G2 Compliance Report

INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com Issue 12-04 • April 2012

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Pathology TC Grandfather Protection To End July 1; Extension Unlikely

The pathology technical component (TC) grandfather protection for clinical laboratories will end July 1, and based on indications from congressional staffers, it appears unlikely that Congress will approve any additional extensions.

The protection allows independent clinical laboratories to bill Medicare directly, as opposed to billing the hospital, for the TC of pathology services to hospital inpatients and outpatients. The TC (preparation of the slide involving tissue or cells that a pathologist interprets for diagnosis) includes anatomic pathology, cytopathology, and surgical pathology. The protection applies to hospital-lab arrangements in effect as of July 22, 1999, the date when the Medicare program first proposed to end such direct billing.

The current grandfather provision expires Feb. 29 but got a four-month extension, through June 30, as part of House-Senate conference committee legislation (H.R. 3630, enacted Feb. 17) that would continue for the rest of this year the Social Security payroll tax cut, unemployment benefits, and a freeze on Medicare physician payments.

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Medical Lab Company to Pay $6 Million To Settle Fraudulent Medicare Billing Charges

A Troy, Mich., laboratory company will pay a total of $6 million in cash and property to the U.S. government to resolve allegations that it fraudulently billed the Medicare program for tests (*United States v. Accela Medical LLC*, E.D. Mich., No. 2:10-cv-14627, 2/7/12).

U.S. Attorney Barbara McQuade said Coventry Diagnostics LLC and Western Slope Laboratory LLC were subsidiaries of Accela Medical LLC, a front company controlled by Thomas McCormick, a Troy, Mich., resident who had been barred from billing Medicare because of a previous health care fraud conviction. The companies, the government alleged, fraudulently billed the Medicare program for lab tests, with McCormick and a co-conspirator splitting the profits of the fraud.

The fraud was detected by an analysis of billing records, which showed the labs were using a particular billing code more than any other Medicare provider in the nation, DOJ said. Coventry and Western Slope allegedly performed the tests, which were billed using a Medicare

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Pathology TC Grandfather Protection, *from page 1*

According to a legislative summary prepared by staff of the House committees on Ways and Means and Energy and Commerce, "The four-month extension provides time for the labs and hospitals to establish payment arrangements. Expiration after a reasonable transition period addresses concerns that Medicare is paying twice for the same service, which causes beneficiaries to make an extra copayment.

"Minimal oversight of the policy by the Centers for Medicare and Medicaid Services (CMS) has also made Medicare susceptible to making inappropriate payments. Further, the Government Accountability Office has recommended that this policy expire."

Kazon adds that labs and hospitals must keep the anti-kickback law in mind as they negotiate rates since the law could be implicated if labs give these services to hospitals for free or at prices below their fair market value.

But in a Feb. 14 bipartisan letter to conference committee chairmen Max Baucus (D-Mont.), who heads the Senate Finance Committee, and Dave Camp (R-Mich.), who heads the House Ways and Means Committee, some 30 members of the House and the Senate argued that allowing the grandfather protection to expire would be detrimental to all parties involved, including Medicare beneficiaries.

"Hospital and independent laboratories will have to establish new, costly, and administratively complex billing systems with little notice. About three-quarters of states would be impacted, with smaller and rural hospitals being affected the most," they wrote. "Using an independent lab allows many small and rural hospitals to access high-quality services when it simply does not make sense to have an in-house lab, usually because they do not necessarily have the surgery volume to support a robust state-of-the-art lab. Unlike a single hospital in this situation, an independent lab providing pathology services to multiple hospitals receives the volume necessary to purchase the most up-to-date equipment and employ skilled laboratory staff."

The College of American Pathologists (CAP) called the phasing out of the grandfather protection an "ill-advised" decision. "It was not instituted to provide a benefit to pathologists; rather it was created to ensure patient care and hospital service in areas that need it most," said Richard Friedberg, M.D., Ph.D., FCAP, chair of CAP's Council on Government and Professional Affairs. "Over the past 10 years, it has helped hospitals that would otherwise not be able to provide laboratory tests and anatomic pathology services to their patients."

CMS has repeatedly sought to end the protection (most recently in the final Medicare physician fee schedule rule for 2012) but has repeatedly been overruled by Congress until now. Conference committee members apparently bought into CMS's argument that the TC of pathology services is included in the hospital's prospective payment and allowing independent labs to bill the TC separately amounts to a duplicate payment.

The conference committee decision sidelines bipartisan bills introduced in the Senate and the House that supported the grandfather protection. The Senate bill (S. 1680) would extend the protection through Dec. 31, 2012. The House bill (H.R. 2461) would make it permanent.

With the expiration of the pathology TC protection on July 1, hospitals will have to absorb new billing costs while independent pathology labs will likely receive less revenue from the hospital compared to when they billed Medicare directly.

So a lab that currently bills Medicare for CPT code 88305, for example, receives global payment of approximately $110 ($73 for the TC and $37 for the professional component (PC)), explains Peter Kazon, an attorney with Alston & Bird and counsel to the American Clinical Laboratory Association. "After the grandfather, the lab can still bill the PC to Medicare, so it still gets the $37, but the TC has to be billed to the hospital. The lab will have to bill the hospital for the TC, and it is probably going to be unable to make up the full $73 when it does. How much it costs the lab will depend on what it is able to negotiate with the hospital."

Kazon adds that labs and hospitals must keep the anti-kickback law in mind as they negotiate rates since the law could be implicated if labs give these services to hospitals for free or at prices below their fair market value.

Lab-Developed Tests Would Be Exempt From User Fees Under Agreement Reached With FDA

The Food and Drug Administration (FDA) has agreed to seek statutory authority that will allow it to waive user fees for laboratory-developed tests (LDTs) under the Medical Device User Fee Amendments (MDUFA).

FDA officials and industry groups have been negotiating for months over the next incarnation of the user fee program. In back-to-back meetings in early February, the FDA and groups representing labs and medical device manufacturers hashed out details of MDUFA III. The meetings followed a tentative accord reached in early February that would double the user fees paid over five years in exchange for the FDA meeting certain performance goals. User fees would double from $295 million to $595 million under the agreement.

User fees would only come into play for labs if the FDA issues guidance requiring LDTs to go through FDA clearance. The FDA says that it plans to regulate LDTs and believes it has the authority to do so. However, legislation pending in Congress would assign LDT oversight to the Clinical Laboratory Improvement Amendments program at the Centers for Medicare and Medicaid Services.

In response to concerns raised by the American Clinical Laboratory Association (ACLA), the FDA said it would seek authority to waive or reduce fees on a case-by-case basis and said that if granted that authority, it would "ensure that no additional LDTs or laboratories would be subject to user fees during MDUFA III due to implementation of the regulation framework under consideration or due to other changes in policy on LDTs."

Groups representing medical device makers expressed concerned that such waivers might throw off the balance of resources to workload. Ultimately, the FDA and the groups—including ACLA—agreed to a deal that would place a $15 million cap on the total value of waivers and would exempt waived applications from the same performance goals as those applied to standard applications.

The agreement now heads to the Department of Health and Human Services and the Office of Management and Budget for approval before making its way to Congress.

Delay Announced for ICD-10 Compliance Date

Health and Human Services (HHS) Secretary Kathleen Sebelius announced Feb. 16 that HHS will initiate a process to postpone the date by which health care entities covered under the Health Insurance Portability and Accountability Act (HIPAA) must comply with use of the International Classification of Diseases, 10th Edition, diagnosis and procedure codes (ICD-10).

The final rule adopting ICD-10 as a standard was published in January 2009 with a compliance date of Oct. 1, 2013, two years from the compliance date initially set in the proposed rule.

"HHS will announce a new compliance date moving forward," Sebelius said in a statement. "We have heard from many in the provider community about the administrative burdens they face in the years ahead. We are committed to working with the provider community to reexamine the pace at which HHS and the nation implement ICD-10 improvements."

Without postponement, all HIPAA-covered transactions, including outpatient and inpatient claims, would have been required to use the ICD-10 code sets by Oct. 1, 2013. The acting administrator for the Centers for Medicare and Medicaid Services (CMS), Marilyn Tavenner, had earlier signaled that the delay was coming, noting, "There is concern that folks cannot get their work done around meaningful use of health information technology, ICD-10 implementation, and be ready for [insurance] exchanges," she told reporters Feb. 14. "So we decided to listen to that and be responsive."

The American Medical Association (AMA) early this month wrote to Sebelius, asking that implementation of the new disease coding system be halted. In a January letter to House Speaker John Boehner (R-Ohio), AMA said that implementing ICD-10 requires physicians and their office staff to contend with 68,000 codes, a "fivefold increase from the current 13,000 codes." This conversion "is a massive administrative and financial undertaking for physicians, requiring education, software, coder training, and testing with payers."

Although she acknowledged the need to revisit the implementation schedule, Tavenner praised ICD-10 as a "good idea and foundational to many positive improvements in our health care system, such as better prevention of fraud and abuse," and which is expected to improve patient care.

Meanwhile, CMS is moving ahead with a prerequisite for using the ICD-10 code sets—namely, ASC X12 Version 5010. While the effective date for adopting Version 5010 remains Jan. 1, 2012, the agency has granted a 90-day grace period, through March 31, for HIPAA-covered entities to achieve compliance.

Nonetheless, the CMS Office of E-Health Standards and Services will exercise its enforcement discretion with respect to any HIPAA-covered entity against which a complaint is filed for noncompliance during the grace period. If requested by this office, covered entities that are the subject of complaints (known as "filed-against entities") must produce evidence of either compliance or a good-faith effort to become compliant during the 90-day period.

All providers not yet in compliance should be following a Version 5010 transition plan that includes testing with payers and other business partners, CMS said. This will help address any potential issues in advance and avoid problems when submitting claims for reimbursement.

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COMPLIANCE PERSPECTIVES

Proposed Rule on 60-Day Repayment of Overpayments Places Increased Burden on Providers

William Mathias, Esq., and Kristin Cilento Carter, Esq., are attorneys in the health law group of Ober|Kaler (Baltimore).

The much-anticipated proposed rule regarding the 60-day repayment of overpayment obligation was issued in proposed form by the Centers for Medicare and Medicaid Services (CMS) on Feb. 16, 2012. If left unchanged, the proposed rule would substantially increase the burdens on providers and suppliers.

Most notably, the proposed rule would create a new 10-year look-back period for overpayments. In addition, the proposed rule would create little certainty by establishing a deliberate ignorance or reckless disregard standard for conducting a reasonable investigation into allegations of potential overpayments, and it includes preamble language suggesting a new standard of "all deliberate speed" on internal investigations into potential overpayments. The proposed rule signifies a move toward more formality and standardization of the existing overpayment reporting process. Providers should carefully examine this proposed rule with an eye toward areas for comment prior to the April 16, 2012, close of the comment period.

The proposed rule aims to define the parameters and process for reporting overpayments to CMS and its contractors utilizing an existing process for self-reporting overpayments through Medicare contractors.

Section 6402(a) of the Patient Protection and Affordable Care Act established a new Section 1128J(d) in the Social Security Act titled "Reporting and Returning Overpayments." Section 1128J(d) specifically requires a person who has received an overpayment to report and return the overpayment to the secretary, state, or other relevant contractor along with a written explanation of the reason for the overpayment. The report and return of the overpayment must occur by the later of (1) the date which is 60 days after the date on which the overpayment is identified or (2) the date that any corresponding cost report is due, if applicable. The failure to make such a report and repayment creates an "obligation" for which a provider can be subject to liability under the False Claims Act, 31 U.S.C. § 3729, and under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a(a)(10), under which the provider could be excluded from participation in federal health care programs.

The proposed rule aims to define the parameters and process for reporting overpayments to CMS and its contractors utilizing an existing process for self-reporting overpayments through Medicare contractors. The proposed rule establishes new standards for repayments of overpayments but only for Medicare Part A and Part B providers and suppliers. CMS states that standards for Medicare Advantage, prescription drug plans, and Medicaid managed care organizations will be addressed at a later date. Nevertheless, CMS cautions that the 60-day repayment obligation is effective even without implementing regulations.

One of the biggest burdens in the proposed rule is the imposition of a new 10-year look-back period, so that providers and suppliers must report any overpayments that are identified within 10 years from when the overpayments are received. Until

now, the reopening rules have seemed to suggest a four-year look-back period. CMS states that this 10-year look-back period is based on the outer limit of the False Claims Act statute of limitations. A change to a 10-year look-back period is a burdensome one where providers and suppliers may have difficulties conducting investigations where documents and information regarding the claims at issue may no longer be readily available. In the rule's regulatory impact statement, CMS seemed to indicate that it considered a shorter period of five years, which would ease the burden on providers. However, CMS ultimately proposed 10 years to "further our interest in ensuring that overpayments are timely returned to the Medicare Trust Fund." In addition, we note that CMS has proposed corresponding changes to the reopening rules in 42 C.F.R. § 405.980.

CMS proposes that an overpayment will be considered "identified" if the provider has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

Critical to the determination of when a provider has an obligation to report and return an overpayment are (1) the definition of the term "overpayment" and (2) when such overpayment is "identified." Under the proposed rule, CMS would adopt the statutory definition of an "overpayment," which is defined as any funds that a person receives or retains under the Medicare program to which the person, after applicable reconciliation, is not entitled. Examples of such overpayments include, among other things, payments for noncovered services, payments in excess of allowed amounts, errors and nonreimbursable expenditures in cost reports, and receipt of funds from Medicare when another party is primarily liable.

With respect to cost report providers, CMS recognizes that an overpayment will not exist until after the reconciliation of interim payments with actual costs, which typically occurs at the time of the cost report submission with two limited exceptions. CMS proposes that providers will not be required to amend the cost report or calculate a change in reimbursement due to an overpayment relating to (1) the Supplemental Security Income (SSI) ratios used to calculate disproportionate share hospital (DSH) adjustment or (2) an outlier reconciliation, until the final reconciliation of the provider's cost report occurs.

CMS proposes that an overpayment will be considered "identified" if the provider has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. CMS believes that applying this standard will require providers and suppliers to exercise reasonable due diligence through self-audits, compliance checks, or other research to determine whether an overpayment exists. For example, a provider who receives information through a compliance hot line or other source that a potential overpayment exists but fails to make a reasonable inquiry to confirm whether an actual overpayment exists could be subject to liability for knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such overpayment. The rule and preamble language remain silent as to whether the actual knowledge refers to the existence of an issue or whether actual knowledge exists only when the amount of the overpayment is quantified.

Notably, in the preamble, CMS specifies that claims submitted in violation of the anti-kickback statute fail to meet the conditions of payment under the Medicare program and would constitute a false or fraudulent claim. CMS acknowledges that in some cases the party submitting the claim (i.e., a hospital) may be unaware of the existence of an improper arrangement (i.e., between a device manufacturer and a physician). CMS states that if a provider or supplier is unaware of the existence of a third-party

arrangement, then no overpayment has been "identified" and the provider has no duty to report or repay an overpayment amount.

If, however, the provider or supplier "has sufficient knowledge" of the arrangement, then the provider or supplier would be required to report the overpayment under the proposed rule. The repayment obligation would be suspended and the matter referred to the OIG for further investigation. CMS, however, fails to specify the mechanism by which it would suspend the repayment obligation, which as discussed below, is generally required at the time of the report. CMS expects the OIG to seek repayment from the parties to the kickback scheme, rather than an "innocent" provider or supplier reporting the overpayment. Of note, the agency does not entirely close the door for seeking repayment from the reporting provider by stating "the government may always seek repayment of claims paid that do not satisfy a condition of payment."

With respect to the reporting deadline, the CMS proposal draws a distinction between overpayments that are claims-based and those that would generally be reconciled on a cost report.

As expected, the proposed rule recognizes that the 60-day reporting period is tolled when a provider submits a self-disclosure to either the OIG through its Self-Disclosure Protocol or to CMS through the Self-Referral Disclosure Protocol (SRDP).

For claims-based overpayments, a provider or supplier must report and return the overpayment within 60 days of identification. If the provider has actual knowledge of the overpayment, the 60 days would run from the date of such knowledge. Where, however, a provider receives information that it may have received a potential overpayment, the provider is under an obligation to conduct a reasonable inquiry, which CMS proposes should occur with "all deliberate speed" after receiving the information. If the inquiry reveals an overpayment, the provider would then have 60 days to report and return the overpayment amount.

For overpayments that are generally reconciled on a cost report (i.e., graduate medical education payments), the provider must report the overpayment within 60 days of identification or on the date the cost report is due, whichever is later. CMS is careful to caution that cost report providers would be permitted to rely on this "later of" approach only for those payments that are reconciled on a cost report. Cost report providers cannot unnecessarily delay reporting of claims-based overpayments, which must be reported within 60 days of identification.

As expected, the proposed rule recognizes that the 60-day reporting period is tolled when a provider submits a self-disclosure to either the OIG through its Self-Disclosure Protocol or to CMS through the Self-Referral Disclosure Protocol (SRDP). The obligation to return an overpayment is suspended as of the date that CMS or OIG acknowledges the provider's acceptance into the program until such time that a settlement agreement is entered, or the provider withdraws or is removed from the protocol.

Interestingly, the proposed rule draws a distinction between reporting through the OIG protocol and through the CMS protocol as to whether the provider has fulfilled its obligations under the 1128J(d) reporting requirements. With respect to the OIG Self-Disclosure Protocol, the proposed regulation recognizes that the provider would fulfill its 1128J(d) reporting requirement by making a disclosure

to the OIG that results in a settlement agreement. By contrast, providers reporting through the SRDP would still be obligated to report the overpayment under the 1128J(d) reporting process set forth in the proposed rules. The basis for this distinction is not entirely clear, but CMS seeks comments regarding alternative approaches that would allow providers and suppliers to avoid making multiple reports.

Instead of developing a new process for reporting and repayment of overpayment amounts, CMS proposes that overpayments will be reported through the existing voluntary refund process as described in Chapter 4 of the *Medicare Financial Management Manual*. Under this process, providers and suppliers disclose overpayment amounts utilizing a form available on the Medicare contractor's Web site. This form requires the provider to provide identifying information (name, tax identification number, national provider identifier, etc.) and information to identify the claim (i.e., health insurance claim number, date of service). In addition, the provider must identify:

- How the error was discovered;
- Reason for the overpayment;
- Description of the corrective action plan to ensure the error does not occur again;
- Whether the provider or supplier has a corporate integrity agreement with the OIG or is under the OIG Self-Disclosure Protocol;
- Time frame that the problem existed and total amount of the refund; and
- If a statistical sample was used to determine the overpayment amount, a description of the statistically valid methodology.

CMS notes that on two prior occasions it proposed regulations to address the repayment of Medicare overpayments. On neither occasion were the proposed regulations finalized. These proposed rules again show the difficulty in trying to create uniform rules to cover what is frequently an individualized process.

CMS anticipates that it will eventually adopt a uniform reporting form for use by all Medicare contractors. In the meantime, however, CMS proposes that providers and suppliers use current forms available through their applicable Medicare contractor. Providers will be required to refund the amount of the overpayment at the time of the report or, if a provider needs additional time due to financial constraints, the provider can request an extended repayment schedules (ERS) through an existing process set forth in Chapter 4 of the *Medicare Financial Management Manual*. CMS notes that an ERS will not be automatically granted and that providers will be required to submit significant documentation to demonstrate financial hardship.

CMS notes that on two prior occasions it proposed regulations to address the repayment of Medicare overpayments. On neither occasion were the proposed regulations finalized. These proposed rules again show the difficulty in trying to create uniform rules to cover what is frequently an individualized process. The statutory requirement of the Patient Protection and Affordable Care Act, however, raises the stakes for establishing effective regulations.

William Mathias and Kristen Cilento Carter can be reached at Ober|Kaler, 100 Light St., Baltimore, MD 21202. Phone: 410-685-1120. E-mail: wtmathias@ober.com and kccarter@ober.com.

Medical Lab Company to Pay $6 Million, *from page 1*
provider number obtained by co-conspirator Charles B. Reinhardt of Tennessee, the government said.

When Medicare raised questions about the ownership and control of Accela, Reinhardt and McCormick submitted falsified documents to Medicare hiding the real ownership and control of the company, DOJ said. According to the government, the labs billed Medicare for about $900 worth of urine drug tests for virtually every patient referred to Accela by a physician, billing for 18 separate procedures for each patient to evaluate urine levels of opiates.

"This fraud was discovered by analyzing data to flag billing anomalies," McQuade said in a Feb. 7 statement. "Providers should be aware that law enforcement is scrutinizing billing records to identify providers who are stealing from taxpayers."

Bone Marrow Registry, Lab Company Settle Deceptive Practice Charges

A Massachusetts bone marrow registry and a medical laboratory company have agreed to pay $520,000 to settle charges that they used unfair and deceptive practices to sign up potential donors and then charged their insurers as much as $4,000 for DNA testing of mouth swabs (*Massachusetts v. Caitlin Raymond International Registry Inc.*, Mass. Super. Ct., No. 12-0421, *consent judgment* 2/2/12).

The two subsidiaries of UMass Memorial Health Care (UMMHC) in Worcester recruited donors at shopping malls and sporting events by using fashion models dressed as medical personnel, distributing free gifts, waiving deductibles and copayments for potential donors, and providing incentives for employees to sign up donors covered by health insurance, according to the complaint and consent judgment filed Feb. 2 in Suffolk County Superior Court.

The recruiting by Caitlin Raymond International Registry Inc. enabled UMass Memorial Health Ventures Inc. to increase the number of donor tests it performed from 7,000 in 2008 to more than 40,000 in 2010, according to the complaint filed by Massachusetts Attorney General Martha Coakley (D).

"No health care provider should be allowed to use gimmicks and free gifts to increase the volume of services covered by health plans for their own financial gain," Coakley said in a Feb. 2 statement. The complaint alleged that the activity violated the Massachusetts Consumer Protection Act.

"We accept full responsibility for the mistakes and errors in judgment that were made," said John G. O'Brien, president and chief executive officer of UMMHC. While agreeing to change its practices, the health provider said it "expressly denies" violation of any laws.

Under the settlement, the UMMHC system agreed not to charge health plans more than $175 over the next five years for donor testing and to pay full restitution to Massachusetts consumers for any out-of-pocket payments they previously made for donor testing.

The companies already have refunded close to $100,000 to consumers and "several times that amount" to reimburse health plans, according to Coakley. UMMHC cooperated with the attorney general's office and immediately halted the alleged unlawful practices once the investigation began, she said.

ALJ: Lab's Certificate Properly Revoked For Misrepresenting Test Volume

An administrative law judge (ALJ) for the Department of Health and Human Services Departmental Appeals Board Jan. 17 affirmed a Centers for Medicare and Medicaid Services' (CMS) ruling revoking a clinical lab's certificate for misrepresenting its annual testing volume and its authority to perform tests not covered by its certificate (*Huntington Beach Clinical Laboratory Inc. v. CMS*, Departmental Appeals Bd., Civil Remedies Div., Dec. No. CR2490, 1/17/12).

While the lab was only certified under the Clinical Laboratory Improvement Amendments of 1988 to perform urinalysis, endocrinology, and toxicology, it billed Medicare for 120,782 tests from February to June 2010, more than 14 times the 8,500 tests it said it would perform, 92 percent of which were outside its certificate.

Supposedly, just two individuals performed all the tests. Neither the lab nor its owner appealed the revocation, but lab director Howard Pfupajena, M.D., argued that he should not be sanctioned because he resigned from his position as director before the lab lost its certification.

ALJ Carolyn Cozad Hughes disagreed, finding the billing documents for the unauthorized testing showed that it occurred between February and June 2010, when Pfupajena admitted he was the director. The fact that he managed to tender a resignation letter a few weeks before CMS sent its first notice, on Sept. 3, 2010, does not make him less accountable for the rule violations that occurred on his watch, she said.

Witnesses Split on Whether Patents Impede Second Opinion Genetic Diagnostic Testing

There is no evidence that patents have inhibited patient access to second opinion genetic diagnostic tests and any access problems that do exist may have other causes, intellectual property professionals, patent attorneys, and biotech association representatives said Feb. 17 at a Patent and Trademark Office (PTO) hearing.

However, medical and patient groups told the PTO that gene and genetic diagnostic test patents have limited the ability of clinical labs to offer genetic testing. And the lead plaintiff opposing a gene patent in the *Myriad* case urged the PTO to postpone issuing such patents until the issue receives full legal, legislative, and administrative consideration.

The purpose of the hearing in Alexandria, Va., was to collect information for a report required under Section 27 of the America Invents Act (AIA). That provision requires the PTO director to deliver to Congress a study and recommendations by June 15 regarding independent second opinion genetic diagnostic testing where patents and exclusive licenses exist that cover primary genetic diagnostic tests.

The study must consider:

- How the lack of independent second opinion testing has affected the ability to provide the highest level of care to patients and those who get genetic diagnostic testing, as well as innovation in testing and diagnoses;
- How providing independent second opinion genetic diagnostic testing would affect patent and license holders of an exclusive genetic test;
- The impact that exclusive licensing and patents on genetic testing have on the practice of medicine; and

- The effects that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

Outside of PTO's Authority?

The hearings began with a video of Rep. Debbie Wasserman Schultz (D-Fla.), who had introduced an amendment to the House version of what became the AIA, H.R. 1249, that would have exempted from infringement a "genetic diagnostic tester's performance of a confirming generic diagnostic test activity" that otherwise would constitute infringement under Section 271(a) or (b). Wasserman Schultz withdrew her amendment before the House passed the bill and introduced a standalone bill, H.R. 2276.

In the video, Wasserman Schultz said that in 20 percent of the situations where a genetic diagnostic test is requested, the laboratory cannot perform the test due to patent exclusivity. Describing a personal experience, she said she was told that the BRCA test for a gene associated with breast cancer showed that she had the gene, but that there is only one BRCA test on the market and it is exclusively licensed. "Therefore, I was unable to question the test results," Wasserman Schultz said, adding that she underwent seven surgeries including a double mastectomy and she has always carried an element of uncertainty.

Thomas Kowalski, a shareholder of Vedder Price PC and an adjunct professor of law at New York University in Brooklyn, testified that Section 27 and the *Federal Register* notice announcing the hearing constituted an example of the classic American desire for a "do-over" of the U.S. Court of Appeals for the Federal Circuit's ruling in *Association for Molecular Pathology v. Patent and Trademark Office*. The Federal Circuit decision in the case, popularly known as *Myriad* after co-defendant Myriad Genetics Inc., which holds patents related to the BRCA breast cancer gene test, currently is under consideration for review by the U.S. Supreme Court.

"In my view, the Federal Circuit correctly held that claims to isolated DNA are patent-eligible subject matter and that method claims directed to only comparing or analyzing DNA are patent-ineligible subject matter. Hence, the Federal Circuit's holding in the *Myriad* case needs no 'do-over' as it is consistent with the goals of the AIA to harmonize U.S. patent laws with foreign patent laws," Kowalski said.

Gene Patent Moratorium Requested

Presenting an alternative viewpoint was Mary Williams, executive director of the Association for Molecular Pathology (AMP), the lead plaintiff in the *Myriad* case. "Members of the life sciences industry have invented and developed amazing new technologies, but if they are not able to access gene sequences, they are not able to put new tests on these new platforms," Williams said. "So in practice, gene patents discourage rather than encourage the widespread provision of genetic testing services."

Williams said that the AMP also is concerned because the PTO is not health care-focused and does not have the expertise needed to adequately assess the impact of patents on patients' ability to confirm testing. She therefore recommended that the panel adopt the assessment of the effect of gene patents on genetic testing by the HHS Secretary's Advisory Committee on Genetics, Health, and Society, which found that patenting and licensing of genetic tests has limited clinical labs' ability to offer genetic testing.

"AMP believes gene sequences are a natural phenomenon whether inside or outside the body. Therefore in light of the recommendations in the report and the solicitor general's brief for the United States and the *Myriad* ongoing litigation, we respectfully request that the PTO place a moratorium on issuing gene patents, including process patents on gene or variant correlations and clinical phenotypes, while the issue receives full legal, legislative, and administrative consideration," she said.

News-At-A-Glance

FRAUD FIGHTING PROPOSAL: President Obama's Feb. 13 budget proposal for fiscal year 2013 includes a 5 percent increase in discretionary spending ($610 million) for the Health Care Fraud and Abuse Control (HCFAC) program from his FY 2012 proposal, which would be a 92 percent jump over actual HCFAC discretionary spending in FY 2011 ($317 million). Obama proposed $581 million in discretionary HCFAC spending for FY 2012, which was not enacted by Congress. Congress has not passed a budget resolution since 2009 (for FY 2010), and has funded the government through a series of continuing resolutions. The $610 million would be distributed three ways, including $410 million for program integrity activities at the Centers for Medicare and Medicaid Services, $102 million for anti-fraud-and-abuse activities at the Department of Health and Human Services Office of Inspector General, and $98 million for anti-fraud-and-abuse activities at the Department of Justice.

MEDICAL FRAUD ALLEGED IN NO-FAULT AUTO INSURANCE SCHEME: Federal prosecutors unsealed charges Feb. 29 against 36 defendants alleging they participated in a no-fault auto insurance scheme to defraud private insurers of more than $279 million (*United States v. Zemlyanksy*). The indictment in U.S. District Court for the Southern District of New York represented the largest single no-fault auto insurance case ever filed and also the first use of the Racketeer Influenced and Corrupt Organizations Act (RICO) civil racketeering statute in a case of its kind, prosecutors said. The defendants included eight members and associates of a criminal organization consisting primarily of people of Russian descent who were the owners and controllers of fraudulent New York City medical clinics, prosecutors said. From at least 2007 to the present, the no-fault ring allegedly engaged in a massive and sophisticated scheme to defraud auto insurance companies of hundreds of millions of dollars through bogus clinics set up to provide unnecessary and excessive medical treatments. In total, 15 defendants were identified as clinic controllers and four as clinic managers. Ten licensed doctors, two chiropractors, two acupuncturists, and three attorneys were also charged.

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GCR 04/12

 G2 Compliance Report (ISSN 1524-0304) is published by G2 Intelligence, 1 Phoenix Mill Lane, Fl. 3 , Peterborough, NH 03458-1467 USA. Tel: 800-401-5937 or 973-718-4700. Fax: 603-924-4034. Web site: www.G2Intelligence.com.

Kimberly Scott, Managing Editor; Dennis Weissman, Executive Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, Chief Operating Officer and Publisher

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