G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

August 2019

INSIDE THIS ISSUE

Compliance Perspectives: Complying with HIPAA Isn't Enough to Manage Data Breach Liability Risks

Memo to lab managers and compliance officers: It may be time to rethink your data breach response strategy. This directive is the result not of any substantive changes to the HIPAA rules but rather to how they are likely to be enforced from now on. The punchline: Messing up your HIPAA breach response and reporting may get you into trouble with not just the federal Office of Civil Rights (OCR) but also the Attorneys General (AGs) of every state of patients harmed by the breach. Here's a look at this new compliance hazard and the nine safeguards you need to manage it.

New Data Breach Case Signals New Approach to Breach Enforcement

The concern over state enforcement comes from a groundbreaking new case involving a medical software provider named Medical Informatics Engineering (MIE). The company licenses a web-based electronic health record application called WebChart and its subsidiary, NoMoreClipboard (NMC), provides patient portal and personal health record services to health care providers

Continued on page 2

Medicare Reimbursement: MIPS Bonuses Are Easy to Earn—IF You Can Get into the Program

On July 11, CMS announced the results of 2018, Year 2 under the Merit-based Incentive Payment System (MIPS). Bottom line: The total number of clinicians participating declined from 1.06 million to 916,058. However, the success rate of participants was higher with 97.6% earning an upward payment adjustment on their Medicare Part B claims for 2020, as opposed to the 93.1% of clinicians who got a bonus last year. The Table below summarizes the key general MIPS participation data among individuals, groups and those who participated through a MIPS Alternative Payment Model (APM).

Continued on page 9

COMPLIANCE PERSPECTIVES, *from page 1*

allowing patients to access and manage their health information. The troubles began when MIE installed two generic accounts, one having a shared password of "tester" and the other having a shared password of "testing." Neither included a unique user identification name. These accounts were flagged as "high risk" by a formal penetration test conducted in January 2015. But MIE decided not to eliminate them because it didn't want to deny a client request for the capacity to login without using unique usernames and passwords.

Later that year, hackers used the generic accounts to launch an SQL (structured query language) injection attack and insert malware on MIE's system, compromising the electronic protected health information (ePHI) of approximately 3.5 million individuals.

First the Feds, then the States Go After MIE

The OCR cited MIE for HIPAA violations resulting in a $100,000 settlement. Although it's not unusual for states to file separate privacy law charges on behalf of state residents harmed by the breach, there had never been a multistate HIPAA data breach lawsuit before. So, it was pretty eye-opening when AGs from no fewer 16 different states (including Arizona, Arkansas, Connecticut, Florida, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Nebraska, North Carolina, Tennessee, West Virginia and Wisconsin) banded together to go after MIE in Indiana federal court.

In addition to wielding their statutory authority to enforce the federal HIPAA laws, the AGs brought claims under their own respective state data breach and personal information protection statutes contending, among other things, that that hackers had exploited MIE's poor password protection policies and that MIE failed to follow its own security management protocols. Result: MIE was accused of 38 separate counts of state law violations stemming from the same breach. Outnumbered and out-resourced, MIE agreed to pay $900,000 to settle all the charges. It also agreed to implement an onerous corrective action plan.

Potential Impact on Your Lab

As if HIPAA and data security breaches weren't already damaging enough, the potential for multistate enforcement stemming from a single breach ups the ante exponentially. Labs are especially vulnerable given:

- Their reliance on web-based applications for ePHI management that hackers love to target; and
- The fact that they manage ePHI of residents from multiple states.

The concern, of course, is that if a data breach occurs at your lab, you could be subject to the same 1-2 punch of the OCR followed by state AGs administered to MIE. The greater the size of your ePHI management

LCA

Glenn S. Demby, Executive Editor
Elayne Demby, Contributing Editor
Paula Santonocito, Contributing Editor
Lori Solomon, Contributing Editor
Barbara Manning Grimm, Managing Editor
Brian Sharples, Layout & Design
Myra Langsam, Business Development
Michael Sherman, Director of Marketing
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.

network and the more states it spans, the greater your liability risks.

9 Things to Do to Protect Your Lab

The key to managing liability risks is to dedicate proper resources and energy to ePHI protections and data response mechanisms and ensure that any and all of your lab business associates that handle that information do likewise. That means ensuring you understand and comply with not only the HIPAA Security Rule but also state privacy, deceptive trade practices and other laws regulating the collection, maintenance and safeguarding of consumers' ePHI.

Exactly what do you need to do to stay out of trouble with the state AGs? Perhaps the best way to answer that question is to implement at least the 10 measures MIE had to agree to under the consent judgment:

1. Implement and maintain an information security program that includes a security incident and event monitoring solution enabling quick detection and response to cyber-attacks;
2. Deploy data loss prevention technology to prevent unauthorized exfiltration of data;
3. Implement controls to prevent SQL injection attacks;
4. Maintain and regularly review activity logs;
5. Ensure password policies require the use of strong, complex passwords and multi-factor authentication as well as single sign-on for all systems that store or are used to access ePHI;
6. Implement additional controls covering the creation of accounts that have access to ePHI;
7. Refrain from using generic accounts that can be accessed via the internet;
8. Ensure that no generic accounts are allowed to have administrative privileges; and
9. Provide appropriate training to all employees regarding your lab's information security policies and procedures at least annually.

Enforcement Trends: New Emphasis on MD Practices Puts Labs at Growing Risk of Antitrust Enforcement

In addition to the usual Medicare and Medicaid anti-fraud laws, labs have a new liability risk to contend with: stepped-up federal and state enforcement of antitrust laws. The driving force behind this new emphasis on preventing and breaking up health care monopolies is consolidation and growing concern over purchases of physician's practices by hospitals and insurers. And, of course, this puts not only physician and hospital labs but just about all labs squarely in the bull's eye.

Higher Consumer Prices & Consolidation

Application of antitrust laws to big transactions within the health

Continued on page 4

ENFORCEMENT TRENDS, *from page 3*

care sector is nothing new. But the rate and scope of enforcement are increasing as a result of the two phenomena within health care that bring the antitrust laws into play, namely, rising consumer costs coupled with market consolidation. The big health care players are gobbling up medical practices at an accelerated rate.

While health care organizations claim that consolidation leads to savings for consumers, the facts seem to indicate otherwise. Researchers have found that acquisitions have increased prices for health care consumers, which in turn drives up the costs of payors footing the bill, including federal and state government. For example, according to one study done in 2018 by the University of California at Berkeley, average outpatient physician prices ranged from 35% to 65% higher in highly concentrated California markets, as compared to less concentrated markets.

Impact on Antitrust Law Enforcement

Although federal antitrust enforcement within the health care sector is nothing new, historically, it has focused on large mergers, acquisitions and other multistate transactions involving major entities like insurance companies, large health care networks and hospitals. Because their smaller in size and market impact, physician practice mergers and acquisitions have flown under the federal radar and been left to state enforcers.

But things are changing. Federal antitrust enforcement targeting physician group mergers and acquisitions is becoming far more common. Consider the following examples in which the Federal Trade Commission (FTC) stepped in to block a big player from acquiring a local physician group.

UnitedHealth's Acquisition of DaVita Medical Group

In June 2019, the Federal Trade Commission (FTC) announced a settlement to unwind UnitedHealth Group's acquisition of DaVita Medical Group's Las Vegas operations. The FTC argued that the acquisition by United's OptumCare of DaVita's HealthCare Partners of Nevada would create a near-monopoly controlling more than 80% of the market for services delivered by managed-care provider organizations to Medicare Advantage plans. The combination, it contended, would also combine a Medicare Advantage insurer and a physician group. Both types of combinations, horizontal and vertical, FTC said would increase costs and decrease competition on quality, services and amenities by forcing rival Medicare Advantage plans to pay more for physician services.

Under the settlement, UnitedHealth agreed to sell DaVita's Nevada medical group to Intermountain Healthcare, which offers a Medicare Advantage product in Las Vegas through its SelectHealth insurance arm.

Sanford Health's Acquisition of Mid Dakota Clinic

In 2017, the FTC and Attorney General of North Dakota stepped in to

block Sanford Health's acquisition of Mid Dakota Clinic that they claimed would eliminate local competition. The federal District Court agreed and issued a preliminary injunction, characterizing the acquisition as a horizontal merger that would leave Sanford in control of 99.8% of general surgeon services, 98.6% of pediatric services, 85.7% of adult primary-care services, and 84.6% of OB-GYN services in the state's Bismarck-Mandan market. In June, as the FTC was settling with UnitedHealth, the 8th U.S. Circuit Court of Appeals upheld the lower court's ruling. The appeals court rejected Sanford's "powerful buyer" argument that Blue Cross and Blue Shield of North Dakota, the state's dominant insurer, had enough market power to resist any price increases on the basis of claims data analysis demonstrating the considerable market power the merged entity would have if the deal went through.

State Antitrust Law Enforcement

Of course, the states also have their own antitrust laws and enforcement regimes, typically targeting smaller transactions whose impacts are felt principally in the local market, including mergers, acquisitions and other transactions involving physician practices–generally state law and enforcement initiatives. Recent cases suggest that state attorneys general are being more aggressive in policing physician acquisition deals.

Colorado's Actions against UnitedHealth

Citing the harmful effects of "consolidation," Colorado Attorney General Phil Weiser recently resolved a lawsuit imposing conditions on UnitedHealth's acquisition of DaVita's physician groups in Colorado Springs. Additionally, under a separate consent judgment, UnitedHealth agreed to lift its exclusive contract with Centura Health for at least 3 1/2 years, expanding the provider network available to other Medicare Advantage plans. Weiser said in an interview, because health care costs in Colorado had been rising at an alarming rate. Weiser said his office had to intervene to protect the ability of Humana and other Medicare Advantage insurers to compete with United by having access to physicians and hospitals. "State attorneys general will be a critical part of protecting competition, both because we're close to our citizens and because of a lack of action by the federal government," he said.

Washington's Actions against CHI Franciscan

In May, Washington settled an antitrust lawsuit with CHI Franciscan setting conditions on the health system's 2016 affiliation with the Doctors Clinic and its purchase of WestSound Orthopaedics, both in Kitsap County. CHI Franciscan will pay up to $2.5 million, distributed to other health care organizations to increase access to care. The state attorney general claimed that transaction was designed to capture a large share of orthopedists and other physicians in Kitsap County, fix prices at a higher level, and shift more services to its Harrison Medical Center in Bremerton.

Continued on page 6

ENFORCEMENT TRENDS, *from page 5*

New State Antitrust Notification Laws May Impact Labs

Washington and other states have either passed or are looking into adopting laws requiring health care providers to give state officials advance notice before finalizing a merger or acquisition. Under federal rules, FTC advance notice is required for deals exceeding $78.2 million in value, a threshold that very few physician acquisitions ever meet.

Takeaway: Antitrust enforcement is becoming more aggressive at both the federal and local levels. For labs, the most immediate impact of this trend is the new focus on physician practice mergers and acquisitions. Ostensibly, these efforts don't directly target labs. However, because of their physician-related ownership and business structures, labs, especially small and mid-sized ones, are likely to get swept into the antitrust enforcement net.

Kickbacks: Massachusetts Practice Latest Provider Busted for Taking Kickbacks from Millennium

A northern Massachusetts medical practice became the latest downstream provider to pay the OIG a five-figure fine to settle kickback claims in the form of accepting free point-of-care test cups from now defunct Millennium Health. The settlement amount, $87,650, is the among the highest announced since autumn 2017 when the feds began targeting the physicians on the receiving end of the Millennium scandal. Millennium used the freebies to pay physicians for referrals of custom profile panels and other tests to carry out what the feds claim is the largest ever kickback scandal involving lab services.

Phase 1 of the Millennium Case

While the key charges against Millennium involved use of custom profiles to bill Medicare for medically unnecessary tests, prosecutors also claimed that Millennium provided free POCT cups with embedded testing strips to physicians in exchange for referral of urine specimens in violation of the Antikickback Statute (AKS) and Stark Law. Physicians allegedly agreed not to bill any insurer for the cups and return the specimen samples in each cup to Millennium for additional, often more expensive lab testing. Millennium also charged physicians who did not return the cup for further testing.

The key to the legal case is the finding that free cups to physicians crossed the AKS and Stark Law line on paying "remuneration" for referrals. The

Stark Law specifically says that banned "remuneration" *does not* include "[t]he provision of items, devices or supplies that are used solely to (i) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or (ii) order or communicate the results of tests or procedures for such entity." Although there is no such "carve out" for *de minimus* remuneration in the AKS, the OIG has made clear in starting with its 1994 Laboratory Fraud Alert that provision of supplies and equipment under those limited circumstances do not implicate the AKS.

But during the trial, the DOJ argued that "the 'cup agreements'. . . create exactly the sort of intertwined financial relationships in the health care system that the Stark Law and AKS are designed to prohibit. . . .The purpose and effect of this arrangement was to give doctors a significant financial incentive to obtain laboratory testing of each sample collected in a POCT cup and to obtain such testing from Millennium rather than a competitor."

In October 2016, Millennium tossed in the towel and agreed to settle all claims for $256 million, a record high settlement involving health care fraud by a lab. Almost inevitably, prosecutors then began to target the downstream providers who accepted the free cups from Millennium.

Phase 2 of the Millennium Case

In the past, federal enforcement efforts have focused on the payer rather than the payee of kickback arrangements for obvious reasons—that's where most of the money is. Going after the one wrongdoer who paid out the money is also far more cost-effective than chasing after the individual payees who accepted the money.

But for sheer scale, Millennium was like no kickback arrangement before it. Given the dollar volume and extent of the scheme, initiating a phase 2 concentrating on the downstream payees made sense. And that's just what the feds have done, spending the past two years going after physicians one practice at a time. The Table below documents the announced settlements these efforts have generated to date.

Continued on page 8

KICKBACKS, *from page 7*

Millennium Free POCT Cup Physicians Settlement Scorecard (as of July 1, 2019)

Date	Provider(s)	Settlement Amount	Individual Physicians Also Charged?
June 14, 2019	HKD Treatment Options, P.C.	$87,650	NO
Dec. 21, 2018	Tulsa Pain Consultants, Inc.	$98,942	YES
Sept. 6, 2018	Doctor's Inlet Pediatrics and Primary Care, P.A., and Avenues Pediatrics and Internal Medicine (Florida)	$58,370	YES
May 24, 2018	Recovery Pathways, LLC (Michigan)	$64,555	NO
April 5, 2018	Affordable Medical Care f/k/a Andalusia Medical Center (Alabama)	$40,500	YES
Feb. 28, 2018	The Pain Institute, Inc. d/b/a Space Coast Pain Institute (Florida)	$95,302	YES
Dec. 5, 2017	Addiction Medical Care of Norwalk, Practice Management Associates Norwalk, LLC, Addiction Medical Care of Columbus, and Practice Management Associates, LLC (collectively, "AMC") (Ohio)	$79,880	NO
Sept. 27, 2017	Advanced Pain Management (Arizona)	$186,210	NO
Sept. 18, 2017	Parallax Center, Inc. (New York)	$64,203	NO

Takeaway: It's Happening Again with HDL

The DOJ and OIG are following the exact same template in cracking down on the other massive lab kickbacks fraud scheme, the HDL and Singulex case. So far, settlements with at least two different sets of practices have been announced with many more sure to follow.

MEDICARE REIMBURSEMENT, *from page 1*

Quality Payment Program (QPP) Participation Results: 2018 vs. 2017

Metric	2018	2017
Clinicians receiving MIPS payment adjustment (positive, neutral, or negative)	916,058	1,057,824
Percentage of clinicians above performance threshold(1)	93.63%	93.12%
Percentage of clinicians at performance threshold	0.42%	2.01%
Percentage of clinicians below performance threshold	1.95%	4.87%
Qualifying APM Participants (QPs) excluded from MIPS	183,306	99,076
Partial QPs (including those who elected to participate in MIPS)	139	52

Source: CMS, *Quality Payment Program Releases 2017 Physician Compare Data and Sees Increases in Clinician Participation Rates and Success for 2018*, July 11, 2019

Note:
(1) The performance threshold was 3 in 2017 and 15.01 in 2018

What It Means

The decline in participation neutralizes at least to some degree the high bonus rates silver lining. What it suggests is that it's too hard for clinicians to get into the program and too easy for clinicians who do get in to earn positive payment adjustments. In 2018, CMS implemented a new rule requiring clinicians to have at least $90,000 in Medicare revenues and more than 200 Medicare patients to participate in MIPS (as opposed to $30,000 and 100 patients in 2017). As a result, excluded clinicians nearly doubled to 183,000 during the year.

Some believe that it's also too easy for clinicians to meet MIPS upward payment adjustment criteria. Clinicians are scored on a scale of 1 to 100 on the basis of three performance categories: quality, clinical practice improvement and interoperability. Costs make up the remaining 10% of the score. To qualify for a bonus, clinicians must exceed a specific score threshold. In 2017, the threshold score was only three points. In response to criticism about the threshold's being too easy, CMS raised it to 15.01 points in 2018. But many still believe the score is too low. And based on this year's 97.6% clinicians earning bonuses rate, they seem to have a point.

Developing Story: Doubt Grows as Obamacare Court War Enters Round 2

Heartburn over the survival of Obamacare is back with a vengeance. It reawakened seven months ago, after a Texas U.S. District Court found The Affordable Care Act unconstitutional—not just the individual mandate but the entire law! Proceedings on the appeal officially began on July 16. Of

Continued on page 10

Labs In Court, *from page 9*

course, we all knew that an appeal was coming. And for those who want to see Obamacare continue, that was supposed to be good news. After all, the consensus among legal experts is that the lower court ruling wouldn't stand.

That may ultimately prove true. But the opening signs suggest that the Fifth Circuit may be prepared to defy expectations. Just two hours into the first day of oral arguments, two of the judges on the three-judge panel, both Republican appointees, aggressively questioned the Democratic attorneys defending the law challenging them to explain how any part of the law can stand if, as all concede, the mandate is unconstitutional.

Should the Fifth Circuit do the unthinkable and strike down the entirety of the ACA, it will pave the way for a Supreme Court showdown, not to mention a massive wave of disruption in health insurance markets. We'll keep you apprised as things develop. Meanwhile, for a complete analysis of the latest court challenge against Obamacare, see *Lab Compliance Advisor (LCA)*, Dec. 31, 2018 and *National Intelligence Report (NIR)*, April 15, 2019.

Labs IN COURT

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

Drug Abuse Treatment Owner Guilty of $57 Million Drug Test Pass-Thru Billing Conspiracy

Case: The owner of a northern Florida substance abuse treatment center pleaded guilty for his role in a $57 million pass-through lab testing billing and money laundering scheme. The way it worked: The treatment center owner cut a deal with a lab owner to send patient urine samples to the lab for urine drug testing in exchange for a 40% share of the insurance reimbursements. The lab owner did his part by arranging with managers of two rural hospitals to bill private insurers to secure the highest possible rates for the tests.

Significance: Making the scheme even more egregious is that the same treatment center owner also brokered parallel urine drug testing deals between the rural hospitals and other substance abuse facilities, pocketing 30% of reimbursements as his commission. In addition to forfeiting $10.2 million in ill-gotten gains, he's looking at a high fine and time behind bars when sentencing is handed down.

Florida Medical Center Fined $102.2K for Accepting Processing Fees from HDL

Case: Southern Florida-based Midland Medical, Inc. and its subsidiary are the latest providers to settle claims of accepting kickbacks in the form of blood collection "process and handling" payment from Health Diagnostic Laboratory, Inc. and Singulex, Inc. The settlement amount of $102,204 is the highest announced so far.

Significance: The HDL case began as a *qui tam* whistleblower lawsuit alleging payments of kickbacks disguised as processing fees of $10 to $17 per test to physicians in exchange for orders of medically unnecessary

blood tests that were subsequently billed to Medicare and TRICARE. In April 2015, the case settled with HDL agreeing to pay $47 million and Singulex $1.5 million and enter into Corporate Integrity Agreements. Now, as happened with the Millennium Labs case, the feds are targeting the downstream physicians to accept kickbacks from a major lab. On May 20, 2019, a pair of physicians and their Missouri practice entered into a $96,880 settlement agreement for accepting process and handling payments related from HDL.

Lab Uses Billing Info of Another Lab to Get Around Payment Restrictions

Case: In 2015, Kentucky Medicaid and private payors began having doubts about the legitimacy of urine drug test claims submitted by CAL Laboratory Services and restricted payments to the toxicology lab. Undeterred, the owner of CAL arranged with his counterpart at Tristate Medical Laboratories to have tests referred to and performed by CAL billed to health insurance programs using Tristate's billing information to make it look like Tristate performed the tests. In exchange, he paid Tristate's owner 40% of the $1.3 million in fraudulent reimbursements received on the tests.

Significance: Four principals of CAL and Tristate pleaded guilty to their role in the conspiracy. Two of the defendants died after being convicted; the other two are awaiting sentencing. In addition to fines and possible prison, the owner of Tristate is likely to get a 10-year Medicare and Medicaid exclusion.

Nevada Clinic Pays $2.5 Million to Settle Genetic Testing Kickback Charges

Case: The feds accused Nevada Heart & Vascular Center (NHVC) of taking kickbacks from a pair of now defunct genetic testing companies Natural Molecular Testing Corp. and Iverson Genetic Diagnostics, Inc., in exchange for referrals of Medicare patients over a roughly two-year period starting in September 2012. Rather than risk trial, NHVC shelled out $2.5 million to settle the case.

Significance: The $2.5 million recovered from NHVC is chump change compared to the $90 million in fraudulent payments ($71 million to Natural Molecular and $19 million to Iverson) allegedly made to the labs that declared bankruptcy before CMS could get any of that money back. Genetic test labs going bankrupt after being busted for Medicare fraud has become a pattern with other notable examples including Texas-based Companion Dx and Pharmacogenetics Diagnostic Laboratory LLC in Louisville.

Florida Marketer Convicted of Genetic Testing Kickbacks

Case: Speaking of genetic testing fraud, a federal jury found the owner of a Tampa medical marketing firm guilty of taking part in a $2.2 million scam involving payment of cash bribes to medical clinics in exchange for referral of DNA swabs collected from Medicare patients. The owner allegedly instructed the clinics to collect DNA from all patients regardless

Continued on page 12

LABS IN COURT, *From Page 11*

of medical necessity.

Significance: In addition to the fact that it went to trial, the other notable thing about this case is the financial dimension. What began as a series of direct cash payments evolved in the course of one year to a sophisticated arrangement involving shell companies. During the trial, the prosecution contended that the defendant went from ATM to ATM across south Florida to make separate withdrawals of thousands of dollars in an effort to conceal the scam and stay under the $10,000 deposit threshold for filing federal currency transaction reports to the US Treasury Dept.

Kickback Scheme Gets Missouri Lab Owner 30 Months & $3 Million

Case: The 62-year-old Illinois man paid "marketers" $150 to $200 (50% of the profits) per urine and saliva sample for referrals of Medicare and Medicaid patients to his labs operating in Missouri and other states under the name of AMS Medical Laboratory Inc. Some test orders listed doctors who never saw the patient and had no idea their names were being used for the scam.

Significance: In April, a federal jury in St. Louis convicted three of the marketers who were on the receiving end of the 50% profit payments. Altogether, 10 defendants have been charged in the case, including a doctor found guilty of conspiracy and four counts of health care fraud at trial last October.