G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

May 2021

IN THIS ISSUE

www.G2Intelligence.com

Compliance Perspectives: Can You Require Lab Employees to Prove They Received the COVID-19 Vaccine?

No Person May Gain Entry to the Laboratory Without Furnishing Proof of Their COVID-19 Vaccination Status

Normally, a sign like this would be highly problematic. Heck, simply asking employees if they've been vaccinated, let alone prove it before letting them enter the workplace would raise the brightest of red flags in normal times. But these are not normal times. And during the pandemic, regulatory authorities have temporarily relaxed the normal restrictions and given employers leeway to implement infection control measures that infringe on employees' personal privacy and rights to accommodations. But nobody should confuse this leeway for a blank check. As with other workplace health and

Continued on page 2

In the News: Ambry Genetics Case Shows Why It's So Hard for Patients to Win a HIPAA Data Breach Class Action Lawsuit

Data breaches that compromise the protected health information (PHI) of massive numbers of patients have become all too common. In addition to steep HIPAA fines and horrible public relations, such breaches have spawned a new nasty consequence: threat of a class action lawsuit. The case against Ambry Genetics is a notable example and one that also illustrates why it's so hard for victims to win these lawsuits.

The Ambry Genetics Data Breach

In January 2020, Ambry Genetics was the victim of a hacking incident that compromised the personal data of up to 230,000 individuals, including patients' names, dates of birth, health

Continued on page 11

Compliance Perspectives: Can You Require Lab Employees to Prove They Received the COVID-19 Vaccine?, *from page 1*

safety protocols, vaccine verification is still subject to legal limits. Here's what compliance managers need to know to keep their labs' own vaccine verification efforts compliant.

The 4 Legal Limits of COVID-19 Vaccine Verification

There are four ways your lab can get into legal trouble by not letting lab employees into the workplace without proof of COVID-19 vaccination.

1. HIPAA Privacy Violations

Whether a person has received a particular vaccination may be deemed protected health information (PHI) that HIPAA bans providers from collecting, using or disclosing (which, for simplicity's sake we'll refer to collectively as "use" unless the context requires otherwise) without consent. However, HIPAA consent requirements are subject to exceptions, one of which allows employers to use PHI to carry out legitimate and essential employment functions. Throughout the pandemic, regulatory authorities have indicated that pre-entry medical screening to keep the infected and recently exposed out of the workplace is not only a legitimate but, at least for labs and other health care facilities, a mandatory infection control measure.

But there's also an important qualifier: Employers are allowed to use only the minimum PHI necessary to accomplish this purpose. Example:

- **OK:** Asking employees if they've been vaccinated or have any COVID-19 symptoms;
- **Not OK:** Asking employees if they have any non-COVID related medical conditions or what medications they use.

The latter inquiries are illegal to the extent they solicit information that you don't need to perform pre-entry COVID-19 screening.

2. Disability Discrimination

The *Americans with Disabilities Act* (ADA) bans employers from requiring employees to undergo a "medical examination." Equal Employment Opportunity Commission (EEOC) guidelines make it clear that the COVID vaccine doesn't count as a "medical examination."

The ADA also bans employers from asking employees (and job applicants) questions likely to elicit information about a disability. The EEOC says that simply requesting proof of receipt of a COVID-19 vaccination is not likely to elicit information about a disability. However, pre-screening may cross the line and become an illegal disability-related inquiry when it includes follow-up questions, such as asking employees why they didn't get the vaccination. In that case, employers would have the burden of proving that those questions are "job-related and consistent with business necessity."

LCA

Glenn S. Demby, Executive Editor

Barbara Manning Grimm, Managing Editor

Jim Pearmain, General Manager

Andrea Stowe, Business Development

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher

Lab Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

3. Genetic Discrimination

Another legal risk that your lab must navigate is ensuring that its vaccination pre-screening protocols don't discriminate against employees on the basis of genetic information in violation of the *Genetic Information Nondiscrimination Act* (GINA). Again, the EEOC guidance provides the greenlight on the GINA concern by specifying that requiring proof that employees have received a COVID-19 vaccine does not involve use of genetic information to make employment decisions nor the acquisition or disclosure of genetic information. But the EEOC also cautions that pre-screening questions that ask about genetic information potentially do violate GINA.

The EEOC also suggests a simple solution to the GINA problem: If employers require employees to provide proof of having received a COVID-19 vaccine from their healthcare provider, they "may want to warn the employee not to provide genetic information as part of the proof." EEOC said. As long as employers provide such a warning, any information they received in response wouldn't be considered unlawful under GINA, the agency added.

4. Duty to Accommodate

In implementing a mandatory vaccination or proof of vaccination policy, your lab must also be mindful of its duty to accommodate employees to the point of undue hardship. Such accommodations may include, depending on the circumstances, exemptions:

- For employees who can't take the vaccine due to disabilities or medical conditions;
- For employees for whom taking the vaccine would violate a sincerely held religious belief, practice or observance (or creed in states where creed is a protected class); and/or
- For employees to whom the vaccine isn't yet currently available, e.g., because they're 30 years of age and current state restrictions limit vaccine access to individuals age 45 or older.

Accommodations may also include allowing employees who cannot or will not furnish proof of vaccination to work from home or admitting them to the lab, provided that they can be physically self-isolated and agree to wear a mask, practice extra hygiene and engage in medical self-monitoring at all times.

Of course, the question of whether a particular accommodation is reasonable or undue hardship will vary by the circumstances involved. The only blanket rule is that there are no blanket rules other than the duty of the lab to perform an individualized assessment of each case, i.e., "engage in a flexible, interactive process to identify workplace accommodation options" based on how big a danger allowing that particular unvaccinated individual to enter the workplace.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Carolina Lab Owners Settle Kickback, False Claims Charges for Over $6 Million

Case: At its apex, Physicians Choice Laboratory Services (PCLS) had over 450 employees in North and South Carolina. But while PCLS is now defunct, the same cannot be said of its two former owners, Douglas Smith and Philip McHugh, who have just agreed to fork over, respectively, $4.5 million and $2,021,795 to settle charges of falsely billing Medicare for millions of dollars in lab drug testing services over a two-year period between 2013 and 2015.

Significance: Smith and McHugh were the kingpins in the alleged scheme under which PCLS paid physicians kickbacks in exchange for ordering tests from the lab. By subsequently billing Medicare for those services, the lab violated the False Claims Act. Smith is also one of the named defendants in a whistleblower lawsuit that a federal court in North Carolina said could go to trial in a May 2020 ruling. In December 2019, a former sales rep and lab manager for PCLS was assessed a penalty of nearly $650,000 for his role in the scheme.

Federal Court Tosses Age Discrimination Lawsuit against LabCorp

Case: Why did LabCorp terminate the 65-year-old microbiology department manager after 42 years of service? The manager claimed she was fired because of her age; LabCorp said she was fired for her steadily declining performance. The lower federal court sided with LabCorp and dismissed the manager's Age Discrimination in Employment Act (ADEA) claim without a trial. After reviewing the case for itself, the U.S. Court of Appeals for the 11th Circuit made the same determination.

Significance: As usual in ADEA cases, this case was all about the evidence, or lack thereof. All the manager had to support her accusation that LabCorp's performance concerns were a pretext for age discrimination was circumstantial evidence. By contrast, LabCorp had detailed records documenting the manager's poor performance, including metrics documenting the decline of the department starting in the years she assumed its management; it also produced warnings and other records of progressive disciplinary actions it took in the attempt, ultimately, unsuccessful, to help her improve [*Henderson v. Lab. Corp. of Am. Holdings*, 2021 U.S. App. LEXIS 10650, __ Fed. Appx. __, 2021 WL 1401462].

Massachusetts Mental Health Hospital Fined $65,000 for HIPAA Right of Access Violation

Case: The HIPAA Privacy Rule gives providers 30 days and, in some instances, 60 days to respond to patients' requests of access to their medical records. But it took Massachusetts behavioral health services provider Arbour Hospital five months and one Office for Civil Rights

(OCR) intervention to finally provide the records one of its patients had requested. In addition to a $65,000 fine, Arbour had to agree to implement corrective actions under OCR's supervision.

Significance: The OCR has now handed out 18 fines under its HIPAA Right of Access Initiative since launching it in April 2019 to enforce rules requiring providers to grant individuals' access to their own protected health information. So far, the highest of these fines is $200,000. Here's a Scorecard of all announced settlements to date.

OCR Right of Access Initiative Settlements Scorecard (as of April 28, 2021)

Provider	Settlement Amount*	Allegations
Banner Health ACE	$200,000	OCR cites two occasions in which Phoenix-based not-for-profit health system took about 6 months to provide patients their requested PHI
St. Joseph's Hospital and Medical Center	$160,000	Phoenix hospital refused to provide PHI to patient's mother even though she was his legal representative
NY Spine Medicine	$100,000	Neurology practice refuses patient's multiple requests for copies of specific diagnostic films
Bayfront Hospital	$85,000	Florida hospital didn't provide expectant mother timely access to the PHI of her unborn child
Korunda Medical	$85,000	After first refusing to provide it at all, Florida primary care and interventional pain management services provider sent patient's PHI to third party in the wrong format and charged him excessive fees
Renown Health, P.C.	$75,000	Nevada private, not-for-profit health system didn't timely honor patient's request to transfer her EHR and billing records to a third party
Sharp Rees-Stealy Medical Centers	$70,000	California hospital and healthcare network didn't timely honor request to transfer patient's EHR to a third party
Beth Israel Lahey Health Behavioral Services	$70,000	Massachusetts provider ignored request of personal representative seeking access to her father's PHI
Arbour Hospital	$65,000	Massachusetts mental health services provider kept patient waiting 5 months before granting access to his PHI
University of Cincinnati Medical Center, LLC	$65,000	Ohio academic medical center failed to respond to patient's request to send an electronic copy of her medical records maintained in its electronic health record EHR to her lawyers

Continued on page 6

Labs in Court, *from page 5*

Provider	Settlement Amount*	Allegations
Housing Works Inc.	$38,000	New York City non-profit services provider refused patient's request for a copy of his medical records
Peter Wrobel, M.D., P.C., dba Elite Primary Care	$36,000	Georgia primary care practice failed to provide patient access to his medical records
Village Plastic Surgery	$30,000	New Jersey practice failed to provide patient timely access to his medical records
Riverside Psychiatric Medical Group	$25,000	California medical group didn't provide patient copy of her medical records despite repeated requests and OCR intervention
Dr. Rajendra Bhayani	$15,000	NY physician didn't provide patient her medical records even after OCR intervened and closed the complaint
All Inclusive Medical Services, Inc.	$15,000	California multi-specialty family medicine clinic refused patient's requests to inspect and receive a copy of her records
Wise Psychiatry, PC	$10,000	Colorado psychiatric firm refused to provide personal representative access to his minor son's medical record
King MD	$3,500	Virginia psychiatric practice didn't provide patient access to her medical records even after OCR intervened, provided technical assistance and closed the complaint

*In addition to the monetary settlement, each accused provider had to agree to implement a corrective action plan and allow the OCR to conduct close monitoring for one to two years

Telemarketer Gets 10 Years in Jail for Genetic Screening Cancer Test Ripoff

Case: High price points have made cancer screening genetic (CGx) tests fertile grounds for false billing and kickback scams—and federal enforcement action. A new case involving the owner of a Florida telemarketing call center is a pretty good illustration of how these schemes work. Telemarketers targeted seniors with calls falsely stating that Medicare covers expensive CGx tests costing up to $6,000 apiece. The call center owner then paid kickbacks to telemedicine companies to get doctors' orders authorizing the tests. He then sold the genetic tests and doctor's orders to labs in exchange for illegal kickbacks, which he concealed by submitting invoices to the labs and other marketers making it look like he was being paid for hourly marketing services, rather than per referral. By the time it was uncovered, the scam had generated over $3.3 million in fraudulent CGx claims.

Significance: What makes this case somewhat unusual is what happened after the you-know-what hit the fan. Rather than take the safe path of settlement, the owner decided to take his chances with a trial. The strategy backfired when the federal jury returned a guilty verdict on seven counts, including health care fraud and receiving illegal kickbacks. And now the court has pronounced sentence: 10 years in a federal prison.

Colorado Grand Jury Hands Down First of What Promises to Be Many COVID Relief Fraud Indictments

Case: Almost from the moment Congress passed COVID-19 relief programs, federal enforcement agents have been sounding the warning on relief fraud scams. And now the prosecutions have begun. In one of the first cases, the Justice Department indicted a 56-year-old Colorado man for stealing nearly $300,000 from three different COVID relief programs. The feds claim the accused siphoned the money from a medical clinic's account into his own personal bank account and spent it on travel and lavish home improvements.

Significance: The COVID relief programs allegedly targeted in this case are the ones in which many labs and lab owners participated, including:

- The Accelerated and Advance Payment Program, which provides reimbursement funds in advance of service to help labs and other Medicare providers maintain cash flow during national emergencies;
- The $50 billion Provider Relief Fund for labs and other providers involved in coronavirus response; and
- The Paycheck Protection Program providing 1 percent loans to help small businesses meet their payroll, rent, mortgage and utilities obligations.

PAMA: Labs Lose a Battle But May Win the War Over Market-Based Pricing

In its crusade to get CMS to fix its warped Protecting Access to Medicare Act of 2014 (PAMA) market-based Medicare Part B pricing scheme, the lab industry lost a battle but may still end up winning the war. Here's a rundown of the rollercoaster PAMA developments and what they may portend for your lab.

The Pollution & Perversion of PAMA Market Pricing

Back in 2014, the idea of substituting traditional Medicare Part B Clinical Laboratory Fee Schedule (CLFS) payment system in which rates were based on local, historical lab charges, updated for inflation, and capped at certain amounts with a system basing prices on real market rates seemed like an excellent idea whose time had come. Nor was there any

Continued on page 8

PAMA: Labs Lose a Battle But May Win the War Over Market-Based Pricing, *from page 7*

real objection to putting CMS in charge of determining what those market rates were by requiring "applicable laboratories" to report data on what they charge private payors for particular tests.

The problems began not with the actual PAMA statute but the way CMS went about implementing it, specifically its decision to exclude hospital labs from the definition of "applicable laboratories" required to report pricing data. As a result, CMS relied almost exclusively on data from independent labs to set CLFS rates, omitting hospital labs who provide so many of those tests and who also have the leverage to command higher rates from payors. As it always did, garbage in led to garbage out, in the form of an artificially deflated CLFS that threatened to drive independent labs out of business.

After repeated delays, the new "market-based" CLFS went into effect in 2018. But while financial damage has already been done, the worst is yet to come in 2025 when the full brunt of previously deferred PAMA cuts are phased in. Although CMS has made some concessions, most notably in January 2019 when it agreed to broaden the definition of "applicable laboratories" to include some hospital labs, independent labs are still reeling from PAMA.

PAMA Resistance: Losses in Court

For nearly a decade, the lab industry has pushed back against CMS' PAMA pricing scheme. Resistance has been along several fronts, including the courts. But other than keeping the pressure on CMS, the litigation effort has borne little fruit. The most recent, and perhaps fatal setback, came on March 30, 2021 when the federal D.C. district court once more tossed the case brought by the American Clinical Laboratories Association (ACLA) challenging the legality of the CMS PAMA system.

One problem faced by the ACLA attorney was the provision in PAMA barring court review of the "establishment of payment amounts." Besides, CMS argued, the definition of "applicable laboratory" was a moot issue since the PAMA pricing scheme already took effect in 2018. We're not challenging the pricing scheme, the ACLA countered, but the pricing data collection scheme which remains very much ongoing. Ultimately, the court agreed with CMS on both the statutory bar on court review and the mootness of the dispute and dismissed the case [*Am. Clinical Lab. Ass'n v. Becerra*, 2021 U.S. Dist. LEXIS 60622].

PAMA Resistance: Promising Developments on the Congressional Front

In fact, the ACLA lawsuit may actually prove to be moot, but for different reasons. Real PAMA pricing relief may be on the way from another source, namely, the Medicare Payment Advisory Commission (MedPAC), an independent, non-partisan agency created by the *Balanced Budget Act of 1997* to advise Congress on Medicare reimbursement to private health plans and providers, care quality and other issues. Congress has charged

MedPAC with reviewing the methodology used by CMS to implement market-based pricing of CLFS tests under PAMA, as well as the reporting methods the agency uses to gather the data on which it bases those prices, and submit a written report of its findings in June 2021.

As bad as things are now, the distorted CMS scheme will drag prices down even further when the deferred cuts take effect in 2025. MedPAC Senior Research Assistant Carolyn San Soucie said payment rates will decrease by an estimated 24 percent once the rates are implemented.

In addition, private payor rates reported by labs were generally lower than Medicare's 2017 average payment rates for 77 percent of tests, but higher for about 23 percent of tests. MedPAC noted that although lab test utilization was stable overall from 2017 to 2019, there were "sharp increases in the use of new, high-cost tests," such as complex genetic tests. As a result, Medicare Part B lab spending actually increased from $7.1 billion to more than $7.5 billion.

Spending on chemistry tests declined 14 percent, in line with PAMA expectations, while molecular pathology spending increased due to higher use of the tests. Panel test spending didn't decline as expected, which MedPAC attributed to unbundling and a "generous phase-in of payment rate reductions under PAMA."

MedPAC & PAMA Reporting

MedPAC is also looking into ways to reduce the reporting burden on labs and asked a third-party contractor, RTI, to perform an analysis of the

Continued on page 10

PAMA: Labs Lose a Battle But May Win the War Over Market-Based Pricing, *from page 9*

different survey methodologies that could be used to collect representative and statistically valid samples. RTI evaluated multiple sampling techniques based on two criteria:

- The extent to which a survey could produce accurate estimates of private payer prices for each type of lab; and
- How many labs would have to report data to generate accurate price estimates.

Using Medicare claims and private payer data to simulate the results of a survey, RTI concluded that setting Medicare payment rates using a survey is feasible and could substantially reduce the reporting burden on labs. RTI found that a survey could produce accurate estimates of private payer rates for all three types of labs that generate the vast bulk of CLFS tests, i.e., independent, hospital outpatient and physician office labs. Even a survey with a minimum as low as 10 labs reporting data for each particular test could reduce the number of labs required to report private payor data by up to 70 percent.

Setting Medicare payment rates on a representative sample of labs would increase program spending by 10 to 15 percent, as compared to the spending that would result from Medicare's current rates. This increase varied depending on different parameters for different labs, such as only including tests from hospital outpatient labs that were furnished to non-patients.

Although the estimates "should not be considered precise point estimates," the MedPAC representative noted that going from rates based largely on independent labs to rates based on data from a broader assortment of labs will likely increase Medicare spending significantly.

MedPAC also noted examples where basing payment rates on a sample of private payor rates may not be ideal, namely for routine tests and genetic tests. For routine tests, RTI found that policymakers should exclude high private payor rates resulting from negotiating power rather than the actual costs of providing the test. Medicare should instead set payment rates to ensure beneficiary access while maintaining incentives on laboratories to make better use of taxpayer and beneficiary resources. Policymakers could focus on "efficient laboratories" instead of all labs to exclude these high private payor rates.

For high-cost tests, MedPAC said private payors may have a limited ability to negotiate rates because they're more complex and proprietary. As a result, the representative suggested that in the future the Commission would "consider alternative ways to set payment rates for new, high-cost technologies, including certain pharmaceuticals, devices, and laboratory tests."

Takeaway

MedPAC has asked for comments on its findings and intends to use the feedback in the final report it issues to Congress in June. And when that report does come out, it will likely have significant influence. Just as important is the timing. While the devastation wrought by PAMA pricing in the past three years can't be undone, there's still time to fix the mess before the bottom falls out in 2025.

■ In the News: Ambry Genetics Case Shows Why It's So Hard for Patients to Win a HIPAA Data Breach Class Action Lawsuit, *from page 1*

insurance and medical information, and in some cases, Social Security numbers. The good news is that unlike many organizations that get hacked, the California genetic testing lab did what HIPPA required it to do in responding to the incident. It investigated the matter, reported the breach to authorities and the victims and promised to implement corrective actions to ensure something like this would never happen again. It even offered affected patients complementary identity monitoring services.

But like so many other providers that suffer cybersecurity data breaches these days, Ambry faced the liability nightmare of a class action suit. A group of 24 victims from 15 states sued, claiming that the provider of more than 300 different genetic tests committed negligence, invasion of privacy, breach of contract and violation of state privacy and business laws, among other things. The data breach, they contended, was a "direct result" of Ambry's failure to implement "adequate and reasonable" cybersecurity systems and protocols in violation of its HIPAA duties to protect the sensitive personal data of its patients. "Had [Ambry] remedied the deficiencies in its data security systems and adopted security measures recommended by experts in the field," the breach wouldn't have happened.

California Court Dismisses the Class Action

Of course, it's one thing to make allegations and quite another to prove them. The US District Court for the Central District of California emphasized this point in dismissing the class action on April 7, 2021, finding that the patients "failed to plausibly allege that their injuries were caused by" Ambry's actions. "The problem," the judge continued, is that the alleged harm "is not fairly traceable—at least not plausibly so—to the conduct they complain of." For example, the patients alleged that unauthorized third parties obtained their passwords but don't allege that their passwords were actually stolen in the breach.

Still, what Ambry won was only a temporary reprieve. The basis of the ruling isn't about the truth and substance of the charges so much as the way the patients expressed them. Thus, the judge gave the patients two weeks to fix their pleadings.

Continued on page 12

In the News: Ambry Genetics Case Shows Why It's So Hard for Patients to Win a HIPAA Data Breach Class Action Lawsuit, *From Page 11*

What Happens Next

If and when they take advantage of the opportunity to restate their allegations, the patients will face the same obstacles that have caused so many other HIPAA data breach class actions: traceability. Specifically, they'll need to come up with evidence of exactly what personal data the hackers stole, something that's difficult even for breach victims. They'll then have to trace how the hackers used that information. Moreover, there's also the risk that the court will break up the class action and require the patients to sue individually based on their own personal losses.

All of this sets up for what is likely to prove the decisive round in the litigation: the motion to dismiss on the merits. Ambry will probably claim that the patients don't have a valid legal claim and ask the judge to dismiss it without a trial. If they win the motion to dismiss, the patients will be hard pressed to continue the lawsuit. However, if they survive the motion and get the right to go to trial, the leverage will shift and the patients will be in the position to obtain a six- or seven-figure settlement. Of course, Ambry could always call their bluff and force them to prove their claims at trial.

Takeaway

The Ambry case is fascinating not only because of its size and the fact that it involves a clinical lab but also because its dynamics are so typical of HIPAA data breach class actions. The bottom line is that these lawsuits fail more often than they succeed, with a favorable settlement representing the best possible outcome for the plaintiffs. On the other hand, the stakes are extremely high and there's always the risk/hope for—depending on your perspective—a finding of liability resulting in a huge damages award.