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Genetic Test Payment Conundrum!

Optum and Avalon Healthcare Solutions Discuss Changing Requirements for Genetic Test Claims

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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

Expect More Z-code Requirements for Genetic Tests

GENETIC TESTING COMPANIES ARE STILL REACTING TO LAST MONTH'S NEWS that one of the nation's largest health insurers—**UnitedHealthcare** (UHC)—will require Z-codes for molecular test claims submitted as of August 1, 2023. UHC's action creates an interesting differentiation among genetic testing laboratories.

On one side are established labs that already have Z-codes for their genetic tests so as to comply with the requirements of **Medicare's** MolDX program. Since the launch of MolDX by **Palmetto GBA**, a Medicare Administrative Contractor (MAC), in 2011, it has expanded to cover 28 states. Over the past decade, many of the nation's largest labs applied for Z-codes so they could submit their genetic test claims to those MACs participating in the MolDX program.

On the other side are many specialty genetic testing companies. They perform proprietary genetic tests and typically offer these tests to patients enrolled in commercial health plans and those Medicare and **Medicaid** patients who are in MACs that do not participate in MolDX. Because a Z-code application requires documentation of clinical validity and clinical utility, it is this class of genetic testing companies that will be most disrupted by UHC's new Z-code requirement for genetic test claims. These labs only have a limited number of weeks to apply for a Z-code in advance of the August 1 effective date for UHC's new policy.

THE DARK REPORT responded swiftly to these developments to help clinical labs by organizing a special free webinar on June 29 to help labs understand the Z-code program and the application process. It will be labs' first opportunity to hear directly from Gabriel Bien-Willner, MD, PhD, Chief Medical Officer of Palmetto GBA, who is the keynote speaker. Joining him with presentations are Valerie Collier, MS, CGC, Genetic Counselor at **ARUP Laboratories** and Kyle Fetter, Chief Operating Officer at **XiFin, Inc.**

This webinar is a must-attend for genetic testing companies needing to apply for Z-codes to meet UHC's new requirement. But it may also prove doubly valuable if other major health plans—think **Elevance**, **Humana**, **Aetna**, **Cigna**—quickly announce implementation of their own Z-code requirements for genetic test claims. Details on registering for the webinar are on the back cover. TDR

Optum, Avalon Discuss Genetic Test Claim Review

One goal is to lessen prior authorization burdens through greater specificity about test validity, utility

Cristi Radford, MS

Jason Bush, PhD

CEO SUMMARY: With the ever-increasing number of genetic tests on the market, payers are understandably frustrated with genetic test claims that don't clearly outline the medical need for a procedure or its clinical validity. One path forward is for labs to present data to justify a genetic test earlier in processing of the claim.

GENETIC TESTING LABORATORIES CAN EXPECT PRIVATE HEALTH INSURERS to require better data about the accuracy and clinical relevance of the genetic tests being submitted for reimbursement. That was a common message—and prediction—during several presentations at last April's *Executive War College* in New Orleans.

That prediction did not take long to come true. On May 2, the week following the *Executive War College*, **UnitedHealthcare** (UCH) published a notice in its monthly provider bulletin that it would require Z-codes on molecular test claims as of August, 1, 2023.

In the first wave of this policy implementation, about 250 genetic test CPT codes will require a Z-code with the test claim. (*See TDR, "UHC's Z-code Requirement to Commence on Aug. 1," May 30, 2023.)*

Those clinical lab leaders who want to better understand the genetic test reimbursement environment should consider two key points shared by speakers in April:

- What may be an obvious medical need for a genetic test from a physician's standpoint does not always translate to what payers encounter.
- Payers want proof of the clinical validity and utility of a genetic test.

"When it comes to evidence supporting a genetic test, the challenge is figuring out what data is needed," said Cristi Radford, MS, CGC, Product Director at **Optum** in Eden Prairie, Minnesota, the health services arm of **UnitedHealth Group**.

"Ideally, it's clinical outcome data. But with genetic tests, that's not always easy to produce," Radford added. She spoke during a keynote at the conference,

'Administrative Burden' Tops Poll on Claims Process

DURING HER DISCUSSION at the *Executive War College*, Cristi Radford, Product Director at Optum, polled the audience of several hundred people using the conference's smartphone app. The question: Which factor is most important to you in the reimbursement process?

The polls results were as follows:

- Less administrative burden—53.5%
- More consistent molecular test reimbursement—39.5%
- Timelier reimbursement—7%

The results were not surprising. As THE DARK REPORT noted previously, misuse of CPT codes, coverage ambiguity, and denials lead to administrative costs for both payers and labs. *(See TDR, "Genetic Tests Grow in Number, Complexity," July 26, 2021.)*

titled, "Driving Precision in Genetic Test Management Lab Benefit: Understanding the Value to Patients, Physicians, Lab Providers, and Payers."

Same Panel, Different CPT Codes

Last summer, Optum launched a laboratory benefit management (LBM) solution for commercial health plans to reduce unnecessary genetic testing and improve utilization of clinically-indicated genetic tests. Optum is working with **Palmetto GBA**—the Medicare Administrative Contractor (MAC) in Columbia, South Carolina, that oversees the Molecular Diagnostics Services (MolDX) Program—and **Avalon Healthcare Solutions**, a lab benefits management (LBM) company in Tampa, Florida. *(See TDR, "Optum to Offer Laboratory Benefits Management to Other Health Plans," June 27, 2022.)*

Confusion is widespread among payers on how genetic tests are used. Radford showed a sample chart for a proposed genetic test panel given to a female patient with newly diagnosed ductal carcinoma *in situ*. Surgical options were pending genetic test results. In the example, the physician ordered a high-risk breast cancer panel for BRCA1, BRCA2, PTEN, TP53, PALB2, and CDH1 to detect any variants.

Four labs submitted different claims for the panel with combinations of six different Current Procedural Terminology (CPT) codes.

"Looking at what the labs submitted, does a payer have any idea what test was ordered? No," Radford noted. "This is the challenge that payers face every day in trying to distinguish one genetic test coming in the door from another.

"CPT codes often don't give the payer the specificity needed," she added. "There are about 400 CPT codes to represent thousands of genetic tests."

At that point, the test must clear hurdles with a payer. "The genetic test can get hung up when the prior authorization portal tries to figure out what the test is," Radford explained. "The same test claim can get hung up later with the clinical reviewer.

"There is a common theme when payers review these genetic test claims: What is this test that the physician ordered?" she said. "When we think about the patient in the breast cancer example, the reason for the test is clear. But when we think about the claim cycle and reimbursement process, it's far from clear."

Moving to Commercial Plans

Optum and Avalon are offering commercial payer plans a different approach for managing CPT codes in genetic test claims.

Of note is CPT code 81479, which covers unlisted molecular pathology procedures. Use of that code often indicates the submitter of the claim doesn't know a more accurate CPT code to use. Thus, the code could represent one of thousands of tests.

"Code 81479 is the ubiquitous code when labs don't know what to bill, and that is the bane of a payer," said Jason

Bush, PhD, Executive Vice President of Product at Avalon.

"It stops claims at the prior authorization portal, at adjudication, and at pricing. It could stop the claim for an hour, a day, or a week, and there could be medical record review requested."

Once a claim is stalled at prior authorization, a laboratory faces a business dilemma: Does the lab delay the genetic test at the risk of angering the ordering physician and patient? Or does it run the test at the risk of the claim being rejected, which would require the lab to fully pay for the procedure.

"Prior authorization and administrative burden are problems and challenges for all of us," Radford said. "Nobody likes it, and we need solutions to handle this."

Prior Authorization Help

Bush, who co-presented with Radford at the *Executive War College*, suggested that improved progress in two areas could ease prior authorization hassles in the future.

- **Transparency of coverage determination and predictability in payments**. "Labs need help in determining transparent coverage," he noted. "How do payers make that pricing more streamlined? It all goes back to test identification."
- **Wider of use of MolDX Z-codes for genetic tests**. "When a Z-code comes into a claims system, it doesn't have to be stopped because the payer already knows exactly what the test is, who the lab is, and the pricing has already been established for it," Bush said.

MACs in 28 states already require Z-code use for genetic lab test claims under Medicare Advantage. And in May, **UnitedHealthcare** announced it would phase in mandatory Z-code use for genetic tests starting Aug. 1.

"We're assigning Z-codes to the Avalon policies, which are adopted by health plans," Bush said. "Labs can learn the coverage for a particular Z-code and the requirements under which these codes will be reimbursed.

"It all centers on how a Z-code applies to a coverage policy," he added. "So, if payer gets a Z-code for BRCA, it will be in the Avalon BRCA policy."

Bush urged labs to be proactive in their payer policy work when it comes to genetic tests. "If a lab has a new test, the lab needs to help educate the medical directors on the plan side as to why the test is important and what is it going to do clinically," he said. TDR

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Can Use of Z-codes Weed Out Fraudsters?

JASON BUSH AT AVALON HEALTHCARE SOLUTIONS predicted that greater use of Z-codes for genetic test claims will dial down fraud and abuse from dishonest labs. Fraudsters may shy away from submitting claims to plans that mandate Z-codes, given the specificity of those codes.

"I've looked at a lot of lab data in my eight years at Avalon," Bush said. "That data can point to nefarious genetic test companies that abuse the system. They're the ones that get caught and paint the entire industry in a bad light. It is this class of labs that gives health plan medical directors a pause when a new genetic test comes out. Is this a good test? Is this a good lab?

"We need some way to separate the good, high-quality labs from those genetic testing companies that aren't doing things above board," he explained. "With Z-codes, health plans should be able to reduce fraud, waste, and abuse."

Z-codes are five-digit, alphanumeric identifiers assigned to individual molecular test components and associated with a Current Procedural Terminology (CPT) code.

Atrium Health's Advice on Epic Beaker Rollouts

Lab team implemented the new LIS in tandem with the health system's deployment of the Epic EHR

Deanne Franke, PhD

CEO SUMMARY: *Starting in 2019, Atrium Health began a years-long process to implement Epic Beaker as its laboratory information system. It was an enormous effort, involving dozens of locations across three states. The lab team's lessons learned can be applied to other technology rollouts, regardless of the size of the clinical lab.*

Jamel Giuma

Moving from an existing laboratory information system (LIS) to **Epic** Beaker can be a long, complicated process for just one location. Imagine doing it for 42 sites, a project that the lab team at **Atrium Health**, based in Charlotte, North Carolina, undertook from 2019-2022.

"This project stretched our clinical laboratory," said Deanne Franke, PhD, Technical Director at the **Atrium Health Core Laboratory** in Charlotte. "This was a total Epic EHR and Beaker implementation across three states in four waves. There were more than 40 sites involved, including hospitals, ambulatory care locations, and physician office labs."

Franke provided lessons learned from the endeavor and important advice that other clinical laboratories can use—even if they are in smaller institutions—during a session at April's *Executive War College for Diagnostics, Clinical Laboratory, and Pathology Management*. Her session was titled, "Implementing Epic Beaker LIS in 40+ Facilities Across Three States: Lessons from Accomplishing the Incredible in Only Four Implementation Waves."

Atrium's lab workforce has about 1,000 employees when fully staffed. Depending on the month, from 150 to 200 of those people were involved with the Beaker project at any given time.

"About 15% to 20% of the lab workforce was heavily engaged in testing and validating the new LIS to ensure that, when this system went live, it was going to work for them," Franke said.

Scope of the Beaker Project

It took years of preplanning before Wave 1 of the rollout started in 2021. *(See the sidebar on page 8 for a timeline of the project.)*

Initial efforts to lay the groundwork for switching Atrium's hospitals and labs to Epic's suite began in late 2019. The health system decided to roll out Epic in four waves, with geography and complexity as major factors.

"It was Q4 2019 when lab services really got engaged and started working from the Epic playbook, essentially as the source of decision points required during the build process for the Beaker LIS," Franke said. "One commitment that the

lab made with the information systems department was to use decision documents. These determined when anatomic pathology would go live and when our core lab would go live."

Decision Documents Set Tone

The decision documents centralized options for dealing with issues of concern during the Beaker rollout and created a library of resources for the project team.

For example, one decision document detailed problems that vendor representatives had when transferring Gram stain susceptibility results from Atrium's existing legacy LIS to the new Epic Beaker setup. A short-term workflow was needed to bypass this issue and the decision document outlined the pros and cons of two major options. The document also provided a recommendation, which was to continue to enter results for Gram stains into the legacy LIS until the problem could be solved.

"Our Beaker project team kept a record of how we got to those decisions," Franke noted. "We documented the options the team considered and identified any risk, whether it was risk to teammate safety, patient safety, or even risk to the project timeline. It also allowed us to identify and document the stakeholders and their responsibilities, such as who made the decisions, how they arrived at those decisions, and what those decisions meant downstream as implementation continued.

"Decision documents were shared in executive leadership meetings with our lab operations leaders, meetings with lab directors and managers, and with teammates," she added. "At lab medical director meetings, the project team explained changes in the Epic Beaker build. This was to make sure that, in their roles as CLIA medical directors, they knew how the project was moving forward."

These assessments also allowed Atrium's laboratories to incorporate into the build those tests for Beaker that were not available earlier. "For example, there were reflex testing algorithms put in place," Franke remembered. "Some were very basic, but we did not have these reflex testing algorithms in legacy systems. There was an opportunity to right that ship."

During each project wave, daily working groups convened to discuss the transition to Epic electronic health record (EHR) and Epic Beaker from the legacy EHR and LIS. "Atrium had to update thousands of tests in the legacy systems to then route them over to Epic Beaker," said Jamel Giuma, President and CEO at **JTG Consulting Group** in Miami, who was heavily involved in the project.

"During the different waves, orders were being performed in different systems at different times—depending on which wave and what geographic market—so it was a big challenge," noted Giuma, who also spoke at the *Executive War College*.

Build Sheets Centralize Work

Standardization was another important aspect of the project that other laboratories can copy for their own technology rollouts. Franke and a counterpart within Atrium developed standard build sheets for the individual labs during the rollout.

"The primary responsibility was to work with all the Epic consultants," she noted. "Depending on the consultant, an individual lab might have a slightly different version of the Beaker build. Standard build sheets helped with consistency across the Atrium system. And that also held true for alignment between the Epic Beaker build when we had to crosswalk back to legacy systems."

The team stored the build sheets on **Microsoft** SharePoint so that there was a single version of any sheet that everyone could view.

"The team did not use email to exchange build sheets," Franke explained. "Instead, everyone logged in to SharePoint to get the

Timeline of Atrium's Epic Beaker Project

ATRIUM HEALTH'S ROLLOUT of Epic EHR and Beaker occurred in four waves:

- **Wave 1** (July 2021), Central and South Georgia markets—involving four locations.
- **Wave 2** (December 2021), Greater Charlotte market—six locations.
- **Wave 3** (April 2022), Greater Charlotte market—six locations, including **Carolinas Medical Center**, Atrium's largest acute care facility and Level 1 trauma center.
- **Wave 4** (August 2022), Greater Charlotte, Northwest Georgia, and Northeast Alabama markets—26 locations.

"Wave 4 was our largest, with the greatest facility count and geographic spread," said Deanna Franke at Atrium Health Core Laboratory. In 2024, the Epic rollout will continue at several additional sites in North Carolina.

"Despite the complexity of the project across the four waves, I would do it again," Franke concluded. "Completing the project and gaining this experience was a great way to give back to our patients and even to our health system."

source-of-truth documentation of the decisions that were made for the build.

"We made sure every single build sheet used the same color and format," she added. "I still go back to those sheets today just to verify and double check. If somebody asks a question about the project now that it's live, I can go back and see what decision the team made."

The build sheets were also an important component of the interface logic that helped map out test names and other information between legacy systems and Epic.

"Labs need a good interface with these types of projects," Giuma noted. "A lot of logic was built into the interface engine—depending on what the specimen source was. For example, the legacy system had certain specimen descriptions, but Epic had different descriptions. It was necessary to map these and relate them to the same test order."

This part of the project was carefully monitored. "The project team watched it like a hawk because patient care was at stake," Franke stated. "The team didn't want to create risk anywhere in the organization that could potentially cause an issue for misinterpretation in the patient record."

Given the effort involved, the interface work proved a time-consuming process. "Plenty of work went into this, along with many hours and sleepless nights for the teams, but they were successful," Giuma said.

Leaning on SMEs

Franke emphasized the need for project teams to identify stakeholders and subject matter experts (SMEs) early on to help guide a rollout forward. "That was another key to success for this project. I can't stress how important that is," Franke said. "Leaders must know who is assigned to do what tasks."

Leaders and even CLIA medical directors may not be deep enough in the weeds to know necessary details about a process. "I know coagulation, but I don't know TEG," she added, referring to a thromboelastography test. "So, I went back to analyzer operators and said, 'Tell me what we're doing with TEG. This is the standard that the vendor gave us of what we should expect across the interface. Does this make sense?'"

Lessons Learned by Atrium

With such a massive project to tackle, the team at Atrium Health bumped into occasional problems. Here are key suggestions based on lessons the team learned:

- **Use tracking tools in Epic during an implementation**. Franke said more could have been done to integrate

Epic's tracking features with activities such as clinical content validation, a process which involves the laboratory verifying test names and test volume numbers. "We definitely should have taken greater advantage of the automated tracking tools that are available in Epic," Franke recalled. "We could have done a better job with that. The tools can document work that's been done. People involved with an Epic Beaker implementation need to be aware of this."

- **Anticipate SME schedules during the project timeline**. If a subject matter expert's presence in the laboratory is critical at a certain point of the rollout, ensure that the SME is aware of this and will be working during that time. "SMEs must understand their responsibilities when mapped record testing and interface testing have to take place," Franke said. "At times, the project team had to reschedule if the teammate was off or got pulled to a different bench. That was a lesson learned in better communication."
- **Strive for real-time feedback after a transition to Epic Beaker**. Giuma suggested in-person observations from project team members or SMEs can identify issues quicker. "It's one thing if someone is on the phone explaining a problem," he said. "But when team members actually go out and see the problem in person, they learn a lot more very quickly." When in-person visits are not possible, use a platform like Microsoft Teams or Zoom to get information in real time.

Methodical Approach to Projects

To summarize, organizations that plan to roll out a new laboratory information system such as Epic Beaker should reflect on two overarching considerations brought up by Giuma and Franke:

- A well-timed, methodical approach to project planning can save the organization from potential surprises that can surface once implementation is underway. The plan should include a clear explanation of what the clinical laboratory needs from a new LIS; a roster of who will comprise the project team; and whether a phased rollout will be necessary.
- Carefully documenting decisions not only creates a record about why the laboratory determined a business choice, but also provides a resource for future reference. Project planners will turn to this documentation for guidance as they move forward.

"The reality is, clinical laboratories will have some issues during any go-live project," Giuma observed. "Planning helps to manage the project and anticipate issues to fix. The lab teams at Atrium did a great job of managing these things." TDR

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Forbes: Epic CEO Is Worth $7.4 Billion

FORBES **LISTED JUDITH FAULKNER**, founder and CEO at **Epic Systems**, as the third-richest self-made woman in the U.S. in 2023.

Epic, based in Verona, Wisconsin, developed a well-established electronic health records system and also sells Epic Beaker, a laboratory information system.

As of June 1, *Forbes* estimated Faulkner's net worth at $7.4 billion. She intends to eventually give 99% of her assets to a private charitable foundation, *Forbes* noted.

Who are first and second on the list of the richest self-made women? They are Diane Hendricks, cofounder and Chair of **ABC Supply** in Beloit, Wisconsin, at $15 billion; and Judy Love, Chairman and CEO at **Love's Travel Stops** and **Country Stores** in Oklahoma City at $10.2 billion.

Essential steps when planning, impleme

Digital Patholog for Both Clinica

Orly Ardon, PhD

W. Dean Wallace, MD

CEO SUMMARY: More pathology groups are ready to consider adopting whole-slide imaging and digital pathology. The decision to proceed should only be made after identifying the clinical benefits of these technologies, accompanied by an implementation plan that will deliver an acceptable return on investment (ROI).

TECHNOLOGY INNOVATIONS AND GROWING DEMAND FOR ACCESS to subspecialist anatomic pathologists are two factors fueling adoption of whole-slide imaging (WSI) and digital pathology (DP). Today, there is consensus that digital pathology is the future of the profession.

Given the growing acceptance and use of WSI and DP, pathology groups across the nation must answer two questions. One: Is this the right time for our practice to implement a full digital pathology system? Two: If the answer is yes, is there a road map or business plan our group can follow to purchase, implement, and operate digital pathology that ensures an acceptable return on investment (ROI)?

The quick answer is yes to both questions. However, success with adoption of WSI and digital pathology systems requires every pathology laboratory to carefully assess its specific needs. That assessment then guides implementation.

"Each pathology laboratory has specific needs that will dictate the size and scope of their digital pathology operation," said Orly Ardon, PhD, Director of Digital Pathology Operations at **Memorial Sloan Kettering Cancer Center** in New York City.

Know How to Get There

"Adoption of WSI and digital pathology costs money, but when project leaders commit the plan to writing, it's not that scary," stated W. Dean Wallace, MD, Professor of Pathology at **Keck School of Medicine at the University of Southern California**. "What's scary is when pathology labs start buying scanners and building a service without knowing where they are going or how to get there."

Wallace and Ardon spoke during a *Dark Daily* webinar in May called, "Digital Pathology Implementation Strategies."

Both Ardon and Wallace agreed that successful digital pathology business

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plans need to include certain steps, which they described during the webinar. These steps include:

- Clearly state the digital pathology project's goals.
- Form a project team that reaches beyond the pathology laboratory.
- Outline the lab's needs and how WSI and DP will contribute to meeting those needs prior to project commencement.
- Consider a full implementation versus phased approach. (Big bang versus incremental approach.)
- Bring in outside experts in WSI and DP to help determine appropriate return-on-investment metrics applicable to the pathology lab's specific case mix, subspecialty expertise, and the regional, national, or international areas serviced by the group.

Financial perspectives need to be considered with each of the above steps.

STEP 1

Set Clear Goals for Digital Path

When considering the pros and cons of using whole-slide imaging and a digital pathology system, every pathology laboratory must start the analysis by matching its unique practice composition with the potential advantages that come with use of WSI and DP.

"Pathology groups won't know numbers until they conduct their needs assessment," Wallace said. "Labs must gather their own information and let it inform the equipment needs and overall costs."

This is the stage where pathologists should identify and gather the metrics that will be used to benchmark the progress of the digital pathology project, as well as its contribution to improved patient care while achieving the desired ROI. For example, turnaround times for conventional glass slide sign-out, courier costs, and weekend biopsy reads are examples where DP can make positive contributions.

Demonstrate Value of DP

"It is important that the pathology group gather data on its turnaround time up front," noted Wallace. "This metric will help demonstrate value throughout the staged deployment of WSI and DP."

He stressed the importance of establishing the goals for implementation. "Is the goal to digitize the entire department or instead do a smaller deployment of some digital pathology services?" he asked.

"Get as specific as possible with the metrics that are gathered, such as the number of slides per day that will be scanned," Wallace continued. "Information of this type guides development of an effective clinical plan, service plan, and business plan. The goal is a successful transition to digital pathology."

Ardon next addressed the need to identify external resources, even at this

early phase. "Will the pathology lab need external consultants for the digital pathology project, or does it have the internal institutional abilities to get there on its own?" she said.

"Pathology groups don't have the resources of large academic medical centers," she continued. "After the pathology practice assesses its in-house expertise, it can tap outside experts in digital pathology who have the needed skills to ensure an effective adoption and use of WSI and DP."

STEP ➤2
Form an Effective DP Team

Digital pathology project teams need pathologists and clinical laboratory managers. But other experts are also required for the team to be successful and anticipate all needs.

"Hospital administrators, lab executives in independent organizations, finance personnel, and IT managers are all likely participants," Wallace advised. "Outside consultants and vendors of equipment and software also are potential choices."

Having at least one senior executive in the group can help in at least two ways. Wallace noted that, one, it provides motivation for the rest of the team, since senior leadership is engaged. Two, the senior executive is positioned to help non-laboratory stakeholders understand the importance of implementing digital pathology into the clinical workflow.

➤Involve Leadership in Project

"The DP project will nudge people out of their comfort zones," Wallace observed. This is why it is really helpful to have leadership helping with implementation instead of standing on the sidelines watching the lab do it.

"When the DP team first meets, don't assume everyone at the table understands the technology involved in digital pathology and how it can contribute to better patient care," he explained. "Education is an important initial agenda item. Not everyone on the team will have experience with digital pathology, nor will they understand its capabilities and limitations."

Wallace next noted that it is essential to forge an effective relationship between the lab and IT managers. "Digital pathology implementation involves installing new technology and the need to integrate it with existing networks, such as a laboratory information system," he stated. "The IT manager and the lab manager must work together very closely, particularly on a large digital pathology project.

"Another key to success is designating a project manager," Wallace continued. "Preferably this is someone with experience guiding business rollouts.

"Communication between the lab manager and the project manager is key to a positive project outcome," he added. "Experience shows that—should the lab manager not provide a sufficient level of oversight—project managers will often create something slightly divergent than what the pathology team intended.

W. Dean Wallace, MD

➤"Communication between the lab manager and the project manager is key to a positive digital pathology project outcome."

"Having regular check-ins as the digital pathology project develops is crucial because it can be hard to backtrack if an unintended aspect occurs," Wallace commented. "It is imperative to keep communication flowing, whether through regular face-to-face team meetings, email-based updates, or other types of check-ins.

"Digital pathology implementation can be disruptive—not just within the laboratory—but also to the whole facility," he noted. "Clarity in communication prevents disruption in culture. A well-written

business plan controls the message while preventing rumors and additional anxiety about costs and staffing roles that could change."

STEP 3

Outline the Lab's Needs

Part of a digital pathology business plan is outlining what the laboratory or pathology practice requires from the project.

"This is particularly true when it comes to staffing," Ardon observed. "Once the digital pathology system goes live, workflows change, along with the need to create whole-slide images from the glass slides.

"Here is where outside experts are useful," she continued. "Digital pathology vendors or consultants can provide a sense of how many full-time employees a lab will need to operate new equipment—a crucial discussion given the shortage of laboratory personnel across the country."

Vendors Have Expertise

"During development of the implementation plan, labs can ask vendors how many FTEs they recommend for their scanners," Wallace said. "If this was not addressed up front, it would be a significant expense later on should the lab need to request additional staffing for this function."

During planning, particular attention needs to be given to how whole-slide imaging and digital pathology change the workflows of the individual pathologists. This is the ideal time to specify the tools that provide pathologists with a supportive working environment and maximize their productivity.

"This is why digital pathology workstation technologies are a key need," Wallace explained. "In an ideal setup, a pathologist uses two screens and a specialized mouse. In some settings, however, viewing can be performed on a laptop."

Every DP system requires the infrastructure to manage whole-slide images, making them accessible to pathologists, then archiving them consistent with regulation.

Alternatives Exist for Digital Image Storage

STORAGE OF WHOLE-SLIDE IMAGES does not have to be a deterrent to rolling out digital pathology in a laboratory.

That was the message from David McClintock, MD, Chair of the Division of Computational Pathology and Artificial Intelligence at **Mayo Clinic** and his colleague, Mark Zarella, PhD, Senior Associate Consultant in the same division. The pair guest authored a blog in March posted by the **Digital Pathology Association**.

"There is no specific requirement for storing whole-slide images and the practical argument for long-term storing of images may, in fact, be quite niche," they wrote, noting also that labs may choose to keep only certain images or store all of them for a short-term length of time before deleting the media.

Also, storage strategies should reflect intended use cases outlined in a digital pathology business plan. Options include on-premises storage in servers, cloud-based storage, and archival storage that may not be immediately accessible.

"Storage [of digital images] should not automatically be considered a major burden for digital pathology deployment," Zarella and McClintock wrote.

"Experience shows us that pathologists may lean into these conversations more than other debates," he said. "Image management systems are very important to pathologists. That's because they are daily hands-on users."

Both Ardon and Wallace agreed pathologists are less engaged in decisions involving scanners. "Commonly, pathologists won't be aware of scanners or have an opinion about them," Wallace noted. "Decisions about which scanners to buy are typically left to the lab managers."

"Additionally, the maintenance cost for scanners should be clearly spelled out

during the planning stage," Ardon recommended. "Maintenance requirements and costs may not always be at the forefront of equipment discussions.

"People don't think about scanner maintenance as an expense," he added. "But if a pathology lab's equipment is down because there is no timely service support, that is a serious issue."

Identify Space Requirements

To maintain continuous operation of Memorial Sloan Kettering's whole-slide imaging equipment, Ardon trained on-site staff to handle common technical issues when they were waiting for a vendor maintenance team to arrive.

Equipment space needs should not be overlooked. Don't tackle this concern after scanners have been purchased, Ardon stressed.

"Memorial Sloan Kettering has limited space," she observed. "It is crucial to have scanners available right where the glass slides are being produced."

Wallace recalled a situation where a lab purchased a high-capacity scanner with the intent of supporting frozen services as well as performing general scans.

It turned out, however, that the scanner wasn't easy to use with frozen sections and was located in a remote location from both the histology lab and the slide archive room.

"Because the lab failed to think through the business plan for this particular instrument, it sat unused and may not have scanned a single frozen section slide," he noted.

"It's wise to review equipment choices with vendors before making any final decisions," he added. "Vendors see the best and worst deployments of their instruments and want their equipment to perform to the lab's requirements.

"Keep in mind that it's common for unplanned expenses to surface and that's okay," Wallace continued. "Labs will stay on track with a well-developed business plan that is based on a detailed, pre-project needs assessment."

STEP ➤4

Full versus Phased Deployment

Some pathology labs—likely in larger hospitals with more resources—go whole hog with plans to launch a full digital pathology implementation, even though it is an involved, laborious process.

"What sort of pathology department do you have? Is it big, complicated, and with a lot of moving parts?" Wallace asked. "For a bigger implementation, the lab needs a bigger project team."

Some pathology groups opt for a phased implementation by first digitizing certain services, then adding additional services over time. "A phased implementation can be easier. The pathology laboratory may want telepathology to support after-hours frozen section cases," he said. "That may be an effective way to start."

Regardless of the size of the rollout, business plans should account for the necessary equipment and software.

"Whether it's a full department or smaller implementation, labs need a complete solution," Wallace noted. "This includes a scanner, image management software, and pathologist workstations. If there's an incomplete implementation, the project team might have to ask for more money."

STEP ➤5

Determine ROI Metrics

ROI thresholds will include finances. For example, the federal government is currently conducting a tryout period for new Current Procedural Terminology (CPT) codes for digital pathology services. If enough labs use the new codes, those codes may eventually receive reimbursement from the **Medicare** program. *(See TDR, "New CPT Codes Debut for Digital Pathology Services," Jan. 23, 2023.)*

"Pathology labs can include the new digital pathology CPT codes when calculating their ROI for these projects,"

Obstacles to Digital Pathology Adoption May Be Generational: Boomer versus Gen X and Y MDs

TODAY, THERE IS CONSENSUS THAT DIGITAL PATHOLOGY IS THE FUTURE OF THE PROFESSION. Yet many pathology groups still wrestle with the economics of "going digital." Often, it is a generational divide within a private pathology group practice.

On one side are the older partners—most of whom spent the majority of their career working with glass slides and traditional light microscopes.

These older pathologist voice two concerns: First is that the disruption and capital cost of implementing WSI and DP cannot be speedily recouped. Second, they are close to retirement and want to keep the status quo for a few more years (with the added benefit that their partner share of year-end profit distribution will not be reduced by the need to fund the cost of digital pathology).

On the other side are the younger pathologists in the group. They are a growing force in the pathology labs where they serve. For more than a decade, pathology residents and fellows have been trained in academic programs that utilize WSI and DP.

Thus, each year, a new group of young pathologists enters the clinical workplace, fully-trained in the use of whole-slide images and digital pathology systems. They recognize the benefits of digital pathology and would like their daily practice workflow to be digital.

Future advances in whole-slide imaging and digital pathology technologies may reduce the cost of these systems. The tipping point to further adoption of WSI and DP will then come when enough senior pathologists retire and the next generation of pathologists make up the majority of partners in private group practices, giving them more power to invest in digital technologies.

Wallace suggested. "Over the next few years, it is anticipated that the new CPT codes will be reimbursable, which can offset the costs of digitization."

Involve Leadership in Project

Ardon and Wallace agree that improvements in workflow following implementation of WSI and DP can help pathologists deliver more value.

"Take the example where a pathology lab has a fully-digitized department," Wallace said. "This makes it quick and easy to pull up cases without the time required to search for the glass slides. In turn, this can shorten conference preparation time from many hours to minutes."

Wallace also suggested digital pathology labs investigate how specific volumes of images could help certain institutions' with their research efforts.

"Keck School of Medicine produces a lot of image data, so I can go to my chair and say that—by scanning these slides—the school will have a million digital images a year for research or education," Wallace said. "That is a very different ROI from a community hospital, so it's not a one-size-fits-all situation."

Another relevant ROI metric is how digital pathology might lead to decreased hospital stays for certain patients.

"For example, transplant service patients can be discharged on the same day of their biopsy appointment if digital pathologists can sign off on their case that same day," Wallace said. "Also, if a lab can show the hospital that the lab can reduce in-patient days by use of digital pathology, leadership will be very happy."

The *Dark Daily* webinar, supported by an educational grant from **Hamamatsu Photonics**, is available free on-demand by going to *www.darkdaily.com/webinar*. TDR

Contact Dean Wallace, MD, at William.Wallace@med.usc.edu.

Regulatory Update

CMS: TJC Made 'Business Decision' to Not Recognize COLA

Medicare agency says The Joint Commission's move has no bearing on deeming authority status

Following up on a prior briefing, *The Dark Report* has learned that the **Centers for Medicare and Medicaid Services** (CMS) does not appear to have an issues with a decision by **The Joint Commission** (TJC) to no longer recognize **COLA** laboratory accreditation in TJC-surveyed facilities.

TJC's announcement was effective Jan. 1, and The Dark Report was the first publication to note the change. *(See TDR, "Joint Commission Will Not Accept COLA Accreditation," Jan. 23, 2023.)*

CMS gives organizations deeming authority to accredit clinical labs and pathology practices on behalf of the **Medicare** program and the Clinical Laboratory Improvement Amendments of 1988. TJC, COLA, and other entities have deeming authority to inspect labs.

CMS Reviews the Matter

In January, The Dark Report asked CMS if a group with deemed status was required to recognize accreditation granted by another deeming organization. The agency noted then that it was aware of TJC's move and was reviewing the situation.

When queried in late May as to whether anything had come of that review, CMS told The Dark Report the matter was not an issue covered by deemed status.

"This was a business decision for accreditation and is not under CMS' deeming authority. We recommend reaching out directly to the Joint Commission for any additional details," CMS said.

In a previous statement, TJC said, "The Joint Commission determined that continuing our recognition of COLA did not best support our mission for quality and safety within Joint Commission accredited facilities."

On the surface, TJC does not appear eager to publicly discuss the matter further. For example, during an accreditation panel discussion at the *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management* in April—which included representatives from COLA and TJC—*CAP Today's* Publisher Bob McGonnagle asked about The Joint Commission's decision during the open question and answer portion. McGonnagle's question was brushed aside, and he instead was encouraged to talk privately to TJC or COLA about the decision.

Hundreds of Labs Affected

TJC estimates that 300 labs across the country are affected by its decision. Those laboratories have three options, as explained by COLA:

- They can remain with COLA if the hospital or system chooses to change its accreditation from TJC to another accrediting organization.
- They can remain with COLA and also enroll in TJC accreditation.
- They can withdraw from COLA.

The Joint Commission has given affected laboratories until December 31, 2024, to change to another clinical laboratory accreditation program. TDR

Proposed e-Signature Rule Has Compliance Risks

Clinical laboratories may need IT or vendor help to carry out the changes should rule be finalized

Emily Johnson, JD

CEO SUMMARY: Proposed HHS rule aims to define and standardize physician electronic signatures. For clinical laboratories, this is important because lab test claims require a signed requisition form. Given labs' longstanding challenges in consistently obtaining signatures from certain ordering physicians, implementation of the new rule might be helpful in such cases.

Part Two of Two Parts

SOME EXPERTS BELIEVE THE FEDERAL GOVERNMENT'S PROPOSED RULE to define and standardize electronic signatures may prove helpful to clinical laboratories and pathology groups by streamlining how test orders are signed by the ordering provider.

However, the proposal may not fully insulate labs from physicians who are intent on gaming the system by simply having staff electronically sign orders in bulk on their behalf.

In part one of our briefing, THE DARK REPORT outlined the **U.S. Department of Health and Human Services'** (HHS) reasoning behind the proposed rule, which would update HIPAA regulations. *(See TDR, "Draft Rule Standardizes Electronic Signatures," April 17, 2023.)*

In part two of our report, we look at:

- Compliance pitfalls surrounding the proposed electronic signature rule.
- How the new rule may help clinical laboratories.
- Why technology can help labs and pathology practices meet the rule's goals.

Under the proposal, HHS will expand the types of electronic signatures that are recognized to encompass most forms of commonly-used digital signatures.

"The proposed rule also offers a new standard format for the transmission of electronic signatures to allow them to be sent, received, and interpreted without interruption," said attorney Emily Johnson, JD, Member at law firm **McDonald Hopkins** in Chicago. "Use of this format will be required for claims submission and referral certifications as part of the prior authorization process."

Exposure Risk for Labs

In some ways, compliance concerns about the rule are beyond a lab's control. "The concern is that the proposed rule creates an opportunity for office staff to just 'rubber stamp' a physician's electronic signature on a requisition form," Johnson observed. "The lab is going to be on the hook for any potential recoupment associated with a rubber-stamped requisition form. That's where the compliance risk lies."

The proposed rule says little about enforcement actions. Generally, HHS

enforces HIPAA mandates, under which the electronic signature proposal would fall. "It remains to be seen what enforcement will look like for the rule," Johnson said.

Enforcement likely will not occur until two years after the rule is implemented, based on typical rulemaking procedures.

It would be timely for laboratory managers and compliance officers to understand the requirements of the proposed new rule, then update physicians about electronic signature changes that will be effective upon implementation of the rule.

"Clinical labs should be educating referring providers about electronic signature requirements," Johnson explained. "In the event of a recoupment action by the government or a payer, labs will be required to prove the legitimacy of the requisition form and the test ordered.

"One way to do that is to point to documentation showing that the lab informed the referring doctor what was required and that the signature on the requisition form is an attestation by the physician who ordered the test that it was medically necessary," she added.

Rule Should Help Labs

Clinical labs have had an ongoing struggle with certain providers in their efforts to ensure that all lab test orders are received with the requisite physician signatures.

In theory, the HHS proposal could alleviate some of that struggle by outlining standardized approaches and technology that would be required for electronic signatures on test requisitions.

"The intent of the rule is to facilitate getting the actual test order signed," Johnson noted. "This would make documentation easier for labs. In turn, that would presumably reduce the likelihood that payers will reject claims for laboratory testing services based on missing signatures.

"Especially in the clinical lab space, it can be difficult to ensure physician signatures are on every laboratory order," she added. "My hope is that this proposed rule streamlines that process and makes it easier."

Digital signature software firms and laboratory information system companies will play a role in how this proposal, once finalized, gets implemented.

"I'm sure the technology vendors are already thinking about this proposed federal rule," Johnson said. "They'll need to create some sort of mechanism to make this changeover easy for labs."

Consult with IT Partners

Clinical laboratories and pathology practices should consult with IT partners sooner rather than later about the upcoming changes. This step is especially important for small or independent labs that don't have in-house IT departments.

"Labs need to comply with the HIPAA Security Rule but can implement safeguards that are reasonable for the organization based on the data the labs maintain and the complexity of the flow of information," Johnson advised.

"For smaller labs, the work needed to comply with the rule will be more of a pain point than for a national lab or hospital-based lab that typically have more resources," she added.

"That said, the definition of 'electronic signature' is broad enough to include the most common forms of electronic signatures available on commonly utilized platforms," she continued. "Labs should be able to find a technology that allows them to comply with the proposed rule."

As this rule progresses, alert laboratory leaders should take two actions:

- Find out if the lab's vendors have early ideas on how they will adjust their software to account for new mandate.
- When the final rule is released—the date is not yet known—pay close attention to how public comments influenced the final language of the rule. TDR

Contact Emily Johnson, JD, at ejohnson@mcdonaldhopkins.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Post-pandemic, many clinical laboratory professionals continue to feel they have too much work to handle in their jobs. **Lighthouse Lab Services** in Charlotte, North Carolina, recently released survey results in which 52% of respondents indicated they were overworked relative to their positions; 33% described their workload as adequate; and 15% said they were satisfied with their current workload.

MORE ON: *Overworked Laboratory Staff*

Although not in the survey results, it's likely continuing lab staffing shortages contributed to respondents' concerns. In a LinkedIn post, Lighthouse commented that the end of the SARS-CoV-2 pandemic didn't seem to adjust lab staff feelings about workloads compared to 2022. "We were surprised there wasn't a larger improvement between this year and last," Lighthouse noted.

LAB OWNER GETS 15 YEARS IN PRISON

On June 8, the owner of five clinical laboratories was sentenced to 15 years in prison for defrauding **Medicare** of $132 million, according to the **U.S. Attorney's Office**. Billy Joe Taylor of Lavaca, Arkansas, pleaded guilty in October to conspiracy to commit healthcare fraud and money laundering. Taylor ran labs in four states that submitted false claims for urine and respiratory illness tests.

HOSPITAL TO PAY UP TO $6.4M TO SETTLE UNBUNDLING SUIT

Baptist Neighborhood Hospital in San Antonio entered a class settlement in May that could reach $6.4 million, all allegedly related to unbundling. Up to 64,000 patients who were part of the class action could receive an average $100 payment as part of the settlement, a lawyer told the *San Antonio Express-News*. The lawsuit started in 2020 when a patient accused Baptist Neighborhood of routinely unbundling lab panels when billing for them. The allegation is that unbundled tests likely recouped higher payments than would be paid by Medicare or a private payer for the bundle.

TRANSITIONS

- Dion Scott is the new Regional Director of Laboratory Operations at **MultiCare Health System** in Tacoma, Washington. Previously, he was Senior Director of Clinical Laboratory at **Providence Health** in Seattle.

- Angelique Levi, MD, will become Vice Chair of Operations and CLIA Laboratory Medical Director for the Department of Pathology at **Yale School of Medicine** in New Haven, Connecticut, effective July 1. Levi is currently Associate Professor of Pathology at the school.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 10, 2023.

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