Volume XXVI, Number 11 Monday, August 12, 2019

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

How Lab Fraud Hurts Hospital Labs, Pathologists

ONCE AGAIN, A HIGH-PROFILE LAB COMPANY faces allegations of fraud and abuse. This time it is **True Health Diagnostics** of Frisco, Texas. Details of this case were revealed last month when True Health filed a lawsuit in a federal court in Texas against the agencies running the federal Medicare program.

In its lawsuit, True Health denies the allegations of fraud. As of press time, True Health had not responded to THE DARK REPORT's request for comments on this case and the allegations of fraud. Detailed coverage of this newly-revealed case is provided on pages 12-21.

It is important for all lab executives and pathologists to know about these cases of alleged fraud and abuse involving lab companies, for two reasons. First, it helps lab professionals recognize fraudulent schemes and understand the details of how they work and the often-clever ways referring physicians and patients may be illegally induced to order lab tests in violation of state and federal law.

Second, knowledge of the specifics and the extent of alleged examples of lab fraud and abuse are necessary if honest lab professionals are to understand why some in Congress and the federal **Centers for Medicare and Medicaid Services** (CMS) want to take punitive actions to curb fraud, but which apply to the entire clinical laboratory industry.

It is a fact of life that bad players cause governments to pass restrictive laws to control behavior that also burden honest citizens. Remember how, in 1997, the federal government's LabScam prosecutions (the unbundling of tests billed to the Medicare program) were the reason that a new federal requirement was implemented that required all labs to create and follow the laboratory model compliance program. *(See TDR, Mar. 10, 1997.)*

Thus, as you read our intelligence briefing about the True Health lawsuit and what the court documents say about the allegations of fraud and abuse, keep in mind that it is these types of fraudulent activities—and the hundreds of millions of dollars in fraudulent lab test claims being paid by the Medicare program—that causes Congress and CMS officials to act punitively against all labs. Whether it is restrictive coverage guidelines, artificially cheap reimbursement for lab tests, or similar policies, their goal is to curb fraud and protect the public purse. That is why a handful of fraudsters can hurt the entire clinical laboratory industry. TDR

Dermatologists Say Anthem Cuts Affect Patient Care

Much lower payments disrupt relationships derms have with pathologists diagnosing complex cases

CEO SUMMARY: Deep cuts in what Anthem pays pathologists for the professional component for certain AP services are having a harmful effect on the long-standing relationships that dermatologists have with dermatopathologists, some physicians say. By disrupting these relationships, Anthem is harming patient care, they add. Since late last year, in a growing number of states, Anthem has cut what it pays for the professional component for certain tests in the 8000 series of CPT codes by as much as 70%.

DERMATOLOGISTS ARE SPEAKING OUT about the negative effects they see as a result of the aggressive cuts that **Anthem** is making in what it pays for anatomic pathology services.

Reductions of 50% to 70% in the rates that Anthem pays to anatomic pathologists are harming patient care for those patients who have complex and serious skin conditions such as melanoma, the deadly form of skin cancer, they said.

Last fall, Anthem cut what it paid for the professional component in Missouri for certain tests in the 8000 series of CPT codes by as much as 70%. Since then, the nation's second-largest health insurance company has cut payments by 50% to 70% to pathologists in Alaska, California, Georgia, Indiana, Ohio, Wisconsin, and Washington State, according to **Vachette Pathology**, a consulting firm in Sylvania, Ohio. *(See, "Anthem Rolling Out More Anatomic Path Price Cuts," TDR, July 1.)*

Next month, Anthem plans to do the same in Kentucky and Virginia. Payment reductions are planned for New York on Jan. 1, 2020, and also in Colorado, Connecticut, Kentucky, Maine, New Hampshire and Nevada, Vachette said.

In a letter to Anthem's Chief Clinical Officer Stephen Friedhoff, MD, in April, George Hruza, MD, the president of the **American Academy of Dermatology** (AAD), objected to Anthem's reductions in what it pays for AP services. Previously, Anthem had been among the best payers for such services for its 40-million members in 14 states

Despite Hruza's complaints, representatives from Anthem told the AAD during a conference call on July 3 that the health insurer would not change its pol-

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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icy, Hruza said in an interview with The Dark Report.

"Basically, Anthem officials said, 'Thank you for your concern, but we don't feel we need to make any changes.' And in fact, they said, they were expanding the cuts to other states," Hruza said.

"Because Anthem has operations in many states, this change will have a big impact—especially in those states where Anthem is the number one health insurance provider," Hruza added. In those states, such deep cuts in payment will have a significant effect on patients' access to dermatopathology care, he said.

Complex Histopathology

Hruza, other dermatologists, and dermatopathologists with whom they work are worried because the professional component of AP services involves complex histopathology processes and assessments that are unlike the routine nature of most clinical laboratory testing, he said.

"Diagnosing tissue is not like doing a blood test, where the physician gets a number from the lab and can tell if the test is normal or not," he said. "In dermatology, many diagnoses depend on careful and precise analysis. I consider the work that dermatopathologists do to be a qualitative examination, rather than a quantitative one.

"That requires a lot of interaction between the dermatologist and the dermatopathologist," Hruza commented. "There are many different ways to interpret patients' specimens, and that interpretation requires dermatologists to consult with dermatopathologists.

"Because we consult with dermatopathologists all the time, we can understand each other," he commented. "That understanding allows us to take good care of patients." Such consults produce accurate, reliable, and timely diagnoses of patients' conditions, he said.

"For many skin conditions, the dermatologist needs to call the dermatopathologist because, for those conditions, a clinical pathologic correlation is required," he added.

"This is equally true when a patient presents with a growth that's suspicious for melanoma," he continued. "The dermatologist can view a number of lesions that might be considered 'in between,' meaning the diagnosis might not be obvious," he said. "In those cases, every dermatologist must be comfortable with the pathologist or the dermatopathologist he or she is using for these consultations.

"In the most difficult cases, the referring physician wants to make sure that a dermatopathologist reads the slide," he commented. "But unfortunately, in some labs a dermatopathologist may not view those slides with skin biopsies and some other specimens. That can lead to additional difficulties." Not having a dermatopathologist read difficult cases has a detrimental effect on accuracy, he explained.

Because Anthem is slashing payments sharply, some dermatopathologists are likely to leave the insurer's network, Hruza predicted. "Reimbursement rates that go down to 50% of what Medicare pays mean pathologists are about to be reimbursed much less than they get now and already they are barely breaking even," he said.

"Most dermatopathology labs can't operate on such low payment rates from Anthem," he added. "Basically, they will not be able to view specimens because they cannot continue contracting at that rate. There's just no way."

Instead, dermatologists will send specimens to the larger clinical lab companies such as **Laboratory Corporation of America** and **Quest Diagnostics**, he said. "But when that happens, dermatologists will have little or no relationship with the dermatopathologists at big lab companies like Quest or LabCorp," he added.

"In such large labs, a dermatologist may never work with the same dermatopathologist each time he or she refers a case," he said. "So, there will be no chance to build a new relationship."

Dermatopathologist Fears Anthem's Goal Is to Shift Cases to Large National Lab Firms

FOR DERMATOPATHOLOGIST M. YADIRA HURLEY, MD, the cuts Anthem is making in payment for anatomic pathology services are a sign that small dermatology practices with physician office labs and dermatopathologists in small AP groups are about to lose access to case referrals.

Hurley is a Professor of Dermatology and Pathology and Director of Dermatopathology at **SLUCare** and in the Department of Dermatology at **Saint Louis University School of Medicine**.

The deep reductions in payment that Anthem is rolling out nationwide will have a significant effect on small private labs and private groups of dermatologists with a dermatopathologist on staff, she said. The large national labs, such as **Laboratory Corporation of America** and **Quest Diagnostics**, can absorb such deep payments cuts with volume, she added.

The effect will be a loss of the relationships that dermatologists have established over many years with dermatopathologists, Hurley commented.

"Anthem is forcing the hand of dermatologists to send biopsies to pathologists with whom they may not be comfortable or that they may not know well," she said. "Dermatologists are losing the right to choose their dermatopathology consultant for biopsy specimens.

"The large corporate labs may not provide the relationship between the dermatologists and the dermatopathologists that is often required for the optimal quality patient care that local labs provide," she added. "Not only that, but many times local labs can get results back faster, especially for rush diagnoses or for an important cancer diagnosis."

For lesions that are difficult to diagnose—in particular melanocyte lesions—dermatopathologists have developed specific language for the various types of specimens in question. "We have different terminology for all the different kinds of ambiguous lesions that we encounter," she said. "When dermatologists work with new pathologists, that terminology may be completely different.

"When making a complex diagnosis based on a specimen under the microscope, the terminology can be very, very different depending on where you trained," Hurley explained. "In those cases, it's important for a dermatologist to be able to choose the dermatopathologist they want to diagnose those specimens.

"Experience shows that, if they can choose the dermatopathologist, when the report comes back, they are more likely to understand clearly what that dermatopathologist means when they use certain wording," she said. "As dermatologists, we know how to identify a benign specimen and we know how to identify melanoma. But in-between lesions are much more difficult to diagnose. For those, you want to be very precise in the language you use to describe them.

"In those cases, the dermatologist will want to call the pathologist or dermatopathologist and know that both physicians are comfortable in the use of similar terms that were previously used," Hurley commented.

In its efforts to get Anthem to reconsider its rate reductions, the AAD is working with the **American Medical Association**, the **American College of Mohs Surgery**, and the **American Society for Dermatologic Surgery**, Hruza said. **TDR**

—Joseph Burns

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Is Pathology Workforce Stable or Shrinking?

Questions raised after *JAMA* study identified a 17.5% decline in pathologists from 2007 to 2017

CEO SUMMARY: After publishing research in JAMA Network Open showing a coming shortage of pathologists in the United States, the researchers heard from pathologists whose experience in the job market did not match what the researchers found. Anecdotal evidence indicates that the demand for pathologists may vary widely from region to region and in urban versus rural practice settings. Still, there is general agreement that pathologists today work harder and get paid less.

Publication of a research study into how the pathology workforce in the United States and Canada changed between 2007 and 2017 triggered a wide range of opinions and comments from pathologists in the United States.

On May 31, *JAMA Network Open* published online the research study, "Trends in the US and Canadian Pathologist Workforces from 2007 to 2017."

In their study, Dallas pathologists Jason Y. Park, MD, PhD, and David M. Metter, MD, and colleagues reported that from 2007 through 2017 there was a 17.5% decrease in the number of pathologists in the workforce of the United States.

There also was a population-adjusted decrease in the number of pathologists working in the United States over the same 11-year period. *(See "JAMA Study: 17% Fewer Pathologists Since 2007," TDR, June 10.)*

As a trend, these findings suggested that the number of pathologists in the United States may have entered into a shortage.

"The *JAMA Network Open* article does not present evidence of a shortage, but rather it presents a number of pathologists per capita that is consistent with shortages in other countries," Park explained.

The reaction among some pathologists who read their study in *JAMA Network Open* suggests that it may not be possible to characterize the market for anatomic pathologists based on a single average national statistic. Pathologists in urban areas may have one view of the job market, while pathologists in rural areas may have a markedly different experience.

Or, it could be that the job market may reflect a shortage of pathologists in the coming years, but there is not a current shortage in the job market, as Park, Metter, and colleagues suggested in their research study.

Comments from Pathologists

In an interview with The Dark Report, Park and Metter said that, following the publication of their research online, they heard from pathologists in a variety of settings who generally disagreed with their findings. In e-mail messages, pathologists who read the study expressed skepticism about the results, saying their individual

experiences did not match the research findings.

One such comment from a middle-aged pathologist who is board certified in anatomic and clinical pathology, and in cytopathology, is presented in the sidebar on page 9, titled, "One Pathologist Discusses a Different View of His Experience Versus Study Findings."

Many of the comments were from pathologists whose experience contradicted what the researchers found, said Park, an associate professor, and David M. Metter, MD, a pediatric pathology fellow, both at the **University of Texas Southwestern Medical Center**.

Findings Prompt a Response

"Some of the feedback we got came from people who were quite upset with our findings," Park said. "David and I are sympathetic to these comments because we understand what they are going through. Unlike most other physician specialties, the pathology profession has been hammered for almost 20 years as reimbursement shrank and narrow networks caused pathologists to lose access to a growing proportion of patients.

"Many comments seemed to suggest that we were misrepresenting what these pathologists have experienced," he added. "That's because—in their daily life and in the job market in their communities—they feel like they're being treated as a commodity."

One reason pathologists are commenting on the research findings in the journal article is that their experience of the job market has been negative—at least in part. Shortages among physician specialists have created opportunities for frequent movement from one job to another and increased pay at each new opportunity, Park said.

But in pathology, health insurers and health systems offer take-it-or-leave-it contracts to pathologists quite often, he added. What's more, the workload of each pathologist has increased significantly in recent years.

"Many pathologists feel that if they don't accept the contracts as offered, then the hospital or health system will find other clinicians who will do the job," Park commented.

Such anecdotal comments appear to contradict the findings Park, Metter, and colleagues published in *JAMA Network Open*. However, the article only identified the downward trend in pathologist numbers in the United States. It did not specifically identify a workforce shortage.

In April 2018, the *Archives of Pathology and Laboratory Medicine* (*APLM*) published an article in which researchers reported on five years of job-market surveys from the **College of American Pathologists**. That article, "The Recent Pathology Residency Graduate Job Search Experience: A Synthesis of Five Years of College of American Pathologists Job Market Surveys," was based on surveys of recent graduates of pathology programs in the United States.

Difficulty Finding Jobs

In the *APLM* article, researchers reported that job-market indicators—including job interviews, job offers, positions accepted, and job satisfaction—remained stable over the five years of the survey. Most survey respondents who applied for at least one position had accepted a position at the time of the survey, and most applicants who had accepted a position were satisfied or very satisfied, the researchers reported.

Park commented that the *APLM* article may be consistent with a shortage because one of its findings indicated the majority of recent graduates had difficulty finding jobs.

Park and Metter said the *APLM* article focused specifically on the job market for those pathologists just entering the workforce after fellowship training. But the article did not match Park and Metter's experience, nor that of many of their colleagues who have years of experience.

"Our initial reaction to the *APLM* article was that we didn't think it was possible that the market for pathologists' services was remaining stable," said Park. "Based on our own experience, that didn't seem right. We actually thought there was an oversupply of pathologists."

Before starting the research that resulted in the publication in *JAMA Network Open*, Park and Metter hypothesized that there was an oversupply of pathologists making it difficult for new graduates to find work. Park and Metter began research into the pathologist workforce and enlisted additional researchers Terence J. Colgan, MD, who is the Head of the Sections of Gynecological and Cytopathology at **Mount Sinai Hospital**, Toronto, and a Professor in the Department of Laboratory Medicine and Pathobiology at the **University of Toronto**; Stanley T. Leung, MD, JD, an anatomic and clinical pathologist with **Incyte Diagnostics** in Bellevue, Wash.; and Charles F. Timmons, MD, PhD, a professor in the Department of Pathology at UT Southwestern.

Pathology Market Paradox?

While the number of pathologists is falling relative to the number in practice in 2007, Park and Metter said the data do not confirm that this is a shortage of pathologists, especially given that the *APLM* research suggests jobs are available for new graduates.

"To those of us involved in the *JAMA Network Open* publication, it certainly doesn't feel like a shortage," Park said. "So, we have a paradox where there is a decreasing number of pathologists, which has been unabated for 10 years. But David and I had anecdotal evidence and personal experience for over 10 years where the pathology market has been very tight. Therefore, 'stable' would be a very generous term to use. We have a significant decrease in the supply of pathologists without an apparent increase in demand."

Metter explained what typically happens for new graduates. "From my experience, I would say that new graduates apply to a lot of places all across the country but may only get a few interviews," he said.

Few Offers Forthcoming

"New graduates are not inundated with job offers," he added. "This paucity of job offers in our experience was the reason for our pre-study hypothesis of a possible oversupply of pathologists."

But then the data in the *JAMA Network Open* study did not show an oversupply or a shortage. "It shows that there is a decrease in the number of active pathologists," Park said. "The data also suggest that there could be a shortage at some point. If you're decreasing the number of pathologists by almost 20% every 10 years, you're going to hit a wall eventually. That said, we don't think we are there quite yet.

"Logically, you assume that as the number of active pathologists declines, both salaries and the number of positions should increase accordingly," Park added. "But when I talk to my colleagues in the pathology community, that's not what's happening."

Both Park and Metter warned against relying on data from recruiters, not because their numbers are inaccurate, but that they might not be parsed sufficiently to reflect the characteristics of each physician specialty. "Most of my friends who are practicing surgeons or in primary care easily get 20 offers a month," Park said.

Specialists Heavily Recruited

"And when they were just coming out of training, they were heavily recruited. I don't think you could find many pathologists who would ever say they had a point in their career where they were weighing multiple job offers."

Park offered a summary of the current literature. "If we can tie everything together, maybe we can say that, yes, there is a dramatic decrease in the number of pathologists. But there aren't many job

One Pathologist Discusses a Different View Using His Experience versus Study Findings

AFTER *JAMA NETWORK OPEN* PUBLISHED A STUDY on the pathologist workforce in the United States and Canada on May 31, a reader wrote to comment that the article was much different from his experience.

"I am a middle-aged pathologist certified in AP/CP and cytopathology," he wrote. "My experience is that the job market for pathologists in the United States is dismal, despite all reports from academia claiming just the opposite.

"I work in a middle-sized community hospital," he continued. "Our hospital frequently had problems attracting qualified physicians and had to hire expensive firms to attract good doctors. However, when we advertised for an open position for a pathologist via [an online service] our secretary received 85 CVs in only five days.

"My young colleague will finish his pathology residency and fellowship in July this year," the commenter wrote. "While his wife, an internist, got 30 job offers, he only recently got a single offer, after nine months of searching."

This pathologist next asked why academic researchers appeared to be inaccurate. "Why do calculations from academic centers always get it wrong?" he asked.

"People in academia live in special environments and have no idea or interest to see what is going on in the real world," he wrote. "Since academic departments of pathology have incentive to train as many pathologists as possible (cheap labor and government subsidies), they choose to see reality as it suits them the most. They do calculations based on previous years and fail to see (intentionally or due to ignorance) the major shift which happened [to the pathology profession] in last 20 years.

"In the last 20 years, the workload for most pathologists working outside academia at least doubled, if not tripled," he wrote. "What caused this sudden increase in workload? It is primarily due to the acquisitions of individually-owned laboratories by large corporations (**Quest**, **LabCorp**, **HCA**, and others).

'Fire Half the Pathologists'

"To increase profit margins, raise stock valuations, and ensure that CEOs are awarded lucrative stock options, corporations have merged many smaller labs into large conglomerates," explained this pathologist. "In most situations, a new corporate entity will fire half of the existing pathology staff and increase work expectations for the remaining employees far beyond the prior norm.

"And how did academia respond to the overall cosmic change?" he asked. "Teaching hospitals—in their quest for more federal money and cheaper labor (in the form of residents)—almost doubled the number of [first-year] positions for pathologists in the same time period—from 335 in 2000 to 605 in 2015. Seeking even more profit, these teaching hospitals recently added pathology to the list of specialties in 'short supply,' enabling them to push for additional slots (and funds) under new legislation."

opportunities and, as the *APLM* article suggests, the job market is somewhat stable.

"The problem is that pathology is an outlier specialty in medicine, because in other specialties there are usually more job openings than physicians to fill them," he added. "In pathology, we have a paradox: There is an unabated decrease in the number of pathologists over the past decade, but pathologists don't have a lot of opportunities." TDR

—Joseph Burns

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Clinical Lab 2.0 Update

In New Mexico, Three Collaborators Improve Patient Care, Outcomes

Innovative program used insights from lab test data to enable early intervention for patients at risk

It's official! A year-long collaboration involving a health insurer, a clinical laboratory, and an analytics company showed that insurers and physicians can use clinically-actionable intelligence developed from medical lab test data to improve patient outcomes.

This important accomplishment in patient care comes with another significant milestone: The health insurer is paying the lab outside of the clinical laboratory fee schedule to develop useful information from lab test results. The three organizations are **TriCore Reference Laboratories** and its software company subsidiary **Rhodes Group**, and **Blue Cross and Blue Shield of New Mexico**.

In a news release on Aug. 2, the three organizations explained that the Rhodes' clinical analytics program uses algorithms to analyze TriCore's clinical pathology laboratory test data. From the data, TriCore and Rhodes Group produced insights that BCBSNM uses to improve the health of members in the state's Medicaid program (**Centennial Care**) who are pregnant or who have such conditions as diabetes or hepatitis C.

The announcement signifies that the health insurer, BCBSNM, is paying Rhodes Group for this information. This is different than paying for a simple lab test result, even a high-quality result reported within an acceptable turnaround time, as clinical labs have done for decades.

TriCore, through Rhodes Group, is believed to be among the first clinical laboratories to collaborate with a health insurer using a Clinical Lab 2.0 model.

Clinical Lab 2.0 describes the attributes that medical laboratories need to succeed in a value-based healthcare environment. TriCore and other members of **Project Santa Fe Foundation**, the nonprofit organization that promotes the Clinical Lab 2.0 movement, supports the idea that clinical labs need to prove that laboratories can do more than deliver diagnostic test results. Labs can activate timely care, and even prevent complications or hospitalizations by helping health insurers and health systems identify and close gaps of care.

Labs as Equal Providers

Michael Crossey, MD, TriCore's CEO and Chief Medical Officer, acknowledged the role that BCBSNM played in helping Rhodes and TriCore develop a different approach to using lab-test data, and to educate TriCore on what the insurer needed from its lab and data analytics partners. "Clinical Lab 2.0 requires laboratory professionals to act as equal partners and clinical colleagues with payers and care providers to achieve the Triple Aim and improve medical care," he said. **The Institute for Healthcare Improvement** describes the Triple Aim as improving the patient experience of care (including quality and satisfaction), improving the health of populations, and reducing the per capita cost of care.

The announcement from TriCore, Rhodes, and BCBSNM reflects the next step in the evolution of laboratory medicine because TriCore is, "putting the medi-

cine back into laboratory medicine," as one expert said. TriCore and Rhodes have developed a way to translate laboratory testing into information BCBSNM can use to manage a population effectively and efficiently by identifying patients in need of care before their conditions become acute and costly.

"These insights assist BCBSNM in risk stratifying their Centennial Care population, thus identifying members who need care or may be at risk due to comorbidity," the three organizations said in the news release. Using TriCore's data and Rhodes' analytics, BCBSNM can target its care coordination efforts effectively, leading to better patient outcomes. *(See, "TriCore Forges Ahead to Help Payers Manage Population Health," TDR, May 20, 2019.)*

For more than a year, BCBSNM worked with Rhodes and TriCore to refine and confirm the algorithms to produce information that care coordinators could use to do outreach to members and connect those members to physicians. "The product has really helped us understand member needs and work more effectively in integrating patients into care," said Eugene Sun, MD, BCBSNM's Chief Medical Officer.

Keeping Score with HEDIS

One way to measure the effectiveness of TriCore's lab test data, and Rhodes' analytics on that data, are HEDIS reports from the state's **Human Services Department**. Those reports show that BCBSNM was rated as the top performer in prenatal and postpartum care last year. HEDIS is the Healthcare Effectiveness Data and Information Set, a data-collection system the **National Committee for Quality Assurance** developed in the early 1990s to measure health plan performance. New Mexico's Centennial Care plan uses HEDIS measures to direct performance improvement incentives among insurers. TDR

—Joseph Burns

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Demonstrating Value of Lab Data Insights

FOR YEARS, CLINICAL LABORATORY DIRECTORS HAVE PREDICTED that health insurers would pay for insights into patient care based on clinical lab data and data analytics. Now that day has come.

On Aug. 2, Rhodes Group, TriCore Reference Laboratories, and Blue Cross Blue Shield of New Mexico announced that the three partners are using medical lab test data to deliver clinically-useful information to payers and to physicians in their provider networks, according to Rick VanNess, Rhodes Group's Director of Product Management.

During a presentation at the *Executive War College* in May, VanNess outlined how TriCore and Rhodes combined clinical lab test data and data analytics to help health insurers improve patient care, fill gaps in care, and manage population health. Over the previous three years, health insurers had been interested in paying for the data analytics that TriCore and Rhodes had sent to BCBSNM.

VanNess is optimistic that—based on the performance that the three partners produced with this proof-of-concept—more insurers may be willing to share savings with their lab partners when collaborating in value-based and shared-savings arrangements. If and when they share such savings, the analytics that TriCore and Rhodes provide would generate new sources of revenue in addition to the fee-for-service payments the clinical laboratory gets for the testing it does.

"Other insurers have signed on to the platform or are actively negotiating," VanNess said. "We are changing the perception of the clinical laboratory."

TriCore, through its subsidiary software company, Rhodes Group, is believed to be one of the earliest clinical labs in the United States to collaborate with health insurers in ways that meet the Clinical Lab 2.0 business model.

Medicare payments stop after audit, allegations of fraud

After Two-Year Battle with CMS, True Health on Verge of Collapse

CEO SUMMARY: In 2017, an auditor for CMS alleged that True Health filed fraudulent claims and the federal Medicare program cut all payments to the lab company and one month later reduced the cut to 35% of the billed amount. Two months ago, CMS ended all payments again. These facts became public on July 2 when True Health filed a lawsuit in federal court, asking for an injunction to compel CMS to pay the disputed lab test claims that by that time totaled over $20 million. When the judge dismissed the lawsuit, True Health filed for Chapter 11 bankruptcy.

Last month, True Health Diagnostics of Frisco, Texas, filed a Chapter 11 bankruptcy petition in federal court in Delaware. On July 30, True Health said the bankruptcy filing was a consequence of Medicare officials suspending 100% of payments to the laboratory company in June, leaving it without the cash needed to continue operating.

On the same day, True Health announced plans to lay off 392 employees in its laboratory in Richmond, Va., and notified officials in Virginia and in Richmond that it may need to cease operations, depending on the outcome of its dispute with the federal **Centers for Medicare and Medicaid Services** (CMS). That dispute began in 2017 when CMS auditors found 'credible allegations of fraud,' prompting CMS to cut 100% of its payments to True Health. By last month, the total loss in payments over two years came to more than $20 million.

This story may be an important one for clinical laboratories because of federal audits and CMS' actions in response. True Health detailed those actions in a lawsuit it filed on July 2 in U.S. District Court in Texas against the federal Secretary of **Health and Human Services** (HHS) Alex M. Azar II and CMS Administrator Seema Verma.

Over the past several years, The Dark Report has reported on bankruptcies and closures of multiple lab companies after federal audits led CMS to assess sizable recoupment amounts—often in the tens of millions of dollars. At times, these amounts have totaled 100% of an audited lab's revenue for three to five years.

The Dark Report believes enough laboratory companies have failed after Medicare audits and sizeable recoupment demands that such aggressive actions from CMS may mean these steps represent a new trend for the clinical lab industry that did not exist five years ago.

That is why the information and allegations contained in the court papers filed by True Health offer useful insights into the actions of Medicare auditors and how CMS officials are using those audit findings to either to assess a substantial recoupment amount against the lab or even completely stop reimbursing claims submitted by that lab company.

"The situation at True Health shows how closely CMS and the federal Department of Justice continue to scrutinize the lab industry," commented Justin T. Berger, a Principal with the law firm of **Cotchett, Pitre and McCarthy** and a lawyer who has represented whistleblowers in *qui tam* actions under the federal and California false claims acts.

➤ Did Fraud and Abuse Happen?

Of equal importance to this story are allegations within the court documents of Medicare fraud and abuse. In its lawsuit, True Health denied that it has committed fraud. The Dark Report sought comment from CMS and True Health and as this issue went to press, True Health had not responded to our request.

In response to True Health's lawsuit, HHS also filed documents with the court that describe the findings of the Medicare auditors and alleging that True Health billed CMS improperly.

The final chapter in this story has yet to be written because statements in the court documents indicate that True Health faces a federal *qui tam* (whistleblower) lawsuit that was filed in 2015 and that remains under seal.

The dispute between True Health and CMS became public on July 2 when True Health filed its lawsuit against HHS and CMS. In its lawsuit, True Health describes its two-year dispute with CMS.

This dispute started when CMS alleged True Health filed fraudulent claims for lab testing and CMS stopped paying True Health's claims in May 2017. Since then, CMS has withheld more than $20 million in payments without due process,

True Health said in the lawsuit. The dollar amounts are significant because True Health serves about 335,000 individuals annually, of whom more than 65,000 are on Medicare, the lawsuit said.

Medicare Withholds Payment

One month later, in June 2017, CMS decided that instead of stopping 100% of all payments to True Health, CMS would pay 35% of the total payments the lab requested in the lab test claims it filed.

At the point when True Health believed it was doing what was needed to end the suspension of payments, the case took an unusual turn in June of this year when CMS again stopped paying 100% of True Health's claims. The move forced the lab company to file for bankruptcy protection and to lay off workers.

In response to CMS' action to cut all payments in June, True Health sought an injunction against CMS on July 2 to require the agency to restore payments. Just three weeks later, on July 22, U.S. District Court Judge Michael J. Truncale dismissed the case, a move that led to the bankruptcy filing and layoffs in Virginia.

Based on information in True Health Diagnostics' court filings, it appears that the private companies working as Medicare auditors used statistical sampling and extrapolation. Under this method, auditors audit a small number of claims, then extrapolate those results across the total number of claims filed over a specific period to determine a larger number that could be considered in error or fraudulent. *(See "Under Audit, Labs Need Statistics on Their Side," TDR, Sept. 10, 2018.)*

Medicare Audits of Claims

True Health's problems began after **Health Integrity**, a zone-program integrity contractor (ZPIC) working for CMS, issued a "Notice of Suspension of Medicare Payments" on May 26, 2017. In the notice, Health Integrity said CMS would immediately suspend Medicare payments on the basis of "credible allegations of fraud," True Health said in its lawsuit. The suspension notice cited eight claims submitted over a year that allegedly did not comply with Medicare guidelines, the court filing said.

As noted earlier, the Medicare auditor's actions would be consistent with the use of statistical sampling to review a small number of claims, then extrapolate those finding across a much larger number of claims.

"For the past 25 months, CMS has been indefinitely withholding at least 35% of True Health's Medicare and Medicaid reimbursements for duly provided diagnostic testing services," True Health said in the lawsuit. "The running total now exceeds $20 million."

Calling the suspension of payments an "unlawful withholding," True Health said it had no way to challenge the order, leaving the company in "financial ruin" and "on the verge of collapse."

100% Holdback by CMS

"As if that were not bad enough, on June 13, 2019, CMS began holding back 100%—every penny—of True Health's reimbursements for duly provided laboratory services. True Health is, as a consequence, just days away from insolvency," the July 2 lawsuit said. The lab company asked for an injunction so that it could receive some payments and continue operating. That injunction was denied when Truncale dismissed the lawsuit on July 22.

True Health's lawsuit also said that, within weeks of receiving the suspension notice in 2017, it submitted a rebuttal statement to Health Integrity asking that the suspension be rescinded and requesting that Health Integrity identify the eight claims in question. "True Health established that the eight claims did not support credible allegations of fraud because they were mere clerical errors made by entities other than True Health," the court filing said.

Timeline of True Health Diagnostics from Its Founding in 2014 through its Bankruptcy in 2019

SINCE ITS FOUNDING, TRUE HEALTH DIAGNOSTICS has attracted much attention, in part because of the perceived links its original executive team had with **Health Diagnostics Laboratory** of Richmond, Va.

In March 2014, True Health Diagnostics was founded and Chris Grottenthaler was named CEO. He had formerly been Vice President of Finance at **AmeriTox**.

On Sept. 16, 2015, a judge in the U.S. Bankruptcy Court approved True Health Diagnostics' bid to spend $37.1 million to acquire almost all of the assets of Health Diagnostic Laboratory (HDL).

Three months earlier, HDL filed for Chapter 11 protection after reaching an agreement with the federal Department of Justice to pay almost $50 million to settle allegations that HDL had paid doctors kickbacks to order HDL's tests. Under the settlement, HDL denied wrongdoing.

At the time, Grottenthaler said in a statement that True Health would adopt "an exacting corporate compliance program that, along with rigorous controls and intensive sales force training, will ensure that True Health will meet and exceed all regulatory requirements."

Timeline

May 25, 2017: CMS suspends 100% of payments to True Health, saying in a Notice of Suspension letter, "the suspension of your Medicare payments is based on 'credible allegations of fraud.'"

June 23, 2017: CMS reduced the payment suspension to 35%.

Nov. 16, 2017: CMS informs True Health that it suspended payments at the request of the federal Department of Justice due to a 2015 False Claims Act suit filed under seal against True Health.

June 11, 2019: CMS suspends 100% of payments to True Health saying in a Notice of Suspension letter, "This suspension is based on recent credible allegations of fraud and is distinct from the suspension that was implemented on May 25, 2017."

July 2, 2019: True Health files a lawsuit in the U.S. District Court for the Eastern District of Texas claiming that the Centers for Medicare and Medicaid Services (CMS) had withheld $20 million in payments to the company since 2017 without due process.

July 3, 2019: True Health Diagnostics files an emergency motion seeking a temporary restraining order to prevent CMS from "suspending, escrowing, or withholding any further Medicare or Medicaid reimbursements" and for the "release of the checks that CMS has made out to True Health since June 13, 2019, but not delivered."

July 5, 2019: CMS asks the court to dismiss the suit and issued a letter notifying True Health Diagnostics that CMS made an overpayment determination, saying it overpaid True Health $27,467,142.30 for Medicare services.

July 22, 2019: U.S. District Judge Michael J. Truncale grants CMS' motion to dismiss the case True Health Diagnostics brought against HHS and CMS.

July 31, 2019: True Health files for Chapter 11 protection in U.S. Bankruptcy Court for the District of Delaware. In its filing, True Health reported that it had more than 100,000 creditors, assets of $10 million to $50 million, and liabilities of $100 million to $500 million. True Health discloses it may need to lay off 392 employees, most of whom have worked in its lab in Richmond, Va.

In denying the request to lift the suspension, CMS said the eight cited claims were a sample "of a non-exhaustive list" of other factors, the lawsuit said. Also, CMS said it would investigate the matter to determine if there were any impermissible overpayments to the lab and that it would promptly notify True Health about its administrative appeal rights.

Hold-Back Was 'Oppressive'

On June 23, 2017, CMS reduced the Medicare suspension percentage from 100% to 35% of all payments. "While the reduction to a 35% hold-back somewhat relieved the immediate financial pressure on True Health and allowed it to stay in business at the time, the hold-back was still oppressive," the filing said. "It represents approximately $800,000 per month held by CMS, which has ballooned to over $20 million in cumulative total."

What's more, True Health could not appeal the decision until CMS issued a final decision on any overpayments. "In the months that followed, however, CMS failed to make a final overpayment determination, even as it continued to withhold millions of dollars from True Health," the lawsuit said.

Meanwhile, CMS apparently continued its investigation of True Health's practices. Later in 2017, Health Integrity requested documentation for 92 other claims.

"Despite repeated requests, to date, CMS provided no further information on any of the claims. Hearing nothing and continuing to suffer under the 2017 suspension, True Health hired an independent third party, **Navigant Consulting**, to evaluate the claims," the lawsuit said.

Navigant Reviewed Claims

"Navigant found that most of the claims in question would be considered medically reasonable and necessary, and that there were only a few minor mistakes and nothing to form the basis for allegations of fraud," the lawsuit said.

True Health sent the Navigant findings to CMS, but the agency continued the suspension of payments, the True Health filing said.

At this point, the story becomes almost surreal. On Nov. 16, 2017. CMS informed True Health that it suspended payments at the request of the federal Department of Justice due to a 2015 False Claims Act suit filed under seal against True Health. "FCA cases are always civil but sometimes prompt a criminal case," explained Berger. "In this case, there was probably a civil FCA case filed that was serious enough that the DOJ opened a criminal investigation."

In its July 2 lawsuit, True Health described a series of meetings it had in 2018 with lawyers from the DOJ's Civil Division. It says it was told that the suspension was due to a [whistleblower] lawsuit filed in 2015 under seal under the False Claims Act against True Health.

On Nov. 16, 2017, CMS informed True Health that it suspended payments at the request of the federal Department of Justice due to a 2015 False Claims Act lawsuit filed under seal against True Health.

"The Civil Division explained that the only circumstance in which it would agree to inform CMS that DOJ no longer requested maintenance of the suspension and dismiss the FCA suit was for True Health to agree to forfeit all escrowed funds," the lawsuit said. "Faced with this Hobson's choice, True Health was prepared to accept the terms.

"To that end, True Health finalized the terms of a settlement agreement with the Civil Division releasing it from liability for the 2015 lawsuit under the False Claims Act. The settlement was intended to culminate in the lifting of the suspension. CMS indicated that it would lift the

2017 suspension upon execution of this civil settlement agreement," True Health said in the lawsuit.

"Yet just as the parties were on the verge of finalizing the settlement, True Health received a new June 13, 2019, suspension [from CMS] that reimposed a full 100% payment suspension on the basis of the very same alleged conduct as the original 2017 suspension," the lawsuit said. "This second, duplicative suspension notice dated June 13, 2019, was issued by **Qlarant**, a third-party Unified Program Integrity Contractor (UPIC) for CMS."

Statistical Sampling

The 2019 notice was based on five 2017 claims reviewed as part of the original investigation, True Health said. Such a determination could be consistent with a Medicare program auditor using statistical sampling and extrapolation.

"Despite being based on claims that were part of the 2017 suspension, the 2019 Suspension Notice incongruously asserts that this suspension is 'based on recent credible allegations of fraud and is distinct from the suspension that was implemented on May 27, 2017,'" the lawsuit said. At that point, True Health submitted a rebuttal but still did not receive payment, it said.

"At the same time that True Health faces an indefinite and complete suspension of Medicare and Medicaid payments, no government agency will take responsibility for its implementation or its release," the lawsuit said. "CMS has indicated that it will not engage in discussions concerning the 2019 suspension until True Health resolves the criminal investigation with the **U.S. Attorney's Office**."

Preliminary Stage

But rather than discuss the case with True Health's attorneys, the U.S. Attorney's Office told lawyers for True Health Diagnostics that its investigation was at a preliminary stage, that it did not request the 2019 suspension, and that it has no control over CMS' actions, the lawsuit said.

"Meanwhile, True Health's settlement with the Civil Division is jeopardized," the lawsuit said.

"These facts are shockingly unjust: CMS is benefitting from the services that True Health is providing to Medicare and Medicaid beneficiaries without paying for them—and without reaching a final decision as to any wrongdoing on True Health's part or allowing True Health to contest any adverse finding. In consequence, CMS has foreclosed True Health from utilizing its administrative appeal rights to which it is entitled …," said True Health in its lawsuit.

In responding to True Health's July 2 lawsuit, one document filed by the federal government was a declaration by Jack J. Geren, a special agent of the Office of the Inspector General.

Geren's declaration describes what he found when investigating True Health. He includes statements about investigative findings that deal with the financial problems True Health claimed it was experiencing as a consequence of CMS' decision to withhold hold back payments to True Health. *(See sidebars on pages 18 and 21.)*

Special Agent's Declaration

In his declaration, Geren said that True Health borrowed $110 million in 2017, then paid out $130 million to investors and stockholders of True Health. Of that amount, Geren added, "$36 million went to True Health Diagnostics CEO, Chris Grottenthaler," and that millions were paid to other THD executives at this time. *(See sidebar on page 20.)*

Since filing for Chapter 11 bankruptcy protection on July 31, True Health has requested that the court auction its assets using a procedure similar to how True Health acquired the assets of Health Diagnostic Laboratories in its 2015 bankruptcy. Could a déjà vu moment happen in coming weeks, with parties related to True Health buying its assets from this bankruptcy court?

—Joseph Burns

Lawsuit: True Health vs. HHS, CMS

Federal Special Agent Makes Declaration about True Health

Findings from his investigation of lab company are filed in case of True Health vs. HHS, CMS

IN THE COMPLAINT TRUE HEALTH DIAGNOSTICS filed on July 2, 2019, against two federal health agencies, the lab company in Frisco, Texas, detailed how the agencies' actions put the company on the verge of financial collapse that could force it into bankruptcy. True Health sought an injunction to compel the federal Centers for Medicare and Medicaid Services to issue payment for lab test claim payments that CMS had withheld since 2017.

The lawsuit True Health filed tells one side of the story. Another side of the story comes from a sworn declaration from Special Agent Jack J. Geren Jr., of the Office of Inspector General of the federal Department of Health and Human Services. Geren's declaration was filed in the U.S. District Court for the Eastern District of Texas, Lufkin Division, in the case True Health filed against HHS Secretary Alex Azar and CMS Administrator Seema Verma. *(See, "After 2-Year Battle with CMS, True Health on Verge of Collapse," page 12.)*

'Scheme to Defraud'

Geren has served as a special agent since 1998 and is assigned to the Office of Investigations for HHS' Office of Inspector General in its Dallas regional office. He investigates fraud in the Medicare and Medicaid programs. While investigating True Health, he said he believes "the company and its principals are engaged in a scheme to defraud federal healthcare programs."

His declaration begins with the fact that True Health purchased the assets of Health Diagnostics Laboratory in 2015 and "hired many of the individuals associated with HDL's fraudulent conduct," he said. "Prior to the acquisition, HDL had been driven out of business as a result of pervasive healthcare fraud," he added. *(See, "In HDL Case, Judge Imposes Damages, Penalties of $114 Million," TDR, May 29, 2018.)*

'Business as Usual'

After the HDL acquisition, said Geren, "… in an internal board of directors meeting on October 15, 2015, True Health noted that it was 'business as usual.'" In his declaration, Geren often refers to True Health Diagnostics as THD.

"Specifically, evidence in the ongoing civil and criminal investigations, which began in 2017, suggests that True Health Diagnostics—following its acquisition of HDL and hiring its former employees—engaged (and continues to engage) in criminal activity commonly referred to as: payment of illegal remuneration, money laundering, billing for services not rendered, and billing for medically unnecessary services."

Then, Geren explained, True Health worked with rural hospitals to route patient blood samples through those rural facilities because Medicare paid those hospitals more to process certain lab tests than it paid non-rural hospitals. Also, True Health recruited physicians and allegedly overpaid them to send patients' specimens to rural hospitals that submitted claims to CMS on behalf of True Health, he said. "Ultimately, the scheme comes at the expense of the taxpayer," he added.

Most claims that these rural hospitals submitted to Medicare stemmed from billing for outpatient laboratory tests, Geren explained. The physicians did not have privileges with these rural hospitals, nor did they visit the hospitals, he added.

The physicians also did not give patients a choice about where to send their lab test specimens, he reported. In several instances, kickbacks were used to entice physicians to order the same panel of clinical laboratory tests for all patients regardless of the patients' diagnoses, Geren said in his declaration.

'Induced Physicians'

True Health induced physicians to refer clinical laboratory tests to benefit the lab company, Geren declared. "For instance, THD provided referring physicians' offices an embedded THD-employed phlebotomist, who would work in the physician's office," he explained.

"This benefited the physician because the THD-employed phlebotomist would provide services ordinarily provided by the physician's staff. Once THD conspired with a rural hospital in order to obtain the higher reimbursement rates, the phlebotomist would become an 'employee' of the rural hospital and patient samples would be steered to that rural hospital instead of THD," Geren said.

True Health Used MSOs

What's more, THD induced lab test referrals in a scheme in which management service organizations or MSOs were used as shell companies, Geren stated. "Based on evidence gathered, it is my belief that THD, through the direction and counsel of its leadership, conspired with the MSOs to influence physicians to steer patient labs to rural hospitals which were working in concert with THD," he said.

True Health recruited physicians to send patients' specimens to the rural hospitals and paid them based on the revenue they generated, Geren explained. "The physicians were grouped by referral volume and compensated for referrals sent to hospitals associated with THD," he said.

"The payments were disguised as returns on 'investments' in the MSOs," Geren said. "However, the physicians' return on investment was not reasonable and demonstrates the fact that the MSOs were merely a conduit for kickbacks.

"For instance, one physician invested $3,000 in an MSO, but was paid $308,000 as a return on investment within a few of years," Geren said. "This represented a 10,000% return on investment. Given the MSOs' structure, physicians could increase their return on investment by increasing the volume of referrals. The investigation has uncovered millions of dollars in kickbacks that were funneled to incentivize [lab test] referrals as part of this scheme."

From the rural hospitals, True Health would "obtain various management fees" and would install its own billing company to bill the [lab test] claims, Geren alleged.

Abusive Arrangements?

Geren said he had evidence that True Health Diagnostics executives were aware that "the arrangements were abusive." He explained, "For example, in February 2016, one of True Health's senior vice presidents wrote to, among others, True Health's CEO and stated that these types of arrangements were 'a powder keg waiting to explode on us.'"

In his declaration, Geren alleged that, three months later, the same senior vice president wrote to another True Health official and mentioned that [federal] authorities were asking about the MSOs and funds paid to referring doctors. "In the correspondence, this senior vice president acknowledged that 'the pain for a lot [sic] of people is coming soon … I think this is all gonna [sic] make HDL [sic-Health Diagnostic Laboratories] look like child's play. [P]eople are gonna [sic] go to prison.'"

Lawsuit: True Health vs. HHS, CMS

OIG Investigator Questions Claim of True Health's Financial Difficulties

In its legal battle with federal authorities since 2017, True Health has maintained that the loss of payment from Medicare placed the company in jeopardy of running out of cash, a situation that could force the lab company to file for bankruptcy.

But in a declaration that Special Agent Jack J. Geren, Jr., filed in federal court on July 5, the investigator from the Office of Inspector General for the federal Department of Health and Human Services disputed those claims in two ways. First, True Health executed a "recapitalization," that Geren questioned, and second, Geren challenged several statements made since early last year that the lab company would run out of funds.

Late in 2016, Medicare investigators visited True Health's headquarters in Frisco, Texas, to conduct a billing audit, Geren said in his declaration.

In January 2017, True Health reported that it was undergoing a "recapitalization" on approximately $110 million in debt, Geren alleged. At the same time, True Health was paying its executives and shareholders approximately $130 million in distributions, he added.

➤ $36 Million Paid to CEO

"This included a distribution of approximately $36 million to True Health Diagnostics' CEO, Chris Grottenthaler. Other THD executives, including its CFO, Christian Richards, received millions of dollars," stated Geren. "The United States is currently investigating the propriety of this 'recapitalization.'"

Geren countered statements by True Health CFO Richards that True Health's financial problems were the result of Medicare's payment suspensions, saying Richards failed "to discuss a 'recapitalization' which stripped over $100 million out of THD."

Also, Geren added, "Evidence suggests that True Health Diagnostics, after receiving an administrative subpoena and becoming aware of a civil investigation, engaged in a scheme to transfer its assets, thereby becoming insolvent, and reducing the United States' ability to recover any judgment against it."

➤ Refuting Declarations

The second way Geren attempted to refute True Health's declarations that it was running out of cash involved his review of all the times True Health claimed to be on the verge of exhausting its funds, but then continued to operate.

Court documents show that, after the billing audit late in 2016, the federal Centers for Medicare and Medicaid Services stopped paying True Health for all of its federal lab testing services in May 2017. Later it reduced the 100% stoppage to 35% but then stopped all payments again in June of this year. After the latest stop payment order, True Health asked the court for a temporary restraining order against CMS.

In its request for a restraining order, True Health submitted a declaration from Richards (called the Richards Declaration) in which Richards said that in True Health's dealings with CMS since the spring of 2017, the lab company claimed many times that it would run out of cash and be forced into bankruptcy as a result of CMS' suspension of payments, Geren explained. "None of THD's claims have proven true," he added.

"The Richards Declaration alleges that 'without the court's intervention, True Health will be nearly out of cash on or before July 8, 2019.' The Richards Declaration offers no support for this statement."

On Jan. 24, 2018, True Health's legal counsel represented that the company was "close to shutting down on the basis of the payment suspension." On Feb. 20, 2018, THD's legal counsel represented that the company "does not expect to be able to continue to operate much longer, unless the suspension is lifted and the funds in escrow are returned." Despite these assertions, the company continued to operate, Geren said.

On Sept. 30, 2018, True Health said in a letter to federal officials that, "As you know, True Health and the Department of Justice have agreed to an expedited 90-day timeline for possible resolution with an end date in mid-November. As previously expressed to DOJ, if that timeline is not met, True Health will no longer have the funding to maintain operations. True Health's financial position has not changed with respect to that date."

Still, True Health continued operations. Court documents show that, on March 28, 2019, Richards sent a letter to the assistant director of the federal Department of Justice Fraud Section in which he said that "absent additional funding or the release of the Medicare funds, the company will run out of operating funds in or around the third week of April. [W]e have serious doubts that additional funding will be forthcoming …."

Geren added, "This was not the case. The Richards Declaration recognizes that as of July 2, 2019, THD had still not run out of cash."

In conclusion, Geren said, "The Richards Declaration does not offer any support for why THD's current representations are any more accurate than the representations it has made for the last seventeen (17) months."

Lawsuit: True Health vs. HHS, CMS

Special Agent: CMS Decision to Suspend Payments to True Health Was Correct

IN HIS DECLARATION TO THE COURT, Special Agent Jack J. Geren, Jr., explained that the evidence in the case supported the decisions the federal Centers for Medicare and Medicaid Services (CMS) made to suspend payments to True Health in 2017 and in June of this year. Geren is a fraud investigator for the Office of Inspector General of the federal Department of Health and Human Services.

The suspensions were needed "to protect the integrity of the Medicare program," he said.

On May 25, 2017, CMS notified True Health that it would stop all payments to the lab company "due to credible allegations of fraud," Geren said. At the time, CMS listed eight claims that it considered to be fraudulent and identified them by date of service (2015 or 2016) and claim control number. Less than a month later, on June 23, CMS reduced True Health's payment suspension percentage from 100% to 35%, Geren said in his declaration.

"But True Health Diagnostics continued its fraud scheme. Even after a partial lifting of THD's Medicare suspension, THD submitted over 4,000 new fraudulent claims," he said.

In a notice of suspension, CMS identified five of the claims by date (2017) and claim control number. "Given these new fraudulent submissions, CMS implemented a 100% Medicare payment suspension and outlined a process for challenging the new suspension," Geren commented. "On June 25, 2019, True Health Diagnostics submitted a rebuttal statement to the suspension; but before CMS could respond, THD filed its request for a temporary restraining order." TDR

Regulatory Update

ACLA Gets Procedural Win in Its Appeal of PAMA Case

In a significant win for the **American Clinical Laboratory Association** (ACLA) and other groups suing the federal **Department of Health and Human Services** (HHS), the U.S. Court of Appeals for the District of Columbia ruled in the ACLA's favor on July 30.

Ruling on the appeal in the case the ACLA brought against HHS Secretary Alex Azar last year, the judge said ACLA is entitled to challenge what it called HHS' "harmful regulatory overreach" when it implemented the Protecting Access to Medicare Act (PAMA) last year.

Under PAMA, the federal **Centers for Medicare and Medicaid Services** cut what it pays clinical labs by 10% and then by 10% again this year. Another 10% cut is scheduled for Jan. 1, and then three years of 15% cuts will begin on Jan. 1, 2021.

Following Intent of Congress

ACLA challenged the implementation of the 2014 law on the grounds that CMS did not follow Congress' intent when it failed to institute a market-based system for setting the rates it pays for clinical lab tests. "HHS' continued flawed data collection process poses a direct challenge to the rule of law and PAMA's intent to support a sustainable, market-based laboratory market for millions of seniors," ACLA said in a statement announcing the decision.

In response to questions from The Dark Report, ACLA President Julie Khani outlined what happens next with this case now that the District of Columbia Circuit Court of Appeals has reversed the DC district court's decision and found that the portion of the PAMA that precludes judicial review of reimbursement rates does not preclude review of the way Azar implemented the data collection provisions in the law.

"Now that this jurisdictional issue has been resolved, the case returns to the district court, and the district court will decide whether the applicable laboratory definition violates the Administrative Procedure Act as arbitrary and capricious," Khani said.

In its lawsuit against HHS, ACLA charged that under PAMA, HHS didn't collect data from enough clinical laboratories so that the data on what private health insurers pay for clinical lab tests represented the full, nationwide market for such tests. Failing to collect enough data skewed the results in a way that was unfavorable to clinical labs, the ACLA argued.

How does the case proceed now? Khani explained that the appeals court sent the case back to Judge Amy Berman Jackson, who heard the case in the D.C. Circuit Court. "Unless she decides to transfer the case, she will hear it again," Khani said.

Asked if the appellate court decision means the next decision could be favorable as well, Khani said, "The appeal was focused on the jurisdictional issue: Does preclusion of judicial review of reimbursement rates also preclude review of the data collection provision?

"Now that the jurisdictional issue has been resolved, the focus of the district court will be on the merits—namely the applicable laboratory definition," she explained "The D.C. Circuit Court's decision does not pre-judge the merits of the arguments, but having eliminated the jurisdictional issues, the chances of success before the district court have increased." TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Add eight more laboratories to the list of lab companies whose patient data were breached when the **American Medical Collection Agency** was hacked. According to *HealthITSecurity*, in recent weeks, these labs reported breaches of their patient records:

- **Natera**
- **American Esoteric Labs**
- **CBLPath**
- **South Texas Dermatopathology**
- **Seacoast Pathology**
- **Arizona Dermatopathology**
- **Laboratory of Dermatopathology ADX**

MORE ON: *Patient Data Breach*

It was national news in June when **Bio-Reference Laboratories**, **LabCorp**, **Quest Diagnostics**, and **Sonic Healthcare** reported that hacks at the American Medical Collection Agency had exposed their patients' personal health information. Those data breaches involved more than 20 million patients. Federal law requires providers to publicly disclose breaches of personal health information (PHI).

LABCORP BUYS SOUTHBEND MF

One of the nation's oldest, independent regional laboratory organizations has been sold. In Indiana, **South Bend Medical Foundation** (SBMF) agreed to sell its clinical laboratory operations to **LabCorp**. The deal was made public on July 30 and the sale is expected to close in September. No purchase price was disclosed. SBMF will keep its pathology and blood banking services. The laboratory was founded in 1910 and was organized as a not-for-profit entity.

TRANSITIONS

- **OncoCell MDx** of Royal Oak, Mich., announced that Christopher Thibodeau is its new Chief Operating Officer. Thibodeau formerly worked at **MDxHealth**, **Agendia**, **Numira Biosciences**, **US Labs**, and **Ventana Medical Systems**.

- **Health Network Laboratories** of Allentown, Pa., appointed Xinjing Wang, PhD, as its new Director of Clinical Genomics. Wang previously held positions at **University of Oklahoma Health Sciences Center**, **National Eye Institute/NIH**, **University of Minnesota**, and the **Johns Hopkins University School of Medicine**.

- **Roche Holding AG**, of Basel, Switzerland, promoted Thomas Schinecker to CEO of **Roche Diagnostics** and made him a member of the firm's corporate executive committee. Schinecker has been with Roche since 2003.

DARK Daily
Clinical Laboratory and Pathology News/Trends

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That's all the insider intelligence for this report. Look for the next briefing on Tuesday, September 3, 2019.

New This Year!
Smart Ways to Cut Costs

★SPECIAL SESSION!★

Bringing Efficiency and Excellence into Anatomic Pathology

Michael B. Cohen, M.D.

Interim Chair and Professor, Pathology
Wake Forest School of Medicine, Winston-Salem, NC

Opportunities, Lessons Learned in Managing Costs, Boosting TAT and Quality, and Increasing Productivity

Pathologists today watch as payers regularly cut reimbursement and narrow their networks. These trends mean less money for the same work, as well as reduced access to better-paying patients.

To protect pathology revenue and sustain pathologist income, innovative pathology groups are proactively cutting costs and identifying ways to increase productivity of staff, systems, and pathologists. This is true at Wake Forest School of Medicine, where—after overcoming unwelcome challenges—the pathology team tapped the new-found unity within the department to achieve significant gains in productivity, managing costs, and reducing turnaround times.

This energizing session will help all pathology labs recognize their best opportunities to improve collections, better manage costs while sustaining quality, and tapping new sources of revenue. These successes can be duplicated in your lab or pathology group!

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