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For Hospitals, Laboratories and Physician Practices

Device Industry Group Asks FDA to Revise Regulation of In Vitro Tests

A medical device industry group has submitted a proposal to the Food and Drug Administration (FDA) that would revamp how in vitro diagnostic tests are regulated and bring clinical labs into FDA's regulatory sphere.

The Advanced Medical Technology Association (AdvaMed) said its risk-based approach should be for regulating all types of diagnostic tests, regardless of where they are produced. Such tests are developed by device manufacturers or by clinical laboratories, but the device group said that numerous lab-developed tests are not under FDA regulation. AdvaMed submitted its proposal to the agency March 27.

The device industry group said that, under the proposal, the FDA would apply a risk-based approach to determine the intensity of review for all diagnostic tests. The agency would exempt low-risk tests from premarket submission. *Continued on page 2*

Labs Deny Wrongdoing in Calif. Lawsuit

At least some of the labs named in a recent California lawsuit alleging overbilling of Medi-Cal have denied wrongdoing and say they will defend themselves against the charges.

California state attorney general Edmund Brown Jr. announced March 20 that his office has joined a whistleblower lawsuit filed against the labs by Chris Riedel, the CEO of Hunter Laboratories in Campbell, Calif. The suit alleges that seven clinical laboratories—including Quest Diagnostics and LabCorp—charged the state Medicaid program up to six times more for tests compared to other clients over the past 15 years.

Quest officials deny any wrongdoing. "We believe that our services were priced appropriately," company spokeswoman Wendy Bost told G-2 Reports. "We intend to vigorously defend ourselves in the case."

Nancy Ogan, the chief executive of Seacliff, one of the labs charged in the case, also maintains that the lab did nothing wrong. "Though we believe our inclusion in this suit is not justified, we plan to conduct an investigation into the allegations, cooperate fully with the authorities, and vigorously defend Seacliff against these charges as we believe we will be vindicated in a court of law," *Continued on page 9*

Kimberly Scott, Senior Editor

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In addition, AdvaMed's petition calls for the FDA to harmonize its requirements with the Centers for Medicare & Medicaid Services (CMS). In Principle 6 of its FDA submission, the industry group also calls for the Medicare payment system to support "timely and adequate reimbursement for all new diagnostics." AdvaMed said that clinical tests account for less than 2 percent of Medicare spending, but influence 70 percent of health care decisions.

Follows Genentech Petition

The AdvaMed effort follows a December 2008 petition filed by biotech drug company Genentech, which asked the FDA to regulate all tests, regardless of whether they were developed by clinical laboratory companies for in-house testing or by device manufacturers for sale as diagnostic test kits (*GCR*, Feb. 2009, p. 2). The petition from Genentech also cited the use of these diagnostic tests in personalized medicine—that is, determining treatments with particular drugs based on testing of patients.

AdvaMed noted in a March 27 letter to the FDA's Center for Devices and Radiological Health that its submission to the FDA is in response to the Genentech petition to the agency. In its submission to the FDA, AdvaMed said there are more than 1,000 genetic disorders where tests are developed in laboratories and not subject to the FDA or Clinical Laboratory Improvement Amendments of 1988 (CLIA) evaluations for safety and effectiveness.

The AdvaMed effort follows a December 2008 petition filed by biotech drug company Genentech, which asked the FDA to regulate all tests, regardless of whether they were developed by clinical laboratory companies for in-house testing or by device manufacturers for sale as diagnostic test kits.

The submission to the FDA noted that the device industry group is working on a final proposal to exempt additional low-risk class I and class II medical devices, "based on scientifically derived criteria, that will be submitted to the FDA in the spring of 2009." Class I is the lowest-risk class for devices, while class III is the highest-risk classification. AdvaMed said that the proposal will lay out a data-driven basis for the FDA to decide which technologies are well-established and appropriate for considering for exemption from the premarket review process.

Lab Industry Group Concerned

In December 2008, the American Clinical Laboratory Association (ACLA) said the proposal from Genentech, if adopted, "would have a chilling effect on innovation and patient care while stifling the promise of personalized medicine." The lab industry group said Genentech's petition "is ill-informed and additional FDA oversight is not needed." It said that all health care-related laboratory tests are already either cleared by the FDA or are performed in a laboratory regulated under CLIA by the Centers for Medicare & Medicaid Services, or both.

ACLA said in late 2008 that its testing services enable "timely inclusion of the most up-to-date medical research and innovations to be used in patient care. This is in contrast to FDA-approved medical device kits, which often undergo such extended reviews that by the time the FDA clears a new assay, it is no longer relevant to the current medical circumstances." The group said the FDA approval process "essentially freezes medical innovations it regulates to the time the test application is submitted for approval."

ACLA President Alan Mertz says his group can "on principle agree with" some of AdvaMed's positions, such as the regulatory approach based on risk and improvements to reimbursement for tests. However, the lab group disagrees with any proposal to move the labs from CLIA's regime into FDA's as device manufacturers.

He said the better approach is to strengthen the CLIA-based regulation of lab-developed tests, noting that his group's comments on the Genentech petition offered a proposal for stronger CLIA-based regulation in consultation with the FDA.

OIG Modifies Self-Disclosure Protocol

The Department of Health and Human Services Office of Inspector General (OIG) said March 24 it is refining its self-disclosure protocol (SDP) for the health care industry by focusing on kickbacks intended to induce or reward a physician's referral.

HHS IG Daniel Levinson issued an "Open Letter" to the health care industry on SDP, saying his office no longer will focus on provider self-disclosures that deal only with physician self-referral issues.

"To more effectively fulfill our mission and allocate our resources, we are narrowing the SDP's scope regarding the physician self-referral law," said Levinson. "OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation."

In April 2006, Levinson issued his first "Open Letter" that promoted the use of SDP to resolve matters giving rise to civil monetary penalty liability under both the anti-kickback statute and the physician self-referral (Stark) law.

In the most recent letter, Levinson also sets forth a new minimum settlement amount. For kickback-related submissions accepted into the ADP after March 24, the OIG will require a minimum settlement amount. For kickback-related submissions accepted into the SDP after March 24, the OIG will require a minimum $50,000 settlement amount to resolve the matter. "This minimum settlement amount is consistent with OIG's statutory authority to impose a penalty of up to $50,000 for each kickback and an assessment of up to three times the total remuneration," the letter stated.

"These refinements to OIG's SDP are part of our ongoing efforts to develop the SDP as an efficient and fair mechanism for providers to work with OIG collaboratively," Levinson said.

The open letter is available at *http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf*.

Lab, Pathology Groups Urge Changes to EHR Safe Harbor

Groups representing independent laboratories and pathologists are urging the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services' Office of Inspector General (OIG) to make changes to the safe harbor for electronic health records (EHRs).

In August 2006, the OIG finalized a new safe harbor provision that protects arrangements involving EHR software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive EHRs. The purpose of the final safe harbor was to make it easier for health care providers to adopt EHR systems—action that would, it was believed, ultimately reduce medical errors, improve the quality of patient care, and increase the efficiency of health care generally.

The centerpiece of the new safe harbor was a provision that allowed entities to donate EHR technology to physicians, hospitals, and other providers, without violating federal fraud and abuse laws, so long as the recipient of the donation paid 15 percent of the total cost of the donated technology.

The American Clinical Laboratory Association (ACLA) believes the safe harbor should be withdrawn. According to ACLA, recent changes made by the American Recovery and Reinvestment Act of 2009 (ARRA), which will provide substantial incentives to hospital and physicians to obtain EHR technology, make the safe harbor unnecessary.

"Given the new financial incentive for EHR adoption, it is no longer necessary for entities to underwrite the cost of EHR technology in order for it to be available to hospitals and physicians," ACLA wrote in comments submitted March 19. "Instead, the incentive payments should make it possible for any physician or hospital that needs an EHR system to obtain it. There is no longer any justification for other health care entities to bear that substantial expense."

Although ACLA would prefer complete revocation of the safe harbor, an acceptable alternative is for the OIG to remove laboratories and laboratory service providers as permitted donors under the safe harbor and for the OIG to clarify and strictly enforce on the remaining donors the prohibitions and restriction of the safe harbor against the offering of EHR technology as an inducement for referrals.

CAP Calls for Removal of Labs

In contrast, the College of American Pathologists (CAP) is pushing for the OIG not to include laboratories in the EHR category of protected donors because it believes some commercial labs are offering these EHR software packages to physicians as a referral inducement.

"These arrangements do not promote widespread adoption and use of health information technology, as intended by the safe harbor, but instead promote fragmented care, duplicate testing, and a reduction in care coordination," states the letter. "In fact, many of our member laboratories have indicated that electronic access to records is even less effective than it had been prior to the adoption of the EHR safe harbor due to impediments and perverse incentives that have resulted due to the permissibility of donated laboratory records under the current safe harbor."

CAP also recommends that the OIG modify the safe harbor to state that a donor cannot tie the donation of software that qualifies under the safe harbor to the acceptance of nonqualifying technology, even if the additional technology is accepted at the recipient's cost.

Court Rules in Lab Competitive Bidding Demo Lawsuit

In a long-awaited ruling, a federal district court in San Diego on March 25 granted the government's motion to dismiss the lawsuit filed by local labs to stop the launch of the Medicare competitive bidding demo for independent lab services, but the court denied the government's motion to dissolve the preliminary injunction and vacate the interlocutory opinions.

The preliminary injunction stopped the demo from going forward on July 1 of last year and barred the Centers for Medicare and Medicaid Services (CMS) from disclosing or using the bid information the labs previously submitted. Congress then repealed the authority for the demo, but CMS declined to return the bids.

The lab plaintiffs—Sharp Healthcare, Internist Laboratory, and Scripps Health—feared CMS would use the bid information to lower rates and demanded that CMS return and not use the information.

Judge Thomas Whelan opted not to hold a hearing last September 22 on motions from the plaintiffs and CMS, saying he would decide the matter based on the briefs they submitted.

The judge's March 25 ruling gives the lab plaintiffs 30 days to amend the existing complaint to raise the document retention issue directly but urges the parties to work out the dispute. More importantly, said the labs' attorney Patric Hooper, the judge refused to vacate the previous orders, suggesting that the court has substantial concerns about CMS's continuing use of the bid data. Hooper is with Hooper, Lundy, and Bookman in Los Angeles.

COMPLIANCE PERSPECTIVES

HIPAA Redux: HITECH Expansion of Privacy & Security Requirement

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The American Recovery and Reinvestment Act, which contains the artfully titled Health Information Technology for Economic and Clinical Health or HITECH Act (the act), was signed into law in February 2009. With the act's promotion of the adoption of electronic health records (EHRs) come concerns about the privacy and security of EHRs. To help calm the frayed nerves of privacy and consumer advocates, the act is loaded with requirements, new enforcement provisions, and penalties for covered entities, business associates, and others.

Clinical laboratories and other health care providers need to brace themselves for expansions to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which will require revisiting their HIPAA compliance programs and updating their privacy and security policies, procedures, and other documents.

Most of the act's provisions will take effect one year after enactment of the law (Feb. 17, 2010), although increased penalty provisions go into effect immediately. Other provisions require implementing regulations and will be on a different schedule.

Privacy and Security Breach Notices

Almost all states have passed data breach notification. However, HIPAA has no explicit notification requirement. The HITECH Act changes this by requiring covered entities to notify individuals whose "unsecured" protected health information (PHI) has been (or is reasonably believed to have been) accessed, acquired, or disclosed as a result of a data breach. Notification provisions also extend to business associates, vendors of personal health records (PHRs), as well as certain PHR-related businesses and third-party service providers.

The act generally requires that the breach notices be sent "without unreasonable delay" and in no case later than 60 calendar days after discovery. Unlike many state notification laws, the act is not limited to breaches of the security of online or financially sensitive information.

Until the Department of Health and Human Services (HHS) issues guidance, the act provides a default definition of unsecured PHI, which includes all PHI that is not secured by an encryption standards endorsed by the National Institute of Standards and Technology.

Entities providing notification have the burden of demonstrating their compliance with the act, including justifying the amount of time taken to provide notice, even if the 60 day outside time limit is met.

Notices to affected individuals generally must be sent by first-class mail. They may be sent by electronic mail if the individual has expressed a preference for it or, in an emergency, by telephone (although this does not obviate the need for written notice). Other notification rules apply if 10 or more individuals require notification for which there is insufficient or out-of-date contact information.

All notices must contain:

- A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known.
- A description of the types of unsecured PHI involved in the breach.
- The steps individuals should take to protect themselves from potential harm resulting from the breach.
- A brief description of what the covered entity involved is doing to investigate the breach, to mitigate losses, and to protect against any further breaches.
- Contact procedures for individuals to ask questions or learn additional information must include a toll-free telephone number or an e-mail, Web site, or postal address.

If the breach involves more than 500 residents of a state, a covered entity also must provide notice to prominent media outlets serving the state. Further, a covered entity must notify HHS immediately if the breach involves 500 or more individuals, and HHS will post on an HHS Web site the names of all covered entities involved in large data breaches. A covered entity must maintain a log of smaller data breaches and submit it to HHS annually.

Increased Duties for Business Associates

Under the act, business associates will be subject to the administrative, physical, and technical safeguard security requirements of the HIPAA security rule, as well as the requirements to maintain policies, procedures, and documentation concerning security activities.

The act takes a slightly different approach to privacy: It does not apply specific HIPAA privacy standards to business associates, but it prohibits business associates from making any use or disclosure of PHI that is not in compliance with each of the required terms of a HIPAA business associate contract.

The act goes on to say that its additional privacy and security requirements that are applicable to a covered entity "shall also be applicable to such business associate and shall be incorporated into the business associate agreement." Regrettably, this language is not entirely clear. There are at least two possible interpretations of this language. The first, and most helpful to covered entities and business associates, particularly those with numerous business associate contracts in place, is that all such requirements are automatically imposed on business associates by application of law.

Another interpretation is that covered entities (and perhaps business associates) are required to amend their existing business associate contracts to include—and include in future business associate contracts—the act's additional security and privacy requirements.

As of the date of this article, HHS had not taken a formal enforcement position on this issue. It is hoped that HHS will provide guidance in the near future. Because of the uncertainty, a risk-adverse covered entity may do well to include the act's requirements in its business associate contracts, as well as to include representations and warranties that the business associate recognizes its added direct responsibilities under HIPAA.

The act imposes the same HIPAA civil and criminal penalties that apply to covered entities onto business associates that violate the HIPAA security standards or the required terms of their business associate contracts.

The act clarifies that health information exchanges and vendors that provide PHRs on behalf of covered entities are business associates and must enter into business associate contracts with the covered entity.

Expanded Accountings of Disclosures

The act expands the HIPAA right of individuals to receive an accounting of dis-

closures for covered entities with EHRs. Under the current privacy rule, covered entities are required to provide an accounting of certain disclosures of health information when requested. However, the accounting need not include disclosures for treatment, payment, or health care operations, which account for the great majority of disclosures.

The act imposes the same HIPAA civil and criminal penalties that apply to covered entities onto business associates that violate the HIPAA security standards or the required terms of their business associate contracts.

Under the act, covered entities that use or maintain EHRs will need to include in their accountings disclosures for treatment, payment, and health care operations made from the EHR during the three-year period prior to the request.

Obtaining Electronic Records

The individual will have the right to obtain from a covered entity with an EHR a copy of his or her record in an electronic format. In addition, the individual has a right to direct the covered entity to transmit a copy directly to another entity or person. The covered entity may not charge the individual any more than its labor costs for such record.

Requests for Privacy Protections for Self-Pay Services

Currently under HIPAA, providers have the discretion to refuse requests for additional privacy protections (but are bound if they do agree). Under the act, a provider must not disclose certain information to a health plan if the PHI pertains solely to an item or service for which the provider already has been paid in full and if the disclosure is for nontreatment purposes.

New Restrictions on Marketing and Fundraising

The act clarifies that marketing communications require authorizations unless the communication: 1) describes a health-related product or service provided by, or included in a plan of benefits of, the covered entity making the communication; 2) is for treatment of the individual; or 3) is for case management or care coordination for the individual, or to direct or recommend alternative treatments, providers, or settings. The act changes the rules if remuneration is involved, except where the communication:

- ❖ Describes only a drug or biologic that currently is prescribed for the individual, and the payment is "reasonable";
- ❖ Is made by the covered entity pursuant to a valid authorization; or
- ❖ Is made by a business associate on behalf of the covered entity and the communication is consistent with the applicable business associate contract.

Prior versions of the act would have required HHS to exclude the activity of fundraising from the definition of "health care operations"—effectively prohibiting the use of PHI for fundraising without authorization. Instead, the act requires HHS to provide by rule that any written fundraising communication shall, in a clear and conspicuous manner, provide an opportunity for the recipient of the communications to opt out of any further fundraising communication.

Preference for Limited Data Sets and De-identified Information

HHS must issue guidance on requirements for "de-identification" and "minimum necessary." The act indicates a strong preference for the use of "limited data sets" to comply with the minimum necessary requirements. A limited data set is almost de-identified, except that it can have dates more specific than year and locations down to zip code.

No Sale of PHI

The act will prohibit a covered entity or business associate from directly or indirectly receiving remuneration in exchange for any PHI without a valid authorization from the individual that

includes a specification of whether the PHI may be sold by the entity receiving the PHI.

This prohibition does not apply if the purpose of the exchange is:

- Public health activities.
- Research and the price charged reflects the costs of preparation and transmittal of the data for such purpose.
- Treatment of the individual.
- The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity or an entity that following such activity will become a covered entity, and due diligence related to such activity.
- Remuneration that is provided by a covered entity to a business associate for activities involving the exchange of PHI that the business associate undertakes on behalf of and at the specific request of the covered entity pursuant to a business associate agreement.
- To provide an individual with a copy of the individual's PHI.
- As otherwise determined by HHS through rulemaking.

Enforcement

The act provides that, for purposes of the criminal provisions, a person (including an employee or other individual) will be considered to have violated HIPAA if the information is maintained by a covered entity and the individual obtained or disclosed PHI without authorization. As indicated, the act also subjects business associates to civil enforcement under HIPAA.

The act requires the development of a methodology under which an individual who is harmed by a violation of HIPAA or the act may receive a percentage of any civil monetary penalty or monetary settlement collected for such violation. It also requires HHS to periodically audit covered entities and business associates for compliance with HIPAA and the act. In addition, HITECH permits the states' attorneys general to get into the HIPAA enforcement picture, allowing states to bring actions in federal court on behalf of the residents who have been (or are threatened to be) adversely affected by a violation of HIPAA or the act. Finally, it amends HIPAA to significantly increase penalties for violations of HIPAA and the act.

The act requires the development of a methodology under which an individual who is harmed by a violation of HIPAA or the act may receive a percentage of any civil monetary penalty or monetary settlement collected for such violation.

What Should Covered Entities Be Doing?

To comply with the HITECH Act, covered entities should:

- Revisit the HIPAA compliance program as a whole and make adjustments to improve protections and efficiencies.
- Revise their HIPAA compliance policies and procedures, particularly those governing individual rights.
- Review their business associate contracts and decide whether to amend or update templates and/or existing documents. This also is a good time to evaluate whether all business associates have been accurately identified and have contracts in place.
- Evaluate state and federal data breach requirements and develop a plan for dealing with a data breach and notification. Preparation will help an organization meet the strict time requirements.
- Update, as necessary, the notice of privacy practices so that it accurately reflects privacy policies and procedures.

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Labs Deny Wrongdoing, *from page 1*

she was quoted as saying in the *Los Angeles Times*.

The qui tam suit filed under the state's False Claims Act (FCA) seeks triple the amount of California's damages, civil penalties of $10,000 for each false claims, and recovery of costs, attorneys' fees, and expenses. Under the state's FCA, the whistleblower receives a share of the recovery if statutory requirements are met.

According to Brown, state law prohibits providers from charging Medi-Cal more for a service than it charges other payers for a comparable service under comparable circumstances. The lawsuit alleges that the defendant labs charged Medi-Cal up to six times as much as they charged some of their other customers for the same tests. Among the examples alleged:

- Quest Diagnostics Inc. charged Medi-Cal $8.59 to perform a complete blood count (CBC) while it charged some of its other customers $1.43 for the exact same test.
- Laboratory Corporation of America charged Medi-Cal $30.09 to perform a hepatitis C antibody screening while it charged some of its other customers only $6.44 for the test.
- Health Line Clinical Laboratories charged Medi-Cal $12.65 to perform an HIV antibody screening while charging some of its other customers $1.75.

Labs Named in Lawsuit

- Quest Diagnostics Inc. (Madison, N.J), its affiliate Specialty Laboratories Inc. (Valencia, Calif.), and four other Quest affiliates.
- Health Line Clinical Laboratories Inc., now known as Taurus West Inc. (Burbank).
- Westcliff Medical Laboratories Inc. (Santa Ana).
- Physicians Immunodiagnostic Laboratory Inc. (Burbank).
- Whitefield Medical Laboratory Inc. (Pomona).
- Seacliff Diagnostics Medical Group (Monterey Park).
- Laboratory Corporation of America (Burlington, N.C.).

'Pattern of Abuse'

According to Brown, these examples are not isolated examples but are a part of a "pattern of fraudulent overcharging and kickbacks that developed over the past decade." Here's how it worked:

- The labs provided deep discounts when paid directly by doctors, patients, or hospitals. Prices were often below the lab's costs and sometimes free.
- In exchange for these discounts, the labs expected customers to refer all of their patients (where the lab was paid by an insurance company, Medicare, and Medi-Cal) to its lab. Under California law, this amounted to an illegal kickback.
- These sharply reduced prices were not made available to Medi-Cal. In effect, the labs shifted the costs of doing business from the private sector to Medi-Cal.
- Additionally, the labs offered their clients who paid them directly (not through Medi-Cal or other insurance) deeper discounts to get a larger share of the lab-testing business. This created an unfair playing field, the lawsuit alleges, and laboratories that followed the law could not effectively compete and sometimes were forced to sell or close down.

Open to Dispute

The Medi-Cal case is not cut-and-dry, say industry sources. The "lowest rate" argument is subject to dispute, says Patric Hooper, an attorney with Hooper, Lundy, and Bookman in Los Angeles. While Hooper declined to comment on the specifics of the case, he did discuss the law in general, which he said allows discounts to physicians.

This was affirmed in a state appellate court ruling in the *People v. Duz-Mor Diagnostic Laboratory Inc.*, which found that the lab's practice of charging discounted fees to physicians' private-pay patients did not violate the state's unfair competition law. The court held: "In our view, the practice of negotiating discounts for physicians' private-pay patients benefits health care consumers. The lower prices are by law passed onto consumers. The

evidence established that if discounts were not negotiated, private-pay patients would pay more for services that Medi-Cal pays on behalf of its beneficiaries or than HMOs pay for their members. We can see no public policy benefit in such a result."

Nor are discounts unfair to the public because Medi-Cal is not offered similar discounts. The court noted that the amount Medi-Cal pays for a test is governed by state regulations and can be no more than the lesser of the amount billing, the charge to the general public, Medicare's allowance, or scheduled amounts. "Medi-Cal, not Duz Mor, controls the amount the program will pay."

A previous ruling by a California court in a separate case came to a different conclusion on discounts. In *Physicians & Surgeons Laboratories Inc. v. Department of Health Services*, which is cited in the quit tam suit, the court held that the defendants could charge any other purchaser any fee for their services as long as Medi-Cal obtained the best price available to other customers under comparable circumstances.

Healthways Agrees to Pay $40 Million to Settle Claims

Healthways Inc. has agreed to pay about $40 million to settle a whistleblower lawsuit alleging violations of federal false claims and anti-kickback laws, the company announced March 13 (*United States v. Diabetes Treatment Centers of America Inc.*).

Healthways, based in Nashville, Tenn., said that under a proposed settlement agreement, it would pay $28 million to the federal government and approximately $12 million to the plaintiff, a former employee, and his attorneys. The company said it had reached the proposed settlement with the plaintiff, which still requires approval by the Department of Justice.

Healthways denied any wrongdoing and said it was settling to avoid the costs, distraction, and uncertainty stemming from continuing litigation.

The lawsuit was filed with the U.S. District Court for the Eastern District of Tennessee in June 1994 by A. Scott Pogue, who had been dismissed by the company in February 1994. Pogue sued Healthways, its wholly owned subsidiary, American Healthways Services Inc., and several medical directors and client hospitals.

Illegal Pay for Referrals Alleged

Pogue alleged that the company's former Diabetes Treatment Centers of America (DTCA) improperly compensated medical directors to induce referrals to its treatment centers.

The lawsuit claimed that the compensation scheme involved the false submission of Medicare and Medicaid claims, and the defendants violated the federal False Claims Act, the Anti-Kickback Statute, and the Stark Law, a statute that prohibits physicians from receiving certain compensation arrangements involving referrals.

In 1999, the litigation was referred to the U.S. District Court for the District of Columbia (*United States v. Diabetes Treatment Centers of America Inc.*), but in November 2008, it was remanded to the U.S. District Court for the Eastern District of Tennessee.

Prior to the remand, DTCA was the lone defendant, and it had been granted summary judgment as to claims under the Stark Law, but the false claims and anti-kickback claims were left intact.

"The settlement of this 1994 lawsuit, which neither relates to nor affects our current operations, will put this prolonged, 15-year litigation firmly behind us," Healthways Chief Executive Officer Ben R. Leedle Jr. said in a March 13 statement. "This settlement is not an admission of wrongdoing."

GAO Says State Oversight of Care Facilities Harmed by Funding Drop, Workforce Issues

A drop in federal funding for state inspections of health care facilities combined with workforce stability problems has left states unable to shoulder the workload in some cases, according to a Government Accountability Office (GAO) report released March 19.

In inflation-adjusted dollars, funding for state surveys of facilities such as nursing homes, hospitals, dialysis facilities, and home health agencies that participate in Medicare or Medicaid dropped 9 percent between fiscal years 2002 and 2007, according to the report, *CMS Needs to Re-examine Its Approach for Funding State Oversight of Health Care Facilities* (GAO-09-64).

GAO also found that most states did not complete the surveys required by the Centers for Medicare & Medicaid Services in FY 2006 and FY 2007, although the workload that states would have to complete to meet statutory and CMS survey frequency requirements decreased by about 4 percent.

However, even if a state fulfilled its requirements, that does not necessarily guarantee the surveys were thorough, according to the report. CMS found, for example, that at least 25 percent of nursing home surveys in seven states missed serious deficiencies, according to the report.

Time Between Surveys

GAO said in its report that most states told investigators that CMS's decision to increase the time between surveys not dictated by statute—from six years to 10 years in some cases—could harm beneficiaries, even though it was designed to reduce state burdens.

Ultimately, GAO concluded that the "evidence is mixed" as to whether federal funding has kept pace with the workload expected of states, although it said weaknesses do exist in the survey system.

GAO recommended CMS re-examine its approach to funding and conducting surveys, considering issues such as the sources and availability of funding and how to ensure adequate survey workforces, as well as implement a series of smaller reforms.

The GAO report is available at *http://aging.senate.gov/letters/gaosurveycert.pdf*.

Exception Granted for Reporting NPIs for Reference Lab Work

Effective March 27, the Centers for Medicare and Medicaid Services is establishing an exception to the standard reporting of the national provider identifier (NPI) on certain Medicare fee-for-services claims for reference laboratory and purchased diagnostic services (Change Request 6362).

The exception applies when a provider in one contractor jurisdiction bills for a reference lab service on the Part B clinical lab fee schedule that was outsourced to a performing provider in another contractor jurisdiction. In this situation, the contractor that is billed will not have a record of the performing provider's NPI.

To facilitate adjudication of the claim, the billing provider must, in addition to reporting its own NPI (as the billing provider), report its own NPI as the performing provider and annotate the electronic or paper claim with the name, address, and ZIP code of the performing provider's NPI in the clinical records for auditing purposes. Previously, this reporting convention was discretionary; now, it is a requirement, CMS said. Electronic and paper claims that do not satisfy this convention will be returned as "unprocessable."

Direct Billing Legislation: Legislation introduced in the House March 25 would allow independent laboratories offering complex, advanced diagnostic laboratory tests to bill Medicare directly without forcing hospitals into a middleman role they don't wish to perform. Under current Medicare regulations, the date of service for a laboratory test ordered less than 14 days after a patient's discharge from a hospital is the date on which the specimen was collected. The effect of this rule is to treat a lab test ordered less than 14 days after a patient is discharged as having been performed when the patient was in or at the hospital, which requires that the hospital bill Medicare for the test. The "Patient Access to Critical Lab Tests Act" would allow labs to bill Medicare and be paid directly for the testing.

Billing Scam: A South Florida physician and a chemist pleaded guilty March 26 to roles in a Medicare billing scheme that relied on manipulated patient blood samples to make it appear infusion treatments were medically necessary, federal officials announced March 26. In separate plea agreements filed in U.S. District Court for the Southern District of Florida, defendants Carmen Del Cueto and Alexis Dagnesses each pleaded guilty to one count of conspiracy to commit health care fraud. Del Cueto was a co-owner of and practicing physician at Midway Medical Center Inc., a Miami clinic that specializes in treating patients with HIV. Dagnesses, a chemist, manipulated blood samples drawn from Midway's patients, the statement said.

Houston Hospital Settlement: One of Houston's largest hospitals will pay the United States $9.9 million to resolve allegations it submitted false claims to Medicare for enhanced reimbursements for outlier payments, the Department of Justice announced March 26. The government's civil settlement with Methodist Hospital resolves claims that the health care facility submitted false claims to Medicare and the military's TRICARE program for inpatient and outpatient outlier payments by increasing its charges, the settlement agreement said. Outlier payments are supplemental reimbursements intended to give hospitals incentive to treat patients where the cost of care is unusually high. The settlement was not filed with a court.

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