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Digital Physician Signatures!
HHS issues proposed rule to update HIPAA statute
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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

What's Next in 2023 for Clinical Laboratories?

As you open this issue of The Dark Report, in New Orleans, about 900 senior lab administrators, executives, and pathologists will be gathered at the *28th annual Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*. One big question that will be asked is: What's next for clinical labs during the balance of 2023?

The good news is that, with the passage of the first quarter of 2023, no significant disruption to the status quo in the clinical laboratory marketplace occurred. It was only 37 months ago—in the first quarter of 2020—that the SARS-CoV-2 pandemic erupted. Life in this country, in healthcare, and in medical laboratories has not been the same since.

Today, probably the two most stressful elements of operating a lab involve constant pressure to cut costs and the inadequate supply of medical technologists (MTs) and other lab scientists. It is true that both sources of stress existed before the outbreak. But the pandemic triggered a host of new factors that have changed the operation of hospitals, clinical labs, and other healthcare providers. This may be best illustrated by the example of temporary workers to fill staffing gaps. Hospitals cannot hire enough nurses at wages double and triple what was common in 2019. It is reported that temporary nurses are being paid as much as $4,000 per week in some states!

This is also true in the lab sector. Clinical labs are paying substantially higher wages for all skilled positions necessary to sustain operations. Nevertheless, they are finding it difficult to attract, hire, and retain enough qualified personnel to meet staffing needs.

All of these issues will be front and center at this year's *Executive War College*. With 125 speakers and panelists scheduled in more than 80 sessions, there will be plenty of discussion and insights about what is and what is not working for today's labs.

At the same time, there will be keen interest in what these innovative lab leaders predict for the lab industry through the balance of 2023. Might the VALID Act that would authorize the FDA to regulate LDTs pass this year? Will multi-hospital health systems continue to buy or merge with each other? Is the time ripe for retail pharmacy chains to establish primary care clinics in their stores? These are just a few of the questions to be addressed next week at the *Executive War College* in New Orleans. Hope to see you there! TDR

Draft Rule Standardizes Electronic Signatures

HHS ready to update HIPAA statute by defining electronic signatures, healthcare attachments

CEO SUMMARY: Every year, payers refuse laboratory test claims on grounds that the ordering provider's signature is missing or illegible—a situation that costs clinical labs million of dollars in missed reimbursements. This situation might change once a proposed rule from the U.S. Department of Health and Human Services is implemented that defines and standardizes physician electronic signatures.

ELECTRONIC PROVIDER SIGNATURES WILL BE DEFINED AND ENABLED by a proposed federal rule to revise the HIPAA statute. Looking forward, implementation of the final rule will be useful to clinical laboratories in helping them meet state requirements that require physician signatures on lab test requisitions.

"Labs lose millions of dollars in payments from government and commercial payers due to claimed missing or illegible physician signatures—in large part due to varying requirements for proof of signatures," said attorney Jeffrey Sherrin, Esq., an attorney with law firm **O'Connell & Aronowitz** in Albany, New York.

Implementing a new federal rule for "standardizing the requirements [for digital signatures] and recognizing that physicians may use different means of showing that tests were properly ordered can help resolve this problem, much to the benefit of providers, payers, and patients," Sherrin emphasized.

On the surface, the proposed rule may benefit clinical laboratories and pathology groups that run into problems obtaining consistent physician signatures on test requisitions. Important information to note about the rule includes the following:

- The rule would expand the types of electronic signatures that are recognized to encompass most forms of commonly used digital marks.
- It would also offer a new format for the transmission of provider electronic signatures that would allow them to be sent, received, and interpreted without interruption.
- The proposed rule would not specify when electronic signatures are required. The healthcare industry would establish that baseline.

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"We do not seek to regulate clinical best practices for documentation or interfere with health plans' business needs," the **U.S. Department of Health and Human Services** (HHS) wrote in the proposal. "Therefore, we are not proposing to specify when an electronic signature must be required, but, instead, we defer to the industry to continue to establish those expectations. We would also limit the scope of the required use of electronic signatures to just healthcare attachments transactions."

Might Final Rule Help Labs?

In this first part of a two-part series, THE DARK REPORT outlines the provisions of the rule. In an upcoming issue, part two will explore specific ways the final rule could help laboratories solve a perennial challenge in reliably getting physician signatures on orders. On December 21 of last year, HHS published the proposed rule in the *Federal Register* to update HIPAA regulations to define and standardize "healthcare attachment transactions" and "electronic signatures."

The healthcare attachment transaction is described as documentation not included in either a healthcare claim or authorization that enables a health plan to decide about reimbursement for treatment. This additional information could include medical data to support a claim payment, proof of eligibility, or workers' compensation forms, among other items.

Electronic Signature Defined

The proposed HIPAA rule defines the electronic signature as an "electronic sound, symbol, or process, attached to or logically associated with attachment information and executed by a person with the intent to sign the attachment information," according to the proposed rule. *(For a full rundown of provisions for electronic signatures, see the sidebar on page 5.)*

The period for public comment on the proposed rule ended. HHS is assessing those public comments in anticipation of issuing a final rule. Generally, once a final rule is published, it goes into effect after 60 days. Clinical lab managers should note that, once the final is implemented, enforcement of the signature final rule occurs two years after the rule goes into effect.

The proposed rule states that there will likely be some IT work needed—whether through an electronic health record (EHR) system, a laboratory information system, or some other network setup—to comply with provisions as currently written.

"For providers, the changes proposed by this rule may involve software upgrades for practice management and EHR systems," the proposed rule states. "Thus, we expect that the vast majority of physicians and other healthcare provider practices will need to make relatively small changes in their systems and in their processes but may incur additional service fees from their system vendors for additional functionality."

HHS and Digital Signatures

Officials at HHS are lagging behind market acceptance of digital signatures. In the business sector, it is now accepted practice to have all parties involved digitally sign documents and accept those digital signatures as legally binding.

Companies like **DocuSign**, **Acrobat Sign**, and **Zoho Sign** have already made banks, stock brokerages, real estate firms, and other companies comfortable with using digital signatures for transactions involving tens of millions of dollars.

There is now a new business sector called the "digital signature market." Growth in this business sector is explosive. Earlier this month, in a press release, research firm **Market Insight Results** estimated that the digital signature market was $5.25 billion in 2022. The firm predicts this market sector will grow to $43.15 billion by 2030, a compounded annual growth rate of 35.1%

Implementation of the rule to revise HIPAA and define "healthcare attach-

Draft HIPAA Rule Revision on Electronic Signatures and How it Affects Labs

ON DEC. 21, THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) published a proposed rule called, "Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard."

Part of the proposed rule delves into how the government will define electronic signatures. That aspect has implication for clinical laboratories and pathology practices given that physician signatures are required on lab test orders.

"For example, in order for a laboratory to submit a claim for reimbursement of a laboratory test, a health plan may first require a physician visit and a signed physician order," the proposed rule states. "When the laboratory later bills a health plan for the test, the plan may ask for evidence that it was ordered by an authorized healthcare provider; if the laboratory is unable to produce a signed order, it may not be reimbursed."

The rule proposes to define an electronic signature as "an electronic sound, symbol, or process, attached to or logically associated with attachment information and executed by a person with the intent to sign the attachment information."

That could include an online check box indicating acceptance, a name entered into an online form, or an image of a signature written by hand and then scanned into a digital format, according to HHS.

Drawing upon prior standards, the proposed rule notes that electronic signatures must meet three criteria:

- **Authentication**, which is the ability of a health plan to identify and verify the identity of the provider who signed a document.
- **Message integrity**, a feature that ensures signed information remains unaltered during its transmission.
- **Nonrepudiation**, which provides assurance of identity such that it is difficult for signatories to later claim that electronic signatures are not valid or that they did not sign the document.

To meet the above three criteria, the rule proposes to adopt guidelines from **Health Level Seven International** (HL7), a standards organization in Ann Arbor, Michigan, that develops methods for the exchange of electronic health information. The guide is formally titled, "HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1."

"The [HL7 guide] promotes these three features by utilizing digital signature technology to implement identity management using digital certificates, encryption requirements to support message integrity, and multiple signed elements to support nonrepudiation," according to HHS.

ment transactions" and "electronic signatures" is overdue, particularly when compared to how rapidly the private sector has accepted digital signatures and electronic documents.

Implementation of this final rule will enable physicians, medical labs, and health insurers to document claims and provide supporting documents in electronic form. As Sherrin noted, payer rejection of lab test claims with missing or illegible physician signatures cost the nation's clinical laboratories tens of millions of dollars each year. If a new HIPAA rule can help that situation, it will be a major benefit to many labs and pathology groups. **TDR**

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Legal Update

Pathologist Sues Hulu Over Depiction in Theranos TV Series

THERE IS AN INTRIGUING NEW TWIST IN THE LONG-RUNNING SAGA of the now-defunct **Theranos**. Pathologist and former Theranos CLIA lab director Adam Rosendorff, MD, is taking Hulu to court.

Rosendorff, the federal government's star witness during the fraud trial of former Theranos CEO Elizabeth Holmes, recently issued a court summons to **Hulu** over the streaming channel's series, "The Dropout." The show offered a dramatic retelling of Holmes' rise and downfall at Theranos and featured a character who was the lab director. A court summons alerts defendants that they are being sued.

The complaint was filed on March 23 in **New York Supreme Court in New York City**. The **Walt Disney Company**, as majority owner of Hulu, is also named as a defendant.

Fictional Lab Director

Rosendorff himself was not a named character in Hulu's "The Dropout." However, at least some observers—including Rosendorff—believe that the character of "Mark Roessler" is a depiction of him. Roessler was played by actor Kevin Sussman and appeared in three of the series' eight episode.

"The character of Roessler is utterly different from that of plaintiff," the four-page summons stated. "Roessler is portrayed and shown as directing other employees to destroy testing results damaging to Theranos, to falsify other records, and to engage in other unethical conduct unworthy of a physician," said the court documents.

"The character is portrayed and shown as covering up Theranos' fraudulent scheme, thereby endangering patients' lives, of abruptly leaving his employment with Theranos without providing notice or discussing his separation, and as otherwise unfit to practice medicine," the summons added.

'Heroic Whistleblower'

In contrast, the summons argued that Rosendorff took gutsy actions by acting as a whistleblower to the government about Theranos' misdeeds.

"Taken both individually and in their entirety, the statements and fictional portrayal have had a devastating effect upon the plaintiff's reputation and professional status as a physician," according to the summons. "At the time of the trial, he was considered a heroic whistleblower, a witness who was instrumental in the jury's verdict convicting Holmes. Now he has been falsely portrayed as a perjurer, a criminal, and of being completely unfit to practice his profession."

Rosendorff's testimony during Holmes' 2021 trial on investor fraud charges grabbed the attention of pathologists nationwide. *(See TDR, "CLIA Lab Director Testimony Shows Risks to Pathologists," Nov. 8, 2021.)*

Holmes is scheduled to report to prison on April 27. A judge ruled on April 10 that Holmes will not be allowed to remain free while she appeals her conviction. Part of the appeal centers on whether the court improperly limited defense questioning of Rosendorff about his work at three other labs. TDR

OIG's New Opinion on Use of Gift Cards for Lab Specimens

Advisory Opinion requested by lab firm that sought higher return rate of specimens from at-home patients

Danielle Sloane, JD

CEO SUMMARY: This new Advisory Opinion from the Office of Inspector General (OIG) outlines a narrow situation in which it may be allowable for clinical laboratories to use gift cards to encourage patients to return specimens collected at home. However, one healthcare attorney advises labs to read the details of the OIG review carefully.

USING GIFT CARDS AS INCENTIVE to get patients to return their at-home specimens to clinical laboratories may be allowable under specific circumstances. So says the **Department of Health and Human Services' Office of Inspector General** (OIG) in a new Advisory Opinion.

That stance may surprise some clinical laboratories, especially given the well-known boundaries set up by the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalty (CMP) to prohibit inducements that lead to improper use of healthcare services and subsequent Medicare reimbursement.

New OIG Advisory Opinion

"The OIG's Advisory Opinion is going to be of interest to a lot of lab companies," said attorney Danielle Sloane, JD, a Member at **Bass, Berry & Sims PLC** in Nashville. "But the situation the OIG reviewed in this opinion is quite unique, so I want to caution lab companies up front—before they start using gift cards—to think very carefully about it."

OIG Advisory Opinions are limited to the specific situation that they address. Nonetheless, these opinion letters do provide insight into the thinking of federal health officials in different areas of **Medicare** compliance efforts.

The document under discussion is OIG Advisory Opinion No. 23-03, which was posted on March 29. The review was prompted by an unnamed laboratory asking about a business arrangement in which at-home patients may be offered non-monetary gift cards, up to $75 in value, in exchange for sending colorectal cancer screening test specimens back to the lab.

The test in question is the only **Food and Drug Administration**-approved, non-invasive, stool-based DNA colorectal cancer screening available by prescription to patients who are at average risk for developing colorectal cancer. Colorectal screenings are recommended as a preventive step by the **U.S. Preventive Services Task Force**.

After the prescription (test requisition signed by the patient's physician) is received, the laboratory ships the collection kit to the patient's home. Patients collect their own samples and return them to the lab company for analysis.

Medicare Part B covers the test once every three years for Medicare beneficiaries aged 45 or older who meet certain criteria.

The lab noted that—as of January 2023—under Medicare's Clinical Laboratory Fee Schedule, the lab is reimbursed approximately $500 for each test it performs.

According to the laboratory that requested the OIG opinion, once the lab company sends the sample collection kit to the patient, if it does not receive the specimen back in a timely manner, the lab company sends the patient reminders through various means, such as letters, emails, and calls. But those efforts are not always successful. Data provided to the OIG by the lab company indicated more than 30% of test kit recipients never return the specimen.

"Under the proposed arrangement, if the [requesting] laboratory has not received the kit following at least two patient contacts, requestors would send the patient a reminder letter ... no sooner than two weeks, and no later than 180 days, after the patient receives the test sample collection kit," the OIG noted.

Prepaid Gift Card for $75

"Unlike the first two patient contacts, the letter also would state that, if the patient returns the kit within the period of time specified in the letter, requestors would send the patient a prepaid card, such as a **Visa** or **Mastercard** gift card, with a value of up to $75," the OIG continued. "The gift card would not be redeemable for or convertible into cash and would be non-reloadable."

Moreover, the gift cards would only be offered to a patient once every three years, and "the proposed arrangement would not apply where the test is ordered by prescribers arranged for through requestors' website."

The lab company told the OIG that it hoped this approach would encourage more patients to comply with test orders and improve preventive care.

"Requestors intend to implement the proposed arrangement to encourage patients to return the kit, thereby promoting patient compliance with the prescriber's order for the test," according to the Advisory Opinion.

Curious lab professionals may wonder why this proposed arrangement with gift cards does not trigger concerns about kickbacks or patient inducements to promote greater use of a particular lab test.

The OIG acknowledged a gray area of sorts in its advisory opinion. It strongly noted that its opinion would be different if the particulars of the proposed arrangement changed.

'Minimal Risk' of Fraud

For example, the Anti-Kickback Statute governs whether an arrangement to induce patients to obtain preventive care will also induce other business payable by a federal healthcare program. "We conclude that the proposed [gift card] arrangement presents a minimal risk of fraud and abuse under the federal Anti-Kickback Statute," the OIG noted, offering the following three reasons:

- The arrangement likely will not lead to improper increases in federal healthcare spending because the test reimbursement is under a fixed rate; the gift card would only be offered every 36 months in accordance with test frequency; and physicians would not receive an incentive to order the test.
- The gift card would promote patient compliance with a recommended screening test.
- Safeguards exist to reduce the risk of fraud, such as the limited frequency of offering the gift card and a lack of any consumer advertising about the incentive.

Meanwhile, the Beneficiary Inducements CMP generally prohibits remuneration that would encourage patients to choose a certain provider over another. However, the Social Security Act carves out an exception that allows incentives for preventive services as long as those services don't directly or indi-

rectly tie to other reimbursable services. Colorectal cancer screening is on the Preventive Service Task Force's list of recommended services. However, this exception does not allow the incentive to be "cash or instruments convertible to cash."

Interestingly, while a gift card seems close to cash, the OIG concluded that a "gift card would neither be an instrument convertible to cash, nor, in this particular case, disproportionately large in relationship to the value of the preventive care service … Although the test may result in individuals eligible for Medicare and state healthcare programs obtaining additional services, like a colonoscopy (as clinically appropriate), the test would not be tied, directly or indirectly, to the provision of those additional services."

In other words, the test result would likely influence the physician to order a colonoscopy, not whether there was incentive offered to return the test.

Narrowly Tailored Situations

The OIG's Advisory Opinion offers a narrow path for gift card use, so labs should be cautious about reading too much into the review, Sloane said.

"I've had lab clients ask about ways to get the test kit back once it has been sent to the patient," Sloane recalled. "There are things a laboratory can do, but any approach involving an incentive to the patient needs to be thoughtfully designed. I don't think this OIG Advisory Opinion gives a green light to use gift card incentives to get patients to return test kits, except for in narrowly tailored situations."

In fact, only a few days before the Advisory Opinion was released, the OIG posted an online FAQ dealing with nuances of gift card use by providers. *(See sidebar on page 9 for more details.)*

One key component of offering gift cards that the OIG seems to support is the effort taken by labs to collect specimens before offering the incentive, Sloane said.

OIG Also Addresses Gift Cards in FAQ

DAYS BEFORE RELEASING ITS ADVISORY OPINION about a proposed arrangement of offering gift cards to encourage patients to return at-home test kits, the Office of Inspector General (OIG) posted a FAQ to its website about general gift card use.

The FAQ asked how the OIG differentiates between cash, cash equivalents, and in-kind gift cards. It also probed whether the OIG views certain types of gift cards differently, such as those for a retail store versus those that limit the scope of a purchase (e.g., gas or fresh produce).

The OIG broke down its answer as follows:

- "Cash" refers to monetary payments in the form of currency, including money that is electronically transmitted online or via mobile apps.
- "Cash equivalents" include items convertible to cash, such as checks, or items that can be used like cash, such as a prepaid Visa or Mastercard gift cards. Gift cards offered by large retailers or online vendors that sell a wide variety of items can easily be converted to cash, so, the OIG considers such gift cards to be cash equivalents.
- OIG considers some gift cards to be "in-kind," such as cards that can be redeemed only for certain services or items (e.g., a meal delivery service or gas). OIG also considers vouchers for a particular service (e.g., taxi ride) to be an in-kind item.

"Understanding these categories is important to understanding what form of remuneration could be protected under certain safe harbors to the federal Anti-Kickback Statute and exceptions to the Beneficiary Inducements CMP," the FAQ states.

"The laboratory in the OIG Advisory Opinion seems to be taking legitimate steps to try and get the kit back before offering the gift card, which reminds me of the efforts laboratories need to take before writing off a patient copay or deductible," she observed. "Ideally, organizations only write off uncollected amounts after making reasonable collection efforts, and most of the healthcare industry considers reasonable collection efforts as having attempted to collect at least three times."

A lab should not let practitioners and patients know ahead of time that if patients wait to return samples until after they receive three reminders, then the patients will receive a gift card offer.

"Labs can't start delivering that message about gift cards," Sloane warned. "That happened with providers who got in trouble with copay waivers. Practitioners would just tell their patients to ignore the collection letters about the overdue copays so they could write off their copays."

➤Be Careful with Gift Cards

The OIG emphasized that its opinion was influenced by the nuances of the particular arrangement. "The OIG is very careful to say before the conclusion of the Advisory Opinion that if any of the facts were different, the OIG would likely come to a different conclusion about this arrangement," Sloane said. "This is a unique scenario."

From a business perspective, when labs send test kits out, they incur shipping costs, so it is reasonable that labs want the specimens returned to justify those costs and receive reimbursement for the test. At-home test kits also satisfy a growing trend of consumers adjusting where they get their health services.

"But the scenario the OIG reviewed is unique. It worries me that labs are just going to start throwing gift cards all over the place without carefully thinking about their approach." TDR

Contact Contact Danielle Sloane at DSloane@bassberry.com.

Whistleblower Suit Challenges Gift Cards

WHILE THE LABORATORY'S NAME IS REDACTED in the Office of Inspector General's (OIG) Advisory Opinion 23-03 about gift cards, only a few companies distribute at-home colorectal cancer tests.

In a March 6 story, DARK DAILY—a sister publication to THE DARK REPORT—wrote about a whistleblower case in which a retired pathologist named Niles Rosen, MD, sued **Exact Sciences** in Madison, Wisconsin.

Rosen's complaint stated that in 2017, a physician ordered an at-home colorectal test from Exact Sciences called Cologuard. When Rosen didn't return the sample, Exact Sciences offered to send him a $75 gift card if he sent in the specimen.

Rosen returned a sample in 2018 and received the gift card. He later filed a whistleblower complaint, claiming that the gift card acted as an inducement to a Medicare beneficiary.

"It was a straight-up kickback," Rosen's attorney, Marlan Wilbanks, JD, Senior Partner at Atlanta law firm Wilbanks and Gouinlock, told COSMOS in October. "You can't offer cash or cash equivalents to anyone to induce them to use a government service." COSMOS is the online site from the **Society of Corporate Compliance and Ethics** and the **Health Care Compliance Association**.

The **Department of Justice** declined to intervene in the case, allowing Rosen to pursue the *qui tam* case on his own.

Exact Sciences has refuted the allegations. In February, a federal judge ruled the court case will proceed following unsuccessful attempts by Exact Science's attorneys to have the matter dismissed. But if OIG Advisory Opinion No. 23-03 was requested by Exact Sciences, that OIG opinion may render this *qui tam* case moot.

Lab Market Update

Quest Acquires Lab Outreach from New York-Presbyterian

It's the latest deal that affirms statements by executives of the Two Blood Brothers that hospital CEOs have a growing interest in selling their laboratory outreach businesses. Recently, **Quest Diagnostics** announced that it will take over the laboratory outreach program at **New York-Presbyterian**.

A joint news release issued on Feb. 14 stated that the health system will maintain ownership of its hospital laboratories. "New York-Presbyterian will still own and operate world-renowned hospital labs, including its anatomic pathology services, to continue providing high quality, complex clinical laboratory services with its academic partners," according to the announcement.

New York-Presbyterian is an integrated academic healthcare system based in New York City. It has 10 hospitals and campuses, as well as nearly 200 primary and specialty care clinics and medical groups.

The news release noted that Quest, based in Secaucus, New Jersey, would buy "select assets of the lab services business" from the hospital system. Quest spokesperson Jennifer Petrella later clarified that the deal was indeed for lab outreach.

"Under the agreement, Quest will acquire select assets of New York-Presbyterian's laboratory services business, commonly referred to as outreach laboratory services," Petrella told The Dark Report. "Assuming the close of the acquisition, certain lab services—including non-inpatient outreach testing—will transition to Quest."

Financial terms of the deal were not disclosed. These transactions can bring a substantial amount of cash to the hospital or health system selling its lab outreach business. With many hospitals reporting significant operating losses due to inflation and increased labor costs, the sale of the lab outreach business can bring a much-needed boost to the selling institution's capital base and balance sheet.

That was true for **Ascension Health**, which operates 139 hospitals in 19 states. In 2022, Labcorp in Burlington, North Carolina, purchased the lab outreach businesses of about 75 Ascension Health hospitals in 10 states for a price disclosed as $400 million. Last September, Ascension Health reported an $879.1 million operating loss and net loss of more than $1.8 billion for the period ending June 30, 2022. *(See TDR, "Labcorp to Buy Outreach, Manage Ascension Labs," Feb. 22, 2022.)*

Interests Beyond Just Cash

New York-Presbyterian did not respond to a question from The Dark Report about what prompted the decision to sell its outreach business.

However, Quest CEO Jim Davis noted during an investor's day presentation on March 16 that New York-Presbyterian had interest in reducing test turnaround time for physicians and tapping into greater insight from Quest's patient datasets. "I can tell you it wasn't just about the cash," Davis said regarding New York-Presbyterian's motivations in pursuing this deal. "It was all about all these other [benefits] that were really important to the New York-Presbyterian system."

Quest Diagnostics noted in its 2022 Annual Report that it spent $162 million on acquisitions last year. TDR

Pharmacogenetic Tests Deliver for Avera Lab

Avera Institute for Human Genetics shares lessons learned in helping doctors with precision medicine

Erik Ehli, PhD

CEO SUMMARY: When Avera Institute for Human Genetics wanted to expand its genomics program, it used its past learning with pharmacogenetics to guide the effort. Two key insights? Ask physicians about what they want from genetic tests and master the nuances of getting provider buy-in when launching new genetic tests.

Leslie Cooper

Initial strategies used by **Avera Institute for Human Genetics** (AIHG) during its pharmacogenomics pilot helped the organization's genomics program expand while winning support from physicians. Other labs in the early stages of offering genetic testing may find AIHG's advice insightful as more and more patients seek answers about how genetics influences their healthcare options.

"We have a lot of experience in next-generation sequencing [NGS]. We have the equipment and the staff," said Erik Ehli, PhD, Scientific Director at AIHG. "We want to leverage that knowledge. During the pandemic, our health system sent out a lot of clinical NGS tests, especially in oncology, women's health, expanded carrier screening, and noninvasive prenatal testing. We were well-positioned to bring those tests in-house."

AIHG is part of 37-hospital **Avera Health**. The state-of-the-art genetics lab is located within the system's flagship **Avera McKennan Hospital & University Health Center**, based in Sioux Falls, South Dakota.

Ehli spoke at the *2021 Executive War College for Diagnostics, Clinical Laboratory, and Pathology Management*. His session was titled, "How Avera McKennan's Institute for Human Genetics Became the Launchpad for Genetic Testing."

Building from Initial Success

"In 2015, we started testing all Avera McKennan surgical inpatients. This means on the day patient were admitted they had blood drawn, the samples were delivered to the lab for testing, and by the end of the day physicians received the results and could alter their patients' pain medications as needed," said Leslie Cooper, MLS(ASCP), SBB(ASCP), Laboratory Operations Manager at AIHG. Cooper also spoke at the *Executive War College*.

"This approach highlighted the benefit of testing for patient populations outside of behavioral health, which is where Avera started its pharmacogenetics effort," she added. "It also allowed for a small gene set, which let Avera focus education to a large group of clinicians."

The Dark Report previously detailed Avera's early use of genotyping to inform precision medicine in 2016. *(See TDR, "Health System Lab Is Genotyping*

to Identify Best Drugs for Patients," Jan. 30, 2017.)

The following year, in 2017, AIHG launched GeneFolio, its home-built pharmacogenetics platform that looked at the entire gene portfolio. "We had success bringing genetic research to bedside testing with GeneFolio," Cooper recalled.

"AIHG's genetic test menu includes multiple panels offering everything from a psychotropics panel to a pain panel and our full pharmacogenomics panel, which also includes a pharmacy consult and personalized report," she continued. "We have a transplant panel as well. In 2019, our lab expanded and obtained out-of-state licensure. This enabled us to accept samples from out of state."

AIHG addresses three goals when it introduces new genetic tests. They are:

- Establishing processes for genetic test development and implementation.
- Increasing clinician buy-in of new tests.
- Making reports quick and easy to view.

Genetic Test Development

GeneFolio allowed Avera Health to cement its approach to pharmacogenetic test development and implementation.

"As the pandemic eased, AIHG began to look at molecular tests referred out to identify how to bring some of that testing back in-house," Cooper explained. "That was part of the reason AIHG was incorporated into the medical laboratory service line. As of 2021, we had performed over 15,000 pharmacogenomics tests while regularly expanding our portfolio. AIHG constantly watches for new testing opportunities."

Test development at AIHG includes processes to define relevant DNA markers, study the utility of the test in clinical samples, obtain regulatory accreditation for the test, and complete validations.

"We work very closely with our clinicians to see what genetic tests they need, as well as to get their input and guidance," Cooper said. "The goal is to personalize medicine, cause fewer side effects, and reduce costs by getting patients on the right drug."

Information Assists Clinicians with Genetic Test Results

TO BE EFFECTIVE, hospital IT departments need to assist genetic laboratories to integrate new reports and data into electronic medical record (EMR) and laboratory information systems, and to continue to evolve with rapid developments.

Convenience should be a prime consideration for presenting genetic testing data to clinicians.

"In the EMR, we created discreet fields, so clinicians can see each gene and each phenotype within the EMR without having to click on a button and read an entire report," said Leslie Cooper at Avera. In addition, a widget was added to clinicians' home screens to notify them when pharmacogenetic results are available and when testing was completed.

For caregivers who want further details, GeneFolio's patient pharmacogenetic report is available in the patient's portal. It is color coded for easy reading of potential effects between a drug and genetic variants in a patient (in this case, green for minimal, yellow for moderate, and red for significant drug-gene interaction).

Decision-Maker, User Buy-In

Support for genetic testing at Avera comes from two critical areas: investment and utilization. As with any pilot health service that is going to expand, hospital leaders want to see a return on investment.

"Labs need to be able to explain to administrators why a test is beneficial, how it impacts the health system, the cost savings associated with a new test, and whether it brings in new revenue," Cooper said.

Utilization is likely a trickier path to navigate thanks to physicians and others who may be used to a different way of

thinking. Education, clinical implementation expertise, electronic medical records integration, and pharmacist services to enhance medication management are key to improving utilization.

"Pharmacogenetics is not something medical schools have historically taught physicians," Cooper noted. "A lot of physicians are trained to try a drug, see what happens, and if it does not work, put a patient on something different. So, finding that physician champion to help encourage other clinicians to order a new genetic test is important."

Labs can foster champions within the physician community by presenting evidence that resonates. Changes that affect physician workflow or contradict previous experience can be difficult to carry out. Full implementation of pharmacogenetics into a practice to guide medication therapy can be one of those changes. "However, as our lab shows physicians evidence of improved patient outcomes and workflows, they buy in," Ehli said.

One effective approach AIHG used to promote physician buy-in of pharmacogenetics was to demonstrate the variability of drug metabolism among the general population. "It's a myth that most 'normal' patients metabolize drugs the same way," Cooper observed.

Patient Responses to Drugs

"When meeting with clinicians to review pharmacogenetic tests, I generally pick CYP2D6," she explained, referring to a gene involved in the metabolism of about 20% of commonly prescribed drugs. "I show them the reports for 20 patients. When clinicians look at the reports and realize how many people don't have normal metabolism, it clicks with them. This is more than just behavioral health or pain medications."

When expanding its genetic research to bedside testing, AIHG embraced a pair of lessons that other genetic laboratories will find useful. The first lesson is the classic adage of the business world: Start small with a pilot program. "Don't roll out genetic testing to your entire system at the same time," Cooper stressed.

"AIHG started with behavioral health for pharmacogenomics, then moved into heart and cardiology for pharmacogenomics," she added. "Then it was rolled out to the surgical team, and then to the entire system. It's easy to get excited and try to do it all at the same time. But that can often take longer than a staged introduction."

Secondly, as labs and hospitals struggle with employee turnover, don't forget to update the education that clinicians receive about genetic testing options.

Comprehensive Education

"Initial education was comprehensive when AIHG rolled these out. We trained the trainer," Cooper said. "However, people turn over and new people come in. Now, AIHG uses several approaches to educate physicians and staff. We continuously do grand rounds, clinical education, and lunch-and-learn sessions," she noted.

"We also have an internship program that allows college students to come to the lab and see what we do," she noted. Our lab also partners with local universities and a medical school. Fourth-year medical students and pharmacy students do a rotation with us for genetics and personalized medicine."

AIHG and the Avera McKennan Laboratory recently underwent an integration to enhance services at Avera. The project involved relocating all laboratory services into the same building while combining resources and expertise to help advance all areas of the clinical lab.

This integration has allowed consolidation of quality, education, billing, and supply chain. As part of the integration, AIHG will undergo a rebranding and soon be called the **Avera McKennan Genomics Center**. TDR

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Legislative Update

VA: 120,000 Cancelled Lab Tests Did Not Route to Physicians

Extensive review of EHR implementation points to problems with laboratory test ordering and more

Officials from the **Department of Veteran Affairs** (VA) and **Oracle Cerner** found themselves on the hot seat before Congress on March 15, answering questions about problems with deployment of the new electronic health records (EHR) system.

One week earlier, the VA had issued a report identifying issues with its ongoing implementation of a new EHR throughout the VA system of hospitals and clinics. When completed, the cost to taxpayers will be $10 billion. Among the problems flagged in the report: 120,000 improperly routed alerts for clinical laboratory test orders that had been cancelled.

However, the most significant issue was revealed by Senator Jon Tester (D-Montana), Chairman of the Senate Committee on Veterans' Affairs, which hosted the hearing. During introductory remarks, Tester noted that four veteran deaths were allegedly connected in some way to the care delivered to them via the Oracle Cerner EHR. It was not clear whether any lab-related mishaps contributed to the deaths.

Alerts Go to Cerner Inbox

The VA's review, formally called the "EHR Modernization Sprint Report," identified four broad patient safety areas that were at risk because of alleged problems with rollout of the Oracle Cerner EHR. The clinical lab test troubles centered on cancelled test orders failing to make it to ordering providers for review. Specific examples included:

- Future lab tests that were subsequently cancelled were not routed to the ordering provider's inbox for review as expected. "Instead, cancelled lab orders have been routing to the message center inbox of a Cerner employee," the VA reported stated. "[More than] 120,000 cancelled lab orders over 90 days for … veterans are in this inbox, and they have not been opened or addressed." The report indicated an audit was underway to determine a cause for the problems.
- Lab tests not ordered correctly got routed to a general default site in the EHR. If the default site was not monitored by VA staff, the lab tests would not be performed. Better staff education will occur, and new alerts for ordering providers will be added to the software.
- The EHR system refused co-signatures for lab reflex tests. Software settings will be updated to fix the glitch.

Billions at Stake in EHR Deal

This past October, the EHR rollout was halted until June 2023 amid concerns. Tester noted that because of the alleged problems, Oracle Cerner refunded the government $325,100 of the $4.4 billion already paid to the company.

Tester—who was critical of efforts by the VA and Oracle Cerner to properly carry out the EHR implementation—called on the agency to renegotiate the EHR contract when it comes due in May.

Meanwhile, a bill has been filed in the House of Representatives (H.R. 592) that would require each VA medical center's director to certify that the EHR system has been correctly configured. **TDR**

IVD Firms Prepare for OTC, Home Test Market Expansion

➤Expert weighs in on what factors drive demand for testing outside traditional collection centers

Bruce Carlson

➤➤CEO SUMMARY: With public interest in home testing growing, some IVD manufacturers are preparing to serve a fast-expanding market for over-the-counter and at-home tests. IVD firms are banking on the idea that consumers—at the first sign of symptoms—will want a self-administered respiratory illness test either at home or easily available at a local pharmacy.

SOME *IN VITRO* DIAGNOSTICS (IVD) MANUFACTURERS are eyeing the over-the-counter (OTC) and at-home lab test markets with enthusiasm.

QuidelOrtho, for example, is building on a history in rapid testing. Quidel, a leading manufacturer of point-of-care (POC) and rapid testing technologies, acquired **OrthoClinical Diagnostics** in 2022.

Looking to 2023, the combined San Diego, Calif.-based company has these sales projections, according to CEO Douglas Bryant, who spoke during the **Raymond James** 44th Annual Institutional Investors Conference in March in Orlando, Florida:

- $200 to $400 million in revenue from rapid testing for endemic COVID-19.
- $230 to $270 million in revenue from rapid influenza tests.

"We've long held that there should be an over-the-counter market," Bryant said during his appearance at the conference, the audio of which was shared online by QuidelOrtho. "The change in philosophy with respect to respiratory diseases—particularly in the U.S.—I think portends well for further decentralization to various segments, whether it's urgent care, small clinics, and even OTC."

Quidel developed the first **Food and Drug Administration** (FDA)-cleared POC test for Influenza in 1999 and was the first to market a rapid SARS-CoV-2 antigen test in the United States.

➤Demand for Rapid Tests

But today, as COVID-19 wanes and the public health emergency ends in May, are QuidelOrtho's rapid test projections feasible?

"QuidelOrtho is being reasonable," said Bruce Carlson, Senior Vice President of Publications at **Kalorama Information**, part of **Science and Medicine Group**, in an interview with THE DARK REPORT. Kalorama projects the flu test market overall to reach $4 billion in 2023 and COVID-19 testing of all types to be $23.4 billion, about 20% less than 2022 sales of $29.3 billion.

New York-based Kalorama, publisher of market research in medical markets including biotechnology and diagnostics, recently released its "Worldwide Market for *In Vitro* Diagnostics Tests 15th Edition."

"QuidelOrtho has a very popular immunoassay system [marketed as Sofia] that's used in many clinics," Carlson noted. "Those systems and rapid tests are Quidel's 'bread and butter.' But they must be performed by a provider, a nurse, or physician assistant. That's what's leading to those sales—not at-home tests."

Flu and COVID-19 Tests

In fact, during an earnings call about Q4 2022 financials, Bryant said 77,000 QuidelOrtho Sofia instruments are situated in U.S. outpatient settings, and that 77% of them run influenza and 70% process COVID-19 rapid tests.

QuidelOrtho's key competitors for rapid tests include *in vitro* diagnostics firms **Becton Dickinson** (BD) in Franklin Lakes, N.J., and **Sekisui Diagnostics** in Burlington, Massachusetts.

BD states its Veritor Plus System provides rapid testing at POC for SARS-CoV-2, flu A and B, respiratory syncytial virus (RSV), and group A strep.

QuidelOrtho submitted a flu/RSV at-home test to the FDA for review, according to Bryant of OrthoQuidel. There is the perception that the COVID-19 pandemic propelled public readiness for testing in people's homes.

At-home tests are different from rapid tests in that they are purchased by people who receive results immediately at home, according to Kalorama. Businesses marketing at-home tests to consumers may face hurdles unless they test for an urgent illness or a potentially fatal one, according to Carlson.

Tests for Other Diseases

"It's tempting to say post-pandemic that an at-home infrastructure is in place and people have become adjusted to testing at home. I still think that's going to be challenging for other diseases," Carlson said.

For a test to be successful, it must relate to something people need to know on a regular basis, Carlson says. Examples are at-home tests for diabetics, who need to do continuous glucose monitoring, and coagulation factor tests geared to people who take blood thinner medications.

"With existing technology, nothing I see right now or the next few years points to a test that the huge majority of people will want to have in a box at home for anything other than COVID-19, glucose, and coagulation," Carlson said.

The leading home test for COVID-19 is **Abbott's** BinaxNOW, according to Kalorama. Abbott, based in Abbott Park, Illinois, said during an earnings call that it delivered about three billion COVID-19 tests worldwide during the pandemic.

"That test is convenient, and it is easy to take. But most importantly, with COVID-19, consumers need to know if they're sick," Carlson noted. "You also want to sell that repeat test. That's what makes a test market. It has to be urgent for the person."

Differences in Rapid, OTC, and At-Home Tests

KALORAMA INFORMATION DISTINGUISHES rapid, over-the-counter (OTC), and at-home tests as follows:

- Rapid tests, also known as point-of-care tests, run on sophisticated systems and instruments situated in outpatient settings, including clinics and physician offices. Samples for these tests are taken by a healthcare provider.
- Over-the-counter tests are sold online and in pharmacies. Customers who buy the tests, which could be genetic tests, are asked to send samples to a laboratory for results and reporting.
- At-home testing involves self-administered tests people purchase and perform at home. They receive results in minimal time without involving a healthcare provider.

Abbott forecasts $2 billion in COVID-19 testing revenue in 2023.

"We expect [SARS-CoV-2] variants will continue to emerge. Therefore, our tests will remain an important part of our respiratory testing portfolio—along with flu, RSV, and strep, which we offer across multiple testing platforms, including lab-based systems and hospitals, small desktop devices in urgent care centers and physician offices, as well as at-home tests," said Abbott CEO Robert Ford during an earnings call on Q4 2022 financials.

People Searching the Web

People appear interested in knowing more about their health symptoms. A study published in March by *RegisteredNursing.org* found that flu symptoms and diabetes symptoms topped the list of the 30 most searched health questions by consumers from February 2022 to February 2023, with 823,000 and 425,000 monthly searches, respectively. "What is RSV?" shared the ninth position with stroke, pneumonia, and depression having 201,000 lookups each on Google.

It should be noted that *RegisteredNursing.org* excluded COVID-19 searches from its analysis to avoid making its list of top terms monotonous and skewed towards the pandemic at the expense of other illnesses.

At-Home Multiplex Testing

Perhaps at-home tests aimed at detecting multiple illnesses from one sample may appeal to consumers who are not sure what illness they have. Susan Butler-Wu, PhD, Associate Professor of Clinical Pathology at the **University of Southern California**, called rapid tests for multiple viruses "the way of the future," in an *NBC News* article published on Jan. 6.

Lucira Health's COVID-19 & Flu Home Test recently became the first at-home test to garner FDA emergency use authorization (EUA). The molecular test provides results in about 30 minutes from a self-collected swab.

"Today's authorization of the first OTC test that can detect influenza A and B, along with SARS-CoV-2, is a major milestone in bringing greater consumer access to diagnostic tests that can be performed entirely at home," said Jeffrey Shuren, MD, JD, Director of the **FDA's Center for Devices and Radiological Health**, in a statement.

Carlson called it a "very smart" product. "The question becomes: Will it be as urgent for people to buy a product for COVID-19 and influenza? The real test is for COVID-19. Flu A and B are more of a 'rule out' test," he said.

Role of Clinical Labs

Similar to some IVD firms, publicly owned clinical lab companies have dipped into the OTC and at-home testing markets.

Labcorp in Burlington, North Carolina, developed the first combined COVID-19, flu, and RSV PCR test. The home collection kit uses nasal swabs that need to be returned to Labcorp, has FDA EUA, and is sold online along with other tests through Labcorp OnDemand.

Meanwhile, **Quest Diagnostics** in Secaucus, New Jersey, also offers consumers the opportunity to select and pay for tests online through QuestDirect.

"The at-home tests are appealing to a market that is not at the expense of clinical labs. It is a convenience market: people who are, for example, going on vacation and have a need to know about their health," Carlson noted.

Diagnostics leaders should monitor how each of the rapid, OTC, and at-home test markets play out in 2023 and beyond, especially as new at-home respiratory virus tests become available. Consumer demand and consumers' decisions to try OCT and at-home tests will likely be influenced by relationships with their providers and clinical laboratories. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There may soon be a new name for the well-known **American Association for Clinical Chemistry** (AACC). The proposed new name is **Association for Diagnostics & Laboratory Medicine** (ADLM). As of press time, AACC members were set to vote on the new name on April 21—either in person at AACC's Annual Membership Business Meeting or online. If approved, the organization will launch the new name at the upcoming 2023 AACC Annual Scientific Meeting and Clinical Lab Expo in July, according to a spokesperson.

MORE ON: *AACC Name*

The change to ADLM, which was previously approved by the organization's board of directors, represents the wider appeal that AACC's programs have with lab specialties beyond clinical chemistry, the spokesperson told THE DARK REPORT. In 2022, the AACC worked with two research firms to test 11 name options with multiple focus groups. The AACC does not intend to abandon its chemistry roots, the spokesperson noted.

END OF PHE BRINGS CHANGES TO LABS

The federal public health emergency (PHE) surrounding the SARS-CoV-2 pandemic will end on May 11. Labs should be aware of the following information from the federal **Centers for Medicare and Medicaid Services** (CMS) once the PHE ceases. 1) Labs will no longer be reimbursed transportation costs for sending technicians to patients' homes to collect samples for SARS-CoV-2 testing. 2) Medicare will require all COVID-19 and related testing that is performed by labs to be ordered by physicians or non-physician practitioners. 3) Temporarily higher Medicare rates will end for COVID-19 testing that uses high-throughput instruments. One thing that will not change after the PHE ends: CMS will continue to exercise discretion that allows pathologists to examine a clinical laboratory's digital images and diagnostic data from remote locations. Go to *www.cms.gov/coronavirus-waivers* to learn more.

TRANSITIONS

- Priyanka Reddy Shivdasani is the new Director of Pathology, Clinical Bioinformatics, and Operations at **Mass General Brigham** in Boston. She previously spent 13 years at the health system's **Brigham and Women's Hospital** on various bioinformatics management roles.
- George Jabboure Netto, MD, has been named Chair of the Department of Pathology and Laboratory Medicine at **Penn Medicine** in Philadelphia, effective Aug. 1. He currently heads the Department of Pathology at the **University of Alabama at Birmingham** and is also an adjunct professor of pathology at **Johns Hopkins University**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 8, 2023.

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