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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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Is New Medicare Affiliation Rule Good, Bad, or Ugly?

THERE IS AN OFT-REPEATED ADAGE THAT what the government gives you with one hand, it takes away with the other. This may be an apt description of the new Medicare final rule that takes effect today, called the Program Integrity Enhancements to the Provider Enrollment Process (CMS-6058-FC).

The goal of the new rule is to give federal officials a way to identify, in advance, bad players as they move from one provider organization to another. In that sense, the new rule is a proactive tool that Medicare officials have needed for decades. One important element of the law is that the Medicare program now has the ability to ban individuals and provider organizations from participating in Medicare for up to 10 years. Previously, Medicare could exclude an individual or entity for just three years.

Lab companies that engage in fraud and abuse—often paying illegal inducements to physicians to encourage them to order medically-unnecessary tests—distort the lab testing marketplace and capture lab test referrals that would otherwise go to compliant clinical labs and pathology groups. So, honest labs will recognize how the new rule can help suppress various types of fraud that constantly plague the clinical lab industry.

That's all to the good. But the new rule also comes with risks for compliant labs. When providers, including clinical labs and pathologists, enroll or re-enroll in the Medicare program, the rule requires them to identify affiliations with individuals or entities that owe Medicare money or have been sanctioned by the Medicare program, going back five years. Even compliant labs can owe Medicare money if they are appealing in response to claims of overpayments or similar situations. *(See TDR, Oct. 14, 2019 and pages 3-9 in this issue.)*

That's why, in this and the previous issue, THE DARK REPORT has interviewed four attorneys for their insights about what clinical lab executives and pathologists need to know about how the new rule could ensnare even compliant labs. Nowhere else will you get such a deep dive on this new and important development. As you will read, these attorneys are still sorting through the implications of the new role. They are identifying landmines within the rule that can catch even honest labs. Most importantly, each attorney warns that there are ways that even a lab diligently trying to comply with the new affiliation rule can find itself facing serious sanctions. TDR

Medicare Affiliation Rule Targets Criminal Behavior

Rule also places significant compliance burden on all providers, including labs, pathology groups

CEO SUMMARY: Under a new federal rule in effect this month, all healthcare providers—including clinical laboratories and pathology groups—will need to scour the records of all officers, directors, and affiliates to identify any that have had negative dealings with CMS or other federal enforcement agencies. Under the rule, the Medicare program is likely to target labs that test for drugs of abuse, such as opioids, and that do genetic testing, said a lawyer who has studied the rule.

As of today, a new federal Medicare rule takes effect that can bring both benefits and headaches to the nation's clinical laboratories and anatomic pathology groups.

The rule, Program Integrity Enhancements to the Provider Enrollment Process, is a long-overdue step to help federal officials identify individuals, investors, managers, and others who have defrauded the Medicare program or who were associated with entities that owe Medicare fines that have not been paid.

When a provider enrolls or re-enrolls in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP), the rule requires that the provider disclose certain affiliates as the rule defines. In this process, however, there are pitfalls to avoid for unwary clinical labs and pathology groups. *(See "Labs Must Respond to New CMS Anti-Fraud Rule," TDR, Oct. 14, 2019.)*

For starters, one attorney familiar with the rule predicted that federal officials would target providers, such as clinical laboratories that Medicare has sanctioned in the past. The attorney, Courtney G. Tito, a member of the law firm of **McDonald Hopkins**, said the federal **Centers for Medicare and Medicaid Services** (CMS) will seek to identify labs or other providers engaged in such behavior.

"I believe CMS will use data analytics to target providers that are a high enforcement priority and have affiliations with a sanctioned event," she stated. "This will probably be most true for those labs that run molecular and genetic tests, toxicology tests, and that do testing for drugs of abuse, such as opioids." Tito represents healthcare providers, including clinical

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laboratories and pathology groups, in cases involving enrollment revocations, federal and private audits and disputes, and reimbursement issues.

"CMS will likely target toxicology labs and any lab doing anything associated with opioids," Tito said in an interview with The Dark Report. "Also, CMS probably will target some genetic testing labs because those labs have been targeted recently for federal enforcement."

In September, the federal **Department of Justice** announced the results of Operation Double Helix, an investigation that led the DOJ to charge 35 individuals in a $2.1 billion genetic testing scam. At least six lab owners were among those indicted. *(See, "DOJ Charges 35 Individuals in $2.1 Billion Genetic Testing Scam," TDR, Oct. 14, 2019.)*

"My guess is that those types of labs would be the areas that CMS would target, but we don't know that yet—at least not for certain," added Tito. "It's logical that CMS would begin with those labs because toxicology labs and opioid testing are prevalent in enforcement now and some of the labs have been cited in recent years."

CMS to Use Data Analytics

Usually CMS will identify problem providers by requesting records and making demands for refunds of overpayments, she added. In addition, Tito said, CMS probably will use data analytics to identify problem labs under the final Program Integrity Enhancements to the Provider Enrollment Process rule. The goal of the rule is to stop fraud before it happens by preventing unscrupulous providers from enrolling or re-enrolling in Medicare, Medicaid, or CHIP.

As a result of asking federal officials about how CMS identifies clinical laboratories, pathology groups, and other providers that could run afoul of the rule, Tito has learned that CMS uses data analytics to select such providers for further scrutiny. Accordingly, she said, it is likely that CMS will use the same process to determine the initial providers that need to respond to requests for more information under the rule. But Tito is concerned about how CMS will use such data analytics tools.

"Using data analytics can be worrisome because what parameters will CMS use when programming these systems?" she asked. "It's not entirely clear from the commentary that CMS published with the rule how federal officials will use data to identify labs or other providers for enforcement.

Choice of Data Points

"The problem is that there are no real standards or requirements for what data analytics CMS will use and which data points it will use for its analysis," she added. "For this process, federal officials can choose whatever data points they want."

One data point that CMS could use is to review the list of individuals, clinical labs, pathology groups, and other providers that have been excluded from federal healthcare programs, she suggested. "The OIG exclusion lists would be a great place to start to match up the individuals and the entities that have been excluded from participation in the past," stated Tito.

"Also, any company or entity that's had a payment suspension, and any provider that has an uncollected overpayment from Medicare, Medicaid, or CHIP, also could be a target," she continued.

The problem with going after labs and providers that have been targeted in the past is that most providers file appeals when facing payment suspensions from federal healthcare programs. But appeals take so long that many labs and providers do not survive the appeals process if their revenue depends heavily on federal reimbursement, Tito said. Such appeals usually take anywhere from three to 10 years and sometimes run longer, she added. *(See sidebar on next page.)*

Another area of concern about the rule is that it imposes a significant burden on all healthcare providers to review the

New Medicare Rule Requires Disclosure of Affiliations, But Could Ensnare Many Providers

EVEN THOUGH THE NEW MEDICARE RULE ON ENROLLMENT AND DISCLOSING AFFILIATIONS is aimed at stopping providers from committing fraud before it happens, the rule will affect all healthcare providers, including clinical laboratories and anatomic pathology groups, said Courtney G. Tito, a healthcare lawyer with McDonald Hopkins.

"CMS is trying to stop the bad guys," she commented. "These are the individuals and entities who—once they are sanctioned—often shut down their companies. Then, to avoid paying recoupment amounts and penalties assessed by federal regulators, they open another similar operation under a different name."

Tito identified two ways that a provider trying to comply with the federal rule, called Program Integrity Enhancements to the Provider Enrollment Process, could ensnare unsuspecting clinical labs, pathology groups, or other providers.

"First, what happens if such a provider has a demand to return an overpayment amount and has appealed that decision to return the overpayment?" she asked. "The overpayment could be a technical or paperwork error, for instance. If the provider disputes that overpayment and it is under appeal, those appeals could take three to 10 years to be resolved because there's such a backlog in CMS' appeals.

Three Years for Appeals

"Just to get such a case before an administrative law judge can take three years or more," she continued. "That's before anyone even looks at that provider's appeal at the third level of Medicare appeals. Technically, that provider would have an overpayment that it has not repaid while the case is under appeal. If that's the case, the provider and its managers would need to disclose that fact under this new rule because the provider has an unpaid overpayment while the case is under appeal.

"In a second example, a provider could have an overpayment demand under appeal and—if that provider had any affiliations with what might be called 'bad' actors—CMS could characterize that provider as a potential source of undue risk of fraud, waste, and abuse," explained Tito.

"Under that reasoning, CMS could deny the provider's request for enrollment or re-enrollment at the same time," she said. "If that happens, that provider's enrollment or re-enrollment could get denied or revoked.

Appeal Enrollment Decision

"In this scenario, the provider would have to appeal that enrollment decision as well," Tito added. "In such a case, the provider would appeal on two fronts because the overpayment appeal would still be pending when the provider then appeals the enrollment or re-enrollment denial or revocation.

"For most providers—especially smaller ones—those two appeals could be devastating," she suggested. "When CMS flags a provider for a payment suspension, a provider has only 15 days to rebut that suspension. Regardless of whether the provider is successful at terminating the payment suspension, that would be a required disclosure for this provider to comply with the new rule.

"When you look at the enrollment and affiliation rule in this way, it seems like CMS is overreaching," she concluded. "That can be a problem for honest providers when, in fact, CMS is seeking to limit fraud, waste, and abuse, and to identify individuals and entities that have been subject to events the new rule requires them to disclose."

records of all "affiliations," over the past five years. This review is to include officers and directors to identify any administrators that Medicare, Medicaid, or CHIP has sanctioned, Tito said.

The rule requires clinical labs, pathology groups, and other healthcare providers to review what CMS calls "all required disclosable events" for each officer and director and all of its affiliates over the past five years, Tito explained.

Undue Risk of Fraud, Waste

After providers submit that information, CMS will review the facts to determine if that provider poses an undue risk of fraud, waste, or abuse based on any of its relationships with companies or individuals that CMS has sanctioned, she explained.

If any individuals or companies have ever been sanctioned, the lab or pathology group would need to disclose that information to CMS, she said.

"The rule also creates new revocation and denial authorities in an effort to stop waste, fraud, and abuse, including increased re-enrollment bars," she wrote in a client alert last week, adding that the new rule imposes another burden on providers to maintain information on any affiliations it has had with excluded individuals or companies.

"The final rule imposes a five-year look-back on affiliations, meaning a provider will need to obtain and maintain all required disclosable events from each affiliation and provide that information to CMS for review," she added. *(See "Labs Must Respond to New CMS Anti-Fraud Rule," TDR, Oct. 14, 2019.)*

"It's not so much that healthcare providers have criminal exposure, but one aim of the rule is to prevent criminal behavior through new enrollment rules," Tito said.

"CMS is trying to weed out the people who try to shortcut the process to enroll in Medicare, Medicaid, or CHIP, or to re-enroll in any of these programs under different names.

"It's not infrequent that after CMS cites owners, operators, corporate officers, directors, and other executives at clinical lab companies, these same individuals form other corporate entities that operate in a fraudulent manner," she commented.

"CMS is requiring compliance with this new rule to prevent these and other shortcuts to get around the Medicare enrollment process," Tito explained. "This new rule is an effort by CMS to short-circuit fraudulent activity.

"But, in trying to short-circuit this behavior, CMS is creating a burdensome and costly process for all good providers—including those providers who have always been compliant," she stated. "This new process basically requires providers to be private investigators. Under the rule, providers have to dig through all of their direct and indirect affiliations to see if CMS has sanctioned any of them."

Burden for Providers

In a commentary, CMS acknowledged that complying with the rule will be burdensome for providers. It therefore adopted a phased-in approach to enforcement of this section of the new rule. In the initial phase, CMS will send requests to targeted providers and those providers will need to comply with the rule fully. Tito suggests, however, that clinical laboratories and anatomic pathology groups start preparing now and suggests the following initial steps:

- Create a plan and set aside a budget for how to collect and maintain this information,
- Consider renegotiating contracts to include obligations for affiliates to provide this information and include similar clauses in all new contracts,
- Watch for sub-regulatory guidance on this topic from CMS, and
- Seek legal counsel to assist in moving forward. TDR

—Joseph Burns

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Labs Need to Act on New Medicare Enrollment Rules

Attorneys provide guidance on several steps lab directors and pathologists should take now

CEO SUMMARY: For all healthcare providers—including clinical laboratories and pathology groups—a new rule became effective this month. The rule allows Medicare to revoke or deny enrollment if a provider or supplier's affiliates pose an undue risk of fraud. Lawyers familiar with the "Program Integrity Enhancements to the Provider Enrollment Process" rule are concerned about its far-reaching and potentially negative effects, especially for compliant labs and pathology groups.

Will the new federal rule intended to fight fraud in federal health programs also end up entrapping compliant clinical laboratories and pathology groups? That's one question an experienced lab industry attorney is asking, following the release of the new rule last month by the federal **Centers for Medicare and Medicaid Services** (CMS).

One situation the rule is designed to prevent is individuals and business entities continuing fraudulent or abusive schemes in different places and under different provider names or identifications, explained Danielle E. Holley, a healthcare attorney and principal at **O'Connell & Aronowitz**, in Albany, N.Y.

The new rule became effective today. It is a concern because it is likely to cause some disruption for clinical laboratories and pathology groups, particularly for those that are, or have worked with, a provider or supplier that has run afoul of CMS' rules in the past.

"The question is whether CMS has gone beyond what is reasonable and necessary, thereby putting otherwise compliant providers at risk," stated Holley.

"The goal of the regulation is laudable: to combat and reduce fraud in federal healthcare programs," she wrote in a summary of the new regulation.

But Holley and other lawyers who represent clinical labs and pathology groups are concerned about the reach of the new rule, which is called the Program Integrity Enhancements to the Provider Enrollment Process. Lawyers also are concerned about the potential challenge of complying with the new regulations under the rule. *(See "Labs Must Respond to New CMS Anti-Fraud Rule," TDR, Oct. 14, 2019.)*

Current, Past Lab Affiliations

"Clinical labs and pathology groups could face problems based on the affiliations they have now or have had in the past with other providers and suppliers," commented Holley. "Providers and suppliers may now have an obligation to disclose to CMS several of their affiliations with other individuals and entities."

The rule outlines whether a lab or pathology group would need to disclose a potentially troublesome affiliation. "Under the rule, all providers and

suppliers who are enrolling initially, or revalidating an enrollment, will need to disclose these affiliations upon CMS request when a disclosable event arises, and CMS determines that the enrolling or revalidating provider or supplier has at least one such affiliation," she wrote. *(See sidebar at right: "Labs, Path Groups Need to Disclose Affiliations.")*

Defining 'Disclosable Event'

Holley restated the CMS rule that defines a disclosable event as including any of the following involving an individual or organization:

- Currently has an uncollected debt to Medicare, Medicaid, or CHIP, regardless of the amount or whether the debt is being repaid or appealed;
- Has been or is subject to a payment suspension under a federal healthcare program, regardless of when it was imposed;
- Has been or is excluded by the federal Office of Inspector General from participation in Medicare, Medicaid, or CHIP, regardless of whether the exclusion is being appealed or when the exclusion occurred or was imposed; or
- Has had its Medicare, Medicaid, or CHIP enrollment denied, revoked, or terminated, regardless of the reason or whether it's being appealed or when it was revoked, terminated, or imposed.

Covers Providers, Suppliers

"All healthcare providers and suppliers will need to disclose affiliations with individuals or entities," stated Holley. "This is required, even if those parties were not enrolled in any of the three federal healthcare programs at the time of the affiliation."

To determine if they have affiliations with disclosable events, clinical labs and pathology groups will need to look back to each of their affiliations over the past five years, she said.

Clinical laboratory directors and pathologists are likely to have questions about what steps they need to take to ensure that they comply with the rule given that it is in effect as of this month.

To address the most pressing questions lab directors and pathologists may have, Caitlin Forsyth provided guidance. An associate attorney with the law firm of **Davis Wright Tremaine** in Seattle, Forsyth serves as general regulatory counsel for clinical, molecular, and toxicology labs.

"Under the new rule, your lab or pathology group needs to know about your affiliates' histories, and if and when CMS requests that you report those affiliations, you would need to disclose it on your enrollment application," said Forsyth.

Questions and Answers

The following are some common questions labs and pathology groups may have and Forsyth's answers.

Q. *Does the rule require existing clinical labs and anatomic pathology groups to file the CMS-855 enrollment form by a certain time? Or take any action now in response to this new rule?*

A. "No, neither clinical laboratories nor pathology groups need to take any action now. We're in a bit of a wait-and-see period with CMS," Forsyth said. "But, laboratories and pathology companies would be well served to get a handle now on the histories of the persons and entities that have ownership or controlling interests in their companies, and consider whether there's anything they'd need to disclose, were CMS to direct them to do so."

Q. *In addition to beginning to collect some information about company owners, officers, and members of the board of directors, what else would you advise that labs and pathology groups do now to comply?*

A. "As mentioned, there's nothing labs and pathology groups need to do right now to comply with the new rule. If and when CMS directs a company to report its disclosable affiliations, we strongly recommend the company

consult with counsel to ensure their reporting of disclosable affiliations is both accurate and complete," she said.

Q. *Given that CMS lists five types of provider enrollment transactions, do clinical labs and pathology groups need to be aware of these five transactions?*

A. "The five enrollment transactions—initial enrollment, change of ownership, revalidation, reactivation, and change of information—are not new," Forsyth explained. "It would be wise, however, for labs and pathology groups to have a general understanding of these transactions and know what circumstances might trigger a transaction and, thus, a reporting requirement.

"For example, is your lab appointing a new board?" she asked. "If so, you'll need to file a change of information to delete the existing directors and report the new directors in Section 6 of the CMS-855 (ownership interest and/or managing control information [individuals]).

"Did your lab or pathology group lab get a notice that you're due for revalidation?" she continued. "If so, be sure to file a revalidation application within the specified time to avoid penalties, which could include revocation of Medicare enrollment."

Q. *Does the new rule require all currently licensed Medicare providers to submit a CMS-855 that includes the new information about affiliations? Or, should labs wait until CMS publishes the enrollment forms?*

A. "No, there's no requirement to act now," she explained. "That's because CMS needs to revise the CMS-855 forms first to accommodate the required disclosures under the new rule. Then, as part of a phase-in process, CMS will give notice to certain providers and suppliers that they need to report their disclosable affiliations to CMS.

"At that point, CMS will determine which providers and suppliers have one or more affiliations that would trigger a disclosure under the new rule," Forsyth explained. "For now, providers and suppliers will not be required to disclose affiliations under the rule unless CMS determines that the provider or supplier may have at least one affiliation that includes a disclosable event and then specifically requests the lab or pathology group to do so."

Q. *Do the new rules require clinical labs and pathology groups to report referring client physicians or other providers who submit patients' lab test orders when they know or suspect these providers have past issues with Medicare?*

A. "No, that's not what the rule requires," she said. **TDR**

—Joseph Burns

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Labs, Path Groups Need to Disclose Affiliations

LANGUAGE IN THE NEW MEDICARE RULE requires providers, including clinical laboratories and pathology groups, to disclose relationships when enrolling or re-enrolling in the Medicare program.

The new rule defines the word "affiliation" as any of the following relationships:

- A 5% or greater direct or indirect ownership interest that an individual or entity has in a lab or pathology group,
- A general or limited partnership interest regardless of the percentage,
- An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of the lab or pathology group,
- An interest in which an individual acts as an officer or director of a corporation,
- Any payment assignment relationship, as the rule defines.

Using Lab Data to Generate New Sources of Revenue

How Labs Can Add Value for Providers, Insurers, Pharma

CEO SUMMARY: For pathologists and clinical, molecular, and genetic testing labs, appropriate reuses of lab data can provide a new source of revenue. Labs that serve as preferred providers of diagnostic testing data can help health systems, ordering physicians, pharmaceutical companies, and other organizations when they reuse lab test data to support evidence-based care and clinical utility for reimbursement and payer contracting. Reusing lab data also can help pharmaceutical companies evaluate medications for effectiveness, safety, and to support research.

First in Our Series on Data

In recent years forward-looking clinical laboratories, pathology groups, and molecular and genetic labs have recognized that the lab test data they produce from patients has value that can be tapped in ways that generate new streams of revenue.

Finding new sources of revenue is essential if clinical laboratories are to remain financially viable and have the resources needed to deliver high-quality lab testing services. That's because government and private payers continue to make deep cuts in what they pay for laboratory tests. Also, corrosive to lab revenue are the trends of narrow networks and the use of lab test prior-authorization rules.

Probably more significant than these factors is the reality that many health plans are steadily moving away from fee-for-service payment for clinical services. Instead, these payers want to reimburse providers—including labs—with new forms of value-based payment. As that trend spreads, more hospitals and physicians get larger portions of their income from bundled payments and capitated or per-member-per-month fees.

Another powerful trend is genetic medicine. New insights into the human genome and new technologies that make gene sequencing faster, cheaper, and more accurate are fueling an explosion in precision medicine. The number of clinical services that now can benefit from a molecular or genetic analysis grows almost monthly.

Moving forward, these two powerful trends will have tremendous influence on how clinical laboratory and anatomic pathology services are organized, delivered, and reimbursed. And it is precisely these developments that create opportunities for innovative labs and pathologists to develop new streams of revenue.

One individual sitting at the intersection of the payer changes and advances in genetic testing and precision medicine is Patricia Goede, PhD, Vice President of Clinical Informatics at **XIFIN**, a company in San Diego that helps labs optimize revenue.

The Dark Report is basing this new series of intelligence briefings on how clinical labs and pathology groups can develop new sources of revenue from the insights Goede shared during a presentation she made at XIFIN's annual user group meeting in September, supplemented by information she provided during multiple interviews with The Dark Report.

Goede is watching the intersection of multiple forces and dynamics now reshaping healthcare, diagnostics, and therapeutics. At this intersection are pharmaceutical companies (with deep pockets for developing promising therapies), integrated health networks, physicians, government and private payers, and even employers.

She commented that labs can leverage test data in multiple ways to develop new streams of revenue independent of the traditional fee-for-service reimbursement for an individual lab test. Moreover, for labs that believe test data belongs to the patient and shouldn't be sold even when de-identified, Goede suggested several clinical service offerings labs could use to leverage that data, while protecting patient privacy.

➤ Why Labs Are Well-Positioned

In this first installment, Goede discusses why labs are well-positioned to deliver value to healthcare stakeholders. She then identifies different ways labs can use their lab test data to improve patient care, for which the lab can be appropriately reimbursed. These strategies and approaches include:

1) Labs stepping into the role of diagnostic experts and diagnostic collaborators.
2) Labs providing hospitals, physicians, and payers with support for healthcare big data/population management at the macro level, and precision medicine at the micro level.
3) Labs helping providers and payers with quality metrics (MACRA/MIPS, HEDIS, Medicare Star ratings).

4) Labs protecting and increasing their own revenue by using lab data with other clinical data to increase collected revenue, appeal denied claims, obtain prior-authorization for key tests, and more.
5) Labs helping both providers and payers in their risk-sharing arrangements by improving diagnostic accuracy, identifying patients at risk or with gaps in care, and similar.
6) Labs collaborating with pharmaceutical companies in the development of new therapies and clinical services.

Inherent Value of Lab Data

Goede emphasizes that it is important for lab administrators and pathologists to understand the inherent value of diagnostic data, especially when the data are combined with clinical and financial data. Laboratory testing is the highest-volume medical activity that generates large volumes of data that provide value in different ways. Lab data has value that is more than monetary because diagnostic information from lab tests can be used to save money as well.

This can be seen with first-mover labs. As they partner with their ordering physicians, laboratories and pathologists begin to understand that, when used appropriately, high quality diagnostic data can also be reused in many ways for health systems, health insurers, pharmaceutical companies, and contract research organizations.

New Era in Lab Medicine

"We are fast approaching a new era in laboratory medicine," predicted Goede. "This new era will emphasize producing an accurate lab test result within an acceptable turnaround time that provides a clear interpretation of the results with reasonable clinical judgment.

"The emphasis on helping caregivers use accurate lab test results to guide effective care will be the foundation for all the collaborations between laboratory clinicians and ordering physicians in addition to value-based reimbursement arrangements that involve the lab," she added.

"Lab medicine's new era will be firmly rooted in how all labs leverage the value of the lab test data they produce to the benefit of patients, physicians, and payers," explained Goede. "Health insurers, government health programs, and employers are willing to pay labs for the value they deliver—but only if labs learn how to convert raw lab test data into actionable clinical intelligence.

"In this new era, healthcare's transformation to value-based payment creates opportunities for clinical labs and pathology groups," she continued. "Providers are forming integrated health networks. Healthcare big data, population management, and personalized medicine are evolving as service lines designed to improve clinical care. The goal is to give physicians new tools to improve patient care and control costs.

Labs as Diagnostic Experts

"Increasingly, health systems rely on pathologists and labs as strategic partners because they have become preferred providers of diagnostic testing," Goede said. "Developing a strategic partnership with ordering physicians in the integrated health network allows labs to develop their own data strategy to extract the most value from lab test data.

"In their role as preferred diagnostic data providers, labs can assist all healthcare organizations in multiple ways," she explained. "For example, lab data can support clinical utility for reimbursement and payer contracting.

"Also, lab data are essential to support evidence-based care, and lab data also are used as a source of subject matter expertise to guide decision-making for test ordering," she said.

"As most laboratory clinicians know, getting the right treatment to the right patient at the right time is not possible with-

out knowing the results of the right laboratory test," Goede commented. "That's why combining diagnostic and clinical data can help hospitals and health systems negotiate favorable managed care contracts.

Quality Reporting Programs

Separate from the use of lab data to support clinical care is another opportunity for labs to leverage the value of their lab test data to support quality initiatives," noted Goede. "Physicians and other providers already use lab data for quality reporting in new payment systems, such as those under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), including the Merit-based Incentive Payment System (MIPS) and any alternative payment models (APMs).

"Physicians and providers participating in their quality reporting programs use diagnostic results as part of the data collection efforts to demonstrate how they are improving the quality of care for patients," she said. "The calculations to determine how well physician groups perform in value-based arrangements are partially dependent on diagnostic data. The good news is that every lab has the opportunity to assist physicians in value-based programs, but only if the lab develops strategies for the reuse and exchange of their test data.

"Also, because of evaluation systems like Medicare STAR ratings and the Healthcare Effectiveness Data and Information Set (HEDIS) from the **National Committee for Quality Assurance**, labs are finding that lab test data have value for health plans in their own compliance with regulatory and quality assurance agencies and for quality reporting," noted Goede.

Boosting Lab Revenue

Goede next discussed how labs can use test data to improve the revenue they collect from payers and others. "Labs should keep in mind that they can and should

Demand Grows for Real-World Data

DEMAND FOR REAL-WORLD DATA will explode within five years, according to respondents in a survey XIFIN conducted with the publisher of *The Journal of Precision Medicine*.

Pathologists and clinical laboratory administrators will see increased demand for real-world data (RWD) to support claims adjudication, coverage decisions, and regulatory submissions, the survey showed. Survey respondents expect to see a continuing demand for RWD to support clinical utility, drug safety and efficacy testing, disease insights, and the development of patient registries.

The problem for medical laboratory professionals is that the current status of information technology systems does not always meet the needs of clinicians engaged in precision medicine (PM), the survey respondents reported. Asked if electronic health record (EHR) systems are meeting the needs of PM users, 26% of survey respondents said no; 33% said somewhat; and only 24% said yes. The other 17% did not know.

One reason EHRs fail to provide what oncologists and other ordering physicians need is that much of the data from clinical laboratories is unstructured, making that data difficult to find in a patient's EHR, said Patricia Goede, PhD, XIFIN's VP Clinical Informatics.

Also, she added, many lab results are provided as PDFs, which are difficult for physicians to use at the point of care, she added. For health systems, the survey revealed that the most pressing challenges in implementing IT systems to support PM included analytics tools for clinical and diagnostic claims and financial data, integrating data for interoperability, reporting on clinical improvements, and curating and annotating structured and unstructured data.

develop strategies to reuse their own lab test data to appeal denied claims," she explained. "Part of the lab data strategy involves developing collaborative relationships with ordering physicians and health systems to exchange diagnostic and clinical information to improve reimbursement when health insurers are concerned about clinical utility."

All labs know that uncertainty about clinical utility leads to denial of claims. Often, these denied claims end up in appeal, a process that can be lengthy, costly, and time-consuming, yet may or may not result in payment.

"For a recent study, XIFIN reviewed the success rate, time to adjudication, and additional cost for the portion of molecular tests denied on submission last year," Goede commented. "The results showed that the average appeal process was completed in 60 to 120 days. For such appeals, the costs incurred for labs and payers often totaled thousands of dollars.

"If labs can adopt strategies with physician partners to integrate diagnostic, clinical, and financial data, they can then start to streamline the claims adjudication process," she added. "In that way, integrated data can be used to simplify the reimbursement, improve lab revenue, and reduce the cost required to bill and collect that revenue.

"Moreover, a lab-focused data strategy can enable a lab to enter into risk-sharing programs with payers and for physician certification programs," she explained. "Some of these programs are similar to that of the MolDx Certification and Training Registry. Several Medicare contractors use MolDx as a way to build trusted partnerships between payers and diagnostic providers. In turn, that can minimize the claims and appeals cycle for the tests listed in the MolDx registry.

Pharma Wants Lab Data

Pharmaceutical manufacturers have long looked to the diagnostic industry to improve the development of and regulatory approvals for new tests and companion diagnostics by linking lab test results to a defined treatment.

"For example, pharmaceutical companies want to use diagnostic information for clinical trials, to evaluate safety and effectiveness, to support research and development, and to analyze how genomic and biomarker testing can be used to assess the effectiveness of new medications," commented Goede. "Therefore, laboratories need to develop data strategies by developing partnerships with pharmaceutical manufacturers."

New Lab Revenue Sources

The consistent theme in Goede's insights and recommendations is that clinical laboratories and anatomic pathology groups become masters of their lab test data. This is consistent with the Clinical Lab 2.0 business model developed by the Project Santa Fe labs in recent years.

Stated differently, the clinical lab profession is seeing a radical shift. Since the 1950s, the economic model of labs was based on increasing volume to lower average cost per test and maximize profits from fee-for-service payments. In this world, to be paid, labs simply needed to provide an accurate, reproductible test result within the targeted turnaround time.

That is no longer the case. The change in how payers reimburse providers and the need for providers to deliver personlized care, tailored to each patient's unique needs, is creating a once-in-a-lifetime opportunity for labs. It is why Goede predicts that the laboratory medicine profession is on the verge of a new era.

In this new era, healthcare big data and precision medicine both will heavily rely on lab data. Consequently, labs are positioned to be the perfect collaborators—and be paid for those collaborations. TDR

—Joseph Burns

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Legal/Regulatory/Compliance

UTC Labs to Pay $41.6 Million in a Civil Settlement With DOJ

One more lab company has settled allegations of fraud and abuse. Last month, **UTC Laboratories** agreed to pay a fine of $41.6 million and will be excluded from all federal healthcare programs for 25 years.

Announced Oct. 9, the settlement resolves allegations that UTC violated the False Claims Act by paying kickbacks in exchange for laboratory referrals for pharmacogenetic testing and for billing Medicare for tests that were not medically necessary, the DOJ said.

In addition to these penalties, the three principals of New Orleans-based UTC Labs, which operated under the name **Renaissance Rx**, agreed to pay $1 million, the DOJ said.

The *Times Picayune* newspaper of New Orleans reported that the three principals were the owners: Tarun Jolly, MD; Patrick Ridgeway; and Barry Griffiths. The three men will jointly pay the $1 million fine, the newspaper added.

An anesthesiologist, Jolly operates **Louisiana Pain Specialists** and is on the boards of the **American Cancer Society**, the School of Public Health and Tropical Medicine at **Tulane University**, and the Isidore Newman School, a private high school in New Orleans, the newspaper reported. Last year, Jolly and his wife, Rupa Jolly, a dentist, contributed $3 million toward a new science and technology building at the Newman School.

In its case against Renaissance Rx, the DOJ alleged that from 2013 through 2017, the lab company and its principals paid physicians to induce them to order pharmacogenetic tests, purportedly in return for their participation in a clinical trial known as the Diagnosing Adverse Drug Reactions Registry.

In the scheme, the lab company paid sales commissions to some individuals and billed Medicare for pharmacogenetic tests that were not medically necessary, the DOJ said. "The payment of cash and thinly disguised referral bribes, as contended by the government, resulted in a more than $42-million-dollar resolution in this case," Special Agent in Charge CJ Porter, of the **Department of Health and Human Services** Office of Inspector General, told the newspaper. Actually, the $41.6 million represents outstanding invoices owed to the lab company, the newspaper added.

Owners Banned for 25 Years

While the 25-year ban applies to a company that no longer exists, the owners and other affiliated officers may be barred from participating in Medicare, Medicaid, and the Children's Health Insurance Program under a new Medicare rule now in effect called the Program Integrity Enhancements to the Provider Enrollment Process. *(See, "Medicare Affiliation Rule Targets Criminal Behavior," page 3.)*

The settlement resolves allegations in six lawsuits pending in U.S. District Court for the Eastern District of Louisiana that were filed under the whistleblower provisions of the federal False Claims Act, the DOJ said. As of early October, the shares to be awarded to whistleblowers had not been determined.

In concluding its announcement, the DOJ said no determination of liability had been made, and that the claims settled in these cases were allegations only. TDR

—Joseph Burns

Health Insurers Spending Billions to Diversify

➤Strategist explains how major health insurers are investing to support different visions of the future

➤➤CEO SUMMARY: One big development affecting the health insurance business is how four of the nation's largest health insurers are diversifying in significant ways. Last spring, a healthcare strategist explained how each of these companies has spent billions of dollars in recent years to acquire other healthcare companies that are not part of the traditional health insurance business model. The question now is what affect these acquisitions will have on clinical labs and pathology groups.

Second of Two Parts

In May, healthcare strategist and entrepreneur Ted Schwab explained how the five of the nation's biggest health insurers are actively reshaping their companies, during his presentation at the 24th annual *Executive War College on Laboratory and Pathology Management* in New Orleans.

In his remarks that day, Schwab outlined how each of the top five health insurance companies was changing its business model in ways that could have a dramatic effect on clinical laboratories and pathology groups.

➤Largest Health Insurers

The idea that seemed to capture the audience's attention was Schwab's assertion that the nation's largest health insurers have spent billions of dollars on acquisitions, and that they were doing so in an effort to diversify their business models away from relying almost entirely on health insurance premiums to meet their annual revenue goals.

Following his presentation, the editors of The Dark Report interviewed Schwab about his comments regarding the changes health insurers have made and how he expects these changes will affect pathologists and clinical laboratory testing.

EDITOR: Your presentation at the *Executive War College* generated a lot of conversation among attendees, particularly your description about how health insurers are changing the way they do business. What captured their attention were your comments about how the big health insurers were spending billions on acquisitions because they wanted to diversify away from health insurance as their sole source of revenue, correct?

SCHWAB: Yes, and the diversification moves these insurers have made are a significant development for the entire healthcare system. The biggest health insurers have decided that selling health insurance by itself may no longer be a viable business model. Therefore, they are spending tens of billions of dollars to acquire other businesses in the healthcare sector.

EDITOR: Yet, at the same time, these companies still offer health insurance to tens of millions of people.

SCHWAB: If you look at where **Aetna's** business is, **Humana's** business is, **Cigna's** business is, **UnitedHealth's** business is, they're all in government health programs [particularly the Medicare Advantage program]. They're all in government programs with both feet. In addition, they decided to go into other businesses. Let me run through the big four. We can start with **Aetna**. Most of us in healthcare know that **CVS**, the national pharmacy chain, acquired Aetna last year by paying $70 billion, the largest acquisition price for a healthcare deal to date.

EDITOR: How will CVS integrate Aetna into its business?

SCHWAB: In addition to selling some insurance in the government health programs, the CVS strategy is to create an alternative delivery system in the retail market. Doing so will force beneficiaries into retail settings, thereby reducing costs. For CVS, the strategy is all about the delivery system. It's about using the CVS drugstores.

EDITOR: What about **Humana's** strategy?

SCHWAB: Humana is fascinating. In addition to being one of the nation's largest Medicare Advantage insurers, it is going in another direction. In December 2017, it bought **Kindred Healthcare** for $4.1 billion, putting them in the home health business. After the Kindred sale in 2017, Humana ended up with about 40% ownership of the home health, hospice, and community care businesses. It is also noteworthy that the headquarters for both Humana and Kindred are in Louisville, Ky. Humana next created new types of health plans in at least two states.

EDITOR: What is different about these new Humana health plans?

SCHWAB: Humana started new health plans in Florida and in Georgia recently with **Doctor on Demand**, a company based in San Francisco. It has reduced the commercial premiums for those health plan by 50%.

EDITOR: What allowed Humana to slash the premiums by such a huge amount?

SCHWAB: These new Humana health plans have two conditions. Number one, the patient cannot go to the hospital. Number two, the patient is encouraged to have virtual visits with the plans' caregivers. The hospital service will be delivered to the patient in the home. Then, Humana will attempt to provide the doctor services online. Now, at Humana's headquarters, they say, "We own the home."

EDITOR: You've shown how CVS now owns Aetna, and you've explained that Humana is moving into home health, hospice, and community care. What is happening with **Cigna**?

SCHWAB: Last December, Cigna spent $67 billion to acquire **Express Scripts**, the nation's largest pharmacy benefit management company. The $67 billion made it healthcare's second largest transaction.

SCHWAB: Among the strategies these companies are pursuing, Cigna's is the most straightforward. It now has a 50% share of the market for prescription drugs, meaning Cigna intends to control the cost of prescriptions.

EDITOR: That leaves **UnitedHealth** and **Anthem** as the nation's two largest health insurers. Each covers about 40 million beneficiaries. Is each pursuing similar strategies as Aetna with CVS, Humana, and Cigna?

SCHWAB: One is and one isn't. **UnitedHealth Group** is the parent company of the health insurer, UnitedHealthcare, and it's diversifying. Anthem, on the other hand, is staying the course and sticking with health insurance as its primary business.

EDITOR: What is UnitedHealth doing to diversify?

SCHWAB: UnitedHealth's diversification strategy goes back almost two decades. When UnitedHealth Group founded **Optum** 20 years ago, it began to exit the health insurance market as

their main business. Optum today is a $100 billion business and has almost half of UnitedHealth's 2018 revenue of $226 billion. Also, it's significant to note that Optum employs 47,000 doctors. UnitedHealth's strategy is to disrupt traditional healthcare and beat the traditionalists at their own game.

EDITOR: That would be worth a deeper dive because clinical laboratory executives and pathologists are watching UnitedHealthcare (UHC) narrow its networks, require preauthorization of many genetic tests, and cut what it pays for lab testing. At the same time, does UnitedHealth have a conflict with its other division, Optum, that employs almost 50,000 physicians, all of whom need access to quality lab test services for their patients?

SCHWAB: There is an interesting tension between UHC's desire to hold down lab test prices and the fact that Optum's physicians need quality clinical laboratory testing services. Therefore, it's likely to take some time for UHC and Optum to sort out those issues.

EDITOR: What's happening with **Anthem**? Why do you say it has a different strategy than the other four large health insurers?

SCHWAB: Anthem is lagging behind if we measure Anthem against what the other insurers are doing with mergers and acquisitions. Anthem has not gone out and done big acquisitions of non-insurance businesses. Also, after years of operating their in-house innovation center, it appears that Anthem has either downsized this center or closed it altogether.

EDITOR: Over the past 20 years, health insurers such as Anthem and UnitedHealthcare acquired smaller health plans to expand the number of beneficiaries and regional markets they served. Today, there are not many obvious opportunities for Anthem to grow in that manner. So, what is Anthem's strategy if it is not diversifying away from offering health insurance?

SCHWAB: Anthem has a solid executive team. But they're **Blue Cross**. And, collectively, the Blues plans have made a commitment to remain in the health insurance business. The message from Anthem is that it wants to partner with physicians and providers to add value. The team at Anthem continues to say, "We are going to be a leading health insurance company."

EDITOR: Thank you, Ted, for sharing these insights about how the nation's largest health insurers are diversifying.

SCHWAB: You are welcome.

Implications for Labs

Clinical lab executives and pathology group business leaders will want to consider the implications of Schwab's insights about how four of the nation's most dominant health insurance corporations have spent tens of billions of dollars to diversify into businesses other than health insurance.

One interpretation of these developments is that the ongoing consolidation of hospitals and physician group practices into ever-larger integrated health networks is a factor. This makes it possible for employers and government health plans to negotiate cradle-to-grave health coverage for their beneficiaries. Reimbursement for these arrangements will probably be per-member-per-month (PMPM). In such cases, why would employers need a health insurer as a middle man?

This model of the integrated health system is used by **Kaiser Permanente** and **Geisinger Health**. Both health networks offer their own insurance products directly to employers. Maybe this is the type of handwriting on the wall that the major health insurance companies see in their own strategic planning. TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Pharmacogenetic testing is gaining acceptance by a growing number of health insurers. On Oct. 1, **UnitedHealthcare** (UHC) began coverage of genetic tests that help physicians identify the anti-depressant drugs most likely to benefit their patients. UHC's policy also extends coverage to multi-gene testing for antipsychotic drugs. In writing about this decision, *www.clinicalomics.com* said, "UnitedHealthcare's policy specifies that the use of pharmacogenetic multi-gene panels to guide therapy decisions is proven and medically necessary for antidepressants and antipsychotics medication when the following criteria are met: 1) The individual has a diagnosis of major depressive disorder or anxiety; 2) The individual has failed at least one prior medication to treat his or her condition; and, 3) The multi-gene panel has no more than 15 relevant genes.

MORE ON: *PGx Testing*

Meanwhile, as reported earlier this year by THE DARK REPORT, the **Food and Drug Administration** (FDA) has sent warning letters to a number of PGx testing lab companies advising them to review the compliance of their laboratory-developed tests (LDTs) with current federal regulations. The FDA's actions directed at pharmacogenetic testing companies unsettled many clinical laboratory executives and generated criticism from several medical laboratory professionals.

STRONG GROWTH AT NEOGENOMICS

In its third quarter earnings report, **Neogenomics, Inc.**, of Fort Myers, Fla., reported revenue for third quarter increased by 51%, to $104.7 million. The company, which does molecular and genetic testing, also reported that revenue-per-test grew 15%, to $369. It also said that clinical test volume increased by 35% from Q3-2018 to Q3-2019.

TRANSITIONS

• Matthew Sause is the new President and CEO of **Roche Diagnostics North America**. He joined Roche in 2002 and held several executive positions. Most recently Sause was a Vice President at **Genentech**, a division of **Roche Holdings, AG**.

• **Anixa Biosciences** of San Jose, Calif., appointed **Thomas Schlumpberger, PhD,** as its new Executive VP, Diagnostics. Previously, he held management positions at **Inivata Limited**, **Singulex**, **Epocal**, **Affymetrix**, and **McKinsey & Company**.

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DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how a pathologist, a neurosurgeon, and a critical care phyisician in different cities have each been charged with manslaughter or murder following the deaths of patients they treated. These cases show that prosecutors are getting tougher with doctors who were negligent or who practiced while under the influence of drugs or alcohol.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, November 25, 2019.

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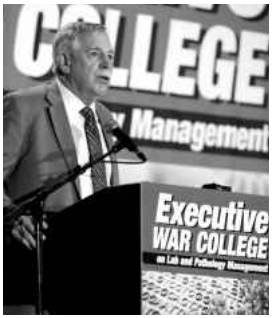

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UPCOMING...

- ***Innovative Labs Gather at Third Annual Clinical Lab 2.0 Workshop to Share Successes and Best Practices.***
- ***Anthem's Deep Cuts to Anatomic Pathology Professional Fees Cause Financial Havoc at Several Established Pathology Groups.***
- ***Two Class Action Lawsuits against National Lab Companies Allege Patients Who Paid Cash for Lab Tests Were Overcharged.***

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