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FDA Draft LDT Rule Moves Forward!

Insights from analyzing 6,707 public comments; FDA, CMS issue Joint Letter on FDA oversight.

See pages 2-9.

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

Read the Tea Leaves… FDA Will Require LDT Review

PROPOSED FEDERAL REGULATION OF LABORATORY DEVELOPED TESTS (LDTs) IS CURRENTLY THE HOT-BUTTON ISSUE within the clinical laboratory industry. Following the close of public comments on Dec. 4, it is the quiet period while the federal **Food and Drug Administration** (FDA) reviews the comments and considers changes to the draft rule it issued on Sept. 29, 2023: Medical Devices; Laboratory Developed Tests.

In this issue, your team at THE DARK REPORT once again brings you a different perspective than "the usual sources." For example, on pages 3-6, we present an intriguing analysis of the public comments. Of the 6,707 public comments released by the FDA, you may be surprised to learn that 78% of these were form letters.

Going further, it turns out that only 56 public comments received in support of the FDA draft rule were individually composed and submitted (and not form letters). This is contrasted by the fact that 1,300 comments in opposition to the rule were individually composed and submitted (and not form letters).

Because the FDA did not identify the organization represented by an individual comment, it is unknown which groups distributed form letters. Reporters at *360Dx* were able to identify a single form letter was used in support and three form letters used in opposition. This is a curious fact, since 99% of the public comments in support of the draft rule were form letters. It would be illuminating to know which organization orchestrated that campaign to support the rule.

Another interesting development in the FDA's push to move the draft LDT rule forward was the public release of a statement by the leaders of the FDA and **Centers for Medicare and Medicaid Services**. Issued on Jan. 24, 2024, the federal agencies said they were in agreement about the roles each agency should have in monitoring LDTs. Lab managers can take this as a sign that both agencies support the FDA as it moves ahead with its plans to regulate LDTS. *(See pages 7-9.)*

Combining the facts above with other developments, the tea leaves should be easy to read: the FDA is on a clear path to issue a final rule this spring and take responsibility for overseeing LDTs. At this point, it is unlikely that Congress or lawsuits by the lab industry can derail the process. TDR

Who's For and Against FDA Draft LDT Rule?

During 60-day public comment period last fall, the federal agency received 6,707 comments

CEO SUMMARY: One analysis determined that 43.2% of the public comments were in support of the proposed LDT rule and 55.2% were in opposition to the rule. More telling, however, is that of the 2,900 comments in support, only 56 were not form letters! In contrast, about 1,300 individual comments were submitted in opposition (with another 2,400 form letters in opposition).

THERE IS ALWAYS A "STORY BEHIND THE STORY." That is certainly true of the news that 6,707 public comments were submitted in response to the federal **Food and Drug Administration's** (FDA) proposed rule: Medical Devices; Laboratory Developed Tests.

One obvious inference is that the 6,707 public comments means a large swath of consumers and stakeholders in the diagnostics and clinical laboratory industries were motivated to communicate their support or opposition to the proposed LDT rule.

This impressive number of public comments submitted during the 60-day comment period demonstrates that many laboratory scientists, health professionals, and members of the public expect the draft rule will have substantial impact, pro or con, especially were the FDA to promulgate a final LDT rule that closely follows the language of its draft rule.

With knowledge that almost 7,000 individuals and organizations submitted comments, the next challenge is to understand and interpret this result.

Question One: What significance should be assigned to the total number of public comments (as a statement of broad concern relating to the language of the draft rule) and the ratio of comments in support versus comments in opposition to the draft rule?

Question Two: Compared to a simple tally of the number in favor versus in opposition, is the content of the individual public comments a better measure of the true intensity (and concern about the consequences of the draft rule if implemented) that motivated an individual or organization to submit a comment?

The two questions above frame another fundamental question. How should the FDA, the lab profession, consumer advocates, and members of Congress parse

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the comments? More to the point, does quantity of responses trump the quality of responses?

A study of the public comments conducted by a news organization might help answer the question of quantity versus quality. That analysis also provides insights into the "story behind the story."

In covering this story, *360Dx* had a team dive more deeply into the public comments submitted to the FDA. Adam Bonislawski, Senior Editor for *360Dx*, wrote that the 6,707 responses were in three general categories, as follows:

- About 2,900 comments in favor (43.2%),
- About 3,700 comments in opposition (55.2%), and,
- About 100 comments offering feedback, but no position as to passage of the rule. (1.6%).

In a first-level analysis of the public comments, these numbers—43.2% in favor/55.2% opposed—indicate that a substantial proportion of the total responses were supportive of the FDA's draft LDT rule. But is that truly representative of the intensity of those who submitted these comments?

➤Form Letters about Rule

Of the 6,707 public comments, it turns out that form letters accounted for approximately 78% of all comments! But a second-level analysis of those form letters provides even more provocative insights.

The first surprise is that—of the 2,900 comments in support of the draft rule—*360Dx* determined that 2,844 "came as a single form letter [submitted multiple times]."

360Dx also found that three form letters made up about 2,400 of the 3,700 comments in opposition to the draft rule.

Starting with the numbers and types of public comments posted on the FDA's website as described by *360Dx*, if the numbers of form letters for both support and opposition of the draft rule are subtracted, a most interesting outcome appears. This deeper dive reveals:

- Unique public comments in support of the draft rule: **56** (plus 2,844 comments using the same form letter);
- Unique public comments in opposition to the draft rule: **1,300** (plus three different form letters totaling about 2,400 public comments); and,
- Remaining public comments (feedback without expressing a pro or con position): about **100**. (*360Dx* described these as "the remainder offering feedback on the proposed rule but neither supporting it nor opposing it.")

➤Deeper Analysis of Data

This second level analysis—the deeper dive—gives these findings useful context. After subtracting form letters from the tally of the 6,707 public comments, only 56 individuals or organizations submitted a non-form letter in support of the rule! Contrast that to the approximately 1,300 individuals or organizations that submitted a non-form letter opposing the draft LDT rule.

Expressed differently, 96% in non-form-letter public comments opposed the draft LDT rule. Only 4% of non-form-letter comments supported the rule.

Readers will need to judge for themselves the significance of these insights. Is a form letter equal in weight of opinion to a letter that was composed by an individual or organization to describe the specific and most relevant points he or she wants to assert?

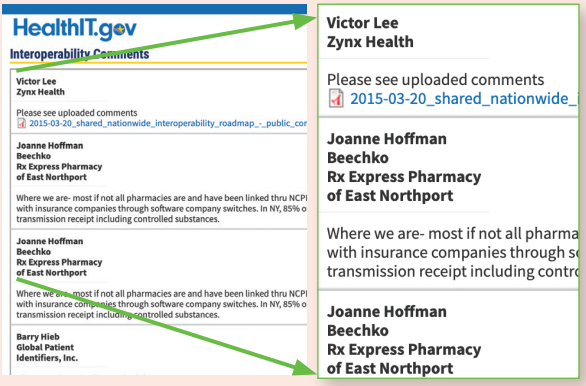
➤Organizations Not Identified

There is another interesting aspect to how the FDA presents the public comments on its website for viewing by the public. It does list all 6,707 public comments. However, it only lists the name of the individual who submitted that comment. It does not name that individual's place of employment or organization.

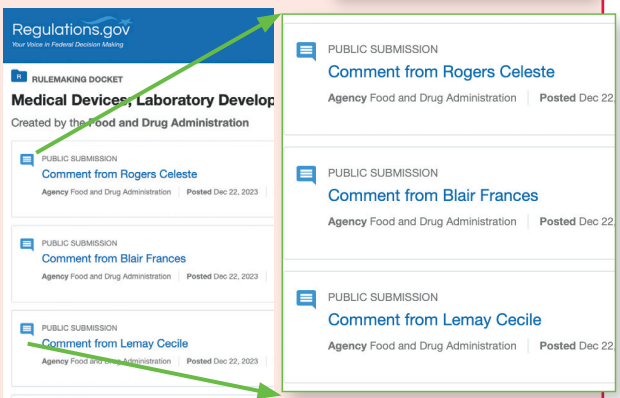
FDA Website Does Not Identify Organizations of the Individuals Submitting Public Comments

When the FDA released the public comments submitted in response to its proposed LDT rule, it only identified the individual who submitted the comments, but it did not identify that individual's organization. That was not the case when HealthIT.gov released the public comments submitted in response to its proposed rule on healthcare data interoperability. This agency identified both the individual and the organization for each comment. Examples from each agency's websites are shown below.

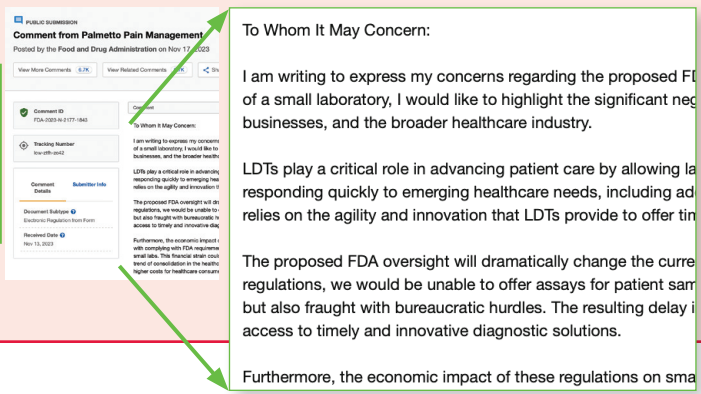
This is the HealthIT.gov page that shows all public comments sent about the draft IT interoperability rule. Note that it includes the name and organization for each comment, along with a link to see a PDF of the full comment as it was submitted to HealthIT.gov.



This screenshot from the FDA's webpage listing the public comments shows that the FDA is only providing the name and date submitted for each comment. It is not identifying the commenter's organization nor presenting the original PDF of the comment it received.



Here is an example of a non-form letter comment on the FDA's webpages.



It would be useful to know the names of the organizations represented by these 6,707 comments. This is relevant information for all parties with an interest in the proposed LDT role. This is just as true for those who support the rule as it is for those who oppose it.

HealthIT.gov Listed Names

It must have been a deliberate decision by FDA officials to withhold the names of organizations that submitted comments in support and in opposition. That's because when another government agency, **HealthIT.gov** published the public comments for its draft rule, "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)" rule, it included both the name of the individual and the organization that submitted the comment. *(See sidebar on page 5.)* Why would one federal agency include the names of the organizations and another exclude the names of the organizations?

Related to the FDA's non-disclosure of the organizations associated with the individuals named as making a public comment is another unanswered question. What are the names of the organizations that created the four form letters that *360Dx* identified in the public comments?

Who Created the Form Letters?

As noted earlier, those form letters made up 78% of the 6,707 public comments. The Dark Report checked with several news organizations and lobbyists involved with laboratory medicine. They all reported that they did not know the name of the original source of the one form letter in support of the draft. Nor did they know the names of the organizations behind the three form letters used to submit comments in opposition to the draft LDT rule.

Would it not be material and important for the American public, Congress, and lab industry stakeholders to know the identity of the organization which created the form letter that was used in 2,844 of the 2,900 comments submitted in support of the FDA's draft LDT rule? After all, that organization was able to encourage thousands of individuals to submit that form letter to the FDA.

The questions above demonstrate that the FDA has not been completely transparent about the true nature of the public comments submitted about the proposed LDT Rule. TDR

FDA's LDT Rule Faces Several Obstacles

One law firm issued a commentary about recent developments involving the proposed rule to regulate laboratory developed tests (LDTs) and the Food and Drug Administration's (FDA) statements about its path forward.

Attorneys at Atlanta-based **Hogan Lovells US LLP**, wrote that the FDA is likely to face serious "pushback from industry stakeholders," not the least because of arguments that the federal agency does not have the statutory authority to require a review of LDTs. Another argument is that "LDTs are medical services, not devices, and therefore should not be scrutinized by the FDA."

Hogan Lovell predicted that the agency would find itself "defending against lawsuits that would challenge the FDA's authority to regulate LDTs (i.e., lawsuits contending that the Federal Food, Drug, and Cosmetic Act (FDCA) does not grant FDA the authority to regulate LDTs)—which we continue to anticipate."

The report stated that another obstacle would be "inadequate agency resources to launch a new oversight program and to implement the phase-out policy" ... as well as "anticipated challenges with Congress for increased appropriations or user fee authorization."

FDA & CMS Issue Letter, Agree on LDT Oversight

It is a public statement that the two agencies are in agreement regarding FDA oversight of LDTs

CEO SUMMARY: With the release of a public statement about the oversight of LDTs on Jan. 24, 2024, officials at both the Food and Drug Adminstration and the Centers for Medicare and Medicaid Service went on record that both agencies are aligned in the specific roles each agency should have in the review and oversight of laboratory developed tests (LDTs).

Last month, something noteworthy happened involving regulatory oversight of laboratory developed tests (LDTs). A statement was published by the two federal agencies involved in overseeing diagnostics products and clinical laboratory testings.

This joint letter was issued on Jan. 24, 2024, by the federal **Food and Drug Administration** (FDA) and the **Centers for Medicare and Medicaid Services** (CMS). The point of the letter was to communicate that both the FDA and the CMS were aligned in the goal of the FDA issuing a final rule that gives it oversight over LDTs.

In recent years, two bills were introduced into Congress. The VALID Act (Verifying Accurate Leading-edge IVCT Development Act) would specifically authorize and empower the FDA to review LDTs. The VITAL Act (Verified Innovative Testing in American Laboratories Act) would clarify that the regulation of laboratory developed testing procedures (LDPs) rests within the CLIA program under CMS. As of this date, neither bill was passed by Congress and signed into law.

With this background, on Sept. 29, 2023, the FDA seized the initiative by issuing a draft regulation titled, "Medical Devices; Laboratory Developed Tests." This rule defines how the FDA proposed to review LDTs. The agency expects to release a final rule as early as April 2024.

Given these developments, it appears the timing of this joint FDA/CMS statement was intended to send a message that the directors of both the FDA and CMS see no conflict in the FDA assuming oversight for LDTs.

Agencies Describe Functions

In their Jan. 24 statement, the two agencies described their functions as they relate to LDTs and confirmed that each agency will work in concert with the other.

Presented below are relevant sections from the joint statement that describe the reasons why the two agencies see the need to change the status quo with LDTs. Sections in boldface are by The Dark Report to call attention to the way the two federal agencies are affirming their respective roles in the oversight of LDTs, as follows:

> *Both CMS and the FDA believe that patients and their doctors need to know that LDTs are valid. The FDA and CMS both provide oversight to*

help assure the accuracy of test results, however, they have different roles.

CMS regulates laboratories that perform testing on individuals in the U.S. through the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by establishing quality standards for all laboratory testing to help ensure the accuracy, reliability, and timeliness of patient test results.

In 2013, CMS published a fact sheet on LDTs, outlining each agency's authority and the complementary roles of the two regulatory schemes. ***That said, a decade later, in connection with the FDA's notice of proposed rulemaking, we are—together—reiterating that CMS' CLIA program is separate in scope and purpose from FDA oversight.***

Some have suggested that concerns with LDTs should be addressed through expansion of CLIA. This is not the answer. ***As was stated in our 2015 testimony, CMS does not have the expertise to assure that tests work; the FDA does.*** *Moreover, establishing a duplicative system for the oversight of tests by expanding CLIA would create more government bureaucracy and inconsistencies. That makes no sense.*

The FDA and CMS have long stood together in mutual support of FDA oversight of the analytical and clinical validity of LDTs. *LDTs play an important role in healthcare, but when they perform poorly or are not supported by science, they put patients at risk. The current approach has enabled some tests to enter the market with unfounded claims of innovation. These claims can mislead the public, undermine legitimate competition, and disincentivize responsible, science-based innovation. Applying the same oversight approach to laboratories and non-laboratories that manufacture tests would better assure the safety and effectiveness of LDTs and would remove a disincentive for non-laboratory manufacturers to develop novel tests that can be available to and used by many laboratories for many patients.*

We are now emerging from a global pandemic that has underscored the importance of accurate and reliable tests. Patients and providers need to have confidence that laboratory tests work. ***We believe the complementary FDA and CMS frameworks are both critical to assuring patients can rely on the clinical accuracy of their test results.***

To emphasize that both federal agencies are aligned in their thinking, the statement noted:

The following is attributed to Jeff Shuren, MD, JD, director of the FDA's Center for Devices and Radiological Health (CDRH) and Dora Hughes, MD, MPH, acting chief medical officer and acting director of the Center for Clinical Standards and Quality at CMS.

The joint statement is significant in another way. It shows that—within the current federal establishment, including the **Department of Health and Human Services** (HSS)—political leadership supports the FDA's drive to take over regulation of LDTs.

HHS Memo During Pandemic

This is the opposite position of the leadership of HHS during the last administration. Remember that, during the COVID-19 pandemic, the HHS Office of General Counsel issued a legal memorandum stating that LDTs are not subject to the premarket review provisions in the Food, Drug, and Cosmetic Act (FDCA).

In the memorandum—issued on June 22, 2020, about 90 days into the pandemic—it was argued that these provisions are triggered by "commercial distribution" of a medical device, and LDTs are considered a "service" rather than a commercially distributed "good." *(See*

TDR, "New Twist: HHS Exerts Authority Over FDA on LDTs," Nov. 16, 2020.)

At that time, this memorandum was intended to exclude COVID-19 LDTs from having to undergo the premarket review requirements as were other medical devices during the pandemic.

After the new administration took office in January 2021, it didn't take long to reverse this position. On Nov. 15, 2023, officials at HHS reversed the June 22, 2020, memorandum which exempted LDTs from the premarket review profisions of the FDCA.

LDT Rule to Push Forward

The 2021 action by HHS, and the January joint statement by CMS and FDA, can be considered as evidence that the political will exists for this administration to push forward with the FDA's proposed LDT rule.

Reinforcing this conclusion is the fact that the FDA was unresponsive to calls by opponents of the draft rule to extend the time for comments by 60 days. Metaphorically, the LDT rule is a train on the tracks and it will not be delayed from reaching its intended destination, which is publication of a final rule by the FDA, maybe as soon as April.

Meanwhile, even as the FDA continues to move forward on issuing a final rule, both the VALID Act and the VITAL Act are bills pending in the current Congress. There are members of Congress who support one or the other of these bills. But Congressional insiders say there is no push to get either of these bills to a vote.

Filing a Court Challenge?

Assuming that the FDA does promulgate a final LDT rule this spring, there are attorneys who predict that the lab industry will file court challenges to the final rule. Labs have won such court challenges in the past, but usually too late to forestall the consequences of the regulators' actions that were in question. TDR

Lab Industry Concerns with FDA's LDT Rule

THERE IS STRONG OPPOSITION within the clinical laboratory profession to the federal Food and Drug Administration's (FDA) proposed rule: Medical Devices; Laboratory Developed Tests. Major concerns include:

- Regulatory Overreach,
- Impact on Innovation, and,
- Lack of Clarity.

There are also many unknowns and serious criticisms about the FDA's four-year transition plan. Labs have pointed out that the draft rule fails to include important details about the framework the FDA will use, a framework that the agency described as having five stages:

- **Stage 1 (Year 1):** FDA's current enforcement discretion policy for LDTs continues. That means labs operate as before and there are no regulatory changes.
- **Stage 2 (Year 2):** FDA takes first steps to phase out its "enforcement discretion." It begins prioritizing enforcement actions for what it deems are either high-risk LDTs or LDTs with public health implications.
- **Stage 3 (Year 3):** FDA shrinks its enforcement discretion. Now labs must comply in specific ways, including submission of premarket notifications (510(k)s) for their LDTs.
- **Stage 4 (Year 4):** Full phase-out of FDA's enforcement discretion. Going forward, all LDTs are subject to the identical regulatory requirements as other *in vitro* diagnostic products. Lab must obtain FDA clearance for their LDTs.
- **Stage 5 (Ongoing):** From effective date of the final rule, the FDA intends to monitor safety and effectiveness of LDTs to ensure safety and benefits to patient care.

Legal Update

Feds Bar Elizabeth Holmes from Government Health Programs

Under the 90-year ban, Holmes cannot participate in federal health programs, such as Medicare, Medicaid

Once again, Elizabeth Holmes, the disgraced former CEO of **Theranos**, is in the news. This time it is because the federal **Department of Health and Human Services** (HHS) Office of the Inspector General (OIG) announced in January that Elizabeth Holmes is barred from participating in federal healthcare programs for a period of 90 years.

Holmes was convicted of three counts of wire fraud and one count of conspiracy to commit fraud in early 2022. She was sentenced in November 2022 to 11 years and three months and is currently incarcerated in a Texas federal prison.

Under her direction, the lab testing company claimed its proprietary Edison analyzer could run more than 200 clinical diagnostic tests using a finger prick of blood instead of specimens collected by a needle. The company also claimed patients and clinicians would have test results within four hours at a cost of less than half of typical lab fees.

HHS Statement

"Accurate and dependable diagnostic testing technology is imperative to our public health infrastructure. False statements related to the reliability of these medical products can endanger the health of patients and sow distrust in our health care system," said HHS Inspector General Christi Grimm in a statement.

"As technology evolves, so do our efforts to safeguard the health and safety of patients, and HHS-OIG will continue to use its exclusion authority to protect the public from bad actors," she added.

Under 1128(a) of the Social Security Act, Holmes can be excluded from participation in Medicare, Medicaid, and other federal healthcare programs. The code states that individuals who have been convicted of certain crimes, including offenses related to healthcare fraud, can be rendered ineligible to receive those benefits.

Barred from Healthcare

"The statutory minimum for an exclusion based on convictions like Holmes' is five years. When certain aggravating factors are present, a longer period of exclusion is justified," the OIG said. "The length of Holmes' exclusion is based on the application of several aggravating factors, including the length of time the acts were committed, incarceration, and the amount of restitution ordered to be paid."

Her exclusion from federal healthcare programs also means she cannot receive any payments in the future from federal health programs for services or products. This significantly restricts her ability to be employed in the healthcare industry after her prison sentence has been served.

The failure of the Edison technology defrauded investors of hundreds of millions of dollars and put patients at risk. Evidence presented at the trial proved that Holmes and her partner Ramesh Balwani were aware they were falsely representing their technology and duping investors into bankrolling Theranos. TDR

Virchow

Medicine Money Managed Care

This column is named after the famous German pathologist, Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

Published Data Show Claim Denials on the Rise, But Why?

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of THE DARK REPORT better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

CLAIM DENIALS BY COMMERCIAL HEALTH INSURERS HAVE LONG BEEN A HEADACHE for healthcare providers, including clinical laboratories. For labs, you could say the problem dates to the emergence of complex genetic testing, coupled with the worldwide COVID-19 pandemic.

However, since the end of the pandemic, complaints about denials seem to have reached a new high. All classes of providers are complaining, including medical laboratories. Confirmation of increased claims denials is found in a May 2023 benchmarking analysis issued by public accounting, consulting, and technology firm **Crowe LLC** of Austin, Texas.

Using data from more than 1,800 hospitals and 200,000 physicians, the company noted in its Crow RCA report that denials by commercial payers increased from 14.1% in 2021 to 15.1% in the first quarter of 2023. The numbers were more striking for prior authorization and precertification (medical necessity) denials, which increased from 2.4% in 2021 to 3.2% in the first quarter of 2023.

Much time, effort, and money is required to get these claims paid. This is especially true for medical necessity denials, which often lead to a lengthy and costly appeals process. Currently, for medical entities, neither time nor money are in abundant supply.

The rise in claim denials could mean one of two things: Either—since the COVID-19 pandemic—entities such as medical laboratories, radiology groups, and hospitals became sloppier in their billing, or managed care companies said to themselves, "More and more claims are coming in. We need to tighten up and become more efficient. We will deny a certain percentage of these claims."

Don't get me wrong—claims are often denied for legitimate reasons. Maybe the test doesn't meet medical necessity, or it doesn't hold clinical value.

For example, if someone bought a **23andMe** at-home genetic test over the counter at **Walgreens** and tried to submit that to insurance, the payers would say, "Whoa, wait a minute. This is not medically necessary."

But when denying claims, many health plans will provide only a vague explanation of the reason. To many folks, it appears that the payers are on a fishing expedition, particularly when it comes to genetic testing. The health insurers refuse to pay the claims. And sometimes that decision is incorrect.

Why is this happening? Let's take a closer look at how payers process claims.

Deep Look at Claims Process

Insurance companies get hundreds of thousands of claims per day. The volume is too much to handle manually. For many years, payers have used software algorithms—we now call them bots—to automate the claims process.

In the background, bots are implementing CMS rules or policy rules stating that a certain patient can have a particular test once in 12 months, or once in a lifetime, or once in a quarter. Assume a claim comes in for a patient who had a test the previous month. The policy rules say this patient can't have this test again, so the bot denies the claim.

This is great when it works. If it is a routine approval—if there is a specific code for the test, and the diagnosis is correct—it goes through. Or the bot might deny the claim, but for straightforward and legitimate reasons. Perhaps the plan member is deceased or is no longer enrolled in that health plan because he or she recently changed jobs or retired.

Another common reason for denying claims is incorrect diagnosis. For example, the doctor might have submitted a code for a screening diagnosis but ordered a test that's not intended for screening. This, too, is something that a bot can check with relative ease.

But now that molecular and genetic testing has gotten more complex, are these bots able to keep up? I don't think so.

Many elements in a claim can lead to denial. Sometimes the denial codes and denial letters will give the laboratory a good idea of why the claim was denied. But often the response lacks specifics about what the laboratory needs to do for the plan to pay up.

In some cases, the bot will flag a claim for review by a human being. This most often happens when the claim involves CPT code 81479 (unlisted molecular pathology procedure), a CPT code that applies to those genetic tests that don't fall under a more-specific code. When a lab uses code 81479, someone at the health plan is going to look at that test. That person is going to ask for prior authorization and will want to see medical records to verify that the test was necessary.

As THE DARK REPORT has previously noted, prior authorization requirements are a notorious pain point for clinical laboratories. *(See TDR, "How to Achieve Success with Genetic Test Prior Authorization," July 26, 2021.)*

More and more claims these days require prior authorization, often resulting in claim denials or payment delays, especially if the ordering physician hasn't initiated the process.

However, not all genetic tests are prone to claim denials. If there's a specific code for that test—such as BRCA testing for breast cancer—generally those will go through as long as the diagnosis is correct. Problems are most likely to arise with complex panels for rare diseases.

And let's be honest—these processes are in place because some unscrupulous labs continue to break the rules.

Use of CPT 81479 Required

The federal **Centers for Medicare and Medicaid Services** (CMS) began requiring genetic testing laboratories to use code 81479 because so many of them were inflating their claims by stacking panels with dozens of codes, often for unneeded tests. *(See TDR, "Private Health Insurers Are Aware of Problems with CPT Code 81408," Sept. 11, 2023.)*

CMS told them, "If you can't find one code that describes your panel, use 81479." So now I tell people, "These new rules were not put in place for people like you. They were put in place for the bad guys."

Typical 90-day windows for filing claims adds more complication. After 90 days, the payer will deny the claim for missing the deadline. Let's take a closer look.

The laboratory bills a managed care plan and then 30 days later the payer returns the claim saying it's been denied. Now, the laboratory must decipher the information from the insurer to determine why the claim was denied.

Maybe the insurer wants medical records—so the laboratory uploads the medical records. Then, the insurer comes back and says, "Okay, A, B, and C were correct. But we still need this document from the doctor."

Lab Needs Help from Doctor

Now the laboratory needs the doctor's help. The lab's billing team might ask the doctor's staff to pull the patient's chart. If the denial involves an incorrect diagnosis, they might ask if the doctor really meant that diagnosis. A cooperative doctor should be willing to provide what the lab needs to rebill the payer.

But doctors aren't always so helpful. At this point, the doctor has no skin in the game. The doctor received the lab results he or she ordered and is not owed any money. And doctors are often short staffed. They might say, "We don't have anybody to pull that chart right now. We'll see when we can get to it." Or the call from the lab might go to voicemail and no one will call back. This happens all the time.

The initial denial caused the claim to be touched multiple times and delayed multiple times, so now the claim is at 92 days. The laboratory has sent everything asked of them, but the insurer comes back and says, "We're beyond 90 days, so we're denying again."

As noted in a previous Virchow column, many health insurers have instituted widespread layoffs over the past year or so, and this is likely to make the problem worse by reducing staff available to handle inquiries about claims. *(See TDR, "Layoffs at Major Health Plans Slow Processing of Lab Claims," Jan. 16, 2024.)*

One big loss here is the opportunity for more direct interaction between payers and providers. In the past, if a particular clinical laboratory had a high volume of denials, an insurer could assign a claims expert to work with the lab to identify the problem areas and suggest corrections.

As long as the laboratory was acting in good faith, each party could accomplish more with a phone call than an exchange of letters or emails. But this kind of dialog about issues with health plans appears to be gone, especially for the smaller regional laboratories.

Claim denials are affecting healthcare providers across the board, in big health systems as well as small regional hospitals. But the big healthcare systems might be in a better position to weather the shortfalls. The smaller ones, though, are desperate across all their departments, including their medical laboratories.

When a sample arrives, the lab is legally obligated to test it. Without timely reimbursement, labs now say, "We have no cash flow. The managed care plans are holding us hostage. We've provided the service. Where else does a provider offer a service on good faith that it's going to get paid?" None that I can think of. TDR

Denial Rates at Medicare versus Private Payers

ONE NOTABLE ASPECT of the Crowe RCA report is that commercial payers denied claims at much higher rates than Medicare. For example, in the first quarter of 2023, Medicare initially denied 3.9% of claims compared to 15.1% for commercial payers.

The report noted that most providers still prefer dealing with commercial payers due to higher reimbursement rates. However, "commercial payers take the longest to pay, require providers to jump through more administrative hoops to get paid, and delay payments to providers via claim denials at a higher frequency than government payers," the report stated.

Compliance Update

European Lab's Data Breach Has Lessons for U.S. Clinical Labs

In what could be a cautionary tale for clinical laboratories, a cybersecurity researcher has reported the discovery of a medical laboratory database that publicly exposed COVID-19 test records containing people's personal data, including their names, passport numbers, appointment details, and test results.

The database, which was not password protected, contained approximately 1.3 million records, wrote researcher Jeremiah Fowler in a report on cybersecurity company **vpnMentor's** website. Certificates and other documents in the database indicated that the records came from **Microbe & Lab**, a clinical laboratory company based in Amsterdam, Netherlands.

Fowler reported that he sent the company multiple responsible disclosure notices—a mechanism for safely revealing cybersecurity breaches—but did not receive a reply. "Several phone calls also yielded no results," he wrote. "The database remained open for nearly three weeks before I contacted the cloud hosting provider, and it was finally secured from public access."

Speaking to *HealthcareInfoSecurity*, Fowler identified **Google** as the hosting provider. However, he said that in this case, the end-user was responsible for misconfiguring the database, not the hosting service.

Although the Microbe & Lab data were publicly exposed, it is unknown whether hackers or others actually accessed the records, Fowler noted.

What does this mean for other clinical laboratories?

"While it happened in Europe, it could just as easily happen to any healthcare provider in the U.S.," said attorney Adam H. Greene, a Washington, D.C.-based partner at the law firm **Davis Wright Tremaine LLP**, in an interview with The Dark Report. "Healthcare providers have to comply with the HIPAA Security Rule and put good information security in place."

Greene, who specializes in health information privacy and security laws, previously served in the federal **Office of General Counsel** and **Office for Civil Rights** at the **U.S. Department of Health and Human Services**. The Office for Civil Rights is responsible for enforcing HIPAA Privacy and Security Rules.

Shared Security Model

For many healthcare providers, Greene said, it often makes sense to use a cloud-based service. But that does not absolve them of their responsibility for the security of their patients' protected health information (PHI).

"Information security is tough, and grows tougher by the day," he said. "A healthcare provider has to protect a thousand doors. Bad actors just have to find one door that's open, even by just an inch. But a healthcare organization doesn't necessarily have the same level of security resources that a cloud provider does. Oftentimes, cloud providers can offer much better security safeguards at a lesser price than what a healthcare provider would be able to do on its own."

Still, Greene added, "it's not merely a plug and play 'Oh, it's on a cloud provider, so I don't have to worry about it anymore.' The cloud generally requires what's sometimes known as a shared security model.

"As a healthcare provider, a clinical laboratory and its cloud services provider each have responsibilities for the security of the protected health information. It's important for each side to understand those responsibilities," he noted.

For example, continued Greene, "the cloud provider may offer technical safeguards, such as encrypting the data, but it falls on the healthcare provider to turn that on or off.

"Labs and other providers must make sure they're configuring the account properly and doing everything else that falls to them," he advised. "A cloud computing provider can provide the greatest security possible, but if customers set their passwords as the word 'password,' all of that will be for naught."

Liability for Lax Security

Poor security practices can have serious legal consequences, Greene noted. "If a U.S. healthcare provider uses cloud services and does not properly configure the security, it is likely in violation of the HIPAA Security Rule."

The rule applies to what are known as "covered entities," he said. "A medical laboratory is a covered entity if it electronically conducts HIPAA-covered transactions with health plans. This generally equates to whether it bills insurance. If a lab—such as a genetics lab—is strictly cash-pay, then it may not be subject to HIPAA."

The potential legal risk doesn't necessarily end at the Office for Civil Rights. "When a big healthcare breach happens, sometimes people focus almost entirely on exposure under HIPAA. They neglect to identify that the bigger risk could be a class action lawsuit under state laws," he noted.

In addition, "if the laboratory is a for-profit healthcare provider, they could also be in violation of Section 5 of the Federal Trade Commission Act, which prohibits unfair and deceptive trade practices," he continued.

Notice of Privacy Practice

Why? "Pursuant to HIPAA, covered entities are required to issue a Notice of Privacy Practices, which states how the entity may use and disclose a patient's protected health information," stated Greene. "The notice cannot say, 'We may disclose your information to some random security consultant or to random hackers.' If a provider has poor security, that could lead to disclosures of protected health information that are not consistent with the notice.

"So, that could be treated as deceptive," commented Greene. "The FTC could also see poor security as an unfair practice, if the harm to individuals is greater than any benefit and they can't do anything about it."

What steps should clinical laboratories take to minimize their risks?

"Labs and pathology groups should make sure they have internal expertise," Greene said. "Under HIPAA, providers are required to have a security officer, and that individual should be looking at the risks related to protected health information. That would include the risks of misconfiguration, and steps to potentially address those risks. It might include redundancies: Having a second individual to double-check that the system is properly configured, rather than relying on the person who set it up to self-audit and be sure everything is done right."

Shared Responsibility Model

Also, "look to whether the cloud services provider has guidance about the shared responsibility model," Greene suggested.

"Many cloud services have white papers and other resources that will help

laboratories understand the steps they should take for good security and to comply with HIPAA."

If a clinical laboratory chooses to outsource data storage, another key "is due diligence on the vendor," said Brad Rostolsky, a Philadelphia-based healthcare attorney with the law firm **Greenberg Traurig LLP**.

"Laboratories should be thoughtful about who they're engaging," he observed. "To the extent that a lab has oversight responsibilities, it should give those responsibilities the credence they deserve."

Clinical labs should also take steps to prevent scenarios where warnings about security breaches go unheeded, he said.

"It's useful to identify staff members within the healthcare organization who are responsible for dealing with those sorts of outreaches, whether it's a subpoena, a letter or email, or a phone call," Rostolsky suggested. "Next, train everyone else so that if they happen to receive anything that deals with security or privacy, they will hand it over to that designated person."

Is COVID-19 to Blame?

In his report about the breach, Fowler, the security researcher, noted that the COVID-19 pandemic posed major challenges for data security for clinical labs.

"There was a massive amount of COVID-19 test data collected in a short period of time," wrote Fowler. "This test data needed to be accessible for patients or verifications, yet still secure from unauthorized access. The rush to process this data increased the risk of security-related errors," he noted.

"Now that the pandemic is mostly behind us, it is time for organizations to review the massive amounts of data they have stored and determine if these records are still needed," he wrote. "If they are, organizations must ensure the data is secured from unauthorized access. The records should be encrypted or anonymized to prevent unwanted data exposures or threats from malicious actors."

Rostolsky explained that, even in normal times, "businesses should periodically look at their data retention policies. Different businesses have different reasons for keeping different types of information," he said. "If they have data they don't need, or are not legally obligated to maintain, they're taking on more risk for no reason." TDR

Contact Adam Greene at adamgreene@dwt.com and Brad Rostolsky at brad.rostolsky@gtlaw.com.

What Was in the Lab's Test Results Database?

INFORMATION IN THE UNSECURED DATABASE that appeared to come from Microbe & Lab in the Netherlands contained what was potentially a treasure trove for cybercriminals.

For example, it included appointment details and email addresses that could have been used in targeted phishing campaigns, wrote cybersecurity researcher Jeremiah Fowler.

"The criminal could potentially reference test dates, locations, or other insider information that only the patient and the laboratory would know," he wrote. "Any potential exposure involving COVID-19 test data—when combined with PII [personally identifiable information]—could potentially compromise the personal and medical privacy of the individuals listed in the documents."

The database also contained QR codes linked to test results. "As useful and as user friendly as QR codes are, they can be a major security risk," Fowler wrote. "For example, the codes can be easily changed to redirect users to fake websites or prompt them to download malware or other malicious applications."

Lab Market Update

Invitae Cuts Costs to Rebuild Oncology Testing Pipeline

Divesture of assets and layoffs expected to result in nearly $100 million in savings

INVITAE CORPORATION, A MEDICAL GENETICS COMPANY that had a $1.34 billion loss during the nine months ending Sept. 30, 2023, recently announced coming actions to cut costs and change operations.

The San Francisco-based company sold "certain reproductive health assets including carrier screening and non-invasive prenatal screening" to **Natera**, an Austin, Texas-based company offering cell-free DNA testing, an Invitae news release noted.

Invitae said it expects the $52.5 million sale will reduce its operating expenses by about $44 million per year after one-time severance-related payments are made.

"Today's announcement further helps us streamline operations and focus our resources on our strengths of clinical germline genetic information and superior variant interpretation in support of millions of oncology and rare disease patients," said Ken Knight, Invitae CEO, in the news release.

Invitae's deal with Natera in January followed its announcement in late 2023 that it is divesting assets of Calif.-based **Ciitizen**, a health technology platform that enables patients to digitally manage and share their medical records.

Invitae acquired Ciitizen in 2021 for $325 million, a statement noted.

Invitae also cut 235 workers in December, reported *The San Francisco Standard*. The company expects the Ciitizen divesture and layoffs to result in savings of $90 million to $100 million.

"While these moves unfortunately involve a reduction in our workforce, we are committed to working closely with those impacted to ensure a smooth transition for them and for our customers and patients," said Knight in a statement at the end of 2023.

Invitae, which started in 2012 as a spin off from **Genomic Health**, Redwood City, Calif., says it aims to "aggregate the world's genetic tests into a single service with higher quality, faster turnaround time, and lower prices." It offers genetic testing, biopharma research services, and rare disease discovery.

Included are genetic testing options in oncology, reproductive health, pediatric and rare diseases, and urology. Most frequently ordered tests, according to Invitae, include:

- BRCA1 and BRCA2 panels with Invitae multi-cancer panel (70 genes).
- Lynch syndrome panel with Invitae multi-cancer panel (70 genes).
- Comprehensive carrier screen (up to 569 genes).

Patent Spat

Natera's purchase was made "after a patent spat," *Fierce Biotech* reported, adding that a suit was filed by Natera early in 2020 against **ArcherDX**, a genomics analysis company, before Invitae acquired the company in October 2020.

In the suit, Natera claimed, "Anchored Multiplex PCR technology at the core of [ArcherDX's] Personalized Cancer Monitoring tests infringed upon several of Natera's own patents," *Fierce Biotech* reported, adding that a verdict favored Natera and that Invitae was planning an appeal.

Financials Show $1.34B Loss

In its report, "From Genetics, Health Third Quarter 2023 Financial Results," Invitae noted a $1.34 billion loss in the first nine months of 2023, as compared to a $3 billion loss in the first nine months of 2022.

Invitae also shared these Q3 data as compared to Q3 2022:

- Total revenue was down 9.7% to $121 million from $134 million.
- Oncology test revenue fell 21.5% to $62 million from $79 million.
- Women's health revenue increased 8% to $27 million from $25 million.
- Rare Diagnostics revenue increased 35% to $23 million from $17 million.
- Data/patient network revenue fell 30.7% to $9 million from $13 million.

Building Onc. Test Pipeline

Further, the report to investors also noted these accomplishments during Q3:

- Reached 4.4 million patients served.
- 64% of people tested agreed to share data.
- Obtained CLIA approval for a "more efficient" version of a personalized cancer monitoring (PCM) assay.

During an earnings call, Knight explained the enhanced PCM assay "is able to achieve the same sensitivity as the prior version with less cell-free DNA, enabling us to test samples that may have previously been rejected."

Invitae seeks to "rebuild" its oncology "pipeline," Knight added. He also referred to commercial insurance payment pressure on hereditary cancer and lower fee-for-service reimbursement contributed to revenue decline.

"We are creating plans that will—over the next 12 months—further reduce operating cash burn and improve the company's liquidity. This is a top priority," he said during the call.

"Overall, we continue to have strong confidence in our ability to operate, and most importantly, our ability to continue offering PCM to pharma partners and patients as we rebuild our fee-for-service pipeline," he continued.

"Longer term, we continue to see synergies between hereditary germline and somatic products. Study after study concludes that the combination of the two datasets results in superior decision-making in cancer care," Knight added.

Challenges Ahead

Business publications have weighed-in on Invitae.

Invitae is "in a financial pickle," *Motley Fool* reported, adding "with enough cuts, it could still survive."

The San Francisco Standard shared that Invitae's stock price has dropped more than 60% since December 2022, and that the company had received a **New York Stock Exchange** notice in September 2023 "for falling under the $1 per share threshold."

THE DARK REPORT has observed that payers, generally, may not be processing genetic test claims in a timely basis or at a level that covers the cost to perform the expensive tests. So, genetic testing companies are often out the money up front as they report on tests and then wait months to be reimbursed.

Pathologists and clinical laboratory leaders will want to stay tuned to see how Invitae fares following cost savings and business rebuilding initiatives. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Australia last December, a clinical lab company was taken to court by the **Office of the Australian Information Commissioner** (OAIC), which deals with privacy issues. The government agency alleges that **Australian Clinical Labs** (ACL) had "serious and systemic" failures that enabled a cyberattack in 2022 to compromise the private health and financial data for 200,000 patients. ACL has revenues of AU$1 billion. Patient data stolen from ALC showed up on the Dark Web.

ADD TO: *Lab Data Breach*

In its court filing, the government agency claims that ACL did not provide timely notification of the cyberattack and breach of patient data, as required under the Privacy Act. Another claim is that ACL "did not have a dedicated cyber security team in place during the incident, with its response being led by an IT team leader and overseen by the company's chief information officer." In another cyberattack during 2022, Australia's largest health insurer **Medibank** was also hit with a cyberattack in 2022. This breach resulted in the personal data and health information of nearly 10 million customers showing up on the Dark Web. These attacks are reminders to lab managers that patient data has great value to hackers and cyberthieves.

CANCER CLUSTER AT LAB TO BE STUDIED

It was reported last week that **UNC Health** requested help to investigate if there is a cancer cluster at **McLendon Clinical Laboratories** in Chapel Hill, N.C. No other details were provided.

CYTOVALE RAISES $84 MILLION FOR ITS RAPID SEPSIS TEST

San Francisco-based **Cytovale** closed an $84 million Series C stock offering last November. It has an FDA-cleared rapid sepsis diagnosis test called IntelliSep that it is marketing to hospital emergency departments and integrated delivery networks. The company states that the test uses a standard blood draw and has a "blood-to-answer time frame of under 10 minutes."

TRANSITIONS

- **Coronis Health** of Sykesville, Md., announced that Jerrald Hendrix is its new Vice President of Strategic Development. His prior positions were with **Change Healthcare**, **McKesson**, and **ABN Amro**.

- Lisa Potter was named Chief Operating Officer at **JTG Consulting Group** of Miami Shores, Fla. She was previously with **Data Innovations**, where she served for 25 years.

- Also joining **JTG Consulting Group** is Jaimie Augustine in the role of Chief Growth Officer. She formerly held positions at **Copan Diagnostics**, **Swedish Medical Center**, and **Oregon Health and Sciences University**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 26, 2024.

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UPCOMING...

- ***Final rule on health IT interoperability will bring important benefits for labs, pathology groups.***
- ***Scott Gottlieb, MD, on navigating an ever-evolving regulatory and policy landscape.***
- ***How recent years of civil, criminal court decisions provide useful insights for compliance with EKRA.***

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