# G2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

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## Inside this issue



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## Ohio State Medical Center Appealing PT Sanctions; Lab Faces Loss of Certificate, Medicare Exclusion

The clinical laboratory at Ohio State University's (OSU) Wexner Medical Center is appealing sanctions levied by the Centers for Medicare and Medicaid Services (CMS) over referrals of proficiency testing (PT) samples.

According to a July 20 report in the *Columbus Dispatch*, the lab in February sent a PT sample of Lyme disease to an outside lab, in violation of federal rules. A subsequent review found that five more blood-culture specimens had been improperly referred to another OSU laboratory between November 2009 and November 2011. Laboratory officials self-reported the violations, which they said were accidental.

In a June 14 letter, CMS officials told the lab's director, Amy Gerwitz, M.D., that the lab was out of compliance with federal rules. The lab responded with more than 100 pages of documents, but CMS on July 12 imposed sanctions on the lab, including revocation of the lab's CLIA certificate and a loss of Medicare and Medicaid reimbursement for

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## 23andMe Takes First Step Toward FDA Clearance

23andMe, a leading direct-to-consumer (DTC) genetic testing company based in Mountain View, Calif., has filed its first round of 510(k) documentation with the Food and Drug Administration (FDA), making it the first such company to seek FDA clearance for its tests.

The company on July 30 submitted filings to the FDA, which in 2010 warned 23andMe and other DTC genetic testing companies that their products were medical tests and that they had to submit them for review and approval. A month earlier, the FDA had quashed plans for another company, Pathway Genomics in San Diego, to sell testing kits through Walgreens stores nationwide.

In a June 10, 2010, letter, FDA noted that 23andMe had never submitted information on the analytical or clinical validity of its tests to FDA for clearance or approval. "However, your website states that the 23andMe Personal Genome Service is intended to tell patients in advance how they will respond to certain medications including warfarin and clopidogrel," the agency wrote. "It also states that the data

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## Ohio State Medical Center Appealing PT Sanctions, *from page 1*

services, said the *Dispatch* report. Because of the appeal, the sanctions have been put on hold until a hearing before an administrative law judge (ALJ). However, if the ALJ sides with the federal government, the lab must shut down for two years.

The OSU Wexner Medical Center says it is confident that the university will prevail in the appeal. In a statement given to NBC4i television news of Columbus, Ohio, which also reported on the sanction, the university said it intends to provide additional information to CMS as part of the process of appealing the action. "Once CMS reviews this additional information, Ohio State is confident that the government's concerns will be addressed."

***Legislation pending in the House and Senate would give CMS more discretion in enforcing the PT referral law. The legislation would replace CLIA statutory language that says a lab's certification "shall be suspended" with language that says the certification "may be suspended" in cases of a PT referral. This would allow CMS to substitute intermediate sanctions where warranted, including a directed plan of correction, civil money penalties, and costs for on-site monitoring, or any combination of these.***

The laboratories at OSU's Wexner Medical Center perform approximately 9.6 million patient tests and 9,200 proficiency tests a year and have been fully accredited by the College of American Pathologists since 1969. According to the university's statement, this is the "first self-reporting of this nature that the laboratories at Ohio State's Wexner Medical Center have had to make."

Under current federal law, labs may not send PT samples to another laboratory for testing even if they typically send patient specimens out for confirmation. Sending PT samples to another laboratory for testing may be considered PT referral and will result in the loss of the lab's CLIA certificate for at least one year. In addition, the lab director cannot direct a laboratory for two years and the lab owner may not own or operate a lab for two years.

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Judy Yost, director of the division of laboratory services at CMS, has told G2 Intelligence that she recognizes there are instances when referrals are made by accident and supports legislation that would give her division more enforcement discretion.

While CMS has prevailed in almost all administrative appeals involving PT referrals, a lab in September 2011 actually won its appeal. In *J.B. and Greeta B. Arthur Comprehensive Cancer Center v. CMS*, an ALJ decided that CMS could not revoke the CLIA certificate of the cancer center laboratory based on it having sent unused portions of the PT samples to a lab operated by Audrain Medical Center of Mexico, Mo., with which the cancer center is affiliated.

  

# Mayo Clinic Agrees to Pay $1.2 Million To Resolve Medicare, Medicaid Allegations

Mayo Clinic Aug. 2 agreed to pay more than $1.2 million to settle a whistleblower's lawsuit alleging the health provider submitted pathology claims to Medicare, Medicaid, and other federal programs for work it did not perform (*United States ex rel. Ketroser v. Mayo Foundation*, D. Minn., No. 07-CV-4676).

The settlement, which still requires court approval, will require the Rochester, Minn.-based medical center to pay $1 million to the federal government, the states of Minnesota and South Dakota, and the four individuals who brought the lawsuit. Once payment is made, the U.S. District Court for the District of Minnesota is expected to approve the settlement. The $1 million is on top of an earlier payment of $262,975.

David Ketroser, M.D., a physician and attorney, sued Mayo in 2007 claiming that the medical center was billing government agencies for surgical pathology slides that it did not prepare. According to the settlement, between September 1999 and September 2007, Mayo surgical pathologists prepared patient tissues for microscopic examinations using frozen slides. The slides can be prepared quickly, allowing pathologists to analyze the tissue during surgeries.

Mayo also prepared permanent slides, which take longer to prepare, so that tissues can be examined later. The permanent slides typically take a day to prepare.

The qui tam lawsuit under the False Claims Act alleged that while Mayo billed for the permanent slides, in certain instances they were not prepared.

The U.S. attorney's office noted in a statement that in September 2010, the Department of Justice intervened in the part of the qui tam action that alleged that Mayo knowingly billed Medicare, Medicaid, and other federal health care programs for the preparation and examination of permanent human-tissue slides Mayo never made or examined.

### Mayo Comments

Karl Oestreich, Mayo spokesman, said in a statement that Mayo discovered the billing error prior to its being aware that a lawsuit had been filed against it. He said Mayo worked with accounting experts to determine how much it had overbilled the government. It settled on $262,975, he said, and voluntarily paid that amount to the federal government in 2009 and 2010.

He said the settlement provides that the initial payment will be kept by the federal government and that Mayo will pay another $1 million. Of the total amount, nearly $980,000 will be kept by the federal government, while more than $20,000 will be shared by Minnesota and South Dakota. About $230,000 will be divided among the men who brought the lawsuit, while another $40,000 will pay for their attorneys' fees and expenses.

Oestreich said Mayo agreed to pay the additional $1 million because it believes continued litigation would have been more costly than the settlement. In addition, he said, settling the lawsuit allows Mayo to direct its resources to patient care, education, and research. He said the settlement is not an admission of liability by Mayo.

Blumenfield said the clinic has seven business days to pay the settlement. Once the money has been paid, he said, the court will examine the settlement. He said he expects court approval by the end of August.

  

# Efforts to Close Self-Referral Loophole Get Boost From *New England Journal*, CMS Analysis

Efforts by lab, pathology, and imaging groups to close the "loophole" in the federal self-referral law got a much-needed boost recently when a study published in the *New England Journal of Medicine* recommended eliminating the in-office ancillary services (IOAS) exception.

The study, "A Systemic Approach to Containing Medicare Spending," by E. Emmanual and others, said the loophole should be closed and the Stark law should be expanded to ban physician self-referrals reimbursed by private insurers. Physicians who use alternatives to fee-for-service payment should be exempt, however, because these methods reduce incentives to increase volumes.

A second article, published in an online journal from the Center for Strategic Planning at the Centers for Medicare and Medicaid Services (CMS), also provides additional fuel for the argument, according to *National Intelligence Report*. That article, "Linkages Between Utilization of Prostate Surgical Pathology Services and Physician Services," presents a trends analysis based on research published in the April issue of *Health Affairs* that compared Medicare billings and prostate cancer detection rates by self-referring urology groups with those that did not refer.

The regression analysis shows that the self-referral share (percentage) of total utilization was associated with significant increases in the use rate of surgical pathology specimens (jars). That rate would be 41.5 units higher in a county where the self-referral share of total utilization was 50 percent compared with a county with no self-referral share.

The conclusion: "Urologist self-referral of prostate surgical pathology services results in increased utilization and higher Medicare spending," suggesting that "exceptions in federal and state self-referral prohibitions need to be reevaluated."

### Aim Applauds Recommendations

The *New England Journal* recommendations were applauded by the Alliance for Integrity in Medicare (AIM)—a coalition of pathology, laboratory, radiology, radiation oncology, and physical therapy groups—which urged Congress to pass legislation to remove anatomic pathology, advanced diagnostic imaging, radiation therapy, and physical therapy from the IOAS exception.

CMS is silent on the IOAS controversy in its proposed Part B physician fee schedule rule for 2013, prompting critics to charge that this leaves the door open for urology, gastroenterology, and dermatology groups to continue to insource pathology work and increase their revenue stream.

With no regulatory relief in sight, AIM continues to press its case in meetings with members of the House and Senate. Key health leaders have asked the Congressional Budget Office to "score" closing the loophole. Scoring is a means of calculating the amount a proposed measure will either increase of decrease federal spending and tax revenues. G2



  

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COMPLIANCE PERSPECTIVES

# Preparing for and Living Through a RAC Audit: A Guide for the Clinical Laboratory

*George B. Breen, Esq., and Daniel E. Gospin, Esq., are attorneys in the health care and life sciences division of Epstein Becker & Green.*

There is no doubt about it—government enforcement is on the rise and with the expansion of the Recovery Audit Contractor (RAC) program, more providers, including clinical laboratories, will be faced with the proposition of navigating the often complex world of a government audit. In this day and age, RAC audits are virtually impossible to avoid; however, providers can take proactive steps to prepare for and to better address a RAC audit once the government is at the door.

### Background on the RAC Program

The Centers for Medicare and Medicaid Services (CMS) first implemented the RAC program in 2005 as a pilot program in five states (California, Florida, Massachusetts, New York, and South Carolina). After three years, the program was expanded to a permanent national program. With the passage of health reform, the RAC program has once again been expanded to include all Medicare claims, not just Part A and B claims. CMS also has begun implementation of Part C and D RACs, as well as the Medicaid RAC program.

Currently, there are four RAC regions, each handled by a different contractor. RACs have historically been tasked by CMS with detecting and correcting past improper payments (over- and underpayments). However, this is changing. Later this month, CMS is expected to implement a new demonstration project that will allow RACs to conduct prepayment reviews on certain types of Medicare claims. The new project will permit RACs to review selected claims to determine compliance with Medicare requirements *before* Medicare makes a payment to the provider. At least initially, the demonstration project is limited to a list of diagnosis-related groups relative to an observed problem by CMS surrounding short hospital stays.

### By the Numbers

RACs began reviewing claims as part of the permanent national program in October 2009. Fiscal year (FY) 2010 was the first year in which the RACs began actively identifying and correcting improper payments under the permanent program. Since the permanent program began, $1.27 billion in overpayments has been recovered and $184 million in underpayments has been returned to providers. In FY 2010, the RACs identified and corrected $92.3 million in combined overpayments and underpayments. In FY 2011, RACs recovered $797 million in overpayments. In the first quarter of 2012, RACs collected $588.4 million in overpayments and returned $61.5 million in underpayments. By all accounts, RACs are getting better at what they do. The dramatic increase in recoveries can be attributed to a number of factors, including more sophisticated data collection and mining techniques, better communication between federal and state agencies to target error-prone providers, and an increase in financial resources being allocated by the federal government for enforcement.

### RACs and Clinical Labs—What Is the Government Looking At?

Guidance from various government contractors and CMS suggests that contractors have focused their attention on auditing certain issues such as the improper use of

  

the 59 modifier, performance of a CBC differential when the physician's order does not specifically include this test, and routine performance of direct-measure LDL tests when such tests may not be medically necessary. Notably, the 2012 Office of Inspector General (OIG) Work Plan discusses the OIG's plan to review Medicare's contractors' procedures for screening the frequency of clinical laboratory claims for glycated hemoglobin A1C tests and determining appropriateness of Medicare payments for these tests.

In addition, the work plan reflects an intent to review trends in laboratory utilization under Medicare with respect to the types of laboratory tests and the number of tests ordered by physicians. This review will include an analysis of how a physician's laboratory test ordering is impacted by medical specialty, diagnosis, and geographic differences. In the near term, clinical labs may also see increased scrutiny surrounding quality measures that are used within the lab to ensure that services are rendered in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). A lack of quality-control procedures could create exposure under CLIA as well as under the False Claims Act.

### Getting and Staying Ahead of the Curve

What can clinical laboratories do to prepare for, and respond to, a RAC audit? The pressure placed on clinical laboratories in having to respond to RAC audit requests (prepayment and post-payment) may raise issues related to staffing, budgeting, and the organization's internal process for coordinating responses to RAC requests and managing appeals. There are certain steps that a clinical laboratory can take to help minimize the impact of responding to RAC audit requests in the first instance and then limit exposure when actually faced with such an audit in the second.

First, it is critically important that clinical laboratories develop and adopt a robust compliance program that contemplates the elements of an effective program described by the U.S. Department of Health and Human Services, OIG, and the Federal Sentencing Guidelines. A tailored compliance program will help cement a culture of compliance and position your organization to proactively address risk areas that are the focus of RACs and other government enforcement bodies.

***There are certain steps that a clinical laboratory can take to help minimize the impact of responding to RAC audit requests in the first instance and then limit exposure when actually faced with such an audit in the second.***

Moreover, an effective compliance program will improve quality of services and provide a central system for disseminating information and guidance to your organization's employees and contractors. It is not simply enough to have a set of policies and procedures maintained in a binder within the laboratory. The compliance program should be tailored to contemplate issues that are specific to clinical laboratories, and the program must be implemented at all levels of the organization. While developing and implementing an effective compliance program requires substantial commitment of resources, the long-term benefits of having such a program in place will ultimately outweigh the costs.

The auditing function of your organization's compliance program is an important one to highlight when discussing ways to prepare for post-payment and prepayment RAC audits. Organizations should ensure that the compliance program audit work plan is reviewed and updated on at least an annual basis. The work plan should reflect those issues that came to light during prior audits as well as newly identified risk areas contemplated by the OIG, CMS, or one of its contractors. Your lab's

  

audit function should be updated as frequently as necessary in order to address significant changes in the regulatory landscape and focus of the government or its contractors. Therefore, it is essential that the compliance team for your clinical laboratory stay current with national and local trends in enforcement as well as the types of claims that the RACs are authorized to review for purposes of determining whether overpayments or underpayments have been made.

In this regard, your organization's compliance department should regularly monitor the guidance issued by the regional RAC, including the RAC's Web site, CMS, and the OIG's annual work plan. In fact, someone within the organization's compliance department should register with the local RAC's list serv as well as CMS's list serv to receive relevant updates. Staying current with government and contractor issuances will allow your compliance team to focus and tailor the compliance program on risk areas that the government deems significant in the clinical laboratory and pathology context.

In anticipation of increased audit activity from the RACs, clinical laboratories should also consider staging mock audits to replicate the RAC review process and use the results of the audit as an opportunity to improve operational and clinical areas that may be the source of detected weaknesses. At a minimum, a mock audit will give your organization a series of benchmarks by which you can measure improvement over the course of many audits. To maximize the value of a mock audit, various operational functions, such as billing, coding, and documentation should be included in the internal review.

RAC audit requests will many times require the submission of documentation that is not within the care, custody, or control of the laboratory. However, the documentation requested substantiates the claim and must be provided to the RAC in response to the audit request. In these situations, clinical laboratories have found themselves reaching out to referring providers (e.g., physicians' offices, nursing homes, and hospitals) to request the necessary documentation. This can create a delay in responding to the RAC, and it also may have the unintended effect of frustrating referral sources. Both of these potential consequences can be avoided.

***In anticipation of increased audit activity from the RACs, clinical laboratories should also consider staging mock audits to replicate the RAC review process and use the results of the audit as an opportunity to improve operational and clinical areas that may be the source of detected weaknesses.***

First, be transparent with other providers from whom you are requesting documentation. Let them know the circumstances under which you are asking for the documentation and this may provide the necessary support for the urgency of their response. To the extent that your clinical laboratory enters into professional services agreements with other providers for rendering clinical laboratory services, consider incorporating a provision in the agreement that contemplates a request for documentation received by a third party (e.g., a RAC). With such a provision, all parties will start the relationship on the same page as it relates to the fulfillment of these requests.

### Challenging the RAC's Findings

Invariably, labs are faced with a decision on how to respond to an overpayment demand stemming from a RAC audit. One option is to appeal the RAC's determination. Historically, providers, including clinical laboratories, have underutilized the

  

appeal process, and in so doing potentially forgo a favorable decision to overturn the overpayment determination. CMS recently released aggregate data for FY 2011 that sheds light on some very interesting statistics regarding RAC appeals. In FY 2011 there were 903,372 claims with an overpayment determination by a RAC. Of these claims, only 56,620 were appealed at any level. Of these, 24,548 claims' decisions were reversed on appeal in the provider's favor.

### Extrapolation

Clinical laboratories should be mindful that RACs are authorized to use an extrapolation methodology to calculate and project overpayment amounts when it is determined that a "sustained or high level of payment error" exists or where there is "documentation that educational intervention has failed" to correct payment errors and it is necessary to calculate the overpayment amounts that may be due to the Medicare program. Extrapolation uses statistical sampling to calculate and project overpayment amounts to be recovered by recoupment, offset, or otherwise. A "sustained or high level of payment error" may be identified through a variety of means including, but not limited to, data analysis, probe samples, provider history, and information from law enforcement.

***The use of extrapolation by RACs presents a key issue for appeal. A provider may appeal the statistical methodology used to determine the sample size, as well as the sample selection.***

When extrapolating, a RAC must use the services of a qualified statistician and the sampling methods used must be well-documented. After the sample size and selection methodology are determined, a RAC staff member will request selected records from the lab and review them. The RAC will calculate the average per-claim overpayment amount in the sample and multiply this by the number of claims in the review population to determine the total overpayment amount.

### Should We Appeal?

There is clear evidence that (1) providers are not appealing overpayment determinations with any regularity and (2) there is a high success rate on appeal for providers. Organizations should carefully consider the strategic value of appealing (or not appealing) certain denials. There may be value in appealing what appears to be a relatively low dollar amount of denied claims; however, these decisions should be discussed internally and with outside advisers who understand the nuances of the appeal process.

The use of extrapolation by RACs presents a key issue for appeal. A provider may appeal the statistical methodology used to determine the sample size, as well as the sample selection. A provider also may appeal the rationale for the overpayment determination and the application of the statistical finding to the entire population of claims.

In any event, providers should carefully evaluate the appeal process, paying particular attention to the many deadlines that are imposed throughout the appeal. It is also beneficial to develop a tracking mechanism to manage appeals and establish a coordinated approach to uniformly and accurately manage the process.

As RAC activities continue to increase and as CMS and its contractors become more coordinated, clinical laboratories will need to take a hard look at their compliance program and audit response process to ensure the effectiveness of both. The current RAC climate suggests that the prudent course is for clinical labs to make the up-front investment in an effective compliance program in order to help mitigate future risk and prepare for the RAC requests and demand letters.

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### 23andMe Takes First Step Toward FDA Clearance, *from page 1*

generated from the 23andMe Odds Calculator, a feature of the 23andMe Personal Genome Service, includes the contribution of single-nucleotide polymorphisms (SNPs) to disease risk. Consumers may make medical decisions in reliance on this information."

23andMe has long maintained that its tests simply provide consumers with information but do not amount to a medical service. However, CEO and co-founder Anne Wojcicki acknowledges that the service is evolving as the number of tests offered has increased from 14 to more than 200. The company now would like government approval and the scientific credibility that comes with it.

"FDA clearance is an important step on the path towards getting genetic information integrated with routine medical care," explains Wojcicki. "As the knowledge around personalized medicine continues to grow, consumers should expect their health care providers to begin to incorporate genetic information into their treatments and preventative care."

Wojcicki adds that the company's ongoing conversations with the FDA and ultimately securing clearance will be very important "as we continue to serve our customers with genetic information that is an essential consideration in their personal health, and continue to grow our community, which is now more than 150,000 strong."

The 23andMe platform is designed to be both fluid and transparent and the filing with the FDA is designed to accommodate this data-driven paradigm, according to the company. "The body of information provided by 23andMe grows over time, not only in adding more traits and health reports, but also in interpreting results based on the continued evolution of scientific literature," the company said in a statement. "23andMe uses a CLIA-certified laboratory to process customer DNA samples. The 510(k) documentation provided to the FDA builds upon the company's scientifically sound practices by demonstrating the clinical and analytical validity of its reporting." G2

## Lessons Learned From Unannounced Inspections; How One Hospital MDx Lab Benefited From Its Mistakes

What do you do when inspectors from the College of American Pathologists (CAP) and the Centers for Medicare and Medicaid Services (CMS) show up at your laboratory unannounced to conduct an inspection in response to a complaint?

Try very hard not to panic, advises Jonathan Heller, administrative director of pathology and laboratory medicine at MedStar Georgetown University Hospital (MGUH), which went through just such an experience in 2010 after reports that the hospital's molecular diagnostics lab had quality-control problems with its HER2 testing. CAP spent two days at the lab focusing on anatomic pathology, flow cytometry, and the laboratory general checklist. CMS stayed at MGUH for an additional seven days focusing on the molecular diagnostics section (immunohistochemistry, fluorescence in situ hybridization, flow cytometry, and polymerase chain reaction). After CMS left, a second CAP team arrived to conduct another inspection focusing on the molecular diagnostic and cytology checklist.

The inspections found no issue with the reliability and accuracy of the patient test results conducted at the lab, stresses Heller, who spoke during the Executive War College in

  

New Orleans May 2. However, they did reveal additional documentation needs, including a quality-management program representing all laboratory sections, easy-to-follow policy and procedure manuals, staff competency assessments, reviews of instrument logs, reagent logs and quality control, and proficiency testing follow-up.

"The key tag line from this was: If it is not documented, it was not done," says Heller.

The inspection also revealed other weaknesses in the molecular lab, including a lack of standardization among faculty members, less experienced and limited technical staff within the molecular diagnostics lab, lack of defined technical leadership who understood how to apply the lab regulations, and misconception of lab regulations among staff and faculty members.

Upon arrival of the first inspection team, MGUH immediately suspended technical testing within the molecular laboratory; formed separate teams to focus on responding to the CAP and CMS citations; created a central repository of all inspection reports, findings, and responses; hired an interim quality management coordinator; established a project plan; and requested assistance from MedStar's corporate office and MGUH leadership.

### Key Next Steps

Once Heller and the molecular lab staff understood where they were deficient in documentation and quality control, they took the following steps:

1. Redesigned each procedure manual. Manuals are now set up by assay and each manual has a procedure on quality control, validation, technical testing process, instrument care, etc.
2. Adopted a proficiency testing checklist from the clinical laboratory to ensure all requirements are absolutely documented.
3. Assigned staff to key deliverables (QC review, procedure writing, etc.).
4. Evaluated test menu and established a partnership with a reference laboratory for the low-volume tests.
5. Revalidated each assay or antibody within the molecular laboratory (100 percent of all molecular tests). Key pathologists were assigned to specific areas, and positive and negative controls were reviewed and assigned.
6. Applied standardization within the molecular laboratory, including adding positive and negative controls to the pathology report dictated by the pathologist; creating a standard form and process to validate current and new assays; adding all key inspection deficiencies to the quality management program meeting as key performance characteristics; removing homebrew assays from the test menu; and drafted a schedule and adopted a process for supervisory review of QC, reagent logs, etc.

Changes made at the molecular lab also included faculty and staff re-education and participation, notes Heller. A culture change was implemented, and each person was assigned a key task or process so that the change was not led just by a supervisor or lab director. New policies and procedures were discussed with all faculty and staff during an open meeting, and once the new policy was established, everyone signed to document their acceptance and understanding.

Heller and the leadership also redesigned the personnel structure of the lab. The laboratory director title and responsibilities were transferred from the chairman to another pathologist, matching the clinical lab structure; a lab supervisor was hired to oversee technical operations of the molecular section; and a quality-management coordinator was hired to cover both pathology and laboratory medicine.

  

The changes implemented at the lab also resulted in a streamlining of the molecular diagnostics tests menu, explains Heller (*see chart*).

**Molecular Diagnostics Test Menu**

| Lab Section | January 2011 | July 2010 |
|---|---|---|
| IHC | 147 antibodies | Over 250 antibodies |
| FISH | 2 analytes: HER2 and EBER | 3 analytes: HER2, EBER, and 1p/19q, d(1, 19) |
| Flow Cytometry | 8 standard panels | 15 customized panels |
| PCR | 11 analytes (InvivoScribe Kit): IGH; T-gamma; t(15, 17); JAK-2 (qualitative); JAK-2 (real-time); BCL-1; BCL-2 (InvivoScribe Kit); HPV (16, 18); BCR-ABL (qualitative); BCR-ABL (quantitative) | 24 analytes: VDJ; Ty; EBNA; t(9, 22); HPV; JAK2; t(15, 17); BCL-2; BCL-1; KRAS; BRAF; INV16; t(8, 21); HHV8; TBC; t(12, 21); t(1, 19); t(11, 22); HHV6; HHV7; t(2, 13); t(X, 18); t(2, 5); t(6, 9) |

The entire process, from initial on-site inspections to subsequent inspections and revalidation, took about six months. Technical testing in the molecular lab was suspended for about five months, from August to December 2010.

Among the lessons learned from the experience, says Heller, is that anatomic pathology is not exempt from the CLIA regulations or the laboratory general CAP checklist. Both clinical pathology and anatomic pathology must fulfill the same basic regulations, he advises, noting that it is important to have a few key people who understand and know how to apply these concepts across both sides of the department.

### Citations Could Have Been Prevented

Heller acknowledges that the CMS and CAP citations and suspension of testing at the molecular lab could have been prevented. The lab should have paid more attention to previous citations, he says, noting that too much customization and lack of attention to detail can be an enemy.

"Do not overlook a checklist question because it would require too much effort to meet the intention of the guidelines," Heller warns. The lab director must ensure that whoever conducts the internal inspection has an appreciation and accurate understanding of the checklist.

Some have asked Heller if previous inspectors missed something. They did not, he stresses, noting that previous citations had been issued but that within the lab there was a lack of understanding of how to apply the standard.

CAP's new checklist lists specific items of compliance in an easy-to-follow format, and refined training for inspectors with CAP is much more robust.

"In the end, it is the responsibility of each laboratory to utilize the resources available to comply with the regulations," says Heller. Resources include continuing education conferences, inspection manuals, outside publication, and outside consultant observation and review.

Today, MGUH's molecular lab is much more efficient and compliant, with regulatory requirements and inspections "hardwired" into the staff culture and a large part of new employee orientation, says Heller. The lab is heavily focused on LEAN, further integration of pathology and laboratory medicine, and growing the molecular diagnostics section.

  

# News-At-A-Glance

**FEDS SEEK MAN IN LAB FRAUD:** A man who allegedly ran an insurance scam out of an office in Reseda, Calif., is wanted by the federal government for bilking Medicare out of more than $2 million in fraudulent laboratory tests in one year, according to a report by the *Daily News* of Los Angeles. Gevork Aidinian, 44, who is also known as Simon Shahapuny, is wanted on charges of grand theft, identity theft, insurance fraud-false wiring, and health benefits fraud. Investigators from the Office of Inspector General for the U.S. Department of Health and Human Services (OIG) began the investigation March 24, 2009. Aidinian listed himself as the owner of American Premier Laboratory in Reseda. He also listed himself as the CEO of Labx, another company in the same location. He allegedly used the identities of physicians to bill Medicare for laboratory work that was never provided or prescribed between 2008 and 2009. His operation appears to be connected to Eurasian organized crime groups, say authorities. Aidinian's name has been added to the OIG's most wanted health care fugitives. He is among more than 170 fugitives wanted on charges related to health care fraud and abuse.

**HOSPITAL ACCUSED OF BILLING FOR SUBSTANDARD LAB SERVICES:** A New Mexico district court recently unsealed a complaint alleging that Mimbres Memorial Hospital violated the federal False Claims Act and two New Mexico laws by billing Medicare and Medicaid for substandard laboratory services. According to Karen Lovitch, an attorney with Mintz Levin (Washington, D.C.), both the United States and the state of New Mexico declined to intervene in the case, but the relator may still proceed with the litigation on their behalf. According to the relator, a medical technologist formerly employed by Mimbres, the hospital's microbiology lab failed to perform quality-control testing as required by the Clinical Laboratory Improvement Amendments of 1988. This case emphasizes the importance of periodically evaluating quality-control procedures and ensuring that the laboratory is conducting and documenting all required quality-control procedures, notes Lovitch.




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