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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

FTC Takes First-of-Its-Kind Action Against Genetic Testing Company

A recent enforcement action by the Federal Trade Commission (FTC) against a genetic testing company highlights the focus the agency has on protecting sensitive data. It should serve as a warning to all who handle such data that the FTC is paying attention to what they say about how that information is protected. *Continued on page 2.*

Labs, Path Groups Should Review Restrictive Covenants in Anticipation of Non-compete Ban

Clinical laboratories and pathology groups should begin reviewing and perhaps modifying restrictive agreements they have with employees in anticipation of a final rule from the Federal Trade Commission (FTC) banning non-compete agreements, says Ryan Neumeyer, an attorney in the Labor and Employment Practice Group at McDonald Hopkins (Cleveland). *More on page 5.*

The Good, the Bad and the Ugly: UnitedHealthcare Implements New Policies

UnitedHealthcare is in the process of implementing three major policy initiatives that will affect clinical laboratories and pathologists, according to Diana Richard, senior director of pathology and strategic development for XiFin Inc. (San Diego, CA). These include changes to prior authorizations, pre-payment audits and use of Z-codes. *Continued on page 7.*

Pathologists Face Medicare Cuts in 2024 Under Proposed Rule

Pathologists will see Medicare payment cuts in 2024 under the Medicare physician fee schedule proposed rule. Under the rule, proposed July 13, professional services would be cut by an average of 2%, and technical services cut by an average of 1%. The proposal also would increase Medicare Quality Payment Program (QPP) requirements for 2024 and implement conforming changes under the Clinical Laboratory Fee Schedule (CLFS) related to data reporting and phase-in of payment reductions.
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FTC Takes First-of-Its-Kind Action Against Genetic Testing Company

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On June 16 the FTC announced an enforcement action against 1Health.io Inc, a genetic testing company that analyzes consumer-provided DNA samples and uses the results of that analysis to generate personalized reports and other tailored products.

According to Ali Jessani, a senior associate with the law firm of WilmerHale (Washington, D.C.), this is the latest in a series of enforcement actions that the FTC has brought in 2023 against companies for processing sensitive data in violation of Section 5 of the FTC Act, although, according to the FTC, it's the first that specifically focuses on both privacy and security practices related to genetic data.

The FTC charged that 1Health left sensitive genetic and health data unsecured, deceived consumers about their ability to get their data deleted and changed its privacy policy retroactively without adequately notifying and obtaining consent from consumers whose data the company had already collected.

Ali Jessani

As part of a proposed settlement with the FTC, 1Health will be required to strengthen protections for genetic information and instruct third-party contract laboratories to destroy all consumer DNA samples that have been retained for more than 180 days.

California-based 1Health.io Inc., also known as Vitagene Inc., before changing its name in October 2020, has sold DNA health test kits and used DNA test results to provide consumers with reports about their health, wellness and ancestry. The health reports include personal information about a consumer's health and genetics, such as their level of risk for developing health problems based on their genotype data.

First-of-Its-Kind Action

In its first action focused on both the privacy and security of genetic information, the FTC said in a complaint that Vitagene deceived consumers about its privacy and security practices. On its website, the company prominently touted its privacy and security, claiming to offer "rock-solid security" and promised users that it "collects, processes and stores your personal information in a responsible, transparent and secure environment." From 2017 to 2020, the company also said it would only share consumers' sensitive health and other personal information in limited circumstances, such as providing information to a customer's doctor or with the lab doing genetic testing.

Vitagene also claimed on its website that it did not store DNA results with a consumer's name or other identifying information; that consumers could delete their personal information at any time; that personal data would be removed from all of the company's servers; and that it would destroy DNA saliva samples shortly after they have been analyzed.

However, the FTC said Vitagene failed to keep these promises. Beginning in 2016, the company did not implement a policy to ensure that the lab that analyzed the DNA samples had a policy in place to destroy them. And in 2020, the company changed its privacy policy by retroactively expanding the types of third parties that it may share consumers' data with to include, for example, supermarket chains and nutrition and supplement manufacturers. This was without notifying consumers who had previously shared their personal data with the company or obtaining their consent to share such sensitive information, according to the complaint.

In addition, Vitagene's security failures put consumers' sensitive data at risk, the FTC said. Vitagene stored in publicly accessible "buckets" on Amazon Web Service's (AWS) cloud storage service nearly 2,400 health reports about consumers and raw genetic data of at least 227 consumers sometimes accompanied by a first name – despite promising users its security practices would exceed industry-standard security practices. Vitagene did not encrypt that data, restrict access to it, log or monitor access to it or inventory it to help ensure its security.

Over a two-year period, Vitagene was warned at least three times that the company was storing unencrypted health, genetic and other personal information in publicly accessible data buckets, according to the complaint. After a security researcher contacted the company in June 2019, the company finally investigated the issue and notified its customers whose data it had exposed publicly.

"This case highlights that the FTC is continuing to expand its enforcement authority by labeling more practices that it views unfavorably as 'unfair,' as well as the fact that the agency is focusing on this issue related to the retroactive changing of privacy policies specifically."

As part of the proposed order, 1Health.io, which Vitagene is now known as, must pay $75,000, which the FTC intends to use for consumer refunds. In addition to the DNA deletion requirement, under the proposed order the company:

- Will be prohibited from sharing health data with third parties—including information provided by consumers before and after its 2020 privacy policy change—without obtaining consumers' affirmative express consent;
- Must ensure any company that purchases all or part of 1Health's business agrees by contract to adhere to provisions of the order;
- Must notify the FTC about incidents of unauthorized disclosure of consumers' personal health data; and
- Must implement a comprehensive information security program addressing the security failures outlined in the complaint.

Increased Focus on What Is "Unfair"

Perhaps the most notable element of this decision is that, according to the FTC, 1Health retroactively changed its privacy policy in a manner that was "unfair" under Section 5 of the FTC Act, says Jessani. The FTC alleged that 1Health's privacy policy changes with regard to the sharing of consumers' sensitive data were "material," such that they required additional steps by the company to notify consumers or obtain their consent. The FTC has historically enforced retroactive material privacy policy changes as a potentially "deceptive" practice under Section 5 but had not brought a recent enforcement action against a company for "unfair" practices specifically.

"This case highlights that the FTC is continuing to expand its enforcement authority by labeling more practices that it views unfavorably as 'unfair,' as well as the fact that the agency is focusing on this issue related to the retroactive changing of privacy policies specifically," says Jessani. "As companies continue to routinely revise their privacy policies in order to comply with new state privacy law obligations, they should be aware that the FTC is paying attention to what they say."

Key Takeaways

There are several key takeaways from this enforcement action, says Jessani:

- **Notify Consumers of Privacy Policy Changes.** One notable part of the FTC complaint is its focus on 1Health's adoption of retroactive privacy policy changes without providing no-

tice to or obtaining consent from consumers, says Jessani. He advises companies to ensure that any material changes to their privacy policies (particularly those that apply retroactively to data collected before the revisions) are accompanied by notice to consumers and, where appropriate, the obtaining of appropriate consent.

- **Comply with Data Deletion Requests.** The 1Health complaint is yet another example of the FTC taking a company to task for failing to adhere to consumers' data deletion requests, says Jessani. The FTC noted that 1Health was unable to fully comply with consumer data deletion requests because it lacked a full inventory of the consumer information that it collected. "Companies that collect consumer personal information should ensure they have a full accounting and inventory of the personal information that they collect and that they fully comply with consumers' requests to delete that information, including by flowing down data deletion requests to relevant third parties," he advises.

"The FTC is embracing its role as a privacy regulator and is looking to expand the types of enforcement actions it can bring."

• **Require Third Parties to Comply.** One of the complaint's allegations centered on 1Health's failure to ensure the destruction of consumers' physical DNA saliva samples after they had been analyzed. 1Health itself did not conduct this analysis; rather, it was outsourced to a third-party laboratory partner. That made little difference to the FTC, which indicated that 1Health should have had a contract provision in place to ensure the destruction of these samples consistent with the company's public-facing representations. "This complaint emphasizes that companies should use contract requirements, where appropriate, to ensure that they are adhering to data protection promises made to consumers," says Jessani.

FTC Looking to Expand Actions

Jessani believes the FTC may increasingly bring actions against companies for violation of data privacy and security under Section 5 of the FTC Act, especially when it comes to sensitive data, such as genetic information.

"I think it's a combination of the new chair, Lina Khan, and her being a bit more aggressive in how she views these issues," he says. [Kahn is a fierce proponent of data protections]. "The FTC is embracing its role as a privacy regulator and is looking to expand the types of enforcement actions it can bring. What they're doing is signaling to the rest of the industry that these are practices the FTC views unfavorably and that could potentially be violations of Section 5."

Jessani also believes the FTC is trying to build new case law for unfair practices by taking "low hanging fruit" – that is companies that are already acting in a deceptive manner – and adding charges of other violations, such as unfair business practices. This is an indicator that the FTC intends to bring more charges under the unfair prong of Section 5.

"The purpose of building case law is so that when they are eventually challenged in court, they can say, you should have been put on notice by all of the other cases," he says. "I also believe the FTC will increasingly go after companies that deal with sensitive data, because the potential harm to consumers is an easier claim to make."

LABS, PATH GROUPS SHOULD REVIEW RESTRICTIVE COVENANTS IN ANTICIPATION OF NON-COMPETE BAN (*cont'd from page 1*)

The FTC earlier this year proposed a new rule that would ban employers from imposing non-competes on their workers, saying the practice suppresses wages, hampers innovation, and blocks entrepreneurs from starting new businesses. The FTC estimates that about one in five American workers are bound by a non-compete clause and are thus restricted from pursuing better employment opportunities. The Commission estimates the proposal would increase American workers' earnings between $250 billion and $296 billion annually.

"I think it's likely to be overturned eventually, but in the short term, employers need to be prepared to comply. For the time the rule is in place, you won't be able to enforce a non-compete agreement."

The Commission has already received more than 27,000 comments on the proposal, with commenters split between those in favor of and those opposed to the proposal. The FTC is expected to vote in April 2024 on the final version of its proposed ban.

The National Labor Relations Board (NLRB) has also come out in opposition to non-compete agreements. In May 2023, NLRB General Counsel Jennifer Abruzzo issued a memo stating that the proffer, maintenance and enforcement of non-compete agreements in employment contracts and severance agreements violate the National Labor Relations Act, except in limited circumstances.

Ryan Neumeyer

The memo left significant ambiguity as to what constitutes these limited circumstances, but gave two examples: "provisions that clearly restrict only individuals' managerial or ownership interests in a competing business" and "true independent-contractors relationships." The NLRB's protections extend only to non-supervisory employees.

What's more, legislation is pending in Congress to ban non-compete agreements with some limited exceptions. The Workforce Mobility Act has bipartisan support.

The measure, introduced by Sens. Chris Murphy (D-Conn.) and Todd Young (R-Ind.), would largely ban the use of non-compete agreements nationwide as a matter of federal law. The bill is co-sponsored by Sens. Tim Kaine (D-Va.) and Kevin Cramer (R-N.D.). Limited exceptions to the ban would permit non-competes under specified conditions, including with the sale of certain interests in a business or the dissolution from partnerships.

Even though there is a great deal of pushback from the business community over the proposal to ban non-compete agreements and the FTC's final rule could well be challenged in court, it is likely there will be a period of time when the rule is in effect, and businesses will need to comply with its requirements, says Neumeyer.

"I think it's likely to be overturned eventually, but in the short term, employers need to be prepared to comply," he explains. "For the time the rule is in place, you won't be able to enforce a non-compete agreement."

Non-compete agreements prohibit workers, such as physicians, from joining a competing prac-

tice or setting up their own within a particular geographic distance from their previous practice for a certain period of time. A Medscape survey in 2021 found that 90% of physicians who responded to a survey were bound by a non-compete clause in their contracts or had been bound by one in the past.

California, North Dakota, Oklahoma and Washington, D.C., ban non-compete agreements with a few narrow exceptions, according to the Society for Human Resource Management. Colorado, Illinois, Maine, Maryland, New Hampshire, Oregon, Rhode Island and Washington state prohibit non-competes unless the worker earns above a certain threshold. In places where they are legal, regulations and enforcement vary from state to state. In Tennessee, for example, non-compete agreements for physicians are limited to a maximum of 10 miles from the county of practice and a maximum duration of two years.

Review Existing Agreements

Neumeyer says this is a good time for employers to re-evaluate their non-competition agreements and other restrictive covenants to see how this proposed rule could affect their workforce. When possible, he says, employers should restructure their agreements to make them more narrow and less restrictive. In general, overly broad non-compete agreements can be problematic if an employer does not have a legitimate business reason for them.

"All businesses should take the FTC proposal seriously. Don't ignore it. I think the writing is on the wall—whether it's by state or federal law, there will be some limitations on restrictive covenants. Try to get out in front of it and get your house in order now."

"Look at the agreements you have currently and the limitations in them," he advises. "Do you really need a non-compete, or is there something less onerous you can do, such as a non-disclosure agreement or a non-solicitation agreement? That's what labs should do right now to prepare for this potential disruption."

In many situations, Neumeyer suggests, clinical laboratories may only need to require their salespeople to sign a non-solicitation agreement rather than a non-compete agreement. In states where non-solicitation agreements are legal, the lab can require salespeople who leave to work for a competitor to not solicit clients for a certain period of time with which the sales rep has had personal contact. This narrow restriction is much more likely to be upheld in court.

If your business's concern is protecting trade secrets, Neumeyer advises using only a non-disclosure agreement. Of course, before requiring an employee to sign a restrictive covenant, you should consult with your legal counsel to ensure that any restrictions are permitted in the state in which you operate.

Neumeyer suggests taking inventory of all existing restrictive covenants in your lab or business. Review the organizational chart to see if the individuals who need to have restrictions do have them, and if they don't need restrictions, get rid of the restrictions. When used, non-competes should be structured as narrowly as possible and for a compelling business reason.

"All businesses should take the FTC proposal seriously," says Neumeyer. "Don't ignore it. I think the writing is on the wall—whether it's by state or federal law, there will be some limitations on restrictive covenants. Try to get out in front of it and get your house in order now."

THE GOOD, THE BAD AND THE UGLY: UNITEDHEALTHCARE IMPLEMENTS NEW POLICIES (*cont'd from page 1*)

Prior Authorizations

First, UHC has announced that it is working to cut prior authorizations by 20%. The initiative is expected to launch in the third quarter of this year. While UnitedHealthcare says it wants to ease the burden on providers, Richard cautions that the move may have more to do with pressure from federal and state initiatives, such as Gold Card programs. The Gold Card program was first introduced in West Virginia in 2019. The legislation allows physicians with 100% prior authorization approval to bypass those requirements on a certain procedure for six months. In 2021, Texas passed similar legislation allowing physicians with 90% approval to bypass prior authorization requirements. Other states that have introduced gold card legislation include New York, Colorado, Indiana, Kentucky, Mississippi and Oklahoma.

UHC plans to launch its nationwide Gold Card program in 2024. However, the program already exists in states where legislation requires it. According to the UHC Texas Gold Card exemptions FAQs, providers who submit at least five pre-authorization requests for services and have a 90% approval rate on all requests will be exempt from requesting pre-authorizations on those services. The approval rate is reviewed every six months. Richard reiterated: "While Gold Card programs will offer providers much-needed relief of burden on resources and time spent on prior authorization request, providers should continue to diligently monitor trends in denials for increases in medical necessity and payor policy denials once the prior authorizations have been removed. One obstacle removed does not preclude others from preventing reimbursement."

Diana Richard

Pre-Payment Audits

Richard notes that obtaining a prior authorization does not eliminate the possibility of medical records request prior to payment. UnitedHealthcare, owned by Optum, plans to begin leveraging pre-payment audits on claim activities that indicate frequent overutilization. Pre-payment audits can wreak havoc on a healthcare provider's practice, says Richard, noting that they can create cash flow shortfalls and other interruptions that can negatively impact their business. While pre-payment audits are not always avoidable, ensuring the documentation clearly supports billing charges can help reduce complications and diversion of time and resources to the audit.

Another form of audit comes in the way of a CO-252 denial, e.g., a request for additional information. "Initially payors only required we provide pathology reports; now we're seeing often they want the requisition included as well," she explains. "Additional information denials account for approximately 70% of our clinical lab appeals, 33% in pathology and 48% in molecular. Fortunately, we're able to automate most of the process, however complying with these payors requests becomes more complex and places additional demand on billing resources for many practices, and the cost to collect can increase substantively if processes aren't streamlined effectively."

Complicating matters is that UnitedHealthcare continues to send paper correspondence in addition to electronic correspondence. This increases the likelihood that additional details regarding a payor's request for additional information might be missed. "As of Feb. 1, 2023, providers are required to submit claim reconsiderations and post-service appeals electronically, but the electronic correspondence is not yet fully operational," says Richard.

Migration to Z-codes

Beginning Aug. 1, 2023, UHC will be migrating to the use of Diagnostic Exchange Registry Z-codes to identify the testing being billed on both professional and facility claims, though it

will not enforce the requirement until Oct. 1, 2023. The initial list of codes, which includes 136 CPT codes as well as 106 proprietary lab analysis codes, is called "Wave 1" by UHC. Additional tests will be added to the process in future waves. Z-codes are five-character alpha-numeric codes assigned to molecular diagnostic tests by Palmetto GBA's MolDx program. Z-codes are used in conjunction with CPT codes on lab test claims.

Z-codes are currently required by four of the seven Medicare Administrative Contractors (MACs). For labs that are not currently required to utilize Z-codes on their Medicare claims, there is an enrollment process for obtaining a Z-code that must be completed prior to using the code for billing to UHC. Labs that already have a Z-code for tests from the initial list will simply update their billing system to send that Z-code on their UHC claims.

Z-codes are a way for UHC to track utilization of specific codes and determine where there is a need for more specific CPT codes, says Richard. Currently, there are more than 75,000 molecular diagnostic tests and only 500 CPT codes to track them all.

"Obtaining a Z-Code can be daunting, but labs need to be diligent," she explains. "Labs that have higher test volume will find it easier to obtain Z-Codes. Justifying clinical utility is one of the requirements to meeting medical necessity, and that's more easily accomplished when the data set has significance. Smaller labs may have challenges making the argument if the volume of their tests are minimal."

Tips on Complying with New UnitedHealthcare Policies

Prior Authorization

- Track tests requiring prior authorizations to ensure you are not spending unnecessary administrative time as the demands are lessened.
- Ensure PA requests are complete and accurate for maximum success in solidifying your enrollment in the Gold Card Program and reducing front-end burden related to PA requests.
- Respond to medical record requests in a timely manner. Consider automating portions of your appeals process to minimize the burden on staff, time to collect, risk of not collecting and overall cost to collect.
- Monitor portals to avoid missing critical requests.

Pre-Payment Audits

- Review coding to ensure that codes are not stacked when they should be bundled or billed as a panel.
- Review ordering platforms to ensure they don't require an ordering provider to order a complete panel instead of individual tests and that they do not encourage the ordering of more complex services than may be necessary.
- Appeal CO-252 denials with appropriate and complete documentation.
- Review paper correspondence from UHC. It may include information about what additional documentation is required.

Migration to Z-Codes

- Register with the DEX Diagnostic Exchange Registry.
- Apply for a Z-Code for tests your performing that are on the Wave 1 list.
- Update your billing system to apply the assigned Z-Code to claims for your applicable tests.
- Monitor tests to ensure accurate payment.

UHC is encouraging providers to enroll and submit tests as soon as possible to allow time to identify and fix possible errors with test submissions. The current turnaround time for most MolDx program technical assessment registration is two to three months from original submission to receiving an initial response. If additional information is needed, the two-to-three-month time span starts again and continues to reset every time a provider has to submit further clarification.

CMS Proposes to Cut Medicare Payments for Pathologists

The Centers for Medicare and Medicaid Services (CMS) has proposed to cut Medicare payments to pathologists by an average of 2% for pathology professional services and 1% for technical services. The cuts are proposed to offset a new evaluation and management add-on code, G2211, that will increase payments to primary care physicians and nurse practitioners. The College of American Pathologists (CAP) successfully lobbied Congress to delay payment for G2211 in CY 2021 when CMS initially attempted to establish payment for the code.

Comments on the proposed Medicare Physician Fee Schedule (MPFS) are due to CMS by September 11, and a final rule is expected to be issued in November.

Among the proposed changes:

- **Surgical pathology (CPT 88305):** The professional component (PC) would be cut by 3.4% to $35.37 while the technical component (TC) would be cut by 0.6% to $35.04.
- **Prostate biopsies (G0416):** The PC would be cut by 3.7% to $168.32 while the TC would drop 0.1% to $188.30.
- **Immunohistochemistry (CPT 88342, IHC, first stain procedure):** The PC would drop by 3.4% to $33.08 while the TC would increase 6.4% to $71.06. Overall, the global rate would increase by 3.1%.
- **Immunohistochemistry, additional stain (CPT 88341)** would increase by 2.7% overall with the PC dropping 4.5% to $26.53, and the TC increasing 6% to $62.88.
- **Special stains (CPT 88312 and CPT 88313)**: The global rate for CPT 88312 would be cut by 2.5% to $110.69, with the PC dropping 3.3% to $25.22 and the TC dropping 2.2% to $85.47. The global rate for CPT 88313 would decline by 1.4% to $81.54, with the PC dropping 3.4% to $11.46 and the TC dropping 1% to $70.08.

The CAP strongly opposes these cuts and is actively lobbying Congress to mitigate the decreases before they take effect.

CLFS Revised Data Reporting Period, Payment Reductions

In accordance with the Consolidated Appropriations Act of 2023 (CAA, 2023), the proposed MPFS would make certain conforming changes to the data reporting and payment period requirements for clinical laboratory diagnostic tests (CDLTs). For the data reporting period of Jan. 1, 2024, through March 31, 2024, the data collection period is Jan. 1, 2019, through June 30, 2019.

In addition, the proposal would make conforming changes to requirements for the phase-in of payment reductions under the CAA, 2023. Specifically, for 2023, payment for an applicable CDLT may not be reduced compared to the payment amount established for that test in 2022, and for calendar years 2024 through 2026, payment may not be reduced by more than 15% as compared to the payment amount established for that test for the preceding year.

New Value Pathways

CMS continues to signal its intent that Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) are the future of MIPS under its Quality Payment Program (QPP). To further this vision, CMS is proposing five new MVPs for the 2024 performance year:

- Focus on women's health;
- Quality care for the treatment of ear, nose and throat disorders;
- Prevention and treatment of infectious disorders, including hepatitis C and HIV;
- Quality care in mental health and substance use disorders; and
- Rehabilitative support for musculoskeletal care.

In addition, CMS is proposing to increase the performance threshold to avoid a MIPS penalty from 75 to 82 points, a move strongly opposed by physician groups.

Laboratory Owner Faces False Claims Allegations Over Covid Testing

A recent Justice Department filing indicates that the government is continuing to go after bad actors that billed for unnecessary Covid-19 tests during the public health emergency.

The Justice Department on July 18, 2023, filed a complaint against Patrick Britton-Harr and multiple laboratory companies he owns, alleging False Claims Act (FCA) violations for submitting claims to Medicare for laboratory tests that were not ordered by healthcare providers, not medically necessary and sometimes never performed.

The complaint also alleges that Britton-Harr and Provista Health submitted claims for RPP tests that were never ordered by physicians.

According to the complaint, Britton-Harr owned and operated Provista Health LLC, as well as multiple other corporate entities that allegedly sought to profit from the Covid-19 pandemic by offering Covid-19 tests to nursing homes as a way to bill Medicare for a wide array of medically unnecessary respiratory pathogen panel (RPP) tests. The complaint alleges that these RPP tests were not medically necessary because the beneficiaries had no symptoms of a respiratory illness and because the tests were for uncommon respiratory pathogens.

The complaint also alleges that Britton-Harr and Provista Health submitted claims for RPP tests that were never ordered by physicians. Multiple physicians denied ever ordering thousands of RPP tests for which Britton-Harr and Provista Health allegedly submitted claims to Medicare listing one of these physicians as the ordering provider.

The complaint further alleges that Britton-Harr and Provista Health submitted claims to Medicare for RPP tests that were never performed, including more than 300 claims that stated the nasal swab test sample was supposedly collected from the beneficiary on a date after the beneficiary had died.

Billed Medicare More Than $7 Million

As alleged in the complaint, Britton-Harr wholly owned and operated Provista Health, AMS Onsite Inc., Britton-Harr Enterprises Inc, Coastal Laboratories Inc. and Coastal Management Group Inc., and these companies—together with Britton-Harr—conspired to carry out these schemes.

Britton-Harr and the companies in question billed and received more than $7 million in reimbursement from Medicare before the fraudulent scheme fell apart, the complaint alleges. The scheme fell apart in the fall of 2020 when Britton-Harr—who no longer had a functioning lab—was unable to find a reference lab that would agree to an arrangement where the reference lab would perform the Covid-19 and RPP testing while Provista submitted those claims to Medicare and paid the reference lab a portion of the proceeds. Even after the scheme collapsed, Provista continued to submit claims to Medicare through August 2021 for purported dates of service between April 3, 2020, and Sept. 17, 2020.

The claims alleges that Britton-Harr used money he received from Medicare to launch a membership-based private air service company in Sarasota, Fl., called AeroVanti.

The matter is being handled by the Justice Department's Civil Division's Commercial Litigation Branch, Fraud Section and the U.S. Attorney's Office for the District of Maryland. Investigative support is being provided by the Health and Human Services Office of Inspector General and the FBI. The allegations in the complaint were identified by a government investigation that arose from a proactive analysis of Medicare claims data.

COMPLIANCE 101:

Taking Disciplinary Action Against Wrongdoers

A viable clinical laboratory compliance program must include the initiation of corrective and/or disciplinary action against individuals who have failed to comply with the laboratory's compliance policies and federal or state laws or who have otherwise engaged in wrongdoing that has the potential of impairing the laboratory's status as a reliable, honest, trustworthy provider, says the Health and Human Services Office of Inspector General (HHS OIG) in its draft program guidance.

"The compliance program should include a written policy statement setting forth the degrees of disciplinary actions that can be imposed upon employees for failing to comply with the company's code of conduct, company policies and the law," writes the OIG in its guidance. "Employees must be advised and convinced that disciplinary action will be taken, and punishments enforced, for a discipline policy to have the required deterrent effect."

Investigation

Laboratory compliance programs should require that when the chief compliance officer or others involved in management of a laboratory learn of potential violations or misconduct, they promptly investigate the matter to determine whether a material violation has in fact occurred, so management can take steps to rectify it, report it to the government if necessary and make any appropriate payments to the government.

Depending on the nature of the allegations, the investigation will probably include interviews and review of relevant documents, such as submitted claims, test requisition forms and laboratory test reports. Some laboratories may wish to engage outside auditors or counsel to assist them with the investigation.

"If an investigation of an alleged violation is undertaken and the compliance officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, the employee(s) allegedly involved in the misconduct probably should be removed from his/her current work activity until the investigation is completed," writes the OIG. "In addition, the laboratory should take steps to prevent the destruction of documents or other evidence relevant to the investigation. Once an investigation is completed, if disciplinary action is warranted, it should be immediate and imposed in accordance with the company's written standards of disciplinary action."

Reporting

If management receives credible evidence of misconduct from any source and, after appropriate investigative inquiry, has reasonable grounds to believe that the misconduct either: a) Violates criminal law, or b) Constitutes a material violation of the civil laws, rules and regulations governing federally funded healthcare programs, then the laboratory should report the existence of the misconduct to the OIG as soon as possible, the agency says.

The OIG recommends that the lab give notice to the OIG within 60 days after receipt of credible evidence of misconduct. If the investigation ultimately reveals that criminal activity may have occurred, the appropriate state or federal authorities should be notified immediately.

Corrective Action

If the investigation reveals that misconduct did occur, corrective actions should be immediately initiated. This might include restitution of overpayments from federally funded healthcare programs.

Compliance programs should also prohibit the employment of individuals who have been convicted of a criminal offense related to healthcare or who are listed by a federal agency as debarred, excluded or otherwise ineligible for participation in federally funded healthcare programs.

In Brief

Docs Agree to Settlement Over Lab Testing Kickback Allegations

Physicians in Missouri and Texas have agreed to pay a total of more than $525,000 to resolve False Claims Act (FCA) allegations that they received illegal kickbacks in violation of the Anti-Kickback Statute in return for referring patients for laboratory testing. The parties have agreed to cooperate with the Department of Justice's investigations into other participants in the alleged schemes. The settlement resolves allegations that Imran Chishti, MD, and his medical practice, C Care LLS, both of Chesterfield, Mo., and Shamim Justin Badiyan, MD, of Frisco, Tx., and Psych Care Consultants LLC of St. Louis, Mo., received kickbacks for making referrals to laboratories in New Jersey, Texas and Florida.

Novitas Rescinds Noncoverage Decision for Cancer Tests

A local coverage decision (LCD L39367) that would have rescinded coverage for multiple cancer tests has been withdrawn by Medicare Administrative Contractor Novitas Solutions. The LCD was supposed to have taken effect July 17, but Novitas says it will publish a new draft LCD for comment. The original LCD would have rescinded coverage for the following tests: Castle Bioscience's DecisionDx-Melanoma and DecisionDx-SCC tests; Pacific Edge Diagnostics' Cxbladder Detect, Enhanced Detect, Monitor, Enhanced Triage and Resolve assays; Interpace Biosciences' PancraGen; Clinical Genomics' Colvera; Abbott's UroVysion fluorescence in situ hybridization tests; and the University of Pittsburgh Medical Center's ThrySeq Cancer Risk Classifier and PancreaSeq Genomic Classifier.

First Coast to Require Documentation for Digitization of Glass Slides

Medicare Administrative Contractor First Coast Service Options Inc. is requiring that on or after Aug. 5, 2023, providers document how the digitization of glass microscope slides is reasonable and necessary. Providers must make a statement on Item 19 of the CMS-1500 claim form. An example of potentially reasonable and necessary digitization is if a slide requires an outside consultation that would necessitate mailing of the slide, but it represents the only slide demonstrating the pathology of interest (and the loss of the slide would mean loss of irreplaceable material).

Jondavid Klipp, Publisher Kimberly Scott, Editor Jennifer Kaufman, Chief Copy Editor

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Laboratory Economics is offering a database of 320,000+ CLIA-certified laboratory facilities. The database is current as of March 31, 2023 and includes more than 9,000 independent labs, 123,000 physician-office labs, 9,000 hospital labs and all other labs

The data is presented in an Excel spreadsheet and includes:

Laboratory Name • Address • Phone Number • Annual Test Volume • Date CLIA Certificate Was Issued

Condensed Sample Data:

LABORATORY NAME	ADDRESS	CITY & STATE	ZIP	PHONE	CLIA Certification Date	FACILITY TYP
Golden Age Senior Care LLC	23727 SE 132ND Way	Issaquah, WA	98027	(425) 369-6069	3/28/23	Nursing Home
Gainesville Primary Care	5469 SW 34Th St	Gainesville, FL	32608	(352) 548-6000	1/11/23	Community Clin
American Health W LLC	2200 Lind Ave SW Ste 909	Renton, WA	98057	(720) 227-7072	10/25/22	Independent Lab
Delfi Diagnostics Inc.	1810 Embarcadero Rd Ste 100	Palo Alto, CA	94303	(408) 497-0047	7/30/22	Independent La
Skip Laboratories	111 NW 183Rd St Ste 115	Miami, FL	33169	(888) 316-7481	6/2/22	Independent Lab
Florida Cancer Specialists & Research Institute	7315 Green Slope Dr	Zephyrhills, FL	33541	(813) 702-7885	6/1/22	Physician Office La
Orchid Bioscience Inc.	9 Laboratory Drive	Durham, NC	27709	(608) 669-0653	5/16/22	Independent Lab
KEDPLASMA	2950 East Desert Inn Road	Las Vegas, NV	89121	(818) 590-9664	4/18/2022	Other
CSI Laboratories	4399-4401 Santa Anita Ave	El Monte, CA	91731	(626) 350-0537	4/13/2022	Independent La
Central Maine Medical Center	17 High Street	Lewiston, ME	04240	(207) 795-2339	4/11/2022	Hospita

- Data available for all 50 states and Puerto Rico
- Includes 7,000+ CAP Accredited Labs
- Find new customers to grow your sales
- Create targeted lists by location or start date to focus on your best opportunities
- Identify underserved markets for geographic expansion
- Save time and money by using accurate, complete and consistent data

PURCHASE COMPLETE CLIA LABS DATABASE

❑ **YES!** Please send me the complete database of 320,000+ CLIA-certified labs in the United States and Puerto Rico for $495.

This database includes every single CLIA-certified lab as of March 31, 2023

❑ Check enclosed *(Payable to Laboratory Economics)*

❑ Charge my:

MC Amex Visa *(circle one)*

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Signature _____

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