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David A. Zetoony, JD, on ...

Internet Tracking Lawsuits Target Labcorp, Quest, Healthcare Providers

Plaintiffs allege violations of protected patient data

(See pages 3-7)

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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

Getting Test Claims Paid & Class Action Lawsuits

WHEN YOU CRACK OPEN THIS ISSUE OF **THE DARK REPORT**, YOU WILL FIND IT ORGANIZED AROUND TWO PRIMARY STORIES. One story introduces you to a new type of legal attack on healthcare providers—including clinical laboratories—by class action lawyers. The second story delivers to you a comprehensive look at which lab test claims are getting paid and which are not.

Leading this issue is the lab industry's first intelligence briefing on the growth of class action lawsuits filed against healthcare providers with allegations that use of website tracking software by providers is a breach of individual and patient privacy. **Labcorp** and **Quest Diagnostics** were both sued by different class action lawyers. Also named as defendants were **Alphabet/Google** and **Meta/Facebook** as the providers of the Internet tracking software tools. *(See pages 3-7.)*

Attorneys following these cases tell THE DARK REPORT that the legal claims are being filed under older state and federal statutes. The legal theories asserted by the class action attorneys are complex because of that fact. At the same time, as filed in the courts, the lawsuits describe patients who were surprised to learn that data about their visits to a clinical lab's website to look up specific tests or make appointments at patient service centers were being captured by the web tracking tools provided to the lab by Google and Facebook.

Our coverage of this novel legal attack involving private patient data typically gathered and stored by clinical laboratories in the normal course of providing lab testing services gives you and your lab team the opportunity to study this new legal threat with your lab's attorneys.

The second major intelligence briefing in this issue addresses trends in how payers are denying lab test claims and handling appeals. We provide the findings of a study that involved almost 20 million lab test claims from about 200 clinical laboratories. Performed by **XiFin, Inc.**, this data was first presented last spring at the *Executive War College. (See pages 10-21.)*

Submitting clinical lab test claims to health plans today is increasingly becoming a crap shoot. That's because payers frequently change how they process test claims without notice. The uncertainty of whether claims will be paid is now widespread across the entire lab industry. We encourage you to use the information and insights found in the XiFin study to increase the number of test claims paid to your lab. **TDR**

Internet Tracking Lawsuits Target Quest and Labcorp

Class action attorneys now filing numerous cases against healthcare providers, including laboratories

David A. Zetoony, JD

CEO SUMMARY: Here is the clinical lab industry's first intelligence briefing on how class action attorneys are filing lawsuits against healthcare providers—including clinical laboratories. The allegations are that providers are using internet tracking tools, such as those offered by Meta/Facebook and Google, that cause private patient and consumer information to become public.

QUEST DIAGNOSTICS AND LABCORP, THE TWO GIANTS OF THE U.S. CLINICAL LABORATORY BUSINESS, are among many companies across a wide range of industries facing class-action lawsuits over their use of tracking technologies designed to facilitate online advertising.

This type of class action lawsuit is increasingly common. Such cases often claim that the healthcare providers' use of common internet tracking software on their websites is one way that patients' confidential information is exposed to the public. Clinical lab managers and pathologists should consult with their legal teams to understand this rapidly evolving area of class action litigation.

The lawsuits filed against Quest and Labcorp were not filed under internet privacy laws. Instead, plaintiffs allege that Quest, Labcorp, and many other companies have violated anti-wiretapping laws passed decades ago.

One case, *Howard v. Laboratory Corporation of America and Laboratory Corporation of America Holdings*, alleges that Labcorp's use of two such technologies—**Google** Analytics and **Meta** Pixel—violated two criminal statutes: The California Invasion of Privacy Act (CIPA) and Pennsylvania Wiretapping and Electronic Surveillance Control Act (WESCA). CIPA was enacted in 1967 and WESCA in 1978. *(See sidebar on page 7.)*

Courts have dismissed many of these lawsuits, but the cases demonstrate that clinical labs, genetic testing labs, and pathology groups should examine their online strategies to minimize their exposure, legal

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FTC Takes Action on Healthcare Privacy

FEDERAL TRADE COMMISSION (FTC) REGULATORS are acting against companies that allegedly compromise consumers' personal health information, particularly those not covered by the Health Insurance Portability and Accountability Act (HIPAA). The agency has two tools for doing so: The Federal Trade Commission Act (FTCA) and the Health Breach Notification Rule (HBNR).

In February 2023, FTC announced that **GoodRx**, which provides drug discounts and telehealth services, had agreed to pay a $1.5 million civil penalty for violations of FTCA and HBNR. FTC claimed that the company had shared users' personal health information with **Facebook**, Google, **Criteo**, and other third parties "contrary to its privacy promises," and "failed to report these unauthorized disclosures as required by the Health Breach Notification Rule."

In March 2023, the FTC announced that **BetterHelp**, an online counselling service, would pay a $7.8 million penalty for similar violations. Despite promises to protect personal health data, "BetterHelp used and revealed consumers' email addresses, IP addresses, and health information to Facebook, **Snapchat**, Criteo, and **Pinterest** for advertising purposes," FTC alleged.

expert David A. Zetoony, JD, co-chair of the U.S. Data Privacy and Cybersecurity Practice at **Greenberg Traurig, LLP**, told THE DARK REPORT. This includes use of online tracking technologies such as cookies, and how the use of those tracking technologies are disclosed to website visitors.

Individuals Cannot Sue

Corporations in the U.S. typically strive to comply with modern data privacy laws passed in approximately 20 states over the past five years. In addition, many aim to comply with the European General Data Protection Regulation (GDPR), widely regarded as the "gold standard across the world," Zetoony noted.

However, "most modern privacy laws in the United States don't have a private right of action, so individuals are not allowed to sue under them," Zetoony explained, adding, "Nor do they provide a way to compute monetary damages to individuals.

"If a plaintiff law firm is trying to make money off of privacy issues, they're not going to use one of the modern state privacy laws," he continued. "Instead, they tend to look at older privacy laws, often passed before the Internet was invented that do have a private right of action."

In addition, the older laws offer what are known as "statutory liquidated damages," he explained. "The statute says they don't have to prove how much someone has been hurt. If they can prove it happened, and that there was some injury, they can argue that they are entitled to fill in the blank, $500, $1,000, or $1,500, for example, for every person they represent. So, those are much more attractive to plaintiffs."

Zetoony declined to comment specifically on the Quest or Labcorp cases, instead speaking more generally about class-action suits that employ similar legal theories.

Wiretapping Laws

Plaintiffs began filing suits under these older state wiretapping laws about a decade ago, but "courts threw out the cases," Zetoony said.

"Wiretapping laws enacted in the 1960s or 1970s envisioned somebody going to a telephone pole and tapping into a landline and intercepting a call. Courts said that plaintiffs couldn't apply that to a situation where somebody goes online and a website intentionally shares that visit with another party. It's fundamentally different than what those laws were set up for," he added.

Fast-forward to 2020, and "plaintiffs tried to breathe new life into the theory and started bringing the cases again," he said. "By and large, when courts have evaluated the merits, the plaintiffs have failed. But plaintiffs have found a few courts that are willing to entertain the theory—or haven't said it doesn't work—and they've just filed and filed and filed. And for every case that they file, there are probably 10 to 15 letters sent to companies demanding payment and threatening to file."

The lawsuits come in "different flavors," he said. "It's evolved in terms of the technology that the plaintiffs focus on. We saw about 60 class actions filed in 2021. Last year, about 520 class actions were filed. This year I'm sure the number will exceed that, and those just could be the federal court filings. There are probably multipliers of that which are being filed in state courts, in arbitration, and then again, in the demand letters."

FTC Sues Health Companies

Plaintiffs have filed lawsuits across all industries, he said, "but healthcare is getting hammered because there's a visceral reaction when health information is shared. It's one thing to say, 'I bought a T-shirt from somebody, and oh my gosh, he shared that with somebody else.' From an optics standpoint, anytime plaintiffs are dealing with a healthcare company, they feel that they have a better hook in terms of convincing a judge or jury that something untoward has happened."

In addition, he noted that the **Federal Trade Commission** (FTC) has acted against some health-related companies for sharing consumer information with third parties. *(See sidebar on page 4.)* In these cases, the agency invoked the Federal Trade Commission Act (FTCA) or the Health Breach Notification Rule (HBNR), not any state or federal wiretapping laws.

"FTC got some big settlements and drew attention to the idea that the government thinks tracking technology in a health context could be problematic," he said. "Although neither the FTCA nor the HBNR allow for lawsuits by private parties, I think they spurred the private plaintiff bar to think that they can get the same type of recovery."

How can healthcare companies—including clinical labs and pathology

Split Decision for Quest in Privacy Court Case

QUEST DIAGNOSTICS CONTINUES TO SEEK DISMISSAL of a class action lawsuit alleging that its use of tracking technology violates the California Invasion of Privacy Act (CIPA), an anti-wiretapping law enacted in 1967.

In 2022, California residents, Angela Cole and Beatrice Roche, filed a two-count complaint alleging that Quest had violated CIPA and the state's Confidentiality of Medical Information Act (CMIA).

The plaintiffs had ordered tests through their primary care physicians and accessed the results through a password-protected Quest website. They contended that Quest's use of the Facebook Tracking Pixel enabled Facebook to receive data about their visits to that site as well as a public-facing website. This data included URLs, page titles, keywords, and page descriptions.

On July 2, 2024, U.S. District Judge William J. Martini granted Quest's motion to dismiss one count—the CMIA claim—but declined to dismiss the CIPA claim. Two weeks later, Quest filed a motion asking the court to reconsider the partial denial.

"This case challenges the use of a common website analytics tool that uses 'cookies' to collect data regarding user activity on websites to better serve users," Quest stated in one filing. In addition, "Quest maintains that Plaintiffs consented to the practices at issue and that Quest did not otherwise violate CIPA."

Labcorp Lawsuit Goes to Arbitration

IN FEBRUARY 2024, LABCORP PATIENTS, Michael Wiggins of Pennsylvania and Teri Stevens of Maryland, filed a class action complaint alleging that Labcorp had disclosed their personal health information to Google by means of three technologies: Google Analytics, Google Ads, and Google Display Ads. They alleged violations of the federal Electronic Communications Privacy Act and other laws.

The plaintiffs contended that Labcorp "violated its privacy policies by failing to disclose the full scope of its data collection efforts, using patients' data for undisclosed purposes, sharing patient data with undisclosed recipients, and allowing those entities to use its patients' data for their own undisclosed purposes."

Labcorp argued that the plaintiffs had accepted its user agreement, which includes an arbitration clause and class action waiver. On Oct. 11, U.S. District Judge Wendy Beetlestone granted the company's motion to have the case referred to arbitration.

The case was heard in the U.S. District Court for the Eastern District of Pennsylvania.

groups minimize their exposure to these types of class action lawsuits?

First, Zetoony said, companies can simply avoid using tracking technologies, which are typically employed to target online advertising to consumers based on their interests.

"Last we looked, about 25% of the Fortune 500 had completely stopped using browser-based adtech [advertising technology]," he observed. "They may still be using browser-based analytics technologies, or other forms of non-browser based adtech, which has different risks, but at least on the browser adtech side, they decided to stop because there's too much risk."

If a company employs tracking or collects user data in ways that might otherwise raise legal issues, it has risk mitigation options. The most effective step is obtaining the user's consent.

"The laws in most states do not require obtaining consent," he said. "But no matter what law you talk about in privacy, the general rule is that consent cures everything. In other words, even if consent is not required, if a company gets a good consent, it will deter plaintiffs' attorneys from trying to find an excuse to bring a suit."

➤ Allowing Users to Opt In

Often, this is implemented by means of pop-up banners designed to comply with Europe's GDPR. "If it says, 'We want to use tracking technology, 'accept' or 'deny,' that's a great risk mitigation strategy," Zetoony observed.

"If the company doesn't use tracking technology until somebody clicks 'accept,' it has a really strong argument that it hasn't done something wrong, regardless of what law the plaintiff tries to bring a suit under," he noted.

Other techniques, Zetoon added, can include such things as disclosure in the company's website privacy notice or terms of use, or cookie notices that disclose the practice but don't solicit affirmative consent.

"They can have a pop-up banner that doesn't ask for consent, but discloses the practice," he added. "Most courts will see this banner as an agreement by the individual that tracking will occur."

This is not just a problem for the Quests and Labcorps of the world. "It is not going to ease up for some time," Zetoony said. "People are paying a lot of attention to privacy overall. It's not about any particular statute, but as long as the issue stays in the media's eye, plaintiffs' attorneys will try to capitalize on it." TDR

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Plaintiffs Accuse Labcorp of Disclosing "Sensitive Medical Information"

IN NORTH CAROLINA, A FEDERAL JUDGE DENIED A MOTION BY LABCORP to dismiss one class action suit alleging privacy violations but admonished the plaintiffs that they need to show more evidence about how the company's website was used.

In *Howard v. Laboratory Corporation of America and Laboratory Corporation of America Holdings*, currently being heard in the U.S. District Court for the Middle District of North Carolina, three plaintiffs—two in California and one in Pennsylvania—alleged that Labcorp's use of tracking and analytics technologies violated the California Invasion of Privacy Act (CIPA), enacted in 1967, and the Pennsylvania Wiretapping and Electronic Surveillance Control Act (WESCA), passed in 1978.

The plaintiffs took issue with Labcorp's use of Meta Pixel, Google Analytics, and other unspecified tracking technologies.

Tracking User Activity

Many website administrators use Google Analytics to measure traffic and track user behavior on their sites. Meta, parent company of Facebook and Instagram, describes Meta Pixel as "a snippet of JavaScript code" that allows administrators to track visitor activity and gauge the effectiveness of their advertising.

W3Techs, which measures use of online technologies, estimates that half of all websites use Google Analytics and approximately 10% use Meta Pixel.

The lawsuit described these technologies as "hidden tracking code" used "to surreptitiously track the activities of people using Labcorp's homepage to search for sensitive medical information."

The plaintiffs alleged that Meta and Google "combined this sensitive information with information about each user gathered from other sources and used it for purposes not authorized by the persons from whom the data was taken."

In seeking dismissal of the case, Labcorp argued that the lawsuit "is one of hundreds across the country attempting to shoehorn use of commonplace internet analytics technologies into criminal wiretapping statutes."

Stretching the Law

If courts adopted the plaintiffs' legal theory, Labcorp contended, "it would expose countless entities to significant criminal and civil liability for everyday website practices and transform these state laws, first enacted before the age of the internet, into regulatory regimes governing websites nationwide."

Labcorp added that the plaintiffs had provided only "scant information" about how they interacted with the Labcorp website. The complaint, Labcorp continued, "does not allege that Plaintiffs' browsers transmitted any information pertaining to medical records, appointments, or payment for Labcorp services. Notably, Plaintiffs again do not allege that they were Labcorp patients."

Labcorp also asserted that the website's privacy statement "explicitly advises visitors about collection and use of browsing related data."

On Sept. 27, 2024, U.S. District Judge William L. Osteen denied the motion to dismiss, stating that the court would await further evidence about whether the data collected by the trackers constituted personal, private information.

"Plaintiffs are forewarned that these vague pleadings cause this court substantial concern with Plaintiffs' class allegations," the judge wrote.

Lab Market Update

Insights from Q3 2024 Earnings Calls Point to a More Robust Lab Market

During Q3, both Labcorp and Quest Diagnostics boosted revenue, closed acquisitions, and added tests

FOR THE THIRD QUARTER OF 2024 (Q3 2024), both of the nation's largest publicly traded laboratories—**Labcorp** and **Quest Diagnostics**—reported growing revenue, more emphasis on specialty testing and advanced diagnostics, as well as progress with acquisitions and partnerships.

LABCORP: Grows Q3 Revenue 7.4%, Advances Acquisitions

Labcorp, Burlington, N.C., shared these Q3 2024 and nine-month financial results as compared to Q3 2023:

- Revenue grew 7.4% to $3.28 billion from $3.06 billion.
- Diagnostic laboratories revenue jumped 8.9% to $2.55 billion from $2.34 billion.
- Biopharma laboratory services revenue was up 2.6% to $737.7 million from $719.1 million.
- Volume (measured by requisitions) increased 5.1%.
- Nine-month 2024 revenue was up 6% to $9.67 billion from $9.12 billion.

Since the end of the pandemic, growth in the lab testing marketplace in the United States has rebounded. This is reflected in Labcorp's third quarter financial performance.

"Price mix increased 3.8% versus last year due to organic base business growth and acquisitions that was partially offset by lower COVID testing," commented Labcorp CFO Glenn Eisenberg. "Base business organic price mix was up 3% compared to the base business last year due to mix as we benefited from lab management agreements, an increase in test per accession, and esoteric testing growing faster than routine. Diagnostics adjusted operating income for the quarter was $387 million, or 15.2% of revenue, compared to $386 million, or 16.5% last year."

During the quarterly earnings call, CEO Adam Schechter shared progress with new and previously announced acquisitions. Labcorp has a new agreement to acquire select operating assets of outreach lab services owned by 21-hospital **Ballad Health**, Johnson City, Tenn.

"Ballad Health expands our comprehensive laboratory and testing capabilities to rural communities in Tennessee, Virginia, North Carolina, and Kentucky. We also entered into a strategic collaboration with two-hospital **Naples Comprehensive Healthcare** in southwest Florida to manage the daily operations of its inpatient operations," Schechter said.

Financial troubles and announced closures at many of the nation's retail pharmacy chains prompted one analyst to ask about Labcorp's patient service centers (PSCs) located in **Walgreens'** pharmacies. "At this point, we do have about 400 PSCs in Walgreens [stores]," Schechter answered. "We expect that many of those [locations]—if not all of those—will continue as [Walgreens announces the stores it will close]. If we have to [establish] stand-alone PSCs, it's not a problem for us to do it ... we do that all the time."

Labcorp's direct-to-consumer testing program—Labcorp OnDemand—continues to show robust growth. "We don't break out the revenue for OnDemand because it's still not a material amount that makes sense for us to break out. But the growth rate of that business is pretty substantial," Schechter explained when answering an analyst's question.

QUEST DIAGNOSTICS: Increases Q3 Revenue 8.5%, Finalizes Outreach

Quest Diagnostics, Secaucus, N.J., reported these Q3 2024 and nine-month financial results as compared to Q3 2023:

- Q3 revenue jumped 8.5% to $2.48 billion from $2.29 billion.
- Volume (measured by requisitions) was up 5.5%.
- Revenue per requisition was up 3.3%.
- Nine-month 2024 revenue increased 4.1% to $7.25 billion from $6.96 billion.

"Total volume, measured by the number of requisitions, increased 5.5% versus the third quarter of 2023 with acquisitions contributing 5% to total volume," said Sam Samad, CFO, during an earnings call.

Quest during Q3 announced acquiring select outreach lab assets from **OhioHealth** of Columbus and completed the transaction in mid-October. Also, Quest finalized deals in Q3 with **LifeLabs**, a provider of laboratory testing based in Toronto, Canada; and with **Allina Health**, a Minneapolis, Minn.-based nonprofit healthcare system serving Minnesota and western Wisconsin.

"We are now on track to complete eight acquisitions this year that meet our criteria for growth, profitability, and returns," said Quest CEO Jim Davis during the earnings call.

Quest saw "double-digit revenue growth across advanced diagnostics areas," Davis said. "The growth was particularly strong in areas of brain health, especially for our AD-Detect blood-based Alzheimer's disease testing, as well as in women's health, cardio-metabolic health, and autoimmune disorders."

Commenting on the company's direct-to-consumer business, Davis told analysts "our consumer-facing platform, QuestHealth.com grew total revenues more than 40%. Our repeat customer rate has grown to 30% from less than 10% two years ago, driven by demand for comprehensive health, chronic disease, and STI testing. During the quarter, we also introduced micronutrient blood tests to help identify vitamin and mineral deficiencies."

Commenting on the one-year delay in implementing the PAMA fee cuts to the Medicare Clinical Laboratory Fee Schedule recently enacted by Congress, Schechter stated, "We were happy with the [proposed] Saving Access to Laboratory Services Act (SALSA) solution, which called for—if enacted—another year of a delay followed by a new data collection process.

"[In this bill] there were agreed-to reductions, but I'm not sure that's the solution we're going to put forth on the table," he continued. "You know, ... we've had five straight years of delayed [Medicare lab test price] cuts and, while that sounds good, in fact it's not good because we've had five really heavy years of wage inflation and other inflation ... we are going to press the case [to Congress] that, in fact, the Medicare [lab test] rates should go up."

On the subject of the tight labor market for skilled clinical lab workers, Davis stated, "Our [staff] turnover rates have come down here in 2024. Last year they were in the low 20s, and we're now below 20%, in the 18% to 19% range. Some of this still depends on job category, but overall we've seen really nice improvement."

On the subject of wage inflation of 3%, Davis noted that in the prepandemic years, annual wage increases averaged in the "2% to 3% range." Currently, it is "100 basis points higher," at about 4% annually. TDR

Stephanie Denham

➤➤ ***CEO SUMMARY: Based on a study of denials and appeals involving about 20 million lab test claims, the team at XiFin Inc. presents here their findings. They also provide recommendations on steps labs can take to reduce denials and win a greater proportion of appeals.***

Diana Richard

Valuable insights on current payer tren

Managing Deni of Clinical Lab,

In recent years, the era of submitting clinical laboratory test claims to payers and having confidence that payers would process and remit payment in a timely fashion ended.

Today, the simple act of submitting a lab test claim to a health plan is fraught with uncertainty. One reason is that many payers frequently change their policies and procedures for handling lab test claims and remitting payment—often without advance notice.

Consequently, many labs do not learn of these changes until weeks later, when expected cash flow from a payer for a specific category of lab test claims suddenly stops. This creates a problem, because now the lab may have a substantial number of submitted-but-unpaid claims that it must investigate and resubmit.

This payer trend is why there are more presentations at the annual *Executive War College on Laboratory and Pathology Management* addressing revenue cycle management (RCM) issues and how labs can level the playing field with health insurers. These sessions offer up-to-the-minute insights on what payers are changing in the way they handle lab test claims, and what innovative clinical labs are doing to increase the proportion of clean test claims that are paid on first submission—the Holy Grail of an effective RCM department.

➤ Lab Claim Denials, Appeals

One company at the forefront of software-as-a-solution-based healthcare RCM and workflow automation solutions is **XiFin, Inc.**, based in San Diego. The company handles a significant amount of RCM data transactions for pathology, hospital outreach, molecular, genetic, and other types of diagnostic laboratories across the U.S. This includes 73% of the largest laboratories and four out of five top integrated delivery networks.

Each year, Stephanie Denham, Associate Vice President, RCM Systems and Analytics, and Diana Richard, Associate Vice President, National Accounts, XiFin, analyze current trends in denials and appeals for clinical laboratory and pathology claims. They then present these findings at the *Executive War College.* (The next EWC will be held in New Orleans April 29-30, 2025.)

tions that outsource their billing to XiFin. The study analyzed approximately 20 million claims worth of data.

For Dates of Service January through July 2023, XiFin extracted the data from its warehouse in December 2023 and then completed the analysis in the first quarter of 2024. Trends for 2023 were evaluated by payer group, denial reason, appeal type, and revenue generated.

nds in the processing of lab test claims

ials & Appeals , Path Claims

What makes this a perennially popular RCM session is the fact that their company handles almost 100 million lab test claims annually, which are submitted to nearly every health plan in the United States. The data presented by Denham and Richard thus reveals the true magnitude of payer actions and impact on how they handle incoming lab test claims.

Denham and Richard organized this year's presentation around four sections:

- Recent payer issues, including updates and trends in denials.
- Trends in appeals of lab test claims.
- Strategic appeal processes.
- Monitoring denials and appeals.

Findings presented during their presentation were based on a recent internal survey that compared 2023 data to the same survey data conducted in 2021. The data set is based on transactions facilitated by both in-house billing and organiza-

SECTION 1
Significant Payer Trends

In terms of good news/bad news, Denham and Richard began with the bad news, or at least what is perceived as negative trends among payers. Four specific developments were identified:

HCPCS G0416: Some commercial payers now require Healthcare Common Procedure Coding System (HCPCS) codes for billing. Although the trend itself is broad, XiFin uses it specifically for HCPCS G0416, which refers to "Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method."

Denham noted that the key for clinical laboratories is to stay on top of payer expectations "so your lab can get claims out the door cleanly. Denial management is essential. If a payer changes its policy, your billing team needs to know that:

- The payer made the change;
- The payer has new expectations;
- Your lab team needs to work differently with this payer."

PAYERS MAKING MISTAKES: Like many organizations, payers routinely update systems and technologies, giving risk to an unintentional manipulation of data or system settings. "For example, an incorrect fee schedule that is linked to a provider or a laboratory can suddenly trigger provider eligibility denials for testing that was previously reimbursed," Denham explained.

Ensuring the lab has robust denial monitoring practices has a material impact on a laboratory's ability to identify payers' mistakes. "It is essential to closely track what the payers are doing and how they process your lab's claims," she noted.

PAYERS DOWNGRADE OF SERVICES: Denham used the example of **Cigna** downgrading the G0483 code to the G0480 code for reimbursement purposes. She pointed out that this is not the only place they have observed downgrades by a payer.

"It's why your lab's diligence in monitoring policy changes is essential to adapt your RCM process in response to these changes, such as payers modifying codes for specific services," she stated. "Monitoring payer reimbursement against contract allowables is a great way to identify this quickly and accurately. Payers often fail to process a lab's claims consistent with the agreement that payer has with the lab."

PAYER POLICIES ON DIAGNOSIS CODES: Another trend is payers changing which diagnosis codes can be in the primary spot or which diagnosis codes should never be in a primary spot. Per the **Anthem** website: "According to ICD-10-CM guidelines for coding and reporting, it is inappropriate to bill certain diagnosis codes as a primary or first listed diagnosis. Instead, these codes should always be sequenced as a secondary or subsequent diagnosis." This was posted on January 1, 2024, and went into effect on April 1, 2024.

"So again, this is another opportunity to monitor denials," Denham said.

Latest Positive Trends

With the bad news on negative payer trends out of the way, Denham and Richard noted that it wasn't all negative. They cited two positives.

DECREASED RESTRICTIONS ON PRIOR AUTHORIZATION FOR MEDICALLY NECESSARY GENETIC TESTING: "That's definitely a positive direction for our industry," Denham said, specifically referring to **Blue Cross Blue Shield Federal's** [for federal employees] removal of prior authorization on medically necessary genetic testing.

"We have a lot of cutting-edge testing that delivers great benefits for patient care. That is why it is a welcome development that payers are starting to loosen these types of restrictions more regularly and allow that type of testing for treatment," she added.

INCREASED PHYSICIAN FEE SCHEDULE FOR MEDICARE: Effective March 9, 2024, the **Medicare** Physician Fee Schedule (MPFS) increased an average of 1.68% due to the Consolidated Appropriations Act. "While this isn't a significant increase, it's movement in a positive direction," Denham said. "Any increase in fees for Medicare and the other government health programs are welcome."

Denham and Richard emphasized that all trends, both positive and negative, can be monitored through denial management, price discrepancy reporting, and analytics. In short, labs should know what the payer should be paying and what the payer actually is paying.

Top Denial Codes

The top denial codes have remained largely consistent year over year. They include:

- **CO151**—Payment adjusted because the payer deems the information submitted does not support this many/frequency of services.
- **CO252**—Claim will be reconsidered when additional claim information is received.
- **CO96**—Non-covered charges.
- **CO50**—Non-covered services because this is not deemed a "medical necessity" by the payer.
- **CO55**—Experimental/investigational: When a procedure code is billed with an incompatible diagnosis for payment purposes, and the ICD-10 code(s) submitted is/are not covered under an LCD or NCD.

"These are the same codes we've discussed for a long time," Denham said. "These denial codes continue to be the most problematic, driving the need for appeals. However, it is not always the same CPT combination and payer policies that drive these denials. The trick here is understanding—from each payer's standpoint—what is shifting, because it will require modifying your lab's behaviors. Something your RCM team thinks it fixed a year ago might appear to be broken again, but odds are it's a new issue."

SECTION 2

Trends In Appeals

Next to be discussed were recent trends in appeals involving clinical lab test claims. Richard explained that when the recent 2023 study was compared to the previously published 2021 study, denials decreased across most major contracted and non-contracted payers.

XiFin categorizes payers into several groupings, such as Medicare, **Medicaid**, Blues, and Commercial, finding that trends in each group varied due to specific plans' adjudication trends. *(See chart in sidebar on pages 16-17.)*

"Commercial contracted denials stayed flat," Richard observed, noting that, when looking at individual segments, there has been a moderate increase in denials in the Commercial (Contracted) group from 2021 to 2023. "The good news is when we assess the claims experience of the laboratory industry as a whole, we see a decrease in denials across most of our major contracted payer groups," she noted.

ANATOMIC PATHOLOGY: This category was stable, largely because it is routine testing. In 2021, reimbursement on appeals accounted for 1.12% of total insurance payments received compared to 1.50% in 2023. The average amount of an appeal in 2021 was $327, but in 2023 dropped to $249.

"However, when broken into payer groups, there is a general decline in denial rates until an examination of Blue Cross Blue Shield's Non-Contracted," Richard explained. "In 2021, the volume of claims denied by BCBS' Non-Contracted plans was around 17%, but in 2023 it had rocketed to almost 30%." Richard noted, however, that overall volume is down.

While the shift seems quite large, the net effect on dollars is relatively low. In its analysis, XiFin found that some Anatomic Pathology customers who did not bill out-of-state BCBS plans in 2021 began to bill them as of the 2023 study.

"Therefore, the volume of transactions that XiFin included in this payer group population increased, but for the payer groups with more consistent and substantive volume, there was an overall decline," Richard noted.

Some of this decline, she added, was the evolution of payer policy: while XiFin continues to evaluate denials on the back end, they try to create processes to manage them through front-end editing. "We don't want to have to deal with appeals or corrected claims on the back end and be

forced to fight for the dollars retroactively. This delays cash by 60, potentially 90 days, and increases the cost to collect."

The top reasons for appeals in Anatomic Pathology were requests for additional information followed by medical necessity. Richard pointed out that additional information denials are not hard denials. "The payers are saying, 'Send us the pathology report and/or requisition so we can confirm that the service being billed is documented and justified.'"

In these cases, only an appeal letter and requested information are required.

CLINICAL: Like Anatomic Pathology, as a percentage of total volume, appeals in Clinical testing are low, with a relatively high success rate. That said, because these are not generally high-dollar tests, these appeals average a lower dollar-value return than found in Anatomic Pathology.

Richard explained that the overall success average of Clinical appeals on the first attempt for clinical tests was 30.9% with an average payment of $96.31 per successful appeal. The percentage of successful appeals dropped significantly on the second (2.0%) and third (0.5%) attempts. The average payment per appeal (paid and unpaid) was $32.13 for clinical tests.

About a third (31.6%) of appeals involved providing additional information, followed by "other" with 21.3% and medical necessity (15.6%). In terms of the average payment per successful appeal, as mentioned earlier, it was $96.31 overall but $136.20 when the appeal was to resolve an additional information request, a low $43.22 for "other," and $154.42 for medical necessity. Timely filing was also higher at $126.34, and prior authorization was $90.67, slightly lower than "out of network" which had $109.68 for average payment per successful appeal.

For clinical denial trends by payer group, Commercial Contracted and Medicaid went up slightly (6% to 9%) and Medicare Contracted stayed flat. BCBS Contracted dropped from about 11% in 2021 to approximately 4% in 2023. BCBS Non Contracted increased from 12% in 2021 to 25% in 2023. Medicaid Non Contracted dropped from 76% to 50%, and Medicare Advantage Non Contracted fell from 48% to 38%, but the volumes for these last three were quite low.

"If you are not contracted with Medicaid," Richard said, "you're probably not going to get paid. A lot of groups are incentivized to make sure that they get in-network based on the states or regions fueling their growth. Compromising revenue or being forced to triage work to another lab is not sustainable in a competitive marketplace. Likely as a result of these business considerations, we did realize a decline in the Medicaid Non Contracted group from 2021 to 2023."

SECTION 3
Strategic Appeals Process

Guided by the study's findings about the rates of denials and the percentage success rates for appeals across different types of lab tests, Denham and Richard identified useful approaches to filing appeals.

Richard explained that payers can get "really crafty" with their denial processes. "Payers are known to shift denial codes from time to time, making it appear as though a problematic denial has started to resolve itself, when in reality we see them picked up in another code's queue.

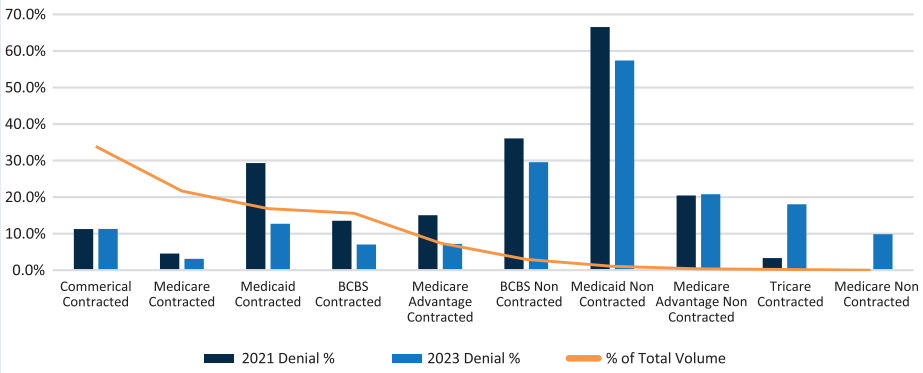
"For example," she noted, "while Prior Authorization may decline due to implementation of Gold Card programs, there's a great likelihood that we will see an increase in policy related denials, like medical necessity.

"The way we manage recovery of revenue ideally happens on the front-end of the RCM process via a payer edit," she added. "However, in cases where the denial is related to additional information or medical necessity, we cannot necessarily confront that issue on the front end.

Risk of Denial: Averages by Payer Group, All Segments: Pathology, Molecular, Clin Lab

EARLIER THIS YEAR, THE TEAM AT XIFIN, INC. STUDIED THE CHANGES IN DENIAL RATES across three lab testing segments: anatomic pathology, molecular, and clinical laboratory. The study involved about 20 million claims from approximately 200 lab clients. The claims experience from 2021 was compared to the claims experience from 2023. The information shown below shows basic findings. More detailed data is presented on the other sidebars accompanying this story.

Percent of Claims Denied by Payer Group in 2023, Compared to 2021



	Appeal Payments as Percent of Total Insurance Payments Received		Average Payment Amount per Appeal	
Segment	**2023**	**2021**	**2023**	**2021**
Clinical	0.43%	0.11%	$96	$121
Molecular	11.17%	6.56%	$1,584	$1,420
Pathology	1.50%	1.12%	$249	$327
Overall Average	**7.38%**	**3.39%**	**$541**	**$623**

Data presented by Stephanie Denham and Diana Richard of XiFin, Inc. at the 2024 Executive War College.

"In these instances, we have to let the claim deny, then appeal, then wait," she noted. "Minimizing what we manage on the back-end of the process to only include what cannot be managed on the front-end plays a big part in how groups effectively manage expectations around revenue generation and acceleration. This is particularly for more expensive testing that has a greater budgetary impact and ROI consideration."

MOLECULAR TESTING: This is where denials and appeals get interesting. The tests, Richard says, are a "very specific, specialized type of testing that, due to lags on payer policy development and coverage, tend to have a much higher propensity for denial.

"By far," Richard continued, "the highest denials in this category were for Medicaid Non Contracted in both 2021 and 2023, about 75% and 73%, respectively. The next highest was for BCBS Non Contracted with 50.0% and about 39%, respectively. The group averaging the lowest denial percentages for Molecular

testing was Medicare Contracted, around 10.5% in 2021 and about 9% in 2023."

However, Richard emphasized the importance of taking into consideration the percentage of total volume. *(See sidebar, "Data Reveals Appeals Trends and Outcomes for Laboratory Test Claims" on pages 20-21.)*

"Under the Commercial Contracted group, there was a slight increase in the volume of denials, but all other payer groups saw some deterioration which is welcome," Richard said. She believes this may be partially due to shifts in payer policy, as well as more front-end editing and management designed to prevent the denials altogether.

The overall percentage of appeals paid after the first attempt for Molecular was 15.5% with the average payment per successful appeal hitting $1,583.61. As with all categories, the percentage of appeals paid drops significantly at each attempt, with the percentage of appeals paid after the second attempt at 3.8% and 1.0% for the third attempt. The average payment per appeal (paid and unpaid) for Molecular was $320.84.

One obvious takeaway is that the reimbursement for highly complex molecular tests is very high compared to clinical and anatomic pathology tests ($96.31 and $248.69, respectively).

The highest percentage of appeals for Molecular were related to medical necessity at 25.2%, followed by additional information (23.0%) and "other" (22.6%). Prior authorization ranked as 11.3%, which is lower than it was for Anatomic Pathology (12.8%). Prior Authorization was 10% of total appeals filed for Clinical.

Success Rates for

Appeal Success Rates by Procedure

Procedure Code	Segment
80053	Clinical
80061	Clinical
82306	Clinical
83036	Clinical
84443	Clinical
85025	Clinical
87491	Clinical
87591	Clinical
81162	Molecular
81220	Molecular
81329	Molecular
81404	Molecular
81405	Molecular
81406	Molecular
81420	Molecular
81432	Molecular
81433	Molecular
88305	Pathology
88307	Pathology
88341	Pathology
88342	Pathology
88360	Pathology

Data based on 20 million lab test claims from 200 lab

SECTION 4
➤Monitoring Denials, Appeals

As noted in the previous discussions, in the clinical laboratory space there were very few appeals that had relatively high success rates on those appeals. They did, however, have a relatively low dollar-value return due to the low-cost nature of the testing.

"Conversely, in the Molecular space appeals are more prevalent largely with a lower success rate because you are fighting new complex methodologies in diagnostic testing that often requires time—years even—for payers to sufficiently evaluate and establish policy and coverage policies," Richard said. "Add to that the fact that these tests are often in the thousands of dollars in reimbursement.

"Until coverage is assigned," she continued, "clients are appealing molecular claim denials with very detailed data, such as clinical history and pathologist-written explanations of the test, to leverage

Appeals Vary by Type of Lab Test Claim

e Code

Code Description	Appeal Success Rate	Avg Revenue Generated per Successful Appeal
Comprehensive Metabolic Panel	87%	$7.97
Lipid Panel	87%	$7.19
25 Hydroxy Includes Fractions if Performed	87%	$10.96
HGB Glycosylated	86%	$5.36
Assay of Thyroid Stimulating Hormone TSH	88%	$5.57
Blood Count Complete Auto&Auto Difrntl WBC	85%	$2.47
IADNA Chlamydia Trachomatis Amplified Probe TQ	58%	$23.21
IADNA Neisseria Gonorrhoeae Amplified Probe TQ	59%	$23.43
BRCA1 BRCA2 Gene Analysis Full Seq Full Dup/Del Alys	44%	$1,460.52
CFTR Gene Analysis Common Variants	35%	$360.59
SMN1 Gene Analysis DOSAGE/DELET Alys w/ SMN2 Alys	34%	$91.37
Molecular Pathology Procedure Level 5	25%	$208.25
Molecular Pathology Procedure Level 6	27%	$194.10
Molecular Pathology Procedure Level 7	25%	$178.76
Fetal Chromosomal Aneuploidy Genomic Seq Analysis	43%	$561.51
Hereditary Breast CA-Related Gen Seq Analysis 10 Gen	41%	$536.47
Hereditary Breast CA-Related Dup/Del Analysis	41%	$352.21
Level IV Surg Pathology Gross&Microscopic Exam	52%	$110.64
Level V Surg Pathology Gross&Microscopic Exam	57%	$80.10
Immunohistochemistry/Cytchm Ea Addl Antibody Slide	51%	$148.05
Immunohistochemistry Tissue Immunoproxidase Ea Antibody	49%	$72.65
M/PHMTRC Alys Tumor Imhchem Ea Antibody Manual	49%	$56.67

clients presented by Stephanie Denham and Diana Richard, XiFin, at the Executive War College on April 30, 2024.

clinical utility and value of the service [to the patient] performed in order to justify reimbursement."

When a Molecular appeal is successful, there is a significantly higher return. "Keep in mind—even in cases where reimbursement is still denied—the appeals act as documentation of a consistent argument for coverage that may be leveraged downstream when your lab is negotiating with a payer," Richard noted." This can be a benefit that makes those unsuccessful appeals still worth the effort."

When denials and appeals are compared across the three lab testing segments, anatomic pathology splits the difference. "It has a fairly high success rate on appeal, but lower returns than on molecular testing, but again, appeals are worth the effort," she emphasized.

An analysis of appeal success rates by procedure codes underscores the point. Very common clinical tests, such as Comprehensive Metabolic Panel (80053), Lipid Panel (80061) and Vitamin D 25 Hydroxy (82306), each have an 87% appeal success rate.

But when compared with more common molecular tests, such as BRCA1/BRCA2 Gene Analysis (81162, for breast cancer), the appeal success rate drops to 44%, with other molecular tests ranging from a 25% success rate (81404, Molecular Pathology Procedure Level 5) to 43%

(81420, Fetal Chromosomal Aneuploid Genomic Sequencing Analysis).

Appeal success rates for anatomic pathology (AP) are generally in between, with the top five AP codes having appeal success rates from 49% (88360: Surgical pathology-single antibody stain, and 88432: Immunohistochemistry tissue immunoperoxidase early antigen antibody) to 57% (88307: Level V surgical pathology gross and microscopic exam).

Denham said, "We constantly do these analyses within XiFin, watching the different appeals for the different types of lab tests, what types of appeals tend to be successful, and where the gaps are so we can either improve the appeals process or eliminate the denial."

Strategic Appeals Process

"Not every denial needs an appeal," Denham noted, adding, "but if your lab is going to appeal, then your documentation must support what you're appealing."

Denham and Richard broke down a strategic appeals process into three steps:

- Ordered
- Performed
- Medically Necessary

The appeals report document must clearly outline the services that were provided and the medical necessity of those services. "In this case, your team should follow what we call 'The Golden Rule of Medical Billing: If it wasn't documented, it wasn't performed,'" Denham said. "That documentation needs to support those three things: ordered, performed, and medically necessary."

Some payers have published policies that might not require an appeal. Denham noted that if these are published, you can avoid them upfront by having edits in your billing systems that resolve the issues before the claims are made.

"The best-case scenario is always a clean claim that gets paid the first time," she commented.

Examples include:

- **CO97—Procedure or Service Isn't Paid for Separately**: This category is where the payer doesn't expect the services to be billed together, usually because both tests aren't required to diagnose and treat the patients. "We know that sometimes your lab needs both tests, not necessarily because it was required for a diagnosis, but because you have two different specimens that you're looking at separately," Denham said. Or perhaps both tests were needed because the first was inconclusive or not specific enough.
- **Local Coverage Determinations (LCD) and National Coverage Determinations (NCD)**: LCD and NCD issues typically fall under Published Payer Policies and should be resolved the same way that Medically Unlikely Edits (MUEs) are resolved. Labs should ensure the edits are appropriately installed in the lab's billing system so they are correct before the claim is filed. "Make sure that the diagnosis code on the claim is supported in your report and make sure it supports medical necessity per the payer policy," Denham said.
- **NCCI Edits and Medically Unlikely Edits (MUEs)**: Medicare National Correct Coding Initiative (NCCI) edits were designed to mitigate improper payment when incorrect code combinations are reported. The response to this is the three-step policy: ensure all the testing conducted was ordered, performed, medically necessary, and documented in the lab's report.

"If your documentation is complete," Denham explained, "you typically have the opportunity to add a modifier to indicate to the payer that the separate services were performed so that your claim will be adjudicated favorably."

Denham added that if labs or pathology groups are getting denials related to NCCI edits on the back end, then they

should send corrected claims, not appeals, and the corrected claim should have the appropriate modifier. "Corrected claims typically have a faster adjudication process than an appeal would have," she said. "And then, of course, implement the edit on the front end so it does not happen moving forward."

The federal **Centers for Medicare and Medicaid Services** defines an MUE as "the maximum units of service (UOS) reported for a HCPCS/CPT code on the vast majority of appropriately reported claims by the same provider/supplier for the same beneficiary on the same date of service."

Denham noted that although labs and pathology groups should be aware of MUEs, "we can't usually get a clean claim out and avoid the denial. With Medicare, if they have a published MUE, we find we have to appeal them with documentation. They can't necessarily be avoided."

There is an accepted three-cycle appeal process for Medicare, with most payers having a similar process:

- The first-level appeal is to provide the documentation that supports the service and possibly a letter explaining why it was performed. Denham and Richard noted that the individual reading these is typically someone with a medical background, such as an RN, but not usually someone with a strong clinical laboratory test background. Denham said, "Refine your documentation and send another first-level appeal. That's an acceptable practice. Just because you file a second appeal doesn't mean you're sending a second-level appeal."
- The second-level appeal is to outside independent contractors with additional documentation. It will be reviewed by a different group of people, not by the Medicare program itself. Attach additional documentation from a genetic counselor or a physician that supports the services that were performed. "This is your opportunity to provide all the documentation you can to support potentially having that denial overturned," Denham said.
- The third-level appeal is to an administrative law judge (ALJ). Denham cautions, "This is a pretty aggressive step. You want to be confident before taking this path. You might annoy the payer a little bit. If you have a larger volume of claims that you feel they are not handling appropriately, and you choose to go to the ALJ, you might want to try out a handful of claims first. If they are successful, you can then approach the payer asking that they resolve the issue on the remaining claims directly, rather than going through the ALJ."

Best Approaches to Appeals

Although it may seem obvious, it's worth emphasizing that clinical laboratories may be better off avoiding the appeals process altogether.

At its best, that means getting claims right before they go out the door. Second best is to utilize corrected claims and avoid appeals:

- Can labs get the claim clean? If not, is a corrected claim warranted?
- Can labs get future claims clean? If not, can they automate their appeal process?

One of the key takeaways is not to give up.

"It's really important not to give up if you don't get the answer you want after the first appeal," Denham advised, adding, "There is some success rate on the second appeal and the third appeal." TDR

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Editor's Note: On the following two pages is a comprehensive summary of the XiFin study's findings of lab test appeals trends and outcomes.

Data Reveals Appeals Trends and O

***Things to Know*:**
Anatomic Pathology Test Claims:

The table at right shows the XiFin study's findings about the success of appeals for different types of denials involving anatomic pathology claims, aggregated across all types of payers. In earlier comments, Denham and Richard revealed that the highest percentage of denied anatomic pathology claims in 2023 originated in the BCBS Non-Contracted category at 30%, contrasted by an average denial rate by commercial contracted plans of 9% in 2023.

***Things to Know*:**
Molecular Test Claims:

It is recognized that denial rates of molecular test claims are consistently among the highest for all categories of tests. As shown in the table at right, in 2023, 25.2% of the time Medical Necessity is the leading reason payers use when denying the first submission of a molecular test claim. The average payment for a successful appeal ranges from $900 to $2,700, depending on the type of molecular test.

***Things to Know*:**
Clinical Lab Test Claims:

Denham and Richard pointed out that the study of 2023 clinical lab test denials and appeals confirmed the conventional thinking that there is a higher success rate with appeals of claims denials—but with a relatively low dollar value return.

Appeal Trends and Successes: Anatomic

Appeal Type	% of Total Appeals Filed	% of aft
Overall Averages		
Additional Information	27.90%	
Medical Necessity	20.60%	
Out of Network	16.60%	
Prior Authorization	12.80%	
Other	8.80%	
Timely Filing	4.40%	
Duplicate	2.60%	
Bundling	2.00%	
Frequency	2.00%	
Non-Contracted	1.70%	
Maximum Benefits	0.60%	

Appeal Trends and Successes: Molecula

Appeal Type	% of Total Appeals Filed	% of aft
Overall Averages		
Medical Necessity	25.20%	
Additional Information	23.00%	
Other	22.60%	
Prior Authorization	11.30%	
Out of Network	7.40%	
Medical Records	4.40%	
Experimental/Investigational	3.20%	
Non-Contracted	1.40%	
Low Payment	0.70%	
Timely Filing	0.30%	
Claim Review	0.30%	

Appeal Trends and Successes: Clinical L

Appeal Type	% of Total Appeals Filed	% of aft
Overall Averages		
Additional Information	31.60%	
Other	21.30%	
Medical Necessity	15.60%	
Experimental/Investigational	10.30%	
Prior Authorization	10.00%	
Out of Network	8.20%	
Timely Filing	3.10%	

Data is based on 20 million lab test claims from approximately 200 lab clients and presented by Stephanie Denha

utcomes for Laboratory Test Claims

c Pathology Claims

Appeals Paid er 1st attempt	% of Appeals Paid after 2nd Attempt	% of Appeals Paid after 3rd Attempt	Avg Payment per Appeal (Paid and Unpaid)	Avg Payment per Successful Appeal
25.10%	2.50%	0.50%	$69.82	$248.69
23.30%	2.00%	0.20%	$68.71	$269.32
25.90%	2.10%	0.50%	$50.42	$176.75
25.00%	1.90%	0.50%	$64.15	$234.25
18.20%	1.20%	0.00%	$53.70	$275.31
37.10%	4.80%	1.80%	$144.00	$329.42
13.50%	3.80%	0.50%	$31.42	$176.86
22.20%	2.70%	0.10%	$80.62	$322.49
54.50%	9.40%	3.60%	$117.21	$173.86
16.80%	2.30%	0.50%	$90.04	$459.49
39.70%	0.30%	0.00%	$42.17	$105.25
36.00%	13.10%	3.80%	$268.24	$507.01

ar Test Claims

Appeals Paid er 1st attempt	% of Appeals Paid after 2nd Attempt	% of Appeals Paid after 3rd Attempt	Avg Payment per Appeal (Paid and Unpaid)	Avg Payment per Successful Appeal
15.50%	3.80%	1.00%	$320.84	$1,583.61
10.20%	2.10%	0.50%	$175.81	$1,376.56
25.30%	7.70%	2.40%	$696.63	$1,969.90
16.90%	4.20%	0.90%	$273.70	$1,245.57
11.80%	2.80%	0.60%	$227.27	$1,496.10
12.10%	1.80%	0.20%	$128.45	$910.32
6.50%	0.30%	0.00%	$78.84	$1,155.03
7.20%	1.30%	0.20%	$233.43	$2,662.82
14.60%	1.00%	0.10%	$237.62	$1,512.34
12.80%	2.10%	0.90%	$169.17	$1,069.43
10.20%	0.60%	0.00%	$97.24	$896.01
55.70%	7.70%	1.90%	$1,001.90	$1,532.80

Laboratory Test Claims

Appeals Paid er 1st attempt	% of Appeals Paid after 2nd Attempt	% of Appeals Paid after 3rd Attempt	Avg Payment per Appeal (Paid and Unpaid)	Avg Payment per Successful Appeal
30.90%	2.00%	0.50%	$32.13	$96.31
40.90%	2.60%	0.90%	$60.58	$136.20
62.90%	2.20%	0.20%	$28.23	$43.22
17.90%	3.60%	0.80%	$34.38	$154.42
7.00%	0.80%	0.40%	$4.25	$51.75
3.10%	0.10%	0.00%	$2.88	$90.67
5.10%	0.20%	0.00%	$5.82	$109.68
10.40%	0.60%	0.00%	$13.89	$126.34

m and Diana Richard of XiFin, Inc. at the Executive War College on April 30, 2024.

Regulatory Update

Change Healthcare Cyberattack Involved 100 Million Americans

Despite this ransomware attack, UnitedHealth Group reported third quarter net income of $6.1 billion

After experiencing what many cybersecurity experts consider to be one of the largest, most disruptive ransomware attacks ever earlier this year within its **Change Healthcare** business unit, **UnitedHealth Group** (UHG) in its third quarter earnings report said net income was $6.1 billion for third quarter, 2024, a 3.7% increase over the same time last year.

Meanwhile, providers and patients across the nation are still dealing with the consequences of the ransomware attack. Change Healthcare is a business operated by **Optum**, itself a division of UHG. The ransomware attack happened on Feb. 21, 2023. In the weeks following the ransomware attack, Change Healthcare stated that it estimated the breach probably involved a "substantial proportion of people in America."

Now, Change Healthcare has provided a more precise number of individuals whose protected health information (PHI) was breached. In an Oct. 22 filing with the **U.S. Department of Health and Human Services** (HHS), Change stated that "approximately 100 million notices have been sent regarding this breach."

In its notification letter to HHS about the breach of PHI, Change Healthcare identified the following categories of data that were stolen by the hackers:

- **Health Data:** Medical record numbers, doctors, diagnoses, medicines, test results, images, care, and treatment.
- **Billing Records:** Records including payment cards, financial, and banking records.
- **Personal Data:** Social Security, driver's license, or state ID numbers.
- **Insurance Data:** Health plans/policies, insurance companies, member/group ID numbers, and Medicare/Medicaid-government payer ID numbers.

Almost $2.5 Billion in Costs

Costs associated with the ransomware attack and data breach continue to climb. The *HIPAA Journal* estimated that—for the nine months ending on September 30, 2024—Change's parent firm United Health Group incurred $1.521 billion in direct breach response costs, and $2.457 billion in total cyberattack impacts.

Despite the magnitude of this ransomeware attack—in numbers of providers and patients affected, and costs associated with the attack—UnitedHealth executives said little about this event during the second quarter and third quarter earnings calls with analysts and investors. It appeared to be "business as usual."

Given UnitedHealth's reported net income, it is not a stretch to imagine that many clinical lab executives and pathologists watching UHG deny payment for large numbers of their lab test claims are asking, "is UnitedHealth motivated to deny large number of legitimate test claims as a way to bolster its financial performance for investors?" TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Artificial intelligence (AI) is coming to the federal **Food and Drug Administration** (FDA) and the **Veterans Administration** (VA). Last week, on Oct. 30, the two agencies issued an announcement that they would partner "to launch an interagency testing ground for healthcare-related artificial intelligence tools." This development will have consequences for the *in vitro* diagnostics (IVD) industry, developers of lab informatics products, and clinical laboratories. It means there will be a specialized laboratory designed to assess healthcare products that utilize AI.

MORE ON: *FDA, VA, AI*

Robert Carliff, Commissioner of the FDA, stated that this joint testing lab will be "the first intergovernmental health AI laboratory." Basing it with the VA will provide "an avenue for developing approaches for assessing safety and performance metrics of AI-enabled healthcare products for product developers at the national level." No timetable for the creation of this new AI lab was provided.

INTERPATH LAB BUYS PATH GROUP

Interpath Laboratory of Pendleton, Oregon, "acquired selected assets" of **Pathology Services, PC**, based in North Platte, Neb., in a transaction handled by **Haverford Healthcare Advisors**. Interpath is family-owned and one of the few remaining independent clinical lab companies that provides routine and reference testing in the communities it services. Pathology Services has three full-time pathologists and two part-time pathologists.

TRANSITIONS

- **SpeeDx** of Sydney, Australia, selected Jeremy Stackawitz to be its new CEO. Previously, Stackawitz served at **Senzo Health**, **Quotient Limited**, **Ortho-Clinical Diagnostics–JnJ**, **McKinsey & Co.**, and **Purdue Pharma**.
- **Eli Lilly and Company** appointed Thomas J. Fuchs, Dr.Sc., as its first Chief AI Officer. His prior positions were with **Icahn School of Medicine at Mount Sinai**, **Paige**, **California Institute of Technology**, **Jet Propulsion Laboratory**, and **Nautikon Technologies**.
- **Delfi Diagnostics** of Baltimore announced the selection of Robert Guigley as its new Chief Commercial Officer. Guigley previously held executive positions at **Invitae**, **Ambry Genetics**, **Omada Health**, **Counsyl**, **Quest Diagnostics**, and **AstraZeneca**.

Leon Vaitaitis, Workflow Consulting Leader at Brea, Calif.-based **Beckman Coulter**, is retiring. This concludes a career at Beckman spanning almost 46 years that saw Vaitaitus travel the world helping clinical laboratories maximize the performance of their automated systems.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, November 25, 2024.

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UPCOMING...

- ***What winning pathology labs do to fill positions as demand for pathologists outstrips supply.***
- ***Attorney Jane Pine Wood on the different legal issues used in the AMP/LaPosata LDT Rule lawsuit.***
- ***Testing in the core lab or point-of-care/near patient? How health system labs are finding the balance.***

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