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Inside this issue

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Labs Get One-Year Reprieve under Final PAMA Rule, New Rates Delayed until 2018

Labs must now begin preparations in earnest to comply with private payor rate reporting requirements under the Protecting Access to Medicare Act of 2014 (PAMA). After much lobbying, debate and delay, the Centers for Medicare & Medicaid Services (CMS) final rule implementing the PAMA changes to the Clinical Laboratory Fee Schedule (CLFS) was released this month.

The good news is that the final rule delays the effectiveness of new payment rates under the CLFS to Jan. 1, 2018, rather than a mere six months away in January 2017, as planned in the proposed rule. The American Clinical Laboratory Association and the American Association for Clinical Chemistry both issued statements applauding CMS for delaying implementation of the new rates until 2018.

The timeline for implementation now requires data be collected for the period Jan. 1 through June 30, 2016 (data collection period). This six-month collection period will be repeated in subsequent collection periods rather than the one-year periods originally contemplated.

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Largest Takedown in Strike Force History Charges 300, Alleges $900 Million in False Billing

Nearly a year to the day after another nationwide Strike Force takedown, the Department of Justice announced last week what it says is a takedown involving "the most defendants charged and largest alleged loss amount in Strike Force history."

While not directly involving labs, the allegations in this takedown are not unfamiliar to labs: submitting claims to Medicare and Medicaid for services that weren't medically necessary or weren't even performed, paying kickbacks for referrals or to get beneficiary information to facilitate fraudulent claims, and allowing nonqualified individuals to perform services billed to Medicare. Most of the cases involved allegations linked to home health, mental health, physical/occupational therapy, durable medical equipment, and prescription drug-related Medicare and Medicaid claims.

Here's a rundown on the details of this takedown:

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Largest Takedown in Strike Force History, *from page 1*

- 301 individuals charged in civil and criminal cases (includes 61 physicians, nurses and licensed medical professionals)
- $900 million in total losses alleged
- 36 federal districts and 23 state Medicaid Fraud Control Units involved in the investigations and arrests
- Payment suspension authority exercised by Centers for Medicare & Medicaid Services against numerous providers
- Criminal charges brought include conspiracy to commit health care fraud, anti-kickback statute violations, money laundering, and aggravated identity theft.

> ***"I believe that the 'takedowns' are designed to put health care providers everywhere on notice that the federal government has the resources to aggressively investigate and pursue fraud."***
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> **—Gina L. Simms, Health Care Attorney, Ober Kaler**

"Taxpayers and Congress provided CMS with resources to adopt powerful monitoring systems that fight fraud, safeguard program dollars, and protect Medicare and Medicaid," Deputy Administrator and Director of CMS Center for Program Integrity Shantanu Agrawal, M.D. explained in a statement—echoing similar comments of fellow government agency heads who commented on the takedown. "The diligent use of innovative data analytic systems has contributed or led directly to many of the law enforcement cases presented here today. CMS is committed to its collaboration with these agencies to keep federally-funded health care programs safe and strong for all Americans."

Just last June, a similarly significant nationwide health care fraud takedown was announced—including 243 individuals charged and $712 million in false billing. Health care attorney Gina L. Simms, of Ober Kaler, explained to *G2 Compliance Advisor* at that time: "I believe that the 'takedowns' are designed to put health care providers everywhere on notice that the federal government has the resources to aggressively investigate and pursue fraud." See "Compliance Perspectives: Take Head: Strike Force Takedowns SignalAggressive, Coordinated Fraud Enforcement," *G2 Compliance Advisor*, September 2015, p. 5.

Takeaway: Coordinated federal and state government enforcement continues to yield large-scale arrests and maintains pressure on providers, including labs, to step up compliance efforts.

Editors note: For tips on how labs can avoid becoming the target of these nationwide takedowns and how targeted labs should respond to such investigations, view G2 Intelligence Training on Demand recording, "Don't Let Your Lab Become a 'Take Down' Target for U.S. Law Enforcement Agencies!" featuring Gina L. Simms and Robert E. Mazer, health care attorneys with Ober Kaler. For more information, visit the Webinars and Training on Demand tab at www.g2intelligence.com or contact customer service at 1-888-729-2315.

OIG Adds PAMA-based Item to Workplan Mid-Year Update

The U.S. Health and Human Services Office of Inspector General released its mid-year update to the Annual Work Plan, adding and revising items relevant to lab enforcement efforts. The OIG released the 2016 Work Plan late last year.

First, not surprisingly a new item in this update focuses on the much anticipated implementation of Protecting Access to Medicare Act (PAMA). The OIG lists "CMS' Implementation of New Medicare Payment System for Clinical Diagnostic Laboratory Tests" as a mandatory review and says it will consider CMS' "ongoing activities and progress

toward implementing" the new market-based payment system under PAMA for clinical diagnostic laboratory tests. PAMA also requires the OIG to analyze "the implementation and effect of the new payment system." It predicts a report to be issued this fiscal year. CMS' final rule concerning PAMA was recently issued with implementation of new rates beginnning in 2018 (See page 1).

The OIG update also notes it may have new and expanded reviews of U.S. Food and Drug Administration oversight, including the agency's oversight of blood establishments and laboratory-developed diagnostic tests.

Revised items in the update include a review of histocompatibility laboratories (which was a new item in the initial 2016 Work Plan)—with the resulting report now expected in 2017 fiscal year rather than 2016 fiscal year as originally reported in the initial 2016 Work Plan. The OIG is concerned about accuracy of costs reported by histocompatibility labs—which reported $131 million in reimbursable costs on recent cost reports. The OIG explains such costs must be reasonable, necessary and proper and detail provided regarding such costs must sufficiently justify payments made.

Recurring items include review of independent clinical lab billing requirements and the OIG's annual mandatory review of the top 25 lab tests (per Medicare expenditures). The update notes the OIG's concern with independent clinical lab billing, which was also included in the 2015 Work Plan as well. The OIG is looking for labs that "routinely submit improper claims" and will seek repayments of overpayments. The OIG notes that prior "audits, investigations and inspections have identified independent clinical laboratory areas at risk for noncompliance with Medicare billing requirements."

The review of the top 25 tests ties in to the OIG's oversight of PAMA. The OIG first performed this review last year and in September 2015 issued its baseline analysis of the top 25 lab tests according to review of 2014 data. That report indicated that $7 billion was paid to 63,000 labs under Medicare Part B in 2014 for 451 million lab tests performed for 27 million Medicare beneficiaries. Medicare paid $4.2 billion in payments for the top 25 lab tests.

The OIG update also notes it may have new and expanded reviews of U.S. Food and Drug Administration oversight, including the agency's oversight of blood establishments and laboratory-developed diagnostic tests. It also added new items focused on FDA review of networked medical devices for cybersecurity risks and controls over networked medical devices in hospitals. The OIG's *Fiscal Year 2016 Work Plan Mid-Year Update* is available on the OIG Website under Reports and Publications.

Takeaway: Labs continue to be a significant focus with several lab payment items highlighted in the latest update to the OIG's Work Plan.

Physician Kickbacks the Focus of OIG "Eye on Oversight" Video

The U.S. Health and Human Services Office of Inspector General's (OIG's) concern about kickbacks to referral sources is nothing new. But the OIG is keeping the heat on the issue with a new video posted to its website this month. "In the federal health care programs, paying a physician for their referrals is illegal," says Robert K. DeConti, Assistant Inspector General for Legal Affairs, in the video.

The OIG's video "Kickbacks to Physicians" is the fourth in a series of Eye on Oversight videos released this year. The OIG's Eye on Oversight web page indicates the month-

"I think these cases are significant because for a long time the government has focused on the provider that pays the kickbacks, often times the corporate payer of the kickback, and these cases involve the individual physicians who received kickbacks."

— Robert K. DeConti, Assistant Inspector General for Legal Affairs

ly video series features "top areas of interest for the OIG" and emerging health care problems or trends. Previous videos focused on Opioids, Medicare Part D Fraud, and Child Care safety.

"Kickbacks in health care are a big problem. They can lead to higher costs for patients, unnecessary tests, and doctors making decisions based on making money versus caring for patients," the video notes, while spotlighting a case against an imaging services provider that is analogous to the government's enforcement efforts against New Jersey-based lab, Biodiagnostic Laboratory Services (BLS), and physicians who allegedly received payments for referring patients to the lab. DeConti explains in the video that the OIG settled kickback claims against a radiologist and imaging center owner for $650,000 and a six-year exclusion from Medicare for the radiologist and the imaging center. The OIG had alleged the radiologist entered into sham medical director agreements with physicians in exchange for referring patients to the center. The OIG also pursued the physicians receiving the payments, achieving a total settlement of $1.4 million in the case. Similarly, in the BLS case, the government has pursued the individual owners of the lab as well as dozens of physicians who allegedly received payments from the lab for referring lab tests.

"I think these cases are significant because for a long time the government has focused on the provider that pays the kickbacks, often times the corporate payer of the kickback, and these cases involve the individual physicians who received kickbacks," says DeConti.

The video highlights the OIG's one-page June 2015 alert regarding sham medical directorship arrangements titled, "Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability." As labs know, the OIG spotlighted the issue of payments to referral sources specifically in the laboratory context the prior year with a lengthier Special Fraud Alert titled Laboratory Payments to Referring Physicians.

The OIG Eye on Oversight series is updated monthly and is accessible on the OIG website along with all video releases at oig.hhs.gov/newsroom/video/

OIG Reports to Congress on "Five-Fold Increase" in Recoveries

The U.S. Department of Health and Human Services' Office of Inspector General (OIG) touted its efforts and achievements for the six-month period ending March 31, 2016, in its most recent Semiannual Report to Congress, released the end of May. The OIG is required by law to report to Congress about significant findings and recommendations. The OIG reports "CMP recoveries have increased almost five fold over the past 3 years, and the OIG is on track to exceed prior recoveries in FY 2016."

The OIG reports the following enforcement results:

- $2.77 billion in recoveries ($554.7 audit receivables, $336.6 non-HHS investigative receivables such as Medicaid restitution)
- 428 criminal actions against individuals and entities
- 338 civil actions such as False Claims cases and Civil Monetary Penalties settlements and self-disclosure program recoveries
- 1,662 exclusions from federal health care programs.
- Strike Force efforts yielding 87 individuals and entities charged, 100 criminal actions and $116.8 million in investigative receivables.

Enforcement cases spotlighted within the report included sentencing of another individual in the Biodiagnostic Laboratory Services case involving alleged payments to referring providers and the Millennium Health $256 million False Claims Act settlement resolving allegations of medically unnecessary testing and kickbacks to referring physicians.

COMPLIANCE PERSPECTIVES

Even Small Labs Can Yield Big Results from Simple, Low-Cost Informatics Strategies

Gary A. Letts, MD, MBA, FCAP

Big Data, informatics and information systems are critical topics for the health care industry as reforms emphasize coordinating care, increasing quality and reducing costs. Capitalizing on the volumes of data generated and collected is a challenge for every laboratory. But the task can seem overwhelming to smaller labs with fewer resources and smaller technology budgets. Even small and mid-sized labs, however, can find ways to make data work for them. Doing so can help the lab's bottom line by improving efficiencies and finding ways to trim costs.

> ***"Practically speaking, informatics includes simply the act of measuring some aspect of operations and using data in some way; and many laboratories may already be implementing an approach to practical informatics in their lab even if they do not think of it that way or aren't fully cognizant that it is informatics."***
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> **— Gary A. Letts, MD, MBA, FCAP**

Gary A. Letts, MD, MBA, FCAP, founder, president and medical director of Corium Diagnostics, a Connecticut anatomic pathology laboratory, learned the importance of clinicians being involved in the development of lab information systems while establishing his own anatomic pathology laboratory and implementing information technology solutions. *G2 Compliance Advisor* talked with Dr. Letts to get some insight on how start-ups and smaller labs can leverage data while minimizing their investment.

Q: Informatics can be an overwhelming term. But you have explained that it should not be intimidating. How do you define informatics in terms of lab and pathology operations?

A: Informatics is variably defined because of the scope of the topic. For example, if you ask Google to "define Informatics" you will get about 4,860,000 results and a general or basic definition that encompasses "the science of processing data for storage and retrieval."[1]

Practically speaking, informatics includes simply the act of measuring some aspect of operations and using data in some way; and many laboratories may already be implementing an approach to practical informatics in their lab even if they do not think of it that way or aren't fully cognizant that it is informatics. For example, when a laboratory wants to improve its turn-around times (TAT) and gathers details regarding its current history of returning results, the data collection and analysis used to make some conclusions about TAT and problems with it, is a practical application of informatics. Informatics helps labs and pathologists identify the low-hanging productivity improvement fruit—that is, measure the parameters of a function that needs improvement. So, many lab managers and directors are already using informatics when they are assessing productivity levels against those promised by new technologies or benchmarking against industry standards, for example. Labs necessarily also need to know current metrics to bring to the table when talking to vendors so they can then identify appropriate technologies including software, that will allow for improvements on those metrics.

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[1] Daniel Cowan, ed., Informatics for the Clinical Laboratory: A Practical Guide for the Pathologist (Springer 2003).

G2 COMPLIANCE PERSPECTIVES

Q: Why is informatics so important to managers and directors of laboratories of all sizes?

A: I embrace the assumption that computers can be more efficient at some tasks than humans and should always be used for said tasks whenever possible, so that humans can focus on the things that computers can't do as well. We are in essence in the information business and diagnostic pathology includes information gathering, analysis and dispersal. We are therefore informaticians, by definition, at least by the definition above. I am drawn to and I seek out every possible way in which computers and information management can enhance my diagnostic accuracy and precision as well as the work processes required to manage all aspects of our interaction with a case, all the way to getting the diagnosis back to the treating physician. Focusing on productivity and quality was critical to surviving in the market place after the big Medicare reimbursements payments reduction for CPT code 88305 in January 2013—our lab was no exception. In the end, as the owner or manager of any company, you are always seeking to achieve maximal efficiency in the various tasks and systems required to run a quality-focused organization. Informaticians buy into the idea that this amorphous and evolving discipline can improve productivity and reduce cost while maintaining quality.

> *"In the worst-case scenarios, if unneeded services and products are purchased or leased, they can actually degrade your productivity with no meaningful or recognizable tradeoffs."*
>
> **— Gary A. Letts, MD, MBA, FCAP**

Q: Why should lab leaders and pathologists have some understanding of and involvement in informatics and IT issues—why not leave those issues to the IT professionals?

A: Laboratory professionals that have a common language with IT professionals, vendors or other external partners can increase the likelihood that the services and products that they purchase, and use, will meet their needs more specifically and at an ideal price point. The more you know, the better you can define what you want, understand what is being sold and negotiate the price based on value in your own organization and industry value standards. In the worst-case scenarios, if unneeded services and products are purchased or leased, they can actually degrade your productivity with no meaningful or recognizable tradeoffs. Flawed implementation and inappropriate tools can create productivity black holes that often lower morale of otherwise motivated staff in your organization—sometimes it is impossible to recover from this without significant or key staff exodus. Input from every rung on the staff vertical is therefore critical and can help to assuage new unsuspecting foci of shifted bottlenecks during implementation. Familiarity with the experiences of others through user groups and conference sessions should not be underestimated. You would be surprised how willing some managers are to share their hard earned knowledge, particularly if you are willing to do the same.

Q: How did IT help you improve overall compliance?

A: We did not have a digital data exchange between our LIS and billing software, so we started with a Quality Management program to monitor and improve data entry, in my mind, one of the low hanging fruit. By simply documenting, tracking, and categorizing our

data entry errors across all protocols in the laboratory, using an excel spreadsheet, we were able to monitor our progress and focus on specific areas that were easy to address but yielded tangible results. Establishing baselines for speed with accuracy in various departments or tasks, and focusing on increasing speed without compromising accuracy and precision (efficiency) are relatively easy and painless undertakings. (Digitally captured data will continue to abolish the paper trail in theory and effect; and eventually helps to reduce issues directly related to poor data entry and improve compliance.) Data interfaces can pay off handsomely, but depend on your labor cost and your capital, especially in the early stages of your laboratory. They are unnecessarily expensive and may have recurring charges.

"We invested in a solution that made transition to ICD-10 less painful, but continued to monitor items flagged in the system or flagged by the billing consultants, and updated misused or discontinued or replaced codes systematically returning us to our baseline of clean code submission relatively quickly."

— Gary A. Letts, MD, MBA, FCAP

We outsourced the lion share of our billing after executing a rigorous Business Associate Agreements with input from our attorneys. We then familiarized ourselves with the various reports available in the software as a first step in understanding indicators of compliance or lack thereof. We worked with the LIS developers to build rules for CPT coding and ICD9/10 selection and assignment and created rules for error checking and flags after manual entry of codes, that would block the sign-out of a case if, for example, there was an inappropriate combination of codes (e.g., Nail for PAS gets an 88300 instead of 88305 along with the 88312 or Coding for multiple IHCs on different blocks on the same specimen is a common error and can be checked automatically and significantly minimized.) Our software modification would return an error with a "fix it" button that takes the user directly to the failure point for review and correction. We invested in a solution that made transition to ICD-10 less painful, but continued to monitor items flagged in the system or flagged by the billing consultants, and continually updated misused or discontinued or replaced codes systematically returning us to our ICD9 baseline of clean code submission shortly after transitioning to ICD10.

Now, with PAMA implementation imminent, our billing system allows for reports that would contain the required data to meet reporting requirements. In addition to our standard reports, we have requested read only access to numerous fields in our LIS and Billing Software that would allow us to combine the data present in any manner we desire. Our previous system allowed us to query the entire database with basic SQL queries. This is a very powerful feature that is often overlooked by users or just not present in many software solutions.

Information systems can also help monitor compliance with regard to relationships with referral sources. Reports stratified by clients, payers and reimbursement rates are often monitored to drive sales and disburse commissions. After a pattern is established for a given client, trends and shifts can be easily recognized by plotting the data output at regular intervals using excel. One might observe different ordering patterns and payor mix simply because clinicians accept new insurances that might cover a different demographic, but such changes could also signify compliance issues to be further investigated.

G2 COMPLIANCE PERSPECTIVES

"The future of healthcare reimbursement is unpredictable and small laboratories are disproportionately susceptible to stroke of the pen risk around rate reduction by Medicare and the third-party payers whose rates are often tethered to CMS or who follow Medicare with reductions themselves within weeks to months."

— Gary A. Letts, MD, MBA, FCAP

Q: What should labs look for in hiring a high level IT person?

A: Hiring can be one of the greatest challenges in running a laboratory. Some technical staff can be easily tested on the bench before you hire them, administrative staff should have a stellar track record. IT professionals come with varied skill sets and focus and often will try to apply the law of the instrument in their decisions on how to approach a problem, if you are not looking carefully you could go down a path that is efficient for them but not the best for your organization. One way around this is to seek out vertical specialization by focusing on professionals that have specific experience in the laboratory space that you occupy or with problems that you are trying to solve. This is a very common issue in selecting a coding platform for product development. One has to consider cost, scale and technical expertise necessary for continuity and transferability and the natural conflicts and contradictions between them. Finding the right person to take over a complex home grown system can be a major pitfall in using the economical route or a niche platform. After you hire your IT professional, ensure that you require them to document their work and decisions exhaustively. This can be a life saver for them and for you, and for anyone who might need to master and take charge of your systems. Consider having an understudy or back up personnel to shadow your main IT contractor or staff from time to time and ensure that your contractors are open to a smooth hand-over process by discussing this ahead of time, early and often, including verbiage in your contract to that end. Consider asking for a reference with whom you could speak, that successfully transitioned away from the contractor you are considering to use. Lastly, ask your potential IT hire to tell you about other companies where they have implemented similar or different systems, before you hire them, get input from those companies' managers, even if they are not in your same lab space, and talk to them about their pain points as well as the reliability of the IT support they received. The down side of doing IT support yourself is that from time to time one can get stuck, deeper than where the original problem occurred—even IT professionals can get stuck occasionally—so backup is key. Your IT person should have an understudy who is familiar with your platform and architecture.

Q: Why should we even invest in developing our informatics capabilities if we are already making money?

A: The future of healthcare reimbursement is unpredictable and small laboratories are disproportionately susceptible to stroke of the pen risk around rate reduction by Medicare and the third-party payers whose rates are often tethered to CMS or who follow Medicare with reductions themselves within weeks to months. If you end up for sale, your suitors might be willing to pay more for a well-oiled and efficient operation than for one with operational or quality problems. Great solutions and operations that can be transferred to a new parent company, can potentially increase the goodwill value of an acquisition and certainly would increase the likelihood of staff retention in a merger. G2

Labs One Year Get Reprieve Under Final PAMA Rule, *from page 1*

Data reporting must be accomplished between Jan. 1 and March 31, 2017 (reporting period). In early September 2017, CMS will publish preliminary CLFS rates for public comment with final CLFS rates published in November 2017 and effective Jan. 1, 2018.

Here's a run down on some of the key changes in the final rule:

- Applicable labs are those that receive more than 50 percent of total Medicare revenues under the CLFS or Physician Fee Schedule (PFS) (unchanged from proposed rule)
- Applicable labs will be determined by revenue under their National Provider Identifier (NPIs) (rather than by Taxpayer Identification Numbers (TINs) as proposed). Commentators predict this change may bring more hospital outreach rates into the data collected
- Applicable labs will not include labs paid less than $12,500 under the CLFS during the data collection period (rather than $50,000 threshold originally proposed)
- Hospital outreach laboratories will need to report if at least 50 percent of Medicare revenues are from CLFS and PFS services, with at least $12,500 from the CLFS.
- The definition of Advanced Diagnostic Laboratory Tests (ADLTs) includes "tests that are solely an analysis of proteins" (The proposed rule defined ADLT to be an analysis of RNA or DNA and may include proteins but protein-only tests wouldn't qualify as ADLTs). One other change that has been introduced into the ADLT criteria is a requirement that labs present evidence and attest to the test's unique algorithm.

Takeaway: With the much-awaited arrival of the final rule implementing PAMA, labs must now get to work preparing there systems to generate the date needing to be reported and bracing for the changes to come for the CLFS.

Editor's Note: A G2 Intelligence webinar, hosted June 28, 2016 in partnership with the American Clinical Laboratory Association, provides analysis of the new final rule. To purchase a recording of the webinar, The PAMA Final Rule: What You Need to Know and Do NOW to Comply with the New Payment Rules and Protect Your Lab Revenue, visit our website or contact customer service at 1-888-729-2315.

OIG Advisory Opinion Says GPO That Includes Labs Has "Acceptably Low" Anti-Kickback Risk

Group purchasing organizations (GPOs) are entities that act as a purchaser of supplies and equipment for a number of other entities—usually health care providers like hospitals. Laboratories, often reference laboratories, can play a role in such arrangements. For example, just last year, molecular laboratory NeoGenomics announced it was entering into a three-year agreement with a GPO named Premier. The arrangement made NeoGenomics an in-network laboratory provider for Premier and gave the lab access to a significant number of hospitals participating in the Premier network. The volume purchasing provides the opportunities for discounts and cost savings.

This month, the U.S. Department of Health and Human Services Office of Inspector General released Advisory Opinion 16-06 addressing whether a proposed GPO arrangement involving laboratory participants would run afoul of the Anti-Kickback Statute. The GPO negotiated "with vendors regarding products and pricing to be offered to the

GPO['s]" members and vendors paid the GPO administrative fees (set forth in written agreements) according to a "percentage of the value of sales to members."

That GPO's membership included more than 84,000 health care entities including hospitals, nursing facilities, clinics, physician practices, home care and … laboratories. The GPO originally had two owners: a health system and a Co-owner owned by 120 health care providers and suppliers. The health system proposed to acquire the individual entities owning the Co-owner to increase efficiencies in the GPO operations. The end result would be that the GPO would still be owned by two entities: The Health System and a New Co-Owner that the Health System would wholly own. 800 of the 84,000 GPO members were also owned or operated by the Health System that now would fully own the GPO.

The OIG evaluated applicability of two Anti-Kickback Statute safe harbors—the discount safe harbor and the GPO safe harbor. The discount safe harbor was relevant to the discounts the GPO negotiated with vendors for the GPO members and the vendor administrative fees the GPO distributed to members. The GPO safe harbor was relevant to the administrative fees the vendors paid the GPO. There were no issues regarding whether the discount safe harbor would be satisfied.

The final rule stated that wholly-owned subsidiaries couldn't do what the owner of the subsidiary couldn't—i.e., get vendors to pay fees in exchange for referrals.

However, the proposed arrangement would cause the GPO to be owned by the same entity that owns one percent of the pool of GPO members—which would mean the GPO wouldn't satisfy the definition of a GPO under the GPO safe harbor. But the OIG decided that such ownership arrangement didn't increase the risk to federal health care programs. The OIG explained that the purpose of the GPO safe harbor was to recognize that GPOs "help reduce health care costs" by the volume discounts it can achieve on goods and services purchased. Specifically referencing laboratories' participation in such arrangements, the OIG noted that in a 1991 final rule regarding the safe harbor a commenter had asked if "a nursing home chain requesting percentage payments from laboratories as GPO fees would qualify for the safe harbor." The final rule stated that wholly-owned subsidiaries couldn't do what the owner of the subsidiary couldn't—i.e., get vendors to pay fees in exchange for referrals. But this proposed arrangement was very different than that laboratory arrangement described in the 1991 final rule, the OIG explained in the Advisory Opinion. Instead, the OIG said, the members owned by the same entity that also owned the GPO were only one percent of the total GPO members. And all the members were subject to the same terms in their GPO agreements whether they were affiliated with the Health System owning the GPO or not—so, the members related to the Health System didn't get better terms than any other members. Therefore, because the GPO would still operate as a purchasing agent for a group of entities a majority of whom were unrelated to the GPO, the arrangement presented "an acceptably low risk of fraud and abuse in connection with the anti-kickback statute."

The Advisory Opinion applies only to the parties requesting it. But the fact that the OIG was willing to look beyond the "letter of the law" in terms of whether the safe harbor was met and look at the realities of the arrangement shows is encouraging and allows an arrangement intended to save health care costs and increase efficiencies.

Takeaway: Takeaway: OIG says a GPO arrangement presented an "acceptably low" risk despite the fact it didn't meet the exact definition of a GPO in the GPO Anti-Kickback safe harbor.

Risk of FCA Liability Increases as Supreme Court Recognizes Implied False Certification Theory

While labs are now busy focusing on gearing up to meet reporting obligations under the new PAMA rule, they should also heed a significant False Claims Act (FCA) decision by the U.S. Supreme Court released this month. In *Universal Health Services, Inc. v. Escobar*, the Court addressed whether FCA liability could arise based on a theory of "implied false certification." This theory allows FCA liability to be based upon failure to disclose a violation of a "material statutory, regulatory or contractual requirement." Such a failure to disclose is considered to render a related claim false or fraudulent. Noting disagreement among federal circuit courts of appeal, the U.S. Supreme Court made two important rulings in the *Escobar* case:

- FCA claims can be based "at least in certain circumstances" on the implied false certification theory. That is, failure to disclose noncompliance with a material statutory, regulatory or contractual requirement can give rise to FCA liability if the omission makes the claim misleading.
- Whether such an omission makes a claim false doesn't depend on whether the requirement violated is expressly made a condition of payment but rather whether the defendant "knowingly violated a requirement that the defendant knows is material to the Government's payment decision."

Ultimately, however, the U.S. Supreme Court returned the case to the lower court for review to determine whether the facts established FCA liability under the Supreme Court's stated interpretation of the implied false certification theory.

Takeaway: U.S. Supreme Court settles circuit court debate, allowing FCA liability based on false representations of compliance with conditions material to federal programs' decisions to pay claims.

G2 Compliance Corner

Do What the OIG Does: Use Analytics to Address Compliance Efforts and Resources

Labs need to use the power of data to make your compliance program more focused, efficient and successful. Take a lesson from the Office of Inspector General. An OIG podcast posted this month features an interview with Caryl Brzymialkiewicz, the Chief Data Officer for the HHS Office of Inspector General, who explains the value of data analytics to the agency's investigation and enforcement efforts. What laboratories can learn from this is not just that the government is using data to ferret out fraud and abuse and false claims but that data can help laboratories find compliance issues within their own operations before the government does. And, compliance officers can also use data analytics to support their compliance budgets and requests for resources.

Brzymialkiewicz explained that the Chief Data Office, which was initiated a year ago, is focused on "how do we help the OIG become even more effective and efficient in what it's doing—which includes improving our access to data"—by determining what datasets are needed and how to ensure high quality data. That's a function laboratories can emulate as well.

The work of the Chief Data Office allows the OIG to plot data geographically to reveal compliance hotspots, to conduct peer comparisons to spot providers who are outliers and identify trends, and to draw connections between providers. The information revealed through analytics also helps the agency internally as well to inform decision makers when setting priorities and allocating resources and staffing. "[T]hen if we need additional resources, we're standing on some very solid ground in terms of our logic of what we need when we go back and ask people for additional money," added Brzymialkiewicz.

Labs can likewise use data to identify trends in test ordering and billing, analyze claims denials, monitor relationships with referral sources, compare billing to those of other labs and set benchmarks. Anomalies spotted in the analytics can identify not only operational or revenue issues but potential compliance concerns. Lab compliance professionals can also use data analytics about their compliance efforts and challenges to support requests to the C-suite, board or senior management for more compliance resources or to justify existing compliance budgets.

News at a Glance

Medicare Fraud Prevention System Saves $1.5 Billion. The Centers for Medicare & Medicaid Services (CMS) claims Big Data has yielded big savings for Medicare. CMS claims its Fraud Prevention System (FPS) has identified $1.5 billion in inappropriate payments "through new leads or contributions to existing investigations." In a recent issue of The CMS Blog, the agency explained the FPS uses big data and predictive analytics to proactively ferret out fraud and abuse and prevent improper payments from happening: "Taking 'big data' mainstream has given CMS the ability to better connect with public and private predictive analytics experts and data scientists, as well as collaborate more closely with law enforcement. The Fraud Prevention System's 'big data' effort has had a profound impact on fraudulent providers and illegitimate payments by allowing us to quickly identify issues and take action."

CMS claims that FPS streams 4.5 million pre-paid claims daily and yielded a $11.60 return on investment in 2015 for each dollar spent on the system, recovering $1 billion in savings between 2013-2015. CMS also promises continued focus on use of analytics to fight fraud: "The CMS is now working to develop next-generation predictive analytics with a new system design that even further improves the usability and efficiency of the FPS."

Theranos Faces More Challenges. The challenges for Theranos continue to mount after the Centers for Medicare & Medicaid Services (CMS) inspected a California facility and rejected initial corrective action measures. The company has invalidated thousands of its tests and now has lost its highly visible business relationship with Walgreens—who terminated its arrangements with Theranos last month. The Chicago-based pharmacy retail giant said that Theranos' need to invalidate the results of approximately 70,000 tests conducted on its Edison platform and other lab equipment and the rejection of a corrective action plan by the CMS for its lab operations moving forward drove the decision. Theranos itself said it planned to continue to operate sites independently. "We are disappointed that Walgreens has chosen to terminate our relationship and remain fully committed to our mission to provide patients access to affordable health information and look forward to continuing to serve customers in Arizona and California through our independent retail locations," the company said in a statement.

Biden Launches Genomic Data Commons to Further Personalized Cancer Care. The Genomic Data Commons (GDC) recently launched, as a core component of the National Cancer Moonshot and the President's Precision Medicine Initiative to promote data sharing between cancer researchers and accelerate the pace of discovery in personalized oncology care. The data platform's initial release included genetic and clinical information from more than 14,000 cancer patients and tumors. GDC centralizes, standardizes, and harmonizes genomic and clinical data on a unified and interoperable platform. "Today, making discoveries from cancer genomic data is challenging because diverse research groups analyze different cancer datasets using various methods that are not easily comparable," said GDC principal investigator Robert Grossman, Ph.D., from the University of Chicago, in a statement. "GDC brings together genomic datasets and analyzes the data using a common set of methods so that researchers may more easily make discoveries, and, in this sense, democratizes the analysis of large cancer genomic datasets."

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