G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

March 2016

Inside this issue

www.G2Intelligence.com

Upcoming G2 Events

Lab Revolution
April 6-8, 2016, Sheraton Wild Horse Pass Resort & Spa, Chandler, AZ
www.labrevolution.com

Lab Institute 2016
Oct. 26-28, 2016, Hyatt Regency Washington on Capitol Hill, Washington, DC

Webinar:
Avoid Costly Penalties and False Claims Liability: Repay Medicare Overpayments Within Medicare's 60-day Deadline
April 13, 2016 2:00-3:30pm EDT
With Robert E. Mazer, Esq. and Kelly J. Davidson, Esq. of Ober Kaler
www.g2intelligence.com/web

Anticipate Health IT Changes in Order for Labs to Participate in Payment Reform, Coordinated Care

Health care reimbursement is quickly moving from the fee-for-service model to value-based payment and coordinated care among providers. This change may affect labs significantly because to get in on the action they'll need to be able to share data with other providers and even team up with them. If so, labs will likely need to reassess their current health IT systems and consider upgrading, adding to or replacing them.

HHS value-based goals

Health care has been shifting away from volume based payment for several years, mainly due to the Patient Protection and Affordable Care Act which created the Medicare Shared Savings Program to pay accountable care organizations (ACOs) to better manage patient care as well as funding to explore alternative care and payment models. It's part of the "triple aim" to improve the patient's care experience, improve population health, and reduce health care costs—such as duplicative blood tests, which are unnecessary.

In 2015, the Department of Health and Human Services (HHS) took this effort a step further, announcing its goal to move the industry away from traditional fee for service health care and into value, care coordination and quality-focused programs, such as the management of a population or an episode of care. HHS planned to have 30 percent of Medicare fee for service payments tied to quality or value through alternative payment models by the end of 2016 and announced this month it has reached that goal ahead of schedule (see News at a Glance, p. 12). Fully half of Medicare payments will be tied to alternative or population based models by the end of 2018.

Continued on page 10

CMS Final Rule Clarifies 60-Day Deadline for Returning Overpayments

Labs and other providers are required by a provision enacted in the Affordable Care Act to return overpayments to Medicare within 60 days of identifying the overpayment. Violations of the rule subject the provider to False Claims liability and a fine ranging from $5,500 to $11,000 per claim. What constitutes identification of an overpayment, however, has caused much debate and concern. A 2012 proposed rule didn't add much clarity and a New York federal court

Continued on page 2

CMS Final Rule Clarifies 60-Day Deadline for Returning Overpayments, *from page 1*

decision last year in *U.S. ex rel. Kane v. Continuum Health Partners, Inc.*, caused much consternation. Now, however, the Centers for Medicare & Medicaid Services (CMS) has issued a final rule interpreting the 60-day repayment requirement.

Health care attorney Robert E. Mazer, of Ober Kaler, explains that the final rule applies to Medicare Part A and B providers and suppliers "reporting and returning overpayments on or after March 14, 2016, irrespective of the date on which the overpayment was received."

> ***"Our general aim of this final rule is to strengthen program integrity and to ensure that the Medicare Trust Funds are protected and made whole and that taxpayer dollars are not wasted. An overpayment must be reported and returned regardless of the reason it happened—be it a human or system error, fraudulent behavior or otherwise."***
>
> **—Centers for Medicare & Medicaid Services**

The final rule clarifies "the meaning of overpayment identification; the required lookback period for overpayment identification; and the methods available for reporting and returning overpayments to CMS," according to CMS press release.

On those three issues, the final rule states:

- An overpayment is identified "when the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment."
- The lookback period is six years, meaning if an overpayment is identified within six years of the date payment was received, the recipient must comply with the 60-day rule.
- Repayments must be achieved using "an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor." The OIG's self-disclosure and CMS' self-referral disclosure protocols also may serve as a method to report overpayments.

CMS clearly emphasizes in the preamble to the rule that an overpayment is any amount which a lab receives to which it isn't entitled—whether the result of fraud, inadvertent error or mistake. This interpretation of what constitutes an overpayment is in keeping with CMS' stated objective: "Our general aim of this final rule is to strengthen program integrity and to ensure that the Medicare Trust Funds are protected and made whole and that taxpayer dollars are not wasted. An overpayment must be reported and returned regardless of the reason it happened—be it a human or system error, fraudulent behavior or otherwise."

Mazer also notes that "in the case of an overpayment resulting from a violation of the Federal Anti-kickback or Stark Statute, or goods or services provided by an excluded individual, the entire amount received is considered to be an overpayment."

We'll provide more detailed analysis of this final rule in the April issue of *G2 Compliance Advisor*. Robert E. Mazer, together with his colleague Kelly J. Davidson, also a health care lawyer with Ober Kaler, will be presenting a webinar addressing this final rule and what it means for labs and pathology groups April 13, 2016. For more information, visit the G2 Intelligence website, www.g2intelligence.com/web/.

Takeaway: Centers for Medicare & Medicaid Services has finally provided labs some clarity about when the 60-day deadline for repaying Medicare overpayments begins to run, how to calculate the overpayment amount and how far back liability for overpayments extends. G2

Labs Urged to Examine Internal Processes to Ensure Accuracy of Patient Identification

The innovator who develops the best solution to accurately identify patients throughout the health care continuum may earn a $1 million reward. That's the idea behind the College of Healthcare Information Management Executives' (CHIME) National Patient ID Challenge. The national association of CIOs and health IT suppliers is partnering with HeroX (a challenge-launching platform) in the year-long crowdsourcing competition that will reward the winner with $1 million.

Labs Advised to Look Internally for ID Gaps

As to labs, pathologists and laboratory leaders may tap matching technology that helps labs match patient records from multiple organizations. Systems still rely on manual entry, pointed out Tejal Gandhi, M.D., president and CEO of the National Patient Safety Foundation (NPSF). She told *G2 Compliance Advisor*'s sister publication, *National Intelligence Review (NIR)* that labs also need to look at processes within the lab itself that could lead to a potential breakdown in patient identification.

"For example, do labs have a closed-loop communication? When they send results out, do they know for certain the provider actually got them? There are lots of things that can fall through the cracks," Gandhi said in an interview with *NIR*. "So, think of processes, potential gaps, and how labs can redesign to make the processes more reliable. That is going to be real important (to patient safety and identification)," she added.

Patient Identification's Important

Indeed, patient identification is important, Challenge organizers also say, because errors continue to occur in health care organizations due to lack of a universal way of accurately identifying a patient.

In fact, the error rate in matching patients to their records is usually 10 to 20% within a health care system. It can rise to 50 to 60% when organizations exchange data through the care continuum, CHIME pointed out in a statement. CHIME data suggest that 60% of members use some form of a unique patient identifier to match patient data within their organizations. Others rely on complicated algorithms. About 20% of CHIME members said at least one adverse medical event can be associated with incorrect patient matching.

"As we digitize health care and patients move from one care setting to another, we need to ensure with 100% accuracy that we identify the right patient at the right time. Anything less than that increases the risk of a medical error and can add unnecessary costs to the health care system," said Marc Probst, CHIME board of trustees chair. He is also vice president and CIO, Intermountain Healthcare, Salt Lake City, which spends between $4 million and $5 million each year on patient identification-related technologies and processes, according to a CHIME statement.

Challenge Guidelines and Deadlines

The Challenge seeks to establish a more secure method of patient identification than the social security number, which is also tied to financial and personal records and could be stolen, CHIME pointed out on the HeroX Web site.

Conversely, a stolen national patient identification number—unlike a social security number—can be terminated and replaced with a new number, CHIME added.

Submissions for the Challenge Concept Blitz Round are due April 8 with final submissions (whether or not people participate in the Concept Blitz) due Nov. 10. The winner will be announced Feb. 19, 2017. A CHIME spokesperson told *NIR* that 86 innovators have signed up at this writing.

CHIME said it is seeking the best plan, strategies, and methodologies that will accomplish the following: 1) easy and quick identification of patients; 2) 100% accuracy in patient identification; 3) patient privacy protection 4) patient identity protection; 5) adoption by vast majority of patients, providers, insurers, and other stakeholders; and 6) scale to handle all U.S. patients.

Gandhi said the NPSF does not have a Challenge entry, but she may be involved another way. "We support the project, because we think patient identification in all these areas is a big issue," she said.

Takeaway: A national IT organization hopes to find an answer to the complex problem of patient identification and protecting patients from medical errors as electronic health records proliferate. A patient safety expert also encourages lab leaders to look at their internal processes and how they help ensure patient identification and accuracy. G2

G2 Compliance Corner

Make Sure Disciplinary Action Doesn't Equal Retaliation

Whistleblowers are a driving force behind many of the recent settlements with laboratories and other providers under the False Claims Act (FCA). Whistleblowers are often former employees of the settling defendant. The FCA not only rewards these whistleblowers with a share of the funds recovered in a *qui tam* case but also protects them from retaliation by the employers they named in their *qui tam* lawsuit.

Section 3730(h) protects the whistleblower from being "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment" because he or she took action to "stop 1 or more violations" of the FCA. The FCA entitles the victim of such retaliation to reinstatement with the same status they would otherwise have, plus "2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees."

But does this mean you can never take any disciplinary action against an employee who raises a compliance issue? No. The FCA prohibitions against retaliation don't say that an employer can *never* take disciplinary action against an employee who has made efforts to stop FCA violations. But you must tread carefully when disciplining such employees.

Don't impose discipline in response to or because of an employee's actions that are protected under the FCA. Make sure your records demonstrate grounds separate and apart from the source of any compliance complaints or questions the employee has raised. In a future article, we'll give you detailed steps you can take to help you successfully impose discipline when it is warranted, without violating the FCA's prohibition against retaliation.

G2 COMPLIANCE PERSPECTIVES

Marketing of Laboratory Tests to Consumers: Is a Practitioner Order Enough to Avoid FDA Enforcement?

Danielle Sloane, Esq.,
Bass, Berry & Sims

Courtney Ginn, Esq.,
Bass, Berry & Sims

Laboratory developed tests (LDTs) are tests designed, manufactured, and used within a single laboratory. Historically, the FDA opted not to regulate LDTs, which were originally relatively simple laboratory tests. As technology has progressed, however, LDTs have become increasingly complex and sophisticated in the ability to diagnosis and influence decision-making; simultaneously, consumers have become more sophisticated and hands-on in their approach to health care.

Together, these trends mean that laboratories are seeking to differentiate themselves in a competitive market by marketing their LDTs directly to consumers, but what is the impact of marketing on a laboratory's ability to remain within the FDA's historic exception for LDTs? The FDA has recently intensified its enforcement against laboratory companies that market LDTs directly to consumers. As evidenced by a number of FDA warning letters, it is clear that the FDA deems any test marketed *and sold* directly to consumers as no longer qualifying for the historic LDT exception, necessitating instead the appropriate level of FDA approval. But the FDA warning letters and recent commentary seem to be expanding beyond tests sold directly to consumers, to tests that are marketed to consumers and ordered by qualified physicians. It seems likely, however, the FDA may be focusing on situations in which the ordering practitioner is affiliated with the laboratory rather than truly independent.

LDTs have historically fallen within an "enforcement discretion" exception to the FDA's regulation of in vitro diagnostic products. When the FDA first began regulating medical devices under the Medical Device Amendments in the 1970s, the FDA declined to enforce applicable regulatory requirements for LDTs.[2]

FDA'S REGULATION FRAMEWORK FOR LDTs

The FDA is the federal agency with the primary regulatory authority over laboratory tests sold directly to consumers ("DTC tests"). The FDA regulates DTC tests as in vitro diagnostic medical devices, a category that includes any products intended for use in the collection, preparation, and examination of specimens taken from the human body.[1] Like other medical devices, these in vitro diagnostic products are subject to premarket and postmarket controls, including appropriate FDA approval prior to being marketed and sold in the United States.

LDTs have historically fallen within an "enforcement discretion" exception to the FDA's regulation of in vitro diagnostic products. When the FDA first began regulating medical devices under the Medical Device Amendments in the 1970s, the FDA declined to enforce applicable regulatory requirements for LDTs.[2] This was due in large part to the fact that LDTs were relatively simple lab tests and generally available on a limited basis, which the FDA concluded were sufficiently safeguarded by the CLIA program. Accordingly, LDTs generally have not been subject to premarket and postmarket controls applicable to other medical devices.

As LDTs have become more advanced and more widely available, however, concerns over the validity and safety of the tests have resurfaced. Specifically, the FDA has taken the position that some modern LDTs have attributes not present in 1976 that create potential increased risk for patients, including tests that are (i) manufactured with components that are not legally marketed for clinical use; (ii) offered beyond local populations and manufactured in high volume; (iii) used widely to screen for common diseases rather than rare diseases; (iv) used to direct critical treatment decisions; and (v) highly complex.[3]

The increased risks that accompany some modern LDTs exposed a perceived gap in regulatory oversight of LDTs. After years of rumblings, on Oct. 3, 2014, the FDA issued a Draft Framework for regulating LDTs.[4] The Draft Framework proposes a risk-based approach to regulating LDTs, similar to the classification used for medical devices, which would be implemented over about 10 years. The FDA would continue to exercise its enforcement discretion against low-risk LDTs while requiring premarket review for moderate and high risk LDTs. Since release of the Draft Guidance, the FDA has been bombarded with industry commentary, held stakeholder meetings,[5] issued case studies in support of its position that regulation is necessary,[6] and presented before Congress.[7] A final guidance document is expected sometime in 2016. In addition, the FDA is exploring regulatory alternatives for genetic testing in relation to President Obama's "Precision Medicine Initiative."

In April 2015, "[a]n F.D.A. spokeswoman said that if doctors place orders, testing companies that operate their own laboratories do not need F.D.A. approval to offer their tests."[8] And, until recently, that concept was supported by the pattern of FDA enforcement and commentary.

FDA'S REGULATION OF DTC TESTING

In the meantime, the FDA continues to target laboratories that market their LDT products to consumers. Traditionally, laboratory marketing was directed at qualified practitioners (e.g., physicians, nurse practitioners, etc.). Because of competitive pressures (and perhaps taking inspiration from pharmaceutical manufacturers), laboratories have identified consumers as a worthwhile marketing demographic, even if the LDT requires a physician order. Is marketing an LDT itself problematic in the eyes of the FDA? Or, is it the combination of marketing and allowing consumers to order directly (absent an order from a qualified professional)—or maybe something in between? Considering laboratories have long had websites touting their lab and testing, one would think it is the latter—the removal of a qualified practitioner from the process—and not simply the marketing of LDTs that would trigger enforcement. In April 2015, "[a]n F.D.A. spokeswoman said that if doctors place orders, testing companies that operate their own laboratories do not need F.D.A. approval to offer their tests."[8] And, until recently, that concept was supported by the pattern of FDA enforcement and commentary.

The FDA's disapproval of marketing and *selling* LDTs directly to consumers was made clear in 2013 when the FDA issued a scathing warning letter to Google-backed 23andMe, Inc. regarding the sale of its saliva collection kit and personal genome service for reporting on, among other things, 254 diseases and conditions, in violation of the Federal Food, Drug and Cosmetic Act (the "FD&C Act"). As part of that letter, the FDA directed 23andMe to immediately stop marketing its personal genome service until it received authorization

from the FDA.[9] More than a year later, 23andMe made news again when the FDA approved 23andMe to market a specific test to consumers for one disease, Bloom Syndrome, a rare inherited disorder. This FDA approval was extremely narrow in comparison to 23andMe's original personal genome service.[10] In conjunction with this approval, the FDA classified autosomal recessive carrier screening tests as a Class II medical device requiring premarket notice (or 510(k) review). The FDA stated that "in many circumstances it is not necessary for consumers to go through a licensed practitioner to have direct access to their personal genetic information" and stated this was the "least burdensome regulatory path" for these types of tests—though notably expects those tests to have gone through FDA 510(k) review.[11]

Recent FDA enforcement activity reaffirms the FDA's disapproval of laboratories marketing LDTs (i.e., tests without PMA or 510(k) clearance) to consumers. In late 2015 and early 2016, the FDA issued five warning letters to companies engaging in DTC marketing of LDTs.

Recent FDA enforcement activity reaffirms the FDA's disapproval of laboratories marketing LDTs (i.e., tests without PMA or 510(k) clearance) to consumers. In late 2015 and early 2016, the FDA issued five warning letters to companies engaging in DTC marketing of LDTs. In several of these letters, it appears the FDA may be going beyond situations in which the consumer can order the test directly to also regulate situations in which the practitioner signing the order is affiliated with the laboratory.

On Sept. 21, 2015, the FDA issued a warning letter to Pathway Genomics, Inc. addressing the marketing of a non-invasive blood test intended for use as a screening tool for the early detection of up to 10 different cancer types in high risk populations. The FDA stated that the "high risk test" was a medical device that required approval and expressed concern that the company's current promotional materials "may harm the public health."[12] According to Pathway's current website, the test kit is shipped directly to patients, but the test must be ordered by a physician.[13] Upon selecting the "patient" identifier on the company's website, the viewer receives the following message: "All Pathway tests must be ordered by a licensed and registered physician or other qualified health care provider."[14] It is unclear, however, whether the company was requiring a qualified practitioner order at the time it received the letter.

On Nov. 2, 2015, the FDA issued a letter to DNA-Cardiocheck, Inc., which notes that the company is "currently marketing a direct-to-consumer test" that "appears to meet the definition of a device," and concluded that the test was a medical device.[15] An archived webpage indicates that the test was available for purchase on Walgreens's website.[16]

The same day, the FDA also issued a warning letter to DNA4Life. DNA4Life's warning letter was related to its direct-to-consumer marketing of its Pharmacogenetic Report, which is "intended to predict how patients will respond to more than 120 of the most commonly prescribed medications."[17] The FDA concluded that this test was a medical device requiring a clearance number.[18] According to DNA4Life's website, the test does not appear to require a physician order.[19] Patients are, however, asked to promise to share the results with their physician by clicking a box in the checkout process. In addition, the company's privacy policy "urges [buyers] to seek the advice of your physician or other health care provider if you have questions or concerns arising from your genetic information."[20]

Similarly, a Nov. 4, 2015 warning letter to Interleukin Genetics notes that the company was marketing unapproved genetic tests intended to identify individuals with a genetic predisposition for increased risk for diabetes, heart attack, and obesity, which "appear to meet the definition of devices."[21] The FDA noted that Interleukin Genetics had previously claimed the tests as LDTs, but that "at the present time, your firm is offering these tests under a [DTC] model." According to its website, it appears that Interleukin sends sample collection kits directly to consumers with no physician order necessary, although the company offers consumers the option to speak with a "licensed, board-certified genetic professional."[22]

In a recent interview by *GenomeWeb*, Alberto Gutierrez, director of the Office of In Vitro Diagnostics and Radiological Device Evaluation for the FDA, said that the FDA is looking into DTC models "that rely on ordering of the test either by the physician that is incorporated into the company or that somehow has a relationship not with the patient but with the company."[25]

Most recently, Sure Genomics received an FDA warning letter on Feb. 16, 2016, stating that the company was marketing a test "which is intended to catch saliva samples for DNA sequencing and reporting of patient information such as disease risks and likelihood of drug reactions."[23] As with the warning letters issued in 2015, the FDA concluded that the SureDNA test met the definition of a device as defined in section 201(h) of the FD&C Act. A press release on the company's website describing the process states that "Users register online for a collection kit to mail-in a saliva sample—testing is physician prescribed...."[24]

The requirement of a physician order should place laboratory tests within the FDA's LDT exception at least until the FDA issues final guidance on regulating LDTs. And yet, it appears that some of the FDA enforcement efforts have involved companies that required qualified practitioner orders, leaving us to question where the line between an LDT and a DTC test lies. Our guess is the answer may depend on the relationship between the laboratory and the physician.

The FDA has signaled as much in recent commentary. In a recent interview by *GenomeWeb*, Alberto Gutierrez, director of the Office of In Vitro Diagnostics and Radiological Device Evaluation for the FDA, said that the FDA is looking into DTC models "that rely on ordering of the test either by the physician that is incorporated into the company or that somehow has a relationship not with the patient but with the company."[25] This shift in focus suggests that marketing LDTs ordered by unaffiliated, independent practices should continue to fall within the LDT category, but affiliated physician orders may shift a test to a DTC test. As a result, in addition to considering fraud and abuse laws when entering into physician relationships, laboratories may need to consider if those relationships impact their FDA compliance.

Danielle M. Sloane *is a Member at the firm, Bass, Berry & Sims PLC, 150 Third Ave. South, Ste. 2800, Nashville, TN 37201 and is available at (615) 742-7763; dsloane@bassberry.com.*

Courtney Ginn *is an Associate at Bass, Berry & Sims PLC, 150 Third Ave. South, Ste. 2800, Nashville, TN 37201 and is available at (615) 742-7741; cginn@bassberry.com.*

End Notes

[1] 21 C.F.R. § 809.3.

[2] Of course, this enforcement abstention assumes that the FDA has authority to regulate LDTs as medical devices in the first place. *See, e.g.*, "Laboratory Testing Services, As the Practice of Medicine, Cannot be Regulated as Medical Devices," Paul D. Clement & Laurence H. Tribe, available at http://www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf.

[3] FDA, "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" at 8, issued October 3, 2014.

[4] *Id*.

[5] *See e.g.*, FDA Public Workshop – Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs), January 8-9, 2015. http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm423537.htm.

[6] FDA, "The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies" (Nov. 16, 2015) available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf.

[7] Jeffrey Shuren, Director of CDRH, FDA "Examining the Regulation of Diagnostic Tests and Laboratory Operations" before the U.S. House, Energy and Commerce, Subcommittee on Health (Nov. 17, 2015) available at http://www.fda.gov/NewsEvents/Testimony/ucm473922.htm.

[8] Andrew Pollack, "New Genetic Tests for Breast Cancer Hold Promise," *The New York Times* (Apr. 21, 2015) available at http://www.nytimes.com/2015/04/21/business/more-accurate-affordable-tests-for-detecting-breast-cancer-genes.html?_r=1.

[9] FDA Warning Letter, 23andMe, Inc. (Nov. 22, 2013) available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm.

[10] FDA News Release: FDA permits marketing of first direct-to-consumer genetic carrier test for Bloom syndrome (Feb. 19, 2015; modified Feb. 23, 2015) available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM435003.

[11] *Id*.

[12] FDA Warning Letter, Pathway Genomics (Sept. 21, 2015), available at http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM464092.pdf.

[13] "Request a Test Kit", available at https://www.pathway.com/request-a-kit/ (last visited Feb. 22, 2016).

[14] *Id*.

[15] FDA Warning Letter, Cardiocheck, Inc. (Nov. 2, 2015), available at http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM471784.pdf.

[16] https://web.archive.org/web/20140517060903/http://dnaidcheck.com/ (last visited Feb. 22, 2016). Although the DNA-CardioCheck test is no longer available for purchase, the company is still offering its DNA-IDCheck (a paternity/maternity test) for purchase on the Walgreens website without a physician order. *See* http://www.dnaidcheck.com/ (last visited Feb. 22, 2016); http://www.walgreens.com/store/c/dna-id-check-dna-sample-collection-kit-fatherhood/motherhood-confirmation/ID=prod1107920-product (last visited Feb. 22, 2016).

[17] FDA Warning Letter, DNA4Life (Nov. 2, 2013) available at http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM471785.pdf.

[18] FDA Warning Letter, DNA4Life (Nov. 2, 2013).

[19] "How It Works" available at https://dna4life.com/how-it-works/ (last visited Feb. 22, 2016).

[20] https://dna4life.com/checkout/ (last visited Feb. 22, 2016); https://dna4life.com/privacy-policy/ (last visited Feb. 22, 2016).

[21] November 4, 2015 Warning Letter, available at http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM471788.pdf.

[22] "How Does DNA Testing Work" available at http://www.inherenthealth.com/the-process.aspx (last visited Feb. 22, 2016; Inherent Health is the brand name of genetic tests that Interleukin Genetics).

[23] FDA Warning Letter, Sure Genomics, Inc. (Feb. 16, 2016) available at http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM486449.pdf.

[24] "Sure Genomics Introduces First Full DNA Sequence to Consumers Delivered on an Interactive Easy to Comprehend Platform" http://www.suregenomics.com/press/ (last visited Feb. 22, 2016).

[25] Turna Ray, GenomeWeb: Q&A: FDA's Gutierrez, Mansfield Discuss Regulatory Efforts in 2015; Set 2016 Expectations (Jan. 13, 2016) available at https://www.genomeweb.com/molecular-diagnostics/qa-fdas-gutierrez-mansfield-discuss-regulatory-efforts-2015-set-2016-0. *See also* GenomeWeb: Sure Genomics Gets FDA Letter (Feb 18, 2018) available at https://www.genomeweb.com/molecular-diagnostics/sure-genomics-gets-fda-letter.

ANTICIPATE HEALTH IT CHANGES IN ORDER FOR LABS TO PARTICIPATE IN PAYMENT REFORM, *from page 1*

This is the first time in history that HHS has set specific goals for alternative payment models and value based payments.

Private payors have followed suit, with at least one coalition of heavy hitters creating a task force committing to put 75 percent of their business into value based arrangements by 2020. Many national payors, including Aetna, Blue Cross and Humana have been actively moving away from fee-for-service care to, and contracting with, ACOs, patient centered medical homes and other coordinated care programs in order to lower their costs and achieve better outcomes.

> ***"Many alternative payment models are being explored at the moment, with opportunities for labs to be carved in and carved out. Diagnostic utilization is also being included into some bundled payments or case rates."***
>
> **—Adam Powell, PhD**

A large component of these programs is the reduction or elimination of wasteful unnecessary duplicative procedures, such as lab testing, according to consultant Adam Powell, PhD, President of Payer+Provider Syndicate, a management advisory and consulting firm based on Boston Syndicate, in Boston. "Lab utilization is a large part of [reducing costs and improving outcomes]," he says.

What underpins these changes is the need by providers to use electronic health records (EHRs) and other health IT to better coordinate care and share patient data. Many of CMS' payment models already require or encourage EHR use, even for ancillary providers such as end stage renal disease entities and long term and post-acute care providers.

Options for labs

Many, if not most, labs are already sending test results and other information electronically to other providers in a basic way. With the push away from fee-for-service reimbursement, labs that are not hospital based and have a choice to determine if it's worth it to take data sharing to a new level, whether to participate in these alternative care models, and how to best share data with them.

"Many alternative payment models are being explored at the moment, with opportunities for labs to be carved in and carved out. Diagnostic utilization is also being included into some bundled payments or case rates," says Powell.

However, whether to invest in a full-fledged EHR to participate in data exchange is big decision, and may depend on the types of opportunities labs have in their particular regions to join these different payment programs. For instance, a lab using a different EHR or data sharing module may encounter problems with interoperability, warns Carl Bergman, an EHR consultant in Washington, DC and former managing partner of EHRSelector.com, a free service that enables providers to compare different ambulatory EHR products.

"It's not enough that the machines talk to each other. There are levels of interoperability. They need to exchange data in compatible formats and the ability to interpret the data in the same way it was sent," he warns. There's also still a lot of uncertainty how these programs will work and labs' role in them. "Things are up in the air with some lab related requirements," warns Powell.

For instance, the Medicare Access and CHIP Reauthorization Act (MACRA) enacted in 2015 creates a new Merit Based Incentive Payment System (MIPS) for reimbursing physicians in the Medicare program that will include a lab component, says Powell. However, the statute didn't provide many details about MIPS, and the rules implementing it have not yet been published. "The lab information system requirements are

evolving. There may be nitty gritty things coming [that providers will need to comply with] that we don't know about," warns Powell.

Take five steps to protect your lab

Before your lab takes the plunge in participating in these programs and investing in expensive health IT systems, consider these five steps:

Explore what kind of new payment programs and ventures are in your area and see if any of them are a good fit for your lab. If so, see what you—compared to your competitors—can bring to that program's/venture's table to maximize your chances of being included, says Powell. For instance, if you can demonstrate that you're more efficient or have prior experience in quality based programs, point that out.

If you're going to indulge in EHRs or other health IT, make sure it has the clinical and interoperability functionality you need. For instance, see what systems your provider and/or payor partners are using and requiring before buying equipment. You may not need to buy anything new, or simply add a module to your existing system, says attorney Gerald "Jud" E. DeLoss, with Clark Hill in Chicago.

Consider sharing data via your local health information exchange (HIE). HIEs facilitate the sharing of information by servicing as a central repository. If your geographic region has a functional HIE organization, you may be able to share data and participate in these payment models via the HIE without having to purchase any new health IT equipment. This would depend in large part if your other potential partners are part of the HIE and the cost to join it.

Don't forget data security and compliance with the Health Insurance Portability and Accountability Act (HIPAA), says Bergman. You need to make sure that any data sharing you participate in protects the confidentiality of the patient data. If you're involved in an HIE or provider arrangement, get assurances—via business associate agreement or organized health care arrangement (OHCA) contract, as applicable—that the others you're working with will also protect the patient data (for more on what an OHCA is, see sidebar on the left).

Consider holding off a bit to get the lay of the land. Investing may be a bit premature without more definitive information about some of these programs. "When you know a new phone is coming out in three months you'd wait until the new one comes out. 2016 should be viewed as a year of caution," says Powell.

Takeaway: Labs may need to partner with other providers to reap the benefits of payment reform and not be left out in the cold. This step, however, will likely involve research and investing in health IT in order to participate, share patient information, and coordinate care. G2

Organized health care arrangements 101

An organized health care arrangement (OHCA) is a specific arrangement allowed under HIPAA (45 CFR 160.103) that permits two or more covered entities engaged in joint activities to share patient protected health information (PHI) to operate and further their joint activities. To qualify, the legally separate covered entities must be clinically or operationally integrated; must hold themselves out to the public as being in a joint arrangement; and jointly perform quality assurance, utilization review and/or payment activities, according to attorney Adam Greene, with Davis Wright Tremaine in Washington, DC, speaking at a recent conference sponsored by the National Institute of Standards and Technology. They also have to be either providers or health plans.

According to the Department of Health and Human Services (HHS), covered entities such as labs that enter into an OHCA can share PHI for their joint health care activities without entering into business associate contracts with each other (in contrast, health information exchanges (HIEs) are business associates of the providers using them, and need to sign business associate agreements outlining how they will use and protect the information). Members of an OHCA can use a joint or separate Notices of Privacy Practices and can contract as one entity with business associates. Since they're not business associates of each other, the participants do not have to say that they meet each other's HIPAA requirements. However, they are independently required to comply with HIPAA.

In the past, OHCAs were found mainly between hospitals and physicians who worked together to treat patients or physicians who banded together in independent practice associations, according to HHS.

However, more OHCAs are expected to be created as more plans and providers come together in accountable care organizations and other joint arrangements, as contemplated by new reimbursement models and health care reform, according to attorney Amy Leopard, with Bradley Arant Boult Cummings, Nashville, also speaking at the conference. "This is where OHCAs are coming into prominence," she explains.

News at a Glance

HHS Achieves Milestone Ahead of Schedule. In January 2015, the Department of Health and Human Services (HHS) set a goal of tying roughly 30 percent of Medicare payments to alternative payment models that focused on quality and value rather than volume of services. It projected meeting that goal by the close of 2016. However, the agency announced this month that, by its estimates, it has already reached that goal. It said that Centers for Medicare & Medicaid Services Office of the Actuary vetted those estimates and found them "to be sound and reasonable"—multiplying the number of Medicare beneficiaries in alternative payment models by estimated cost of health care and comparing that figure to Medicare spending projections. HHS cited the current 477 Medicare Shared Savings Program and Pioneer Accountable Care Organizations (ACOs) with saving $411 million and for creating incentives to coordinate care.

Fraud and Abuse Recoveries Decline. The Department of Justice (DOJ) and Department of Health and Human Services (HHS) released their annual report regarding the achievements of the Health Care Fraud and Abuse Control (HCFAC) Program for Fiscal Year 2015 and it indicates the government recovered $2.4 billion in judgments, settlements and administrative penalties from fraud cases. A press release announcing the report touts that recovery as a return on investment of $6.10 for every dollar spent over the last three years. Impressive numbers, yet not quite as impressive as 2014's—when the government reported $3.3 billion in recoveries and estimated $7.70 per dollar spent over the prior three years. Overall, since the HCFAC program's launch in 1997, the government has recovered $29.4 billion for the Medicare Trust Fund. Recoveries in any one year are the culmination of efforts that span more than one fiscal year. This year, the report indicates that for 2015, the government "won or negotiated over $1.9 billion in health care fraud judgments and settlements." That's down from the $2.3 billion reported as won or negotiated in Fiscal Year 2014. Note, however, that enforcement efforts don't appear to be waning. In its 2017 Budget Request, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) is requesting a total budget of $419 million to oversee the administration of the HHS programs—that includes $334 million for oversight of Medicare and Medicaid and the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative.

Record-breaking $646 Million Anti-Kickback Settlement. The Department of Justice announced last week that Olympus Corp. of the Americas (OCA) agreed to pay $623.2 million in settlement of criminal and civil cases alleging payment of kickbacks to hospitals and physicians. The settlement was reported to be the largest settlement of anti-kickback allegations by a medical device company. Another $22.8 million would be paid by a subsidiary to settle alleged violations under the Foreign Corrupt Practices Act. OCA has agreed to the settlement amount plus a three-year deferred prosecution agreement (DPA). A DPA is an agreement under which the government will defer prosecution and dismiss the charges if the defendant company fulfills various obligations. OCA also entered into a corporate integrity agreement with the U.S. Department of Health and Human Services Office of Inspector General (OIG). The company acknowledged the settlements on its website and expressed a commitment to compliance: "Olympus leadership acknowledges the Company's responsibility for the past conduct, which does not represent the values of Olympus or its employees. Olympus is committed to complying with all laws and regulations and to adhering to our own rigorous Code of Conduct which guides our business processes, decisions and behavior. The Company has implemented and will continue to enhance its robust compliance program." G2

Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Marla Durben Hirsch and Donna Maria Pocius, Contributing Writers; Stephanie Murg, Managing Director, G2 Intelligence; Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Jim Pearmain, General Manager; Michael Sherman, Marketing Director; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.