of the demonstration project. Plaintiffs are directly and immediately affected by the policies as reflected by the fact that, because their request for a TRO was denied, they had to submit (as best they could) bids to the secretary by Feb. 15, 2008. Under well-established case law . . . plaintiffs should not have to wait "for the ax to fall" on April 11, 2008, before they obtain preliminary injunctive relief, which they will be seeking in a separate motion."

CMS Rejects Appeal

Meantime, CMS has told the American Clinical Laboratory Association (ACLA) that it sees "no basis" for delaying the bidding demo. ACLA had written to the HHS secretary on February 13, requesting a delay of at least 180 days. In a reply for the secretary on February 27, CMS said it has made modifications to the original project design to accommodate concerns of small businesses and niche labs.

One of ACLA's primary concerns about the pilot's design is that required bidders, including niche and esoteric labs, must bid on all 303 codes from the Part B lab fee schedule that are included in the demonstration, even though many of these labs use as few as 10 of the codes. "Further, and inexplicably," ACLA said, "they must provide winning bids on those codes in order to participate, an almost impossible challenge since they have no experience with a vast majority of these tests nor relationships with laboratories that perform them."

CMS said it has analyzed claims data and the market structure of potential demo areas and found only a few labs that bill only a few codes under the entire lab fee schedule.

HHS Proposes Medical Error Reporting System

The Department of Health and Human Services (HHS) has proposed establishing a process in which health care providers can report medical errors voluntarily without fear of legal liability. Comments on the proposed rule are due April 14.

Under the proposal, patient safety organizations (PSOs) would be established to collect and analyze medical data that HHS said would allow aggregation of information to uncover trends in patient treatment that would help lower the incidence of medical errors.

"The health care system is behind in its attention to ensuring basic safety. The reasons for this lag are complex and varied. Providers are often reluctant to participate in quality review activities for fear of liability, professional sanctions, or injury to their reputations."
—HHS

Providers, which in many cases are collecting the data, could provide data to the PSOs without fear of legal prosecution, according to the rule, published by HHS's Agency for Healthcare Research and Quality.

Breaches of confidentiality would be subject to civil monetary penalties of up to $20,000 per act, to be enforced by HHS's Office for Civil Rights, the department said in the rule. Providers participating in the effort also will be expected to comply with privacy standards established under the Health Insurance Portability and Accountability Act of 1996, it added.

The patient safety organizations were authorized under the Patient Safety and Quality Improvement Act, which was signed into law in July 2005. HHS has been under pressure from lawmakers and health care providers to publish the proposal.

HHS said the rule will encourage the formation of PSOs with expertise in patient safety, which can advise providers on medical error issues as well as analyze data.

HHS said it expected a "broad range of organizations" to seek status as PSOs, although such organizations will not be entitled to federal funding. Organizations that conduct regulatory oversight of health care providers, including accreditation or licensure, will not be eligible to become a PSO, HHS said.

The department said it expected about 100 PSOs to be operational three years after enactment of a final rule.

IOM Report Cited

HHS said passage of the Patient Safety Act was spurred by a 1999 Institute of Medicine (IOM) report that found at least 44,000 and as many 98,000 individuals die in U.S. hospitals annually as a result of preventable medical errors. Medical errors cost the United States up to $50 billion annually, IOM said.

HHS said PSOs may reduce the frequency of preventable adverse medical events by between 1 percent and 3 percent during the first five years of operation, saving the nation up to $435 million.

IOM determined that most medical errors were not caused by individual mistakes but by "faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent adverse advents."

The HHS proposed rule said that, as compared to other high-risk industries, "The health care system is behind in its attention to ensuring basic safety. The reasons for this lag are complex and varied. Providers are often reluctant to participate in quality review activities for fear of liability, professional sanctions, or injury to their reputations."

Legal Protections

The proposed rule sets forth a uniform set of federal protections that will allow providers to share data without fear of legal liability.

"For that reason, implementation of this proposed rule can be expected to accelerate the development of new, voluntary, provider-driven opportunities for improvement, increase the willingness of health care providers to participate in such efforts, and, most notably, set the stage for breakthroughs in our understanding of how best to improve patient safety," the rule stated.

HHS said that, while providers are not required to participate in the program, "many providers will do so in order to take full advantage of the protections of the Patient Safety Act."

HHS said it expected about a quarter of hospitals to be participating a year after the program is enacted, rising to 40 percent after two years, 60 percent after three years, 75 percent after four years, and 85 percent after five years.

Costs for all hospitals establishing systemic reporting systems during the first five years of the program would range from $7.5 million the first year after enactment to about $64 million in the fifth year, according to the proposed rule.

PSO costs would total about $61 million in the first year after program enactment to $122.8 million in each of years three, four, and five, HHS said. PSOs will garner some of their revenues from providers.

DOJ Objects to False Claims Act Amendments

The Department of Justice (DOJ) is not supporting proposed legislation that would amend the False Claims Act (FCA), instead calling for more limited changes that would not include language allowing federal employees to bring qui tam lawsuits.

While DOJ is "sympathetic" to some of the proposals laid out in the False Claims Act Correction Act of 2007 (S. 2041), it is unwilling to support the bill in its current form, Deputy Assistant Attorney General Civil Division Michael F. Hertz told the Senate Judiciary Committee on February 27.

Chief among DOJ's concerns is a provision in the bill that explicitly would allow government employees to bring qui tam (commonly known as whistleblower) actions after certain requirements were met.

Hertz told the Judiciary panel that government employees already have an obligation to report fraud and that giving them financial incentives to use their role in the government to access information that could be used in a lawsuit poses ethical concerns and could erode public trust in government employees.

Sen. Chuck Grassley (R-Iowa) introduced the bill in September 2007. During the hearing, Grassley said the 1986 qui tam amendments to the False Claims Act, which he authored, never were intended to preclude government employees from being whistleblowers. However, some courts have barred qui tam actions from government employees.

The bill seeks to give clear authority to government employees to bring qui tam actions, but would require government whistleblowers to follow defined protocol and give the government at least a year to respond to the complaints before any action could be filed.

Hertz said government employees already had the right to take complaints about fraudulent conduct to the inspectors general in government agencies or could go directly to the Department of Justice with concerns. "I think these employees have a place to go," Hertz said.

However, Judiciary Committee Chairman Patrick J. Leahy (D-Vt.) and Sen. Richard J. Durbin (D-Ill.), both cosponsors of the Grassley bill, said that, without the express ability to bring whistleblower actions, government employees had no recourse if agencies failed to act on complaints of fraud.

COMPLIANCE PERSPECTIVES

Genetic Testing: An Evolving Market

Christopher Young is president of Laboratory Management Support Services in Phoenix.

The promise and potential of genetic testing as a means of improving patient care, coupled with advances in technology that put these tests within the reach of nearly all laboratories, has spurred the entrepreneurial growth of this kind of testing at a nearly phenomenal rate. I use the adjective "entrepreneurial" because that word represents risky enterprises, which is certainly applicable in this arena.

These genetic tests are the foundation that makes personalized medicine, with all of its promise for more effective treatment of patients based on individual genetic makeup, possible. Ultimately, personalized medicine could result in much improved medical care for each patient and reduce costs to the overall health care system. The complexity and variety of issues involved in this testing create some risk, but the business opportunities fuel the willingness to accept risk.

As laboratories rush to adopt this testing so as to not be left behind or miss the opportunities presented by these emerging technologies, the government is rushing to develop oversight for it because it recognizes the potential for abuse and harm to the public from these tests. These two forces are headed for a collision in the near future that is certain to create problems and changes for all laboratories but specifically for those laboratories directly involved in this testing arena. In this article, I hope to point out some of the risks and areas of concern for laboratories that are currently involved in or are contemplating becoming involved in genetic testing.

Genetic vs. Traditional Testing

Are genetic tests different from other laboratory tests? The answer to this question lies in understanding the concept of "genetic exceptionalism." Proponents of this viewpoint believe that genetic tests are different than other tests primarily because of these features of genetic tests:

- They can be used to make predictions about an individual's health future;
- The results do not change throughout a person's life;
- They can reveal information about family members; and
- There are instances where the information from genetic tests has been used to discriminate against individuals or selected populations.

Furthermore, genetic tests can provide diagnostic and predictive information about disorders that have no current treatment or preventive measures, raising questions about their clinical utility and the psychological impact this information may have on a patient. Opponents of this concept cite the existence of tests for HIV or high cholesterol which can, to a certain extent, predict a person's health future.

However, according to a report from the Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), a 2007 survey conducted by the Genetic and Public Policy Center found that 92 percent of people are concerned that information gained through the use of genetic tests could be misused to harm them in some way. This public fear concerning genetic tests may in and of itself provide ample evidence that genetic tests should be

handled differently and deserve special consideration when it comes to oversight and regulatory control.

Changing Regulatory Environment

The document that provides the most comprehensive view of the oversight risks the industry faces in the near future related to genetic testing is the draft report issued by SACGHS titled, *U.S. System of Oversight of Genetic Testing*. The 192-page report covers all aspects of genetic testing, including a brief history of previous oversight attempts by the government.

The draft report is the product of the work of a task force specifically charged by SACGHS "to develop a comprehensive map of the steps needed for evidence development and oversight for genetic and genomic tests and to consider questions about the regulatory policies related to genetic testing, the scientific information and oversight structures needed to ensure that tests are properly developed and used, and the transparency of the oversight system.

CLIA addresses accuracy, reliability, timeliness, confidentiality, and safety. CMS has generally enforced its standards for analytical validity, but the standards for clinical validity present a more difficult challenge since clinical utility data may be unavailable for years after a test is developed.

The draft report identifies significant gaps in the oversight of genetic testing that it says could lead to the public's harm if not corrected. The report was available for public comment from November 5 through December 21, 2007. The public comments will be considered in preparation of the final report that will be submitted to the Secretary of HHS.

The report identifies five key areas of consideration for genetic testing oversight and makes recommendations for how the government should address these key areas.

1 Establishing the analytical and clinical validity of the emerging testing technologies through the development of assay validation tools, improved data sharing, and clear evidentiary standards.

2 Developing benchmarks for proficiency testing and quality assurance for these emerging technologies.

3 Demonstrating the clinical utility of tests to guide the translation of genetic research and new technologies into medical practice.

4 Ensuring the accurate use and interpretation through education and guidance for the physician or other health care practitioner using the tests, as well as the laboratory professionals who provide the testing.

5 Coordinating public and private sector activities at the state and federal levels to avoid duplication or conflicting requirements.

Currently, oversight of genetic testing is shared by multiple governmental and nongovernmental bodies that may or may not be coordinating their efforts. At the federal level, the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) provide oversight for genetic tests. Currently there are two main pathways for genetic tests to get to the marketplace. They can be developed by in vitro diagnostic test manufacturers for distribution in a test kit through interstate commerce, which is regulated by the FDA, or they can be created as a laboratory developed test (LDT) for use solely in the test developer's laboratory.

These LDTs are generally not subject to FDA oversight but are regulated through CMS via the CLIA (Clinical Laboratory Improvement Amendments) regulations. These laboratory developed tests are

the subject of some controversy because they are not subject to FDA regulation, thus making them easier and less costly to get to market.

How long before the final report is completed and what will happen to the recommendations contained in it are anyone's guess but that does not reduce its importance.

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The overarching recommendation of the report is this:

> *"The HHS Secretary [should] take steps to enhance interagency coordination of the activities associated with the oversight of genetic testing, including policy and resource development, education, regulation, and knowledge generation."*

To this end, the report recommends changes to the CLIA provisions for proficiency testing for genetic tests, which are considered to be the most rigorous form of performance assessment. Yet, there are no commercially available proficiency tests for genetic testing, leaving laboratories on their own to develop a way to assess this critical aspect of analytical performance.

Further, the report recommends that inspectors who will be inspecting genetic testing laboratories be specially trained so they understand the technologies involved. The report makes several recommendations in support of additional funding for CMS to ensure it can carry out the recommendations regarding these oversight gaps identified in the report.

The report also recommends the development of some kind of registry for laboratories that are conducting genetic tests and for the tests themselves. One of the findings of the task force was that there is a lack of information in this regard. The report also recommends FDA oversight of LDTs that are genetic tests.

In the area of clinical utility, which is a key factor in developing coverage determinations for genetic tests, the report finds insufficient information regarding how to determine clinical utility. It makes 11 separate recommendations in this area. Clinical utility and evidence to support it is increasingly a factor used by health care payers before they will pay for genetic testing. With no consistent standards available, individual plans develop their own standards and labs find themselves having to meet differing standards for each payer.

The report also recommends that more work be done in the area of understanding the impact of direct to consumer marketing and consumer-initiated genetic testing.

Another area of risk that laboratories must take into consideration relates to one of the longstanding concerns about genetic testing and that is the possibility of discrimination against individuals based on genetic tests results. The two main areas of concern here are discrimination in the workplace and discrimination by health care insurers.

Genetic tests can identify individuals and populations with a greater risk for health problems than the general population. Companies and/or insurers may avoid hiring or providing coverage for individuals identified by these tests as a means to steer clear of the potential increased costs associated with the increased health risk.

The report contains many details about genetic testing and is an important document for any laboratory involved in genetic testing or considering getting involved in it. There is not enough space here to fully address the content of the report. How long before the final report is completed and what will happen to

the recommendations contained in it are anyone's guess but that does not reduce its importance.

Legislation

Federal and state lawmakers have also been active in the genetic testing oversight arena. The work of the agencies is, for the most part, guidance and recommendations, not laws and regulations. However, if a new law is passed and signed by the president, it will force the agencies to take action and perhaps develop regulations that will cause change in our industry.

The Genomic Research and Accessibility Act (H.R. 977) was introduced in February 2007. The purpose of this bill is to prohibit the patenting of human genetic material, specifically nucleotide sequences, its functions or correlations, or the naturally occurring products of its specifics. The bill is an attempt to address the debate concerning the promotion of private research and development over public interests. The bill would not be retroactive, so existing gene patents would remain in effect until they expire.

The Genomics and Personalized Medicine Act of 2007 is of particular interest because it is proposed by Sen. Barack Obama. The bill's stated purpose is "to secure the promise of personalized medicine for all Americans by expanding and accelerating genomics research and initiatives to improve the accuracy of disease diagnosis, increase the safety of drugs, and identify novel treatments." This bill is essentially a spending appropriations bill allocating funds for development and communication of issues in genetic testing.

The Genetic Nondiscrimination Act of 2007 (GINA) was passed in the House of Representatives by a vote of 420-3. The act will protect individuals from discrimination based on their genetic information when it comes to health insurance and employment. These protections should help encourage patients to take advantage of genetic testing as part of their medical care by addressing the fear that genetic information may be used to harm them subsequently. A Senate version was introduced in January 2007 by Sens. Edward Kennedy and Olympia Snowe (S. 358).

In addition to the federal activity, many states have passed laws to protect their citizens from discrimination based on genetic information. Generally, these kinds of laws are good for the laboratory industry because they allay public fears about genetic tests.

Conclusion

The government and its various agencies are determined to gain some control over the development and use of genetic tests and their application in the care and treatment of patients. There is a great concern that these tests, if not properly used, can cause harm to the public.

The growth of genetic testing and companies designed to take advantage of it has been relatively unchecked even though there are many controversial issues surrounding these tests. These controversial issues create a great amount of risk for the companies who have invested money and resources to develop and market these tests as state and federal government agencies struggle to catch up with the private sector that is moving at a rapid pace.

This government oversight could have a negative affect on the burgeoning genetic testing market and laboratory leaders, and those investing in genetic and genomic testing are well advised to make certain they are tracking government oversight efforts and preparing for the changes that are just over the horizon in this market.

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In addition, the OIG said that although CMS has demonstrated "vigilance" in reducing overall paid claims error rates, significant improper payments continue to occur in specific areas of the Medicare program, such as in the area of durable medical equipment (DME). The OIG noted in the report, though, that CMS has begun addressing overpayments in DME.

Other top areas of concern include appropriateness of Medicaid and State Children's Health Insurance Plan payments and the administration of the Medicaid program.

The OIG said that until 2007, little was known about Medicaid payment error rates, but that CMS has begun assessing Medicaid improper payments and will fully roll out the payment error rate testing program for Medicaid in 2008.

Furthermore, the OIG raised long-standing concerns about problems with state Medicaid financing arrangements involving intergovernmental transfers.

"Once payments are returned to state governments through IGTs, funds cannot be tracked, and they may be used by the states for purposes unrelated to Medicaid," the OIG said.

The report highlighted some steps CMS has taken to address the problem, including regulations meant to curb abuses by states. The report also discussed HHS management challenges and agency progress in dealing with quality-of-care problems and oversight of food, drug, and medical device safety through the National Institutes of Health and the Food and Drug Administration.

The OIG report is available at *www.oig.hhs.gov/publications/challenges/files/TM_Challenges07.pdf*.

The full HHS agency financial report is available at *www.hhs.gov/afr/index.html*.

Connecticut Hospital Reaches False Claims Settlement

Yale-New Haven Hospital (YNHH) has agreed to pay the federal government $3.7 million to settle charges that it violated the False Claims Act under the terms of a settlement agreement announced by the Department of Justice (DOJ) March 7.

U.S. Attorney for the District of Connecticut Kevin J. O'Connor said the allegations against the 944-bed, not-for-profit hospital located in New Haven, Connecticut, involved charges to Medicare for infusion therapy, chemotherapy administration, and blood transfusion services.

The federal government explained that during the time period in question, Medicare allowed payment for only one unit of infusion therapy and chemotherapy administration per visit and one unit of blood transfusion services per day.

However, according to DOJ, on many occasions, the hospital allegedly billed Medicare for multiple units of those services instead of billing for one unit per patient visit or one unit per day.

O'Connor's office said the allegations also involved claims for services provided in the hospital's oncology infusion service that were not adequately documented in the patient medical records. This included such items as dispensing medication and conducting laboratory studies without written orders signed by a physician.

Voluntary Disclosure

The government noted that the improper conduct was self-reported by Yale-New Haven Hospital to the federal government.

The hospital said in a statement that it is pleased with the terms of the settlement with the DOJ and stressed the settlement agreement, which was signed March 4 is the result, in large part, of a proactive, voluntary disclosure by Yale-New Ha-

ven Hospital to ensure compliance with Medicare guidelines.

"YNHH provided all of the patient services in question, and this matter has no bearing on the nature and quality of services that the hospital provided," the hospital said in a statement.

Yale-New Haven said the issue at the center of the settlement concerned the hospital's compliance with technical billing and documentation requirements.

Yale-New Haven said that in an effort to determine whether these requirements were being met, the hospital retained an outside consultant to verify conformity with present guidelines and then voluntarily reported its findings directly to Department of Health and Human Services (HHS). Upon submission of the hospital's self-reporting, HHS and DOJ conducted further reviews, resulting in the settlement, which involves HHS's Office of Inspector General.

"We are pleased that the Department of Justice and HHS recognized the hospital's voluntary efforts and, as a result, felt it was unnecessary to issue any form of compliance agreement that often typifies these situations," Yale-New Haven said. "The hospital is confident that it has taken extensive steps to ensure continued compliance and appropriate documentation with respect to this matter."

Drug Company May Put Kiosk in Docs' Offices, Says OIG

The Department of Health and Human Services Office of Inspector General (OIG) determined that a proposed arrangement by a pharmaceutical company to place electronic kiosks in certain physicians' offices offering patients free disease screening questionnaires would not generate prohibited payment under the anti-kickback statute.

In Advisory Opinion No. 08-05, released February 22, the OIG determined the proposed arrangement could present a potential kickback from the drug and health care company to the patient users of the kiosks to induce them to self-refer to the company's drugs. The OIG also found that the proposal could pose a potential kickback from the company to participating physicians to induce them to prescribe the pharmaceutical company's drugs.

However, the pharmaceutical company certified that the kiosks would provide only a printout reprising the questionnaire and each patient's answers and the questionnaires would not offer patients incentives for using the kiosks, such as coupons or offers of free items, the OIG determined.

Accordingly, the OIG said, the proposed arrangement would not provide anything of value to patients and, therefore, the anti-kickback statute was not implicated.

Reimbursable Products

The requestor is a pharmaceutical and health care company that develops, manufactures, and markets pharmaceuticals for a number of diseases and conditions, and its products are reimbursable under federal health care programs, including Medicare and Medicaid.

The company now places in physicians' waiting rooms informational pamphlets on different diseases that the company says can help patients determine if they should talk to their physician about a particular disease or condition.

Under the proposed arrangement, the company would place freestanding kiosks that offer voluntary interactive questionnaires in the waiting rooms of certain physicians. Each kiosk would have a touch screen, keyboard, printer, and software that would enable it to display interactive questionnaires about four specific diseases states. The requestor asserts that the kiosks would help patients determine whether they should discuss

symptoms of any of the four disease states with a physician.

In addition to the safeguards for patients, the OIG concluded that the proposed arrangement would not generate prohibited payments for participating physicians.

The kiosks would remain the property of the pharmaceutical company, and the physicians would host the kiosks, but would not receive space rental or utilities fees or other compensation in connection with the proposed arrangement.

The OIG found it unlikely that the kiosk-generated questionnaires would save any appreciable amount of physician or staff time. The kiosks would not enhance the attractiveness of participating physicians' office practices to prospective patients or increase the likelihood of selecting a physician because he or she offered a kiosk in the waiting room, the OIG determined.

Finally, the proposed arrangement contains safeguards to protect patient privacy, the OIG found. The pharmaceutical company certified that the proposed arrangement would comply with all applicable privacy laws. Neither individual patient information nor data related to prescriptions that participating physicians ultimately might write under the proposed arrangement would be conveyed to the pharmaceutical company or its affiliates via the kiosks, the OIG said.

Based on the totality of facts and circumstances, the OIG concluded that the proposed arrangement would not generate prohibited payments under the anti-kickback statute. For the same reasons, the OIG concluded that the proposed arrangement would not be subject to sanction under Section 1128A(a)(5) of the Social Security Act.

The advisory opinion is available at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-05B.pdf*.

Data Lacking on Reprocessed Medical Devices: GAO

Not enough information is available to draw conclusions about the comparative safety of reprocessed medical devices, according to a Government Accountability Office (GAO) report released March 3.

GAO said that neither existing data from the Food and Drug Administration (FDA) nor data from studies performed by other organizations are sufficient to draw conclusions about the safety of reprocessed single-use devices (SUDs), compared to "original" devices that have not been reprocessed.

However, the report did note that FDA has "taken a number of steps" to increase its oversight of reprocessed devices since 2000, the last time GAO examined this issue. These changes at FDA are partly from the agency's initiative and partly due to the 2002 Medical Device User Fee and Modernization Act or MDUFMA.

Examples of changes made at FDA include revising the form for reporting adverse events to indicate whether a reprocessed device was involved, the report said. In addition, MDUFMA required that labels of reprocessed devices specifically state that they are reprocessed SUDs, as well as identify the reprocessor.

In the area of data shortcomings, the GAO report said that in some cases, FDA data were not available or not sufficiently reliable "to allow us to develop detailed information or perform analyses." In addition, the GAO report said that neither industry nor FDA representatives were able to provide comprehensive information on the size of the reprocessed SUDs market in the United States, in terms of either value or volume, compared to the overall U.S. market for medical devices.

The report, *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk*, is available at *www.gao.gov/cgi-bin/getrpt?GAO-08-147*.

News-At-A-Glance

Lab Employee Pleads Guilty: An employee of a South Florida medical billing company on March 7 pleaded guilty in connection with a $2.1 million Medicare laboratory billing scheme. Defendant Lenka Slepickova pleaded guilty in U.S. District Court for the Southern District of Florida to one count of health care fraud conspiracy. The case against Slepickova arose from billings submitted from 2004 through 2006 by Washington Medical Laboratory Inc., a former Hallandale clinical laboratory, for services not provided. In April 2007, Slepickova's employer and the laboratory's owner, Marcelo de Jesus Serrano, was sentenced to 57 months in prison.

RAC Recovery: More than $371 million in improper Medicare payments has been collected from or repaid to health care providers and suppliers as part of a demonstration program using recovery audit contractors (RACs) in California, Florida, and New York in 2007, according to the Centers for Medicare & Medicaid Services (CMS). Nearly $440 million has been collected since the program began in 2005. Approximately 96 percent of the improper payments identified by RACs in 2007 were overpayments collected from health care providers; the remaining 4 percent were underpayments repaid to health care providers.

NPI Now Required: Effective March 1, 2008, all 837P and CMS-1500 Medicare claims must have a National Provider Identifier (NPI) or NPI/legacy pair in the required primary fields. Failure to include an NPI will cause the claim to be rejected. Providers whose claims are rejected and returned to them should immediately contact their contractor before resubmitting that claim or submitting new claims for services provided to Medicare beneficiaries, says CMS.

DME Owner Gets Jail Time: A South Florida man who authorities said orchestrated a $48 million durable medical equipment billing scheme was sentenced March 7 to more than 19 years in prison. In addition to the 235-month prison term, the U.S. District Court for the Southern District of Florida ordered Angel Castillo Jr. to pay $7.2 million in restitution. According to U.S. Attorney R. Alexander Acosta, Castillo owned more than eight durable medical equipment companies in Miami during 2005 and 2006. The companies submitted billings totaling more than $48 million, of which Medicare paid approximately $7 million to two companies.

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