G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Labs Feeling Impact of California Audits

Quest Temporarily Suspends Medi-Cal Billing

Quest Diagnostics (Madison, N.J.) has agreed to temporarily suspend billing the California Medicaid program (Medi-Cal) program for up to six months pending resolution of a lawsuit alleging that the company overcharged Medi-Cal for testing services.

In 2006 and 2008, Quest and several other clinical laboratories received subpoenas from the California Attorney General's Office seeking documents related to the company's Medi-Cal billings. Subsequently, the state intervened as a plaintiff in a lawsuit against Quest and six other labs, *California ex rel. Hunter Laboratories LLC et al. v. Quest Diagnostics Inc. et al*. The suit alleged that the labs charged Medi-Cal up to six times more for tests compared to other clients over the past 15 years. The lawsuit was ultimately split into several separate complaints.

In the third quarter of 2010, the California Department of Health Care Services (DHCS) conducted audits of Quest and other labs. While Quest "believes it is in compliance in all material respects

Continued on page 2

Kimberly Scott, Managing Editor,
kscott@ioma.com

Inside this issue

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CMS Final Rule on Screening, Enrollment Shifts Fraud Focus to Prevention

The Centers for Medicare and Medicaid Services (CMS) has issued a final rule designed to strengthen public health program enrollment and screening procedures. The rule also allows for payment suspensions on credible allegations of fraud.

The rule, authorized under the Patient Protection and Affordable Care Act (PPACA), was published in the Feb. 2 *Federal Register*, has a 60-day comment period, and will take effect March 25. Comments will be allowed only if they pertain to the fingerprinting provisions, one of the new screening measures. The proposed rule was published Sept. 23, 2010.

The rule is designed to help CMS move from a pay-and-chase enforcement model to an enforcement model based on preventing the possible payment of fraudulent claims. Under the rule, all providers and suppliers would be placed in one of three levels of risk (limited, moderate, and high) based on an assessment of their overall risk of fraud, waste, and abuse. Screening procedures would

Continued on page 9

Labs Feeling Impact, *from page 1*

with California requirements applicable to billing for clinical laboratory testing, the company entered into an interim agreement under which it had agreed to temporarily suspend billing Medi-Cal for a period of up to six months, during which it continues to provide services, pending resolution of the California lawsuit," the company says in its third-quarter report filed with the Securities and Exchange Commission (SEC).

"An unfavorable outcome of the California lawsuit could result in reduced reimbursement from the Medi-Cal program," it adds. "Annual revenue from the Medi-Cal program in 2009 was approximately $66 million."

LabCorp also was audited during the third quarter of 2010, the company says in its quarterly filing with the SEC. DHCS subsequently provided the company with a proposed agreement related to the company's billing of the Medi-Cal program, including a requirement that the company charge Medi-Cal the "lowest price" it charges others for a particular laboratory test.

"The company disagrees with DHCS's contention and interpretation of its regulations and believes that it has properly charged the Medi-Cal program under all applicable laws and regulations," LabCorp said. "The company is continuing to cooperate with DHCS with respect to the audit."

LabCorp has also received three other subpoenas since 2007 related to Medicaid billing, the company said: Florida (June 2010), Virginia (February 2009), and Michigan (October 2009). In addition, the company responded to an October 2007 subpoena from the U.S. Office of Inspector General's regional office in Massachusetts regarding certain of its billing practices.

New Jersey Clarifies EMR Safe Harbor Exemption

Clinical laboratory owners and directors in New Jersey are allowed to donate electronic medical record (EMR) systems to physician offices if they do not—and do not intend to—operate a collection station in the office, according to the state Department of Health's Clinical Laboratory Improvement Service (CLIS).

In a Jan. 7 letter providing additional guidance on rules governing collection stations in physician offices and freestanding patient-service centers, Dennis McDonough emphasizes that the donation should not be an inducement for establishing a collection station in the office, or contingent upon the referral of increased volume to the laboratory. The letter was first reported by the College of American Pathologists (CAP).

According to the letter, donation of EMR systems to physician offices in which the laboratory operates a collection station that were made prior to the July 19, 2010, rule adoption are permissible. However, laboratories shall not continue to pay monthly service, maintenance, or other fees for the EMR system.

CAP says it "is disappointed with New Jersey's decision to allow these EMR donations, as it has long been critical of the potential for abusive business practices, such as those outlined in McDonough's letter. The college believes that these arrangements tie the physician group's referrals to the donor of the technology by incorporating software and interfaces that can only be used for specimens sent to a specific laboratory or pathology provider."

The New Jersey letter follows a letter sent Sept. 27, 2010, to clinical laboratories operating in New York state (NYS) in which the Department of Health said that state

law prohibits labs operating in the state from providing electronic health record (EHR) systems and software packages to referring physicians even though federal law allows labs to donate or cost-share up to 85 percent of the cost of EHR software, technology, and training (G-2 Compliance Report, *Nov.-Dec. 2010, p. 1*).

While labs operating in NYS may not donate EHRs to physicians, they may provide limited types of software and hardware that facilitate test ordering and transfer and storage of laboratory-generated data. For example, labs may interface their laboratory information system to the client's existing EHR to enable seamless laboratory test ordering and laboratory test reporting and facilitate other laboratory-related functions and may assume, as a cost of doing business, the cost of such a limited interface.

Professionals Seek Info on Consideration Given to Ethics, Compliance Programs in Enforcement Decisions

The Department of Justice (DOJ) needs to provide the ethics and compliance professionals community with general statistics on the consideration given to ethics and compliance programs in making enforcement decisions, according to a new survey.

The survey was conducted jointly by the Ethics Resource Center (ERC), the Ethics and Compliance Officer Association (ECOA), and the Society of Corporate Compliance and Ethics (SCCE).

"Ethics and compliance practitioners need this information to demonstrate to their leadership that the United States sentencing guidelines, Chapter 8, actually means something," said Roy Snell, chief executive officer of the Society of Corporate Compliance and Ethics. Chapter 8 of the sentencing guidelines governs the punishment of an organization when it is found guilty of criminal conduct. However, if the organization can demonstrate it had an effective ethics and compliance program in place, it can substantially mitigate the impending fine.

Among the data being sought:

- Descriptions, without identifying information, of individual cases in which ethics and compliance programs were a mitigating factor in enforcement decisions;
- Information about what specific aspects of an ethics and compliance program factored into enforcement decisions; and
- Information about the benefits of an effective ethics and compliance program, such as helping avert a decision to prosecute or avoidance of other sanctions, such as appointment of a monitor.

"This information is desired by ethics and compliance practitioners so that they may educate their boards of directors and management on the importance, value, and benefit ethics and compliance programs bring to the companies," said Keith Darcy, executive director, Ethics and Compliance Officer Association. "That data can help business leaders see that the cost of ethics and compliance programs can be far outweighed by the benefits that they bring."

The joint survey was conducted among the individual members of the ERC, ECOA, and the SCCE. Membership and stakeholders of the organization include chief ethics and compliance officers (CECO) and other ethics and compliance practitioners. organizations' CEOs and boards of directors.

New IT Data-Tagging Proposal Raises Concerns Among Labs

The American Clinical Laboratory Association (ACLA) has expressed concerns over a proposal by a presidential council that specific data elements in a new universal information-sharing structure be tagged to allow better control over privacy and patient preferences.

In a report issued in December, the President's Council of Advisors on Science and Technology (PCAST) called upon the government to facilitate the widespread adoption of a "universal exchange language" that allows for the transfer of relevant pieces of health data while maximizing privacy.

Unlike conventional electronic health records, such a system would allow health data to follow patients wherever they are, with appropriate privacy protection and patient control, while giving patients' various doctors a more complete picture of those patients' medical conditions and needs.

The report says that the technology for creating the necessary infrastructure and exchange language is already proven and available. But since the development of those systems is not likely to be a profitable venture in itself, the federal government should facilitate their creation and then leave the private sector to develop products that build on them.

Specifically, PCAST recommends that the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) develop guidelines to spur adoption of an exchange language for use by health information technology systems. That would facilitate a transition from traditional electronic health records to a more medically useful and secure system in which individual bits of health care data are tagged with privacy and security specifications.

These individual pieces are called "tagged data elements" because each unit of data is accompanied by a mandatory "metadata" tag that describes the attributes, provenance, and required security and privacy protections of the data.

"To the extent that labs would be required to tag data elements with patient privacy preferences, they are generally not in a position to do so."
– ACLA

Lab Concerns

According to ACLA, the implementation of metadata-tagged elements incorporating patient privacy preferences may be problematic for clinical laboratories. "First, as indirect providers clinical laboratories typically do not have contact with patients," says Jason DuBois, vice president of government relations. "To the extent that labs would be required to tag data elements with patient privacy preferences, they are generally not in a position to do so.

"Second, even if metadata tagging is accomplished through middleware or some other methodology not involving intervention by the clinical laboratory, it is possible, depending on how patient privacy preferences are expressed and implemented, that data exchanges to and from clinical laboratories that are legally permissible or required could be blocked. Many unintended and harmful consequences could potentially result."

ACLA adds that the federal government needs to coordinate and sequence its health IT initiatives to reduce the burden on providers facing multiple initiatives at the same time. Meaningful use of electronic health records, a transition to ICD-10, and conversion to a universal exchange language with metadata-tagged data elements cannot be achieved simultaneously, the association maintains.

COMPLIANCE
PERSPECTIVES

Accountable Care Organizations, Clinical Laboratories and Fraud and Abuse—What's Old Is New Again

Carrie Valiant is a senior member of the health care and life sciences practice of the national law firm, EpsteinBeckerGreen, practicing in its Washington, D.C., office. She is the co-author of the American Health Lawyers Association *book,* Legal Issues in Health Care Fraud and Abuse: Navigating the Uncertainties, *in its third edition.*

An ambitious health reform subtitle, "Transforming the Health Care Delivery System," promises health care transformation through Medicare payment innovations, including accountable care organizations (ACOs). ACOs contemplate loose affiliations of providers acting cooperatively and sharing risks and rewards in the care of a defined Medicare patient population. While ACOs show promise for gaining efficiencies and quality of care, these arrangements will inevitably operate in ways that have long been viewed as suspect under traditional fraud and abuse analysis and will require careful consideration by participants.

Specifically, the Medicare shared savings program contemplates groups of providers working together as ACOs to manage and coordinate care for Medicare beneficiaries. ACOs that meet certain quality standards will be eligible for shared savings payments. Medicare will set quality measures for ACOs in areas such as clinical processes and outcomes, patient and caregiver experience of care, and utilization and quality performance. ACOs will submit data so that Medicare can evaluate ACO quality of care. Services furnished by ACO providers will continue to be paid under fee-for-service Medicare as always, and the ACO also will be eligible to receive additional Medicare shared savings payments, based on meeting quality standards and utilization benchmarks for Medicare beneficiaries.

Groups of providers with a mechanism for shared governance are eligible to participate, including the following:

- ACO professionals in group practices;
- Networks of individual ACO professional practices;
- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Hospitals employing ACO professionals; and
- Others determined to be appropriate.

Thus, clinical laboratories and pathologists could participate in ACOs in a number of ways: as ACO suppliers, as ACO owners and partners, and as integrated components of ACOs.

Fraud and Abuse Concerns

Each alternative raises distinct fraud and abuse issues, depending on whether there is physician ownership of the ACO and the incentives for physicians to utilize the laboratory. Although ACOs must have a "mechanism" for distributing shared savings to participating providers, the law is silent on the details. Presumably, ACOs will seek to align the financial incentives of its providers to meet quality and cost-saving objectives, including patient-centeredness, care coordination, and adherence to evidence-based medicine. ACOs, may also venture into health reform's other innovative Medicare payment models, such as bundled payments, global payments for episodes of care, and possibly shared risk. These downstream

financial relationships, and the practices ACOs adopt to achieve savings, will make all the difference to the success of the ACO. They also will pose the greatest risks under the fraud and abuse laws.

The three major fraud and abuse authorities implicated in the ACO model are (1) the federal health care program anti-kickback statute, (2) the federal physician self-referral law (a/k/a the Stark law), and (3) the civil monetary penalty law prohibiting payments to physicians for reducing or limiting care. In contrast to the post-health reform care models that emphasize and reward clinical integration and quality, these laws were designed in an era of fee-for-service payment methodologies, where the government's focus was on controlling financial arrangements that could lead to overutilization of services and compromise patient choice and quality.

The anti-kickback statute generally precludes paying or receiving remuneration in return for or to induce referrals of federal health care program business or patients. It carries both civil and criminal penalties. While the anti-kickback statute's proscriptions can be overcome by voluntarily meeting a safe harbor or, because it is an intent-based statute, through a facts-and-circumstances analysis, there is broad case law holding that if even "one purpose" of remuneration is to induce referrals, the statute is violated.[1] Moreover, the Office of Inspector General has issued a fraud alert and a compliance guidance addressing anti-kickback issues in clinical laboratory services.

Other fraud and abuse authorities are more "black and white" in their application. The Stark law prohibits physicians having any financial relationship (either ownership or compensation) with an entity that furnishes Medicare-covered "designated health services" (DHS) from referring patients to that entity and prohibits the entity from billing Medicare for any DHS performed as a result of such referrals. Included among the DHS are clinical laboratory services (the original DHS) as well as inpatient and outpatient hospital services. There are mandatory exceptions that must be met to allow physicians to refer to entities with which they have a Stark-covered financial relationship. If there is no relevant exception, referrals are prohibited.

Likewise, the civil monetary penalty law prohibits all payments to physicians that may reduce or limit patient care, whether or not the reduction in care is medically necessary. There are no regulatory exceptions to this prohibition, and HHS's position is that it has no authority to create exceptions.

Are Labs at Risk?

In light of today's aggressive fraud and abuse enforcement environment, and the ways in which the contemplated ACO structures and payments seem to hit squarely longstanding fraud and abuse interpretations, serious questions arise as to the protection available for clinical laboratory-ACO arrangements.

Anticipated ACO structures, contemplating loose affiliations and networks of providers, have been targeted for years as suspect by the fraud and abuse enforcement authorities, especially when ownership of any DHS, such as clinical laboratory services, is involved. The last go-round of health reform, in the 1990s, spawned an alphabet soup of similar structures, including PHOs (primary health organizations) and MSOs (medical service organizations), as well as so-called "Groups Without Walls"—structures that then were vilified by the fraud and abuse enforcement authorities as potentially illegal referral schemes.

One pressing issue then was that the financial viability of integrated delivery structures depended on cross-subsidization among specialist and primary-care physicians as well as ancillary revenue sharing among participants. These shared

[1] *United States v. Greber, 760 F2d 68 (3rd Cir.), cert. denied 474 U.S. 988 (1985)*

payments were viewed as potential referral fee payments and they were especially suspect when made across the loose affiliations contemplated by ACOs.

More recently, the government has taken issue with gainsharing efforts among hospitals and their medical staffs. A 1999 OIG Special Advisory Bulletin stated that gainsharing arrangements were flatly prohibited by the civil monetary penalty law, irrespective of whether the payment was tied to an actual diminution in care, to a specific patient, or to a reduction in medically necessary care. While certain gainsharing arrangements since that time have been OIG-approved through advisory opinions, they offer limited protection, covering product standardization and protocols for opening packages and performing certain tasks "as needed"—not the kind of game-changing behavior that ACOs will adopt to drive costs down through adherence to evidence-based medicine and care coordination.

Role of Labs, Pathologists

Other pronouncements in the clinical laboratory area also may implicate the role of clinical laboratory and pathology services in ACOs. For instance, in advisory opinion 04-17, the OIG determined that a pathology services joint venture arrangement would constitute grounds for anti-kickback and civil monetary penalty sanctions. The OIG found the arrangements between the pathology laboratory and physician groups, allowing physician groups to expand into pathology services, to be tantamount to a suspect contractual joint venture, designed to share profits with physician groups from their laboratory referrals. As ACOs will consist of networks of physicians that provide comprehensive services to a defined patient population, similar arrangements for pathology services are likely to arise with ACOs.

Other pronouncements in the clinical laboratory area also may implicate the role of clinical laboratory and pathology services in ACOs.

Fair market value has been a central theme of the fraud and abuse laws since their inception. The OIG's 1994 Clinical Laboratory Fraud Alert states, "Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business." But what is fair market value when there are shared savings, bundled payments, or risk sharing? In fraud enforcement actions, the government has taken the questionable, but unchallenged, position that payments above the Medicare fee schedule are evidence of payment for referrals.

Related questions will arise with ACO physician payments that may include ancillary service revenues. 1990s Stark law analysis allowed only bona fide group practices to distribute payments for ancillary services performed and/or supervised within the group. More recently, in 2008, Cox Medical Center entered into a $60 million settlement of charges that included allegations that physician agreements included in salary Medicare revenue from various ancillary services (including clinical laboratory services). Clearly, similar issues will arise in the ACO context as well.

From a Stark law perspective, physician-owned ACOs will be constrained from clinical laboratory ownership unless they fit within one of the Stark law exceptions, such as the in-office ancillary services exception. Generally, qualifying for this exception depends on being a bona fide group practice, not the networks of physicians and physician-hospital joint ventures contemplated for ACO formation.

The 1994 OIG fraud alert targeted as suspect free goods and services that might be provided to a referral source, such as phlebotomists that provide office services, free pick-up and disposal of biohazardous waste products (such as sharps) unrelated to the collection of specimens, and the provision of computers or fax machines unless integral to, and exclusively used for, performance of the laboratory's work. The increased emphasis of ACOs on value-added propositions with respect to access, cost, and quality, including timeliness of service, may implicate these OIG issuances.

As ACOs assume risk, many of the integrity principles relevant to Medicare managed care plans could apply to ACOs. The OIG's fraud alert warned against out-of-network clinical laboratories that offer free managed care testing for referral sources. To the extent ACOs may operate in part fee-for-service, in part risk-assuming, the OIG's concern about "swapping" may apply. In this regard, the fraud alert mentions clinical laboratories that offer below-market testing to end-stage renal disease (ESRD) facilities for composite rate work in order to obtain the fee-for-service referrals.

Is There Protection?

Under the existing fraud and abuse authorities, there are various avenues for obtaining guidance and protection. One is the safe harbor authority, under which the OIG can create regulatory exceptions under the anti-kickback statute. CMS has similar authority to adopt regulatory exceptions under the Stark law. CMS has been reluctant to use its regulatory authority with respect to the CMP provisions regarding reduction of care, apparently believing the scope of its authority is limited.

There are no safe harbors or exceptions that specifically address ACOs or the financial arrangements among the parties participating in ACOs. Safe harbors and statutory exceptions, while helpful in providing generalized standards, do not address or provide comfort with respect to specific arrangements among particular providers. There is advisory opinion authority under which the OIG can protect specific arrangements. Similarly, CMS has advisory opinion authority under the Stark law, although few decisions have been published to date through this process. Unfortunately, the advisory opinion process is notoriously slow.

In addition, health reform authorizes HHS to "waive" certain Medicare program requirements, including the fraud and abuse laws. HHS has not yet set out the particulars of the waiver process it will follow, if it will at all, and it is not entirely clear whether HHS will exercise its waiver authority in the fraud and abuse area to the full extent necessary for ACO development.

What is different about health reform that should ease the government's enforcement concerns and encourage the issuance of broad waivers, safe harbors, and advisory opinions as needed to protect ACOs? There is a high level of organizational and clinical integration required for ACOs, and the fraud and abuse laws always are more lenient with integrated delivery systems such as academic medical centers or bona fide medical group practices. Also helpful is the emphasis on quality measures and quality reporting for ACOs, especially since the measures are created by and reported to CMS. This is different from earlier gainsharing approaches, where participants designed their own measures and there was no CMS reporting.

Probably most convincing is that, under health reform, in contrast to provider integration in the 1990s, these gainsharing structures now are sponsored by the government, and Medicare will benefit from the ACO's savings. This is in substantial contrast to the past, when OIG could say in the fraud alert "There is no statutory exception or 'safe harbor' . . . because the federal programs do not realize the benefit of these 'free' services."

In a sea-change from the 1990s, Congress now has favored legislatively ACO development. As such, HHS should view as protected a broad range of activities designed to promote successful ACO development and incentives designed to achieve Medicare savings and should exercise broadly its congressional waiver authority to enable organizations to do so. In the meantime, those seeking to develop and participate in ACOs will need to review past government pronouncements and their potential relevance for ACOs.

Carrie Valiant can be reached at EpsteinBecker-Green, 1227 25th St., N.W., Suite 700, Washington, DC 20037. Phone: 202-861-1857; e-mail: cvaliant@ebglaw.com.

CMS Final Rule, *from page 1*

differ for every risk level, with high-risk providers and suppliers receiving the most attention. Independent clinical laboratories fall in the moderate-risk category.

Specifically, the final rule:

- **Creates a rigorous screening process** for providers and suppliers enrolling in Medicare, Medicaid, and children's health insurance programs (CHIPs) to keep fraudulent providers out of those programs. Types of providers and suppliers that have been identified in the past as posing a higher risk of fraud, for example durable medical equipment suppliers, will be subject to a more thorough screening process.

- **Requires new enrollment process for Medicaid and CHIP providers.** Under PPACA, states will have to screen providers who order and refer to Medicaid beneficiaries to determine if they have a history of defrauding government. Providers that have been kicked out of Medicare or another state's Medicaid or CHIP will be barred from all Medicaid and CHIP programs.

- **Temporarily stops enrollment of new providers and suppliers**. Medicare and state agencies will be on the lookout for trends that may indicate health care fraud—including using advanced predictive modeling software, such as that used to detect credit card fraud. If a trend is identified in a category of providers or geographic area, the program can temporarily stop enrollment as long as that will not impact access to care for patients.

- **Temporarily stops payments** to providers and suppliers in cases of suspected fraud. Under the new rules, if there has been a credible fraud allegation, payments can be suspended while an action or investigation is under way.

The rule, "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers," is available at *www.gpoaccess.gov/fr/*.

Justice Department Intervenes in FCA Case Alleging Fraudulent Billing by Mayo Clinic

The Department of Justice Dec. 20, 2010, filed a complaint in partial intervention in a False Claims Act (FCA) case, alleging the Mayo Clinic violated the FCA by billing several federal programs, including Medicare, for surgical pathology services it had not performed (*United States ex rel. Ketroser v. Mayo Clinic*, D. Minn., No. 07-cv-4676, *complaint in partial intervention filed* 12/20/10).

The filing follows the government's Sept. 20, 2010, notice that it intended to intervene, in part, in a qui tam lawsuit filed by Dr. David Ketroser and others. The government's complaint alleges that the Rochester, Minn.-based clinic has for years billed Medicare, Medicaid, and other federal health care programs for the preparation and examination of human tissue slides, despite never doing the slide work.

Bryan Anderson, a spokesman for the clinic, said the allegations represent just a portion of the original complaint filed against the Mayo Clinic by Ketroser and the other qui tam relators. He said the federal government has chosen not to pursue its claims on how the clinic conducted tissue pathology. As to the remaining claim, he said it is Mayo's belief that it was the result of a billing error.

A news release issued by the U.S. Attorney's Office for the District of Minnesota stated that the lawsuit stems from allegations made by Ketroser that federal government programs were billed for a number of years for services that were never rendered. It is alleged that each claim for payment Mayo submitted to the government for surgical pathology slides and examinations was false. The complaint does not allege how much Mayo falsely billed the federal government.

Anderson said the Mayo Clinic discovered a billing error in 2007. It corrected it, he said, and voluntarily refunded more than $240,000 to the federal government.

The release stated that while Mayo has asserted that it has paid back some of the money it received as a result of the alleged false claims, the refunds were only paid after the government had issued a subpoena. It added that the U.S. attorney's office believes the Mayo payments were insufficient.

Anderson said the Mayo Clinic discovered a billing error in 2007. It corrected it, he said, and voluntarily refunded more than $240,000 to the federal government. He said the clinic worked with outside accounting experts to ensure that the payment represented the complete and appropriate reimbursement amount.

He added that the reimbursement was made before the clinic was even aware that the relators had filed a sealed complaint. Mayo believes it has fully complied with the law, he said, and believes its reimbursement was the right thing to do. Anderson said the clinic is confident in its position and plans to defend itself vigorously.

Pathologist Could Be Held Liable for Remote Review of Biopsy

A Washington pathologist and her group practice may be subject to liability for the unlicensed practice of medicine under Idaho law stemming from the remote review in Washington of a biopsy from a patient in Idaho, a federal court ruled Dec. 30, 2010 (*Smith v. Laboratory Corp. of America*, W.D. Wash., No. C09-1662, 12/30/10).

The U.S. District Court for the Western District of Washington said Idaho's Medical Practices Act (MPA) potentially applies to the Washington pathologist, Dr. Jane J. Yin, if she is found to have rendered a medical diagnosis for an Idaho resident without holding a license to practice medicine in that state.

The court refused to dismiss claims brought under the Idaho licensing statute by Brad Smith and his wife Tammie stemming from Yin's review, in August 2007, of a pathology slide prepared by LabCorp on a biopsy taken from Smith by an Idaho physician. Although Yin—a temporary pathologist with Pacific Northwest Pathology Associates (PNPA)—found the biopsy to be noncancerous, a subsequent review found that Smith actually had a curable stage of malignant melanoma.

The Smiths originally filed suit in an Idaho court against Yin, LabCorp, and PNPA, but Yin removed the case to federal court and then sought to dismiss the case for lack of jurisdiction over her. The federal court in Idaho agreed that it could not entertain the case against Yin and transferred the case to the federal court in Washington.

There, the Smiths sought to press their Idaho MPA claims and negligence causes of action under Washington law. Claims asserted against LabCorp and PNPA were for the most part derivative of the claims asserted against Yin, the court

said. The court's decision, however, addressed only the defendants' efforts to have the Idaho MPA claims dismissed.

Idaho Statute Applies

In refusing to dismiss those claims, the court said the fact that the Idaho court may not have had personal jurisdiction over Yin did not mean she was not required to comply with Idaho law.

Finding that Idaho law could apply to Yin, the court then asked whether Washington's or Idaho's law regarding the interstate practice of medicine should be applied. The court found that the parties' contacts with the two states did not weigh in favor of applying the law of one state over the other and ultimately determined that the interests of Idaho in the issues in dispute, as well as that state's public policies, favored application of Idaho law.

"Plaintiffs argue that the Washington legislature has expressed no interest in regulating interstate medical practice, whereas the Idaho legislature has established clear limitations on such practice. The court agrees," the court said.

"Under Washington law, there are no limits on the practice of an out-of-state physician, provided she does not open an office in Washington," the court noted. "On the other hand, Idaho has created an aggressive statute to prevent unlicensed out-of-state doctors from practicing on Idaho residents."

Board Affirms Ruling in Victor Valley Case; Lab Loses Certificate Over PT Violations

The Health and Human Services Departmental Appeals Board (DAB), Appellate Division, has upheld a decision by an administrative law judge (ALJ) to revoke Victor Valley Community Hospital's (Victorville, Calif.) certificate to operate as a clinical laboratory.

Victor Valley's certificate was revoked for intentionally sending proficiency testing (PT) samples to another laboratory for analysis that it is certified to perform in its own laboratory. The DAB rejected Victor Valley's argument that the ALJ erred in treating its referral of PT samples to an outside laboratory as "intentional."

The board ruled that Victor Valley's action in referring out the PT samples was the product of a conscious decision to send the samples to another laboratory for analysis (including repetition of tests done by Victor Valley) while well aware that these were PT samples. The board said that such a knowing and willful action establishes that referral was intentional within the meaning of the regulations.

Victor Valley's certificate to operate as a clinical laboratory is revoked for one year from the date of the decision. The hospital's owners and operators are barred from owning or operating a clinical laboratory for two years from the same date.

Victor Valley filed for Chapter 11 bankruptcy protection in September 2010. The hospital is $20 million in debt and faces a large cut in reimbursement from Medicare and Medicaid. More than 60 percent of patients at Victor Valley, one of four hospitals in the High Desert region of California, receive Medicare or Medicaid Services.

The hospital is continuing to operate as it pursues a new owner. Prime Healthcare Foundation Inc., which owns Desert Valley Hospital, has been cited as a possible buyer.

News-At-A-Glance

HEALTH FRAUD RECOVERY: Health care fraud recoveries to the Medicare Trust Fund in fiscal year 2010 totaled approximately $2.8 billion, according to the *Health Care Fraud and Abuse Control (HCFAC) Program Annual Report for Fiscal Year 2010*, released by the government Jan. 24. The HCFAC report said that the $2.8 billion represented a $350 million increase from FY 2009, according to figures from the report. The report, released jointly by the departments of Health and Human Services and Justice, said that a record $4 billion in overall health care fraud recoveries was returned to the federal government in FY 2010, including $57 million returned to TRICARE, $46 million returned to the Office of Personnel Management, and $33 million returned to the Department of Veterans Affairs. The report also said that DOJ won or negotiated roughly $2.5 billion in health care fraud settlements—a 50 percent increase from FY 2009 and the largest annual figure ever.

OIG OFFERS TRAINING PROGRAMS: The Department of Health and Human Services Office of Inspector General Jan. 31 announced it would be conducting six free compliance training programs for health care providers in 2011, beginning with a Feb. 16 session in Houston. Sessions will focus on understanding fraud and abuse legislation, creating effective compliance plans, and handling compliance violations. The half-day programs will feature speakers from the HHS OIG, the Centers for Medicare and Medicaid Services, U.S. attorneys' offices, and state Medicaid fraud-control units. In addition to Houston, the compliance sessions will take place in Tampa, Fla., on March 2; Kansas City, Mo., on March 23; Baton Rouge, La., on April 12; Denver on May 3; and Washington, D.C., on May 18.

MOST WANTED HEALTH CARE FUGITIVES: The Office of Inspector General of the Department of Health and Human Services has launched its Most Wanted Fugitives List—the first-ever list of individuals sought by authorities on charges of health care fraud and abuse. The agency is asking for the public's help in tracking down these people. The list is available at *http://oig.hhs.gov/fugitives.*

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