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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
Genetic Test Utilization Management: Practical strategies for achieving efficiency, cost savings and appropriate test selection
Feb. 24, 2016 , 2-3:30pm EST
Cheryl Hess, MS, CGC, NextGxDx
Jessie Conta, MS, LCGC, Dept. of Laboratories, Seattle Children's Hospital

Four Fraud and Abuse Enforcement Trends That Labs Should Be Aware Of

The Department of Justice's shift to prosecute more individuals responsible for corporate wrongdoing, as evidenced by the Yates Memo (see *G2 Compliance Advisor* December 2015) is not the only change in the way the government is fighting fraud and abuse by labs and other providers. The government has additional new tools and strategies in its arsenal that it has begun to use, according to inside experts.

"Enforcement is increasing. Efforts in health care fraud and abuse are picking up," reported attorney John Kelly, with Bass Berry & Sims in Washington, DC, speaking at the American Bar Association's Health Law Section's Annual Washington Health Law Summit in Washington, DC in December. Here are four enforcement trends and changes that labs should know about:

1. The increase in whistleblower lawsuits–& how they've evolved

There's been a "dramatic" increase in the number of *qui tam* lawsuits brought by whistleblowers claiming that providers have violated the False Claims Act (FCA) in the past few years. For example, the Department of Justice (DOJ) announced in December 2015 that it had recovered over $3.5 billion in fiscal year (FY) 2015 in FCA enforce-

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3 Legal Protections to Include in Your Patient Debt Collection Agency Services Contract

Outsourcing can be an effective way to overcome patient collection challenges. But it can also backfire if the collection agency you contract with uses illegal, unethical or insensitive collection tactics. One of the keys to managing these risks is to include proper legal protections in your services contract. In this article we'll review the three legal protections you should include in your collection agency contract. Next month, in part two of this article, we'll concentrate on the seven business provisions you need to ensure that your agency delivers you the highest quality services and support.

Why the contract is so important

Of course, services contracts with your vendors are important no matter what business you are in or which function you outsource. But contract terms are even more important when the service provided is debt collection and the debts collected are medical debts:

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3 Legal Protections to Include, *from page 1*

- **Liability Risks:** Medical debt collection is subject not just to general commercial consumer lending laws like the Fair Debt Collection Practices Act (FDCPA) and Fair Credit Reporting Act (FCRA), but also healthcare-specific regulation including the Health Insurance Portability and Accountability Act (HIPAA).
- **The Ethical Dimension:** Debt collection requires not simply compliance but sensitivity and recognition that debtors are the client's customers. And when the client is a medical lab and the customers are patients, conducting the collection process with dignity and respect becomes not only a business but an ethical imperative.
- **The Community Dimension:** Labs and their representatives must be guided by not just the provider-patient relationship but the mission to serve their community. Unsavory collection practices by your vendors can also generate negative press that harms the reputation you worked so hard to build.

To help it collect the debt, you may have to provide the agency what HIPAA defines as "protected health information" (PHI) about patients

3 essential legal protections

The first thing you need to do is to select a reputable collections agency, preferably one that adheres to industry guidelines like the best practices for medical debt collection created jointly by the Healthcare Financial Management Association and Association of Credit and Collection Professionals. The next step is to ensure your services agreement includes three protections.

1. HIPAA Liability Protection

Problem: To help it collect the debt, you may have to provide the agency what HIPAA defines as "protected health information" (PHI) about patients, including their name and tests performed. In so doing, the agency becomes your "business associate" under HIPAA. *Result:* If the agency compromises the PHI, *you* may be liable. *Example:* The Minnesota Attorney General charged a pair of local hospital systems with failing to protect the privacy of PHI they provided to their debt collection agency/revenue cycle management vendor.

Solution: You and the agency must make a separate agreement called a "HIPAA business associate contract" that:

1. Specifies how the agency will use and disclose the PHI you provide;
2. Bans agency uses and disclosures for any purpose not expressly allowed under the contract or required by law;
3. Requires the agency to take security measures to protect the PHI;
4. Requires the agency to provide notification of security breaches or unauthorized uses or disclosures as required by the Health Information Technology for Economic and Clinical Health Act (HITECH);
5. Requires the agency to give patients' access to their own PHI in accordance with HIPAA requirements, e.g., letting patients request copies and amendments to the information;
6. Requires the agency to make its books and records available to HHS auditors;
7. Requires the agency to destroy the PHI after the agreement ends;
8. Requires the agency to hold the subcontractors to which it entrusts your PHI to privacy restrictions at least equivalent to the ones set out in your services agreement; and
9. Lets you terminate the contract if the agency violates its privacy obligations.

2. Other Liability Protection

Problem: Agency violations can result in liability to your lab under *other* laws, including:

- The FDCPA, which bans deceptive or abusive conduct, e.g., calls at odd hours or to the debtor's employer, to collect consumer debts;
- The FCRA, which requires agencies to investigate and verify accuracy of information about debtors they provide to credit bureaus, medical information companies and other consumer reporting agencies;
- The Gramm-Leach-Bliley Act, which requires agencies to protect the privacy of debtors' personal information;
- The Federal Trade Commission Act, which bans debt collection activities that constitute deceptive or unfair trade practices;
- The Affordable Care Act, which requires hospitals to use fair billing and debt collection practices; and
- State laws including those banning agencies from harassing, abusing, or deceiving debtors to collect a consumer debt.

Solution: Insert a clause that:

- Requires the agency to comply with all applicable laws;
- Gives you the right to terminate if the agency commits any violations:

Model Language

Consequences of Noncompliance: Laboratory may, at its sole discretion, treat an Agency violation of the foregoing compliance obligations as a material breach justifying termination of the Services Agreement.

- Requires the agency to "indemnify," or repay you for any losses you incur as a result of the violations it commits.

3. Limits on Agency Collection Procedures

Problem: The agency is your representative and its actions reflect on your lab and its reputation.

Solution: Require the agency to follow collection methods and techniques that are sensitive to and consistent with your ethical principles and commitments to patients and community. Three options:

1. Specifically describe the procedures the agency will use to collect debts from your patients. Issues to address:
   - The point in the patient revenue cycle when the agent will be called in;
   - Procedures for pulling back files; and
   - Procedures for collecting from different kinds of patients, e.g., self-pay, Medicare/Medicaid, charitable care, etc.
2. Expressly require the agency to adhere to your lab's own internal policies, procedures and mission statements, which should be attached as Exhibits to the agreement;
3. Make adherence to the required patient policies, procedures, and/or mission statements one of the criteria used for evaluating the agency's performance under the agreement.

Takeaway: When labs outsource collection activities, a written agreement should require the collection agency comply with various laws affecting healthcare and debt collection and follows lab policies and procedures.

FDA's 2016 Guidance Plans Include LDTs and Other Diagnostics Topics

In a series of three recent *FDA Voice* blog articles, the U.S. Food and Drug Administration (FDA) surveyed its accomplishments in 2015 and detailed its 2016 agenda. The FDA also separately issued its annual list of guidance documents that it plans to finalize in 2016. Both of these releases address issues of importance for clinical laboratories and the diagnostics industry.

The first *FDA Voice* blog focused on medical product innovation, noting "unprecedented innovation in the sectors we regulate" and the agency touted a 36% drop in the agency's average time to decide on premarket approval applications since 2009. A word of advice was also shared, recommending drug and device makers engage in conversations with the FDA "at the early stages of development" to weed out products that are likely to fail. In that blog, Stephen M. Ostroff, M.D., acting commissioner of Food and Drugs addressed next generation sequencing tests and the agency's efforts to facilitate development of new technologies and achieve more precise diagnosis using "state of the art diagnostics"—including the launch of its precisionFDA web platform that allows stakeholders to "come together" to further this technology.

In the annual report listing guidance documents to be issued in 2016, the agency predicts it will finalize its framework for regulatory oversight of laboratory developed tests (LDTs). LDT guidance was listed on the "A-list" as a prioritized guidance document intended to be published during 2016. The A-list also includes draft guidance regarding companion diagnostics co-development.

The B-list, for documents the agency intends to issue as "resources permit," includes blood glucose monitoring test systems for prescription point-of-care use and self-monitoring blood glucose meters for over-the-counter use. Dual 510(k) and Clinical Laboratory Improvement Amendments Act (CLIA) Waiver by application also appears on the B-List.

Previously issued guidance documents the Agency lists for retrospective review in 2016 include:

- Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations
- Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery
- Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices
- Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable

Takeaway: The FDA once again reiterates its commitment to finalize LDT guidance this year. G2

G2 Compliance Corner

Set Specific Compliance Goals for the New Year

A new year is a time for new year's resolutions. This year, consider setting some compliance goals as the new year's resolutions for your laboratory. Healthcare attorney David Gee of Davis Wright Tremaine LLP suggests laboratory compliance officers and compliance committees list the "three top things we need to be doing, how we are going to do them, [and] how can we measure our efforts." Then reevaluate mid-way through the year, in June, to see how the lab is doing in accomplishing those three goals.

He also suggests compliance professionals approach their boards, "impress upon them now more than ever, the importance of having the board and corporate management engaged in compliance" and have monthly or regular meetings to review the goals you set for the year. "This keeps the compliance officer's efforts focused, and sets specific objectives and clear accountability for other members of the management team," says Gee. The Yates Memo and the push for individual accountability reinforce the value of such an exercise for company leaders. Gee thinks companies don't engage in this exercise enough–setting and evaluating specific compliance goals—and that lack of focus and follow-up is a common weakness of laboratory compliance programs. He and his colleague Caitlin Forsyth will be discussing similar compliance best practices at G2 Intelligence's live conference event, Lab Revolution, April 6-8, 2016, in Chandler, Arizona. For further discussion of the Yates Memo and the top 10 compliance issues for 2016, see *Compliance Perspectives* on page 5.

Top 10 Compliance Issues and Tips for 2016

January is a time for reflection and resolutions. For compliance officers that means evaluating compliance risks. *G2 Compliance Advisor* surveyed experts in laboratory compliance for the top issues compliance officers should be focusing on for 2016 and we have compiled a list of the top 10 issues and tips for how to address them.

1. Medical Necessity

Hands down, medical necessity (and documentation thereof) was the most cited compliance issue. "It is the single biggest thing we see in audits today—particularly audits dealing with pharmacogenetic testing and toxicology testing—anything with panels," said health care attorney Jane Pine Wood, of McDonald Hopkins.

"Laboratories are going to increasingly have to justify the medical necessity of their tests, particularly testing that is done with any frequency," agrees Nashville lawyer Danielle Sloane, of Bass, Berry & Sims. Florida lawyer Bruce Reinhart of McDonald Hopkins expects "most of the attention to be in the substance abuse area. They are taking a very skeptical and aggressive approach toward confirmatory urinalysis testing, particularly in light of the *Millennium* settlement." Reinhart also expects genetic testing to receive attention.

Sloane predicts: "After the enforcement focus in the past year on over-utilization of urine drug testing in combination with the increasing use of data analytics, I would expect these concepts to spill over to other areas of laboratory testing. I expect laboratories to increasingly receive Medicare audit requests and to be called upon to support the medical necessity of any tests ordered in aberrant patterns or with unusual frequency. Laboratories are likely to join the durable medical equipment industry in having to increasingly gather and supply patient medical records from physicians to support medical necessity."

"These pressures won't just be from the government," adds Reinhart. "Insurance companies are getting even more aggressive about claims denials and clawback lawsuits if they perceive overutilization and unnecessary testing, particularly for high reimbursement items." Charles C. Dunham IV, a health care lawyer with Epstein, Becker & Green agrees, adding "I see the audit of medical necessity and physicians orders—the appropriateness of diagnosis and treatment—being used by public and private payers to tighten the belt."

Compliance Tips: For high dollar testing in particular, "laboratories may consider requesting submission of supporting medical records along with the test requisition to ensure the medical necessity support is there on the front end," suggests Sloane. Dunham advises laboratories to do their own internal review of accuracy to ensure that, especially on new accounts, the physician information is correct, signatures are correct, these are valid Medicare/Medicaid providers, and the tests ordered are medically necessary and appropriate. "Do an internal audit that includes random sampling of records from ordering physicians to make sure these accounts can provide the documentation that would be needed if a payer asks for that information," he says.

Additionally, Wood recommends laboratories make sure requisition forms provide an option to individually order tests comprising a panel. She advises that when CMS sees a requisition that doesn't give that option, "they are beginning with the assumption that there is medical necessity issue or fraud."

Health care attorney David Gee of Davis Wright Tremaine suggests taking advantage of new technology and electronic health records to help address the issue. "Work with interface vendors to make sure electronic ordering systems capture the physician's signature. We are in an era where that is much more possible. [Laboratories] just need to be smart about how they are taking advantage of or using those systems."

2. PAMA

The second most cited issue was no surprise—preparing for PAMA! Sloane predicts: "While implementation of the pricing changes may be delayed beyond 2017, I would expect the reporting to be finalized and laboratories having to compile and report data related to their commercial payer reimbursement in 2016." Dunham agrees and posits that there will not likely be significant guidance and CMS will expect laboratories to "figure it out" in terms of how to collect and report the data with their software.

Compliance Tips: The attorneys we spoke with advise that laboratories shouldn't wait for the final regulations to be released to begin preparing to report the data. "While it is a bit difficult to predict the precise information that laboratories will need to report pursuant to PAMA, the proposed rule gives enough insight to allow laboratories to review and consider how they can most efficiently set up a system to capture the data," says Sloane.

3. Sales/Marketing

Another often cited issue is "aggressive sales and marketing practices." "There was a lot of enforcement in 2015 with respect to remuneration to referral sources," notes Kristin Carter, a health care attorney with Ober Kaler in Baltimore. Gee says laboratories, especially start-up and specialty labs, are challenged to market their services with a limited sales staff and may agree to percentage-based payments with third-party marketing resources—which raise many compliance issues.

Additionally, Sloane cautions that specialty laboratories increasing their marketing focus on consumers even if a physician order is required to order the laboratory test (the same strategy used by pharmaceutical companies) could find themselves on the FDA's radar. The FDA has issued several warning letters to laboratories regarding "direct-to-consumer" marketing absent FDA approval of the test, she says.

Compliance Tips: Gee recommends against percentage-based third-party marketing arrangements. Even if you don't contract out your marketing and sales, you still need to be concerned that your people and practices are compliant. Carter recommends compliance officers "really know what your sales people are doing out there." Wood advises laboratories to "review marketing materials, particularly as they relate to appropriateness of test ordering and ensure your laboratory has strong compliance training for sales and marketing representatives."

"Compliance officers should continue reinforcing messaging to sales and marketing personnel regarding what is appropriate when interacting with referral sources. In the end, many of the laboratory compliance issues that arise are the same things we have heard about for years (e.g., gifts, fancy dinners, client billing proposals), so reinforce the old lessons too," advises Sloane. Finally, she suggests compliance officers "may want to identify internal data analytics resources that will help the laboratory monitor unusual or outlier behavior that may implicate compliance concerns with sales and marketing practices."

4. Individual Responsibility

Thanks to last year's Yates Memo, discussion of liability for responsible officers and directors is a central compliance concern. "The Yates Memo is an enforcement tool and everyone should be concerned about this," Dunham warns.

Compliance Tips: Dunham recommends compliance officers "make sure all directors, officers, and managers are properly educated and trained, not just sales and marketing staff. Make sure they are aware of their oversight responsibilities" he advises; "they can't just defer to the compliance officer to make decisions."

5. Out of Network

The out of network issue is a thorny one for laboratories. Gee says "unless you are LabCorp or Quest, there is a better than even chance that you are out of network with a fair number of plans for patients for which you perform testing." With higher deductibles and copays and testing that is less than routine and priced high, "this becomes a substantial issue," he adds.

Compliance Tips: Unfortunately, there are no easy answers on this one. In addition to federal issues, Dunham calls attention to the variation in state laws and warns that laboratories make sure any out of network billing is done in accordance with state law, especially any waiver of copayment and deductible practices. While most of the surprise bill legislation on this issue addresses hospital services, he warns it can affect laboratories too. Gee also advises laboratories that the safest course is to do everything the insurers tell you to do and follow the directions on EOBs when billing. He also recommends, in any case, laboratories should establish a clear policy to handle copayment and deductible obligations on a similar basis for all patients so that billing practices are not driven by client or referral source.

6. Cybersecurity

Dunham predicts we will see the volume of compliance activity increase in the area of cybersecurity. As many have said, "it's not if but when" a cybersecurity incident or breach will occur and laboratories need to be prepared to respond. Dunham says many in not just the lab sector but health care industry at large are not up to speed on the latest issues. "HIPAA privacy and security issues are different than cybersecurity," he says.

Compliance Tips: "It's important to know what to do and how to respond [to a breach or incident] and have an appropriate response," advises Dunham. Make sure policies are up to date and address not just HIPAA privacy and security compliance but address the latest with regard to cybersecurity risks as well.

7. LDTs

No top 10 list would be complete without a mention of laboratory developed tests (LDTs). As we have reported, the FDA has expressed an intent to release final guidance this year regarding LDTs.

Compliance Tips: Dunham recommends that, in general, laboratories should plan for the future. For example, laboratories that are upgrading or expanding their facilities would be wise to take steps to incorporate good manufacturing practices as part of that process in anticipation of some FDA regulation.

8. 60-day Repayment Rule

The *Kane v. Continuum Health Partners* court decision last year addressing the 60-day requirement for reporting and returning overpayments "puts some guidance out that there indicates a standard that would be tough to meet—providers may have identified a problem [triggering the 60-days] when they are on notice that an overpayment likely existed but hadn't yet conclusively determined the overpayment's existence." Carter notes that while CMS issued a proposed rule in 2012, on Feb. 17, 2015 it delayed publication of a final rule for one year. Thus providers continue to operate without agency guidance on when an overpayment is "identified" for purposes of triggering the 60-day reporting and repayment deadline.

Compliance Tips: Carter reminds providers to keep the case in perspective as "the ruling was in response to a motion to dismiss in a single district court and was very fact-specific." However, it signifies that the government and *qui tam* relators would be willing to challenge providers that delay in reporting and returning overpayments. Carter advises that "once a potential problem is identified, continue to diligently investigate the scope of the issue, document that investigation, and once you do know there's an issue, make the repayments without any unnecessary delay."

9. ACO and Alternative Payment Model Participation

"Labs are starting to wade in and can provide a valuable role in patient care in alternative payment models," says Carter. But compliance issues can arise when participants are exchanging reimbursement with referral sources.

Compliance Tips: Carter cautions clients to make sure what they are doing for accountable care organizations (ACOs) or other alternative payment model programs fits within the fraud and abuse waivers where applicable. For example, a number of the waivers under the Medicare Shared Savings Program require that remuneration be reasonably related to the purpose of the shared savings program. She adds that some waivers require the governing body or board to make a formal determination that the remuneration is for purposes of the shared savings program. While the fraud and abuse waivers for certain alternative payment models offer some additional flexibility, they are not unlimited.

10. Outdated Compliance Programs

"Compliance plans aren't just meant to be put on the shelf," warns Carter. "The compliance plan should be a living breathing document and you should be working with your organization to ensure compliance is top of mind."

Compliance Tips: Dunham recommends labs review compliance procedures at least annually and revise to respond to changes in federal or state law or enforcement trends. Make sure third parties such as vendors and agents are aware of your compliance expectations too, he adds. Carter notes that many choose to consult the OIG Work Plan to update policies and procedures but she also suggests compliance officers sign up for the OIG's "What's New" email alert and look at it every day. It includes advisory opinions, enforcement actions and state enforcement and "also helps you stay on top of what settlements are out there and what the OIG is doing." "It's easy to read through that blurb and see what is relevant to labs," she explains.

Four Fraud and Abuse Enforcement Trends That Labs Should Be Aware Of, *from page 1*

ment efforts, the fourth consecutive year that DOJ recovered more than $3.5 billion under the FCA, according to Gejaa Gobena, Deputy Chief, Health Care Fraud, Fraud Section, Criminal Division for the DOJ, also speaking at the conference.

The majority of that amount, $1.9 billion, was recovered from health care entities, and most were due to whistleblowers, who receive up to 30 percent of the recovery. Whistleblowers filed 638 new FCA lawsuits in FY 2015 alone, and the DOJ recovered $2.8 billion from these and earlier suits. The whistleblowers' awards totaled $597 million. That's quite an incentive for employees, contractors and others to file them.

> ***"The government has become much more adept at using data analytics to ferret out fraud and abuse."***
>
> **—Gejaa Gobena, DOJ**

But what's changing is more than the sheer volume of FCA lawsuits being filed. It's that more individual whistleblowers are proceeding on their own with their lawsuits even when the DOJ chooses not to join in—or intervene—and take over the costs and handling of the lawsuit, warns Edward Crooke, DOJ, Senior Counsel for Healthcare Fraud (Civil Division), also speaking at the conference. The DOJ only intervenes in 15-20 percent of FCA lawsuits filed, and in the past most whistleblowers who didn't get DOJ assistance would not proceed with the litigation. That is no longer the case—and some of these whistleblowers have been "quite successful," said Crooke. (For more information on how to reduce the risk that a whistleblower will turn on your lab, see *G2 Compliance Advisor*, May 2015).

2. The use of data mining

The government has become much more adept at using data analytics to ferret out fraud and abuse, said Gobena. The DOJ is using claims data on a macro level to identify overall trends, unusual information that may need additional scrutiny, and outliers in different regions of the country, since fraud schemes vary in different cities, he explained.

The DOJ is also using the data on a micro level to bore down into a provider's claims and see what doesn't make sense. "We peel back the layers of the onion to go down to the individual provider and see what sticks out," he said. The DOJ also now has more real time access to the data and its own in-house staff to conduct the analyses, he added.

3. Coordinated government enforcement

The different enforcement agencies have stepped up their collaboration on provider investigations, filling in gaps for each other. "There are a lot of advantages [for us] in efficient collection of evidence and coordinating interviews with witnesses," says Gobena.

While this has been the DOJ's mission for years, it ramped up considerably in September 2014 with the announcement that all new whistleblower FCA investigations, which are civil in nature, will be shared with the DOJ's criminal division to see if a parallel criminal investigation should also be opened. Previously this was optional.

And now, when the DOJ settles with a payor of a kickback, such as a lab or pharmaceutical company, the Department of Health and Human Services' Office of Inspector General, which handles administrative sanctions against providers, will initiate enforcement actions against the physician recipients of the kickback, said Lisa Re, Branch Chief, HHS Administrative and Civil Remedies Branch Office, Counsel to the Inspector General, also speaking at the conference.

"It levels the playing field. Everyone has to be compliant. The doctor can't just shop around to find someone [else] to pay [a kickback]," she said.

4. The emphasis on defendants' cooperation

The DOJ is also looking for more cooperation from the health care organization being investigated. This cooperation, the focus of the Yates Memo, aims, among other things, to have the corporation proffer the identities of the individual(s) who caused or allowed the corporate wrongdoing. Entities that cooperate more may receive lighter penalties; the Yates Memo clarifies how much cooperation is expected.

"The degree of cooperation is important. It's not just responding to what's being asked [by investigators] but also volunteering factual information," said Gobena.

Takeaway: Labs have historically been in the government's crosshairs; and the risks are only getting greater. Labs should revisit their compliance programs and ensure that they have mechanisms in place to comply with the anti-kickback, Stark and other laws. G2

Diagnostics Data Analytics Inform Treatment, Utilization, Safety & Quality

Attention to laboratory-related data and analytics is "surging" in light of the health care industry's quest to cut costs and improve quality, according to a new Cain Brothers' report, "Strategies for Healthcare Leaders: 2016 Healthcare Industry Outlook."

"We note an increasing focus on value of lab, including expanding use of information it generates and the potential leverage offered by its positioning along the continuum of care," Cain Brothers' authors write.

Lab data behind consolidations

This finding should come as no surprise to pathologists and laboratory executives, who know so well that lab data make up more than 70% of a clinical record. Now this data gold mine, which some industry experts have long considered untapped, is at the center of mega industry agreements.

Cain Brothers, an investment banking firm focusing on health care, named in its report transactions such as LabCorp-Covance, Roche-Foundation Health, and OPKO-BioReference as examples of transactions that appear to move labs beyond traditional diagnostic testing. Quest Diagnostics has also expanded to offer analytics and data services to hospitals, physicians, health plans, and others seeking to integrate and aggregate data.

Data to enlighten therapies

For example, Medivo, a health care data analytics company, and Quest announced in November their intention to use laboratory data to educate physicians about new drug therapies that could improve patient outcomes.

Their plan is for Quest to provide clinical and bioinformatics expertise as well as analysis of its de-identified lab data to Medivo. Then, Medivo will use the information, along with other datasets, to identify physicians with patients who may benefit from FDA-approved drugs, according to a Medivo statement.

Quest reportedly has more than 20 billion lab test results in its database. Conditions include diabetes, cholesterol, oncology, pregnancy, and others. "The addition of Quest's data to Medivo's analytics solutions will greatly improve the ability to focus outreach programs to help patents gain access to therapies," said Harvey Kaufman, M.D., senior medical director, Quest, in a statement.

"Through this relationship, Quest and Medivo will enhance the ability of lab data to inform physicians and improve the odds that patients can access the treatments that will help them," added Sundeep Bhan, CEO, Medivo.

Real-time insight on quality, utilization, finance

Also, Quest, with Inovalon (an analytics software provider), recently launched a Data Diagnostics service to offer real time patient-specific reports. Providers can order the reports individually at point-of-care to help them identify and address gaps in quality, risk, utilization, and medical history insights.

Reports are drawn from Quest's lab test database and Inovalon's clinical datasets on more than 123 million patients, according to a statement. As to what makes Data Diagnostics reports unique, Inovalon points to the capability of integrating and aggregating data for analysis in real-time. "Translating petabytes of data into actionable insights on demand is enabling clinicians to treat their patients more effectively at the point-of-care," said Keith Dunleavy, M.D., CEO, Inovalon in a statement.

Providers can order reports as they need them, as opposed to engaging a subscription-based service. Here is how the companies partially describe Data Diagnostics available reports:

- **Quality-related reports** aid caregivers in getting insight on a patient's status as compared to models such as NCQA HEDIS, Medicare Advantage 5-Star Quality bonus programs, managed Medicaid, and more;
- **Historical-related reports** are designed to help clinicians get a heads-up on a disease progression, lab results, medications, and more to evaluate the patient.
- **Risk score reports** are aimed at sharing insight on historical risk score status, and predicted future risk score models including Medicare Advantage, state-specific managed Medicaid, Affordable Care Act, and Accountable Care Organization models;
- **Eligibility reports** give providers on-demand insight on patient eligibility for payment; and
- **Waste avoidance reports** share information about factors impacting care costs and explore insights on how, for example, unnecessary duplication of tests can be avoided.

Cleveland Clinic counsels on test utilization

Speaking of unnecessary duplication of tests, the Cleveland Clinic, in a white paper, "Strategies for Appropriate Test Utilization: The Right Test for the Right Patient at the Right Time," reported that over utilization of laboratory tests presents patient satisfaction and safety issues and creates financial burdens for hospitals, patients and payers.

Cleveland Clinic Laboratories shares these test utilization strategies (involving data analytics, IT, organizational multi-disciplinary participation and more) to optimize lab testing: 1) eliminate duplicate testing (stopping duplicate same day orders); 2) restrict molecular genetic test orders to practitioners who regularly order those tests; 3) engage lab-based genetic counselors for inpatient testing; 4) notify caregivers about expensive tests with a goal of allowing them to consider a test's absolute necessity; and 5) create smart alerts providing education that allows ordering providers to consider additional information about a test.

Takeaway: Lab data analytics can help enhance quality of care, ensure better test utilization, and manage the organization's financial performance and risk. G2

News at a Glance

CMS Transitions Away from Meaningful Use As We Know It. Acting CMS Administrator Andy Slavitt announced Jan. 11 at the J.P. Morgan Healthcare Conference in San Francisco that the Centers for Medicare & Medicaid's (CMS) Meaningful Use program that awards incentives for using certified electronic health records (EHR) will be ending in 2016. "The Meaningful Use program as it has existed, will now be effectively over and replaced with something better," said Slavitt. About a week later, on Jan. 19, Slavitt co-authored a CMS Blog entry with Karen DeSalvo, acting assistant secretary for health at the Department of Health & Human Services, discussing a "transition from the staged meaningful use phase to the new program as it will look under MACRA." The blog stated, however, that MACRA "continues to require that physicians be measured on their meaningful use of certified EHR technology for purposes of determining their Medicare payments," and existing regulations—including stage 3 meaningful use requirements—are still in effect.

CDC Future Plans Include Laboratory Safety. Laboratory safety and diagnosis of infections figure prominently in the Centers for Disease Control and Prevention's (CDC) review of 2015 and its agenda for 2016. After establishing the Office of the Associate Director for Laboratory Science and Safety (OADLSS) in 2015, the agency said its goals for 2016 include using "lessons learned and best practices to mitigate" lab risks. The OADLSS is intended to lead "development and enhancement of laboratory safety programs," "provide transparent flow of information across the laboratory community regarding laboratory science, safety and quality and sharing of best practices," and oversee lab safety and quality management at the CDC. Other items on CDC's 2016 agenda include: issuing a 2016 report on antibiotic resistance, and prescribing practices and an interactive web platform offering access to relevant antibiotic resistance data; promoting the Global Health Security Agenda's objective to enable detection and prevention of infectious diseases throughout the world.

Congress Lobbies CMS on PAMA Regulations. Members of Congress have been busy pleading with the Centers for Medicare & Medicaid Services (CMS) to delay and revise the implementation of the Protecting Access to Medicare Act (PAMA). Dec. 14, 2015, 19 U.S. Senators signed a letter to Andy Slavitt, Acting Administrator of CMS expressing their concern about the timeline for implementing PAMA and objecting to exclusion of a "significant part of the laboratory market," and the definition of Advanced Diagnostic Laboratory Tests (ADLTs). Days later, 44 members of the House of Representatives, submitted a letter to CMS objecting to the reporting timeline, exclusion of protein biomarkers from the definition of ADLTs and arguing that a "number of laboratories are prohibited from participating in the reporting process" which could "skew the market data, resulting in Medicare rates that are not reflective of true market prices." Finally, Chairman of the Senate Committee on Finance, Orrin Hatch, and Ranking Member Ron Wyden wrote to Slavitt Jan. 6, 2016, saying use of Tax Identification Numbers to identify reporting laboratories would exclude "important segments of the laboratory market, especially hospital outreach laboratories," which they note serve beneficiaries and compete with community-based labs. Instead, they suggested Clinical Laboratory Improvement Act numbers be used to identify reporting labs. G2

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