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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

Discovery of Pathology Errors Shows Quality Flaws

MOST PATHOLOGISTS WOULD AGREE THAT PATIENTS AND THEIR PHYSICIANS have every right to expect a timely, accurate lab test result. Stated differently, patients and physicians implicitly trust that a pathology laboratory in the United States will not make errors in specimen processing (technical component) and diagnosis (professional component).

For these reasons, the recent federal **Centers for Medicare and Medicaid Services** (CMS) decision to issue the most severe sanctions against **Wake Forest Baptist Medical Center** (WFBMC) for deficiencies in its pathology laboratory that could cause immediate "jeopardy to patient health and safety" should be a wake-up call to the anatomic pathology profession.

Laboratories and banks don't have much in common, except that they succeed only as long as customers trust them. Once customers have reason to believe a bank is in financial distress, they are likely to withdraw their funds in a run that could cause the bank to fail.

As with banks, laboratories must maintain public trust, and they do so by producing accurate and high-quality test results. Look no further than the example of **Theranos** to confirm that fact. Once credible news articles revealed systemic quality and accuracy failures at Theranos, it collapsed financially and multiple federal agencies commenced civil and criminal investigations.

The administrators at Wake Forest Baptist Medical Center now must assure the public that they have identified and corrected all the problems that caused multiple pathology errors which occurred since at least last year and possibly going back to 2014. In addition to the public fallout the medical center faces, Wake Forest Health administrators can expect malpractice lawsuits from patients whose erroneous pathology results caused them to get care that was inappropriate and life-changing.

One message to take away from this episode is that clinical laboratories and pathology groups should devote all necessary resources to ensuring the quality of all processes in their laboratories. Adoption of a quality management system is a productive first step. Encouraging a culture of continuous improvement, and a system of prevention are proven ways to drive out errors, improve quality and customer satisfaction, and help the lab remain financially sound. TDR

NC Hospital Reviewing Path Lab Deficiencies

Wake Forest Baptist must review more than 9,000 histopathology cases going back 38 months

CEO SUMMARY: Discovery of multiple diagnostic errors occurring in an anatomic pathology department triggered a complaint investigation and a 54-page report from the federal Centers for Medicare and Medicaid Services. The report shows that Wake Forest Baptist Medical Center is reviewing more than 9,000 pathology cases to identify incorrect cancer diagnoses. Last month, the medical center found 10 cases of patients in which errors in the pathology lab caused inaccurate diagnoses.

EVERY MEDICAL DIRECTOR of a CLIA-licensed lab understands that each day brings the risk of two types of unwelcome events. One is a Medicare program inspection that identifies deficiencies that might rise to the level of posing immediate jeopardy to patient safety. The second is the lab's discovery that diagnostic errors have compromised patient care.

News stories report that both events happened in recent weeks at 885-bed **Wake Forest Baptist Medical Center** (WFBMC) in Winston-Salem, N.C. Between Feb. 5 and Feb 8, 2018, officials from the federal **Centers for Medicare and Medicaid Services** (CMS), and members of **North Carolina's Division of Health Service Regulation** (DHSR) CLIA staff conducted a joint complaint investigation to determine the facility's compliance with the federal Medicare conditions of participation (COP) for hospitals.

From that inspection and subsequent disclosures, regulators determined that the primary source of deficiencies were in histopathology. For a period reported as June 2014 through August 2017, the hospital is reviewing 9,291 histopathology cases. As of March 26, only 1,422 cases had been reviewed. A statement in the CMS report indicates that the hospital is in "a review process and was re-reviewing '100%' of the breast cancer cases."

Based on the February inspection, CMS sent a 54-page statement of deficiencies and plan of correction, dated March 26, to **North Carolina Baptist Hospital**, the previous name of Wake Forest Baptist Medical Center. CMS then sent a notice

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to the medical center that, effective March 26, the medical center "is to be terminated as a provider" to the Medicare program.

As of press time, WFBMC has until April 19 to submit a corrective plan acceptable to CMS and it has until June 12 to resolve the issues with the anatomic pathology lab. Otherwise the hospital would face suspension of inpatient Medicare billing privileges.

Big News Story

The possibility that the hospital loses its ability to bill Medicare has made this a significant story. What has added to the public interest in the news about WFBMC's problems are the reports of patients who were misdiagnosed. Patients whose cancer was missed did not get appropriate treatment while patients diagnosed with a cancer they did not have underwent unnecessary surgery or other forms of therapy.

In the story that follows on pages 6-8 THE DARK REPORT provides information about the deficiencies described by CMS in the report it issued to WFBMC on Mar. 26.

To help pathologists and lab administrators understand the role of the pathology laboratory in the problems at WFBMC, this story outlines what was reported about issues involving the pathology department.

Medical center administrators were notified about issues in the pathology department in the fall of 2017. The CMS report stated, "Interviews on 02/05/2018 at 1505, 02/06/2018 at 1050 with the Director of Risk Management, revealed in September of 2017, risk management was made aware of concerns regarding 10 patients of MD #7 [which news stories report to be a pathologist].

"Interview revealed the concerns were brought to the director's attention as a result of several complaints by employees from the laboratory," the report said.

This fact is significant. It is reasonable to assume that some staff in the pathology laboratory recognized an issue that they thought managers in the pathology department were not addressing. For this reason, the employees reported this information to the hospital's risk manager.

The CMS report stated that the risk manager began the process to review the cases and prepare those cases for external review. At least some of these cases involved patients with breast cancer.

"Risk management's review of the 10 patients' case files revealed four of the 10 patients' plans of care would be affected with an incorrect diagnosis," the CMS report said. Physicians were notified. As of the CMS inspection in February, "The interview revealed the investigation is still ongoing and all updated results were going to the Medical Review Committee who report to the Medical Executive Committee," said the report.

Who Complained to CMS?

Since CMS wrote that the reason for the February visit was a joint complaint investigation, a fair question would be, "Who complained to CMS? Could it have been one or more of the laboratory staff who reported these problems to the hospital's risk manager in September and felt that follow-up action was moving too slowly, thus exposing patients with inaccurate diagnoses to further harm?"

Hospitals and health systems that become aware of medical errors, including misdiagnosis of a patient, are sensitive to the potential of malpractice lawsuits that result in multimillion dollar settlements against the institution and the negative publicity that results when a case of misdiagnosed cancer becomes news.

Another relevant fact is the hospital stated that it believed one individual was responsible for the situation. Reporter Richard Craver of the *Winston-Salem Journal* wrote that medical center

President Kevin High, MD, "has not identified hospital officials responsible for the erroneous laboratory results." The hospital determined that "most, if not all, of the misdiagnoses centered on a single individual who is no longer with Wake Forest Baptist," Craver reported.

Unaddressed Issue

A hint at the identity of this pathologist is contained in the CMS report, which said, "Interview on 02/05/2018 at 1245 and on 02/08/2018 at 1415 with MD #10, the Chair of the Pathology Department, revealed he had been in his position since August of 2017. Interview revealed he was asked to chair after the previous Chair (MD #7) separated from the organization."

If this is true, it provides more insight into the problems within the pathology department at WFBMC. If staff members had evidence to believe that the chair of pathology was misdiagnosing certain types of cancers, what options did staff have to use the lab's internal procedures to call attention to this situation?

The former chair's departure in August 2017, and the lab staff's meeting with the hospital risk manager in September 2017, might be interpreted as evidence that—even after the departure of that pathologist—some employees within the pathology department thought that not enough was being done to notify patients identified as having been given a wrong diagnosis—and where timely intervention could minimize negative consequences to those patients.

The CMS deficiency report and the news stories about the problems at Wake Forest Baptist Medical Center show that fundamental problems went unaddressed for about three years. Did the June 2014 through August 2017 time period—when the 9,000 cancer cases under review were diagnosed—coincide with the former chair of pathology's time at the medical center? If so, what took lab staff so long to take their concerns to the hospital administration?

These events trigger another interesting and relevant question: What was the role of the pathology lab's CLIA accreditor during the time that problems were known to some lab staff? The website lists the **College of American Pathologists** as an accreditor. Did someone from the pathology lab notify CAP? When onsite, during that three-year period, did CAP inspectors identify any of the deficiencies CMS reported in its February inspection?

If these assumptions are close to the truth, then it appears serious, ongoing issues happened at the WFBMC pathology lab, at least between 2014 and 2017. TDR

Statement from President of Wake Forest Health System

IN A STATEMENT RELEASED APRIL 11, Wake Forest Health System President Kevin P. High, MD, said, "Wake Forest Baptist and the entire Wake Forest Baptist Health system continue to fully participate as a provider of medical services under the Medicare program.

"CMS made its decision after surveyors returned to Wake Forest Baptist last month and found corrective actions in place and evidence of ongoing monitoring and improvement. The surveyors recommended rescission," High added.

"Physicians and patient advocates at Wake Forest Baptist continue to provide information and care to those concerned about their diagnoses following biopsy or surgical removal of tissue, and other teams continue to work on improvements to ensure the quality of care and safety of our patients," he wrote. "We expect a CMS survey team to return within the next few months to confirm compliance with the processes and procedures that have been put in place."

CMS Report, News Stories Describe Pathology Issues

Pathology lab at Wake Forest Baptist MC had turnover in leadership, other internal problems

CEO SUMMARY: In response to information the pathology lab staff provided to the hospital's risk manager last fall, and following a federal Centers for Medicare and Medicaid Services inspection in February, the Wake Forest Baptist Medical Center is taking corrective action to fix serious deficiencies in its anatomic pathology laboratory. In reports issued in February and March, CMS described these deficiencies as "an immediate jeopardy to the health and safety of patients" at the 885-bed hospital.

FOLLOWING A REVIEW of 1,422 pathology lab cases, the **Wake Forest Baptist Medical Center** (WFBMC) found 10 cases in which patient care was compromised, according to a 54-page report from the federal **Centers for Medicare and Medicaid Services**. In addition, the CMS report shows that the medical center needs to review a total of 9,291 pathology cases.

Last week, CMS announced that the medical center had taken steps to correct deficiencies that CMS found during an inspection of the medical center's pathology lab conducted over four days, from Feb. 5 to 8. The deficiencies were cited as an immediate threat to patient safety and resulted in CMS saying it would stop Medicare payments in March.

The corrective steps prevented CMS from revoking the medical center's participation in the Medicare program. CMS also told the medical center that it had until June 12 to correct the pathology lab deficiencies, which included failures in training, equipment maintenance, supply shortages, missing or incomplete documentation, and problems with the laboratory director's management of the lab. Those problems date back to 2014, and in some cases possibly earlier, according to reporting by Mark Tosczak of *North Carolina Health News*.

On Feb. 8, CMS issued a 23-page list of deficiencies. Six weeks later, on March 26, CMS issued a revised list of deficiencies that identified the need for the medical center to review the 9,291 cases.

'Did Not Meet Standards'

In the March 26 report, CMS quoted Russell M. Howerton, MD, the Chief Medical Officer of Wake Forest Baptist Health, as saying that hospital administrators were concerned about problems in the pathology lab. "We've internally and externally reviewed and found our care did not meet our standards," Howerton told CMS.

In the March 26 report, CMS said problems were found in reports on four patients from one pathologist, identified as MD #7 in the report. "For three patients whose cases are described in the report, incorrect breast cancer diagnoses from pathology reports led to unnecessary care in 2016 and

CMS Cited Multiple Times Laboratory Director in Pathology Lab Failed to Follow Procedures

IN ITS STATEMENT OF DEFICIENCIES, the federal Centers for Medicare and Medicaid Services cited multiple times that the laboratory director in the department of pathology failed to follow proper procedures.

CMS based the findings on its review of procedure manuals, personnel records, and interviews with staff on Feb. 5 through 8. "The laboratory director delegated responsibilities to another pathologist (surgical pathology director) but failed to ensure the delegated duties were performed as required," the CMS statement of deficiencies said.

Review of personnel records showed that the histology supervisor did not meet the education requirements to serve as a technical supervisor or general supervisor in a high-complexity histopathology laboratory, the CMS statement said, adding, "The responsibilities for review of records and testing personnel competency assessment could not be delegated to the histology supervisor (assistant manager)."

In addition, the pathologist serving as surgical pathology director "at the time of the delegation" was no longer employed at the pathology lab as of September 2017. But, the documentation of the delegation was not updated to reflect the specific responsibilities delegated "to current designees," CMS added.

The lab director also failed to ensure that 20 of 21 testing personnel received appropriate training and had shown they could reliably perform all testing operations. For one laboratorian, identified as TP #2 and hired on Dec. 29, 2017, there was no documentation of training available for review and yet this laboratorian was doing grossing of pathology specimens in the operating room pathology lab, CMS reported.

What's more, there were no training records for review for all 19 residents who perform grossing of pathology specimens in the OR pathology laboratory, CMS added.

2017," Tosczak wrote. "Two patients had lumpectomies and radiation treatment. A third had a lumpectomy and chose a more aggressive surgery—double mastectomy."

A pathology report on a fourth patient resulted in what CMS characterized as being "underdiagnosed" in a report done on breast tissue removed in a biopsy. "Thirteen months later she was diagnosed with breast cancer and subsequently received treatment," Tosczak added.

Change in Leadership

In an interview with CMS inspectors on Feb. 5, Howerton said of the pathology lab, "We've had a work flow/work force imbalance." Problems in the lab led to a change in leadership, he told CMS. "We are deep in the midst of a complex and deep review to see if we have a quality issue."

"The interview revealed the organization had not reached a 'summative conclusion' and they had disclosure meetings with all patients involved, they had 'attempted to put more qualified individuals into the workflow,' new leadership, and upregulated the process of dual reads (already had dual reads on all outside cases)," the CMS report said.

As of April 10, the medical center had taken corrective steps to prevent CMS from stopping Medicare payments to the medical center, CMS said in an announcement. Federal officials said the **North Carolina Baptist Hospital** (also known as Wake Forest Baptist Medical Center) would continue as a provider of services under the Medicare program.

In its report on Feb. 8, CMS listed failures that federal inspectors identified in

the lab's histopathology section; personnel competence assessment policies; procedure manual, test systems, equipment, instruments, and reagents; and in how the laboratory director managed the lab. Based on the severity of the deficiencies, the immediate jeopardy situation was not abated and the laboratory was placed on a 23-days revocation track, CMS said.

After the federal **Department of Health and Human Services** issued a Retraction of Termination Notice on April 10, the medical center announced the next day (April 11) that CMS rescinded its decision to revoke the medical center from the Medicare program. The pathology lab at the 885-bed medical center does some 25,000 surgical pathology cases annually.

On March 9, CMS sent the medical center a notice saying it would stop payment for services in a "Public Notice for Involuntary Termination of Medicare/Medicaid Provider Agreement," as follows: "Notice is hereby given that effective March 25, 2018, the agreement between North Carolina Baptist Hospital … and the Secretary of Health and Human Services, as a provider of Hospital Services in the Health Insurance for the Aged and Disabled Program (Medicare) is to be terminated."

Statement of Deficiencies

In its statement of deficiencies, CMS said, "The laboratory failed to identify and correct problems in the subspecialty of histopathology. The laboratory failed to ensure the procedure manual was complete for all testing performed." The lab also failed to ensure equipment and procedures were validated prior to use for patient testing; failed to perform manufacturers' specified maintenance as required, failed to monitor water quality, temperature, and humidity, as required; failed to perform and document quality control for H&E (hematoxylin and eosin) stains as required; and failed to discard expired supplies, CMS said.

The statement of deficiencies appeared to show that the most serious deficiencies involved the failures of the laboratory director. "The laboratory director failed to provide overall management and direction of the laboratory," the CMS statement said. The laboratory director failed to ensure delegated duties were performed as required, failed to ensure testing personnel were trained prior to testing patients, and failed to ensure policies and procedures were established and followed for monitoring testing personnel competency, CMS said.

Duties and Responsibilities

Commenting on the CMS statement of deficiencies, Elissa Passiment, a lab management consultant, said, "The lab director's lack of compliance led to the major failures cited in the report. Each of the deficiencies cited can either be directly linked to the duties and responsibilities assigned to the laboratory director by the CLIA regulations or to poorly-qualified personnel, the hiring of whom is also a regulatory responsibility of the laboratory director."

The medical center's case illustrates a problem inherent in the CLIA rules, she added. "This case is a prime example of relying only on one person to ensure compliance and quality," she wrote in an email to THE DARK REPORT. "In my opinion, this has always been a major flaw in the CLIA regulations. Labs should delegate the responsibilities of ensuring compliance and quality to a number of lab staff members."

For pathology laboratories, the most competent laboratory directors should have a range of experience, she added. "The best type of person to be laboratory director is one who has been appropriately educated and trained in quality management systems, good laboratory procedures and practices, and management leadership," she wrote. TDR

—Joseph Burns

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Georgia Micro Lab Slashes TAT by Almost Two Days

Microbiology lab combines Lean workflow with new test to help improve patient care

CEO SUMMARY: Two projects to boost the performance of the microbiology laboratory at University Health Services in Augusta, Ga., significantly reduced test turnaround times in ways that contributed to improved patient outcomes. The first project was in 2016, when the lab introduced mass spectrometry and MALDI-TOF for bacterial infections, cutting turnaround times from 104 to 74 hours. Last year, a new antimicrobial-testing system cut TAT by an average of 42 hours.

New diagnostic technologies and automated systems are helping microbiology labs to cut test turnaround times and improve patient care.

The experience of the microbiology lab team at **UH Lab**, the for-profit lab company of **University Health Services** (UHS) in Augusta, Ga., is a prime example. Since 2016, the microbiology team has combined Lean management methods with new microbiology tests and systems. These innovations have contributed to improved patient care, substantially reduced test turnaround times, and helped increase the productivity of the microbiology lab staff.

In the first of two initiatives, the lab introduced mass spectrometry and MALDI-TOF to cut turnaround times for these tests from an average of 104 hours to 74 hours. In the second project, the lab introduced a test system that the FDA had cleared for clinical use just weeks earlier. Using this test allowed the lab to drive down TAT by an average of 42 hours and by more than 50 hours for some bloodstream infections, said Christa Pardue, MBA, MT(AMT), Laboratory Director at University Health Services.

In addition to these positive outcomes, local news teams made University Health Services and UH Lab the centerpiece of stories about how the latest innovation would benefit patients by improving the diagnosis and treatment of bloodstream infections. After reading these stories, patients took the unusual step of calling the lab to ask if such testing would be available to them and their family members.

Successful Lab Outcomes

In a lab case study that Pardue presented at the THE DARK REPORT'S *Lab Quality Confab* in October in New Orleans, the lab director explained how the lab took steps starting in 2016 to improve workflow efficiency in the micro lab. Founded in 1818, the nonprofit hospital is the second oldest in Georgia. It has three acute-care facilities, 831 licensed inpatient beds, and serves patients in 25 counties in what Georgians call the Central Savannah River Area.

The University Hospital Laboratory, known as **UH Lab**, is a for-profit private

reference lab that holds about 60% of the local market share. "We gained that market share through our customer service and turnaround time," Pardue said. "In September, UH Lab absorbed a local reference lab, which doubled our pathology volume overnight and brought in additional microbiology and core-lab testing. This lab chose to merge with us because of the customer support that we provide."

UH Lab's clients include several critical access hospitals, a long-term acute care facility, and a rehabilitation center. "All of these places refer those patients who need a higher level of acute care to the University Hospital, and some admit our bundled-payment patients as well," she said. "These patients have the potential to be our outcomes.

Fully-Inclusive Micro Service

"We consider these facilities as key clients," noted Pardue. "Our lab strategy is to offer a fully-inclusive microbiology service and interact daily with their infection prevention departments. That gives us a chance to sustain the local level of antibiotic resistance within our community."

Two years ago, Pardue saw the need to reconfigure its microbiology workflow. "We've always had an excellent microbiology lab, but in January 2016 we began to bump up against some capacity and near-future staffing constraints," she explained. "Our more senior staff began expressing concerns about our ability to absorb additional volume. And, we were approaching the point where more than half of the microbiology staff were eligible to retire.

"We recognized that more automation and improved workflow were the only ways to prepare for the imminent retirement and transition to new-grad staffing," she added. "Our Lean studies of work processes revealed that our existing instrumentation was driving a hands-on, off-line workflow.

"For bacterial infections, we used a chemical methodology and some bench testing," stated Pardue. "We also had a batch process for microbiology that was not effective. For example, we plated out of positive blood culture bottles."

Ineffective Batch Processing

In May 2016, UH Lab introduced mass spectrometry and MALDI-TOF for bacterial infections. "We also reduced batch sizes to give us a less time-consuming workflow and started multiple-plate reading benches," she said. "These steps reduced our turnaround time by 30 hours—from 104 to 74 hours. In so doing, the staff felt relief because of the changes the new workflow brought to their day.

"The new workflow still required experienced staff but less effort," she added, "and so plate reading for infectious disease and microbiology are still done on the day shift only, but we've had no more complaints about workload from our staff.

"While we had a faster process and reduced turnaround times, our equipment still required an experienced plate reader, meaning we had not addressed our staffing concerns," Pardue explained. "As long as we needed an isolate, we had to have experienced microbiology techs."

Rapid Pathogen ID

Last year, Pardue learned of the recently FDA-cleared PhenoTest BC Kit from **Accelerate Diagnostics,** in Tucson, Ariz. "This system would provide rapid pathogen identification and sensitivity to antibiotics straight from a positive blood culture bottle," she said. Seeking to get other lab workers involved in the decision, she asked staff about it. "They were a bit pessimistic that it could do what it said it could do, but if it could, they wanted it," she commented.

Next, she presented the idea to the Laboratory Utilization Committee (LUC), a medical staff-level committee that the chief medical officer chairs. The LUC includes the chiefs of hospital intensivists,

infectious disease, and pathology; and representatives of radiology, pharmacy, and performance improvement. "The LUC's role is to establish an effective and efficient testing formulary," Pardue said.

Preparing for the New Test

Over six months, the laboratory utilization committee analyzed the test. It reviewed such metrics as turnaround time, cost per inpatient stay, sepsis readmission rates, and costs per antibiotic day. Following this review, the LUC agreed with lab staff that Accelerate Diagnostics' performance verification program would allow hands-on review *(see sidebar)*. The result of the LUC's analysis and the patient verification program (PVP) allowed UH Lab to assess how the test would work in real-time. Less than a year later, UH Lab went live with the test.

There is another interesting aspect to this story. As one of the first labs in the nation to begin using the new test after it gained clearance from the FDA, the news media gave this event wide coverage. These news stories triggered patient calls into the lab, according to Pardue. "The coolest part of this day was when patients' families started calling me, asking, 'Are we going to be able to use this new technology on our family members?' These are the calls you want your lab to get," she said. TDR

—Joseph Burns

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Utilization Committee Helps UH Micro Lab Analyze New Diagnostic Test Over Six Months

WHILE THE LAB AT UNIVERSITY HEALTH SERVICES was evaluating Accelerate Diagnostics' PhenoTest BC Kit for inclusion on its test menu, the test developer suggested UH Lab participate in its performance verification program (PVP).

"The PVP would allow us to install the system and gain experience with it while the test awaited FDA clearance," explained Christa Pardue, MBA, MT(AMT), UHS Laboratory Director. "That way, we could gather data on what the test could actually do, and we could do our CLSI validation early.

"We established an implementation team and trained our staff in two days because it's an easy test to run," she said. "You just put 500 microliters in a vial, pop the vial in the kit, and pop the kit in the instrument.

"We also did performance studies, including a manufactured blood product inoculated with a known pathogen," she added. "Of course, we monitored the kit's actual turnaround times.

"These assessments showed us how we could use this new test to engineer a streamlined workflow that would be–on average–about 42 hours faster than the 74 hours we had on the mass spec system," she said. "While 42 hours was the average, we did MRSA testing 50 hours faster, and *klebsiella* and *e. coli* testing each were completed 54 hours sooner. Cutting the turnaround time came mostly because we didn't need to plate out positive blood cultures.

"Our validation outcomes were very good. Sensitivity and specificity were great," she commented. "We predicted that the accelerated panel would cover 91% of the pathogens seen in our lab. In actual use, it covered 97% of the pathogens that we've had in our lab.

"The Laboratory Utilization Committee determined the analysis to be a success because we had great sensitivity and specificity, and it showed that, for blood infection testing, we could reduce our turnaround time by 42 hours. That is almost two days sooner than what was typical with MALDI-TOF," she concluded.

CEO SUMMARY: Several developments have moved the case forward since December when the American Clinical Laboratory Association filed suit in federal court against the Department of Health and Human Services. In recent weeks, ACLA filed for summary judgment; HHS responded with its own request for summary judgment; and most recently ACLA filed its rebuttal to the HHS. In addition, several lab associations filed amicus briefs in support of the ACLA as did the National Association for the Support of Long Term Care.

Deep Cuts to Medicare Lab Fees Have Consequences

Legal Briefs Explain Problems with PAMA Implementation

IS THERE REASON TO BE OPTIMISTIC about the prospects of the clinical laboratory industry prevailing in a federal lawsuit challenging how Medicare officials conducted a market study of private payer lab test prices, then used that data to enact deep price cuts to the 2018 Medicare Part B Clinical Laboratory Fee Schedule?

In the lawsuit filed Dec. 11 in the U.S. District Court for the District of Columbia, the plaintiff, the **American Clinical Laboratory Association** (ACLA) sued the federal **Department of Health and Human Services** (HHS). ACLA charged that the agency failed to comply with the requirements of the Protecting Access to Medicare Act of 2014 (PAMA) when it set the 2018 Clinical Laboratory Fee Schedule (CLFS). In a 32-page filing, ACLA charged that HHS disregarded the requirement in PAMA that all applicable laboratories report relevant market-rate data private health insurers paid to clinical laboratories.

THE DARK REPORT has provided extensive coverage of the lawsuit's key issues, including analysis from legal experts about the strengths and weaknesses of each party to the suit. *(See TDRs, Jan. 2 and Mar. 5, 2018.)*

This intelligence briefing updates developments in the lawsuit. In February, ACLA filed a motion seeking summary judgment in the case. Several lab and healthcare associations filed briefs with the court in support of ACLA and its request for a summary judgment.

Last month, attorneys for HHS responded to that motion and filed a cross-motion seeking a summary judgment in the government's favor.

Early this month, ACLA filed its response to HHS, refuting the government's defense and reiterating its arguments for a summary judgment (or ruling without trial) to continue requesting a summary judgment in its favor.

In the following analysis and commentary, THE DARK REPORT presents some of the major points made in the *amicus curiae* briefs filed in support of ACLA by other lab and healthcare associations. Also included are several of the significant statements made by HHS and ACLA in the documents as each tries to win a summary judgment in its favor.

Useful Information

Understanding the issues in these filings will be useful to pathologists and lab executives for two reasons. First, it will help them understand the key arguments each side is presenting in court. Second, it will be useful for lab managers seeking to educate elected officials about the negative consequences such deep Medicare fee cuts are having, such as causing labs to lose money and go out of business and Medicare patients in many communities and rural areas to lose access to quality lab testing.

During recent months, four organizations filed *amicus curiae* (or friend of the court) briefs in support of ACLA's motion for summary judgment:

- **American Association of Bioanalysts** (AAB)
- **Advanced Medical Technology Association** (ADvaMed)
- **College of American Pathologists** (CAP)
- **National Association for the Support of Long Term Care** (NASL)

Clinical labs already feel the effects of PAMA because the federal **Centers for Medicare and Medicaid Services** (CMS) used the rules implemented under PAMA to set the 2018 Clinical Laboratory Fee Schedule rates. Those rates are much lower than CMS estimated and have caused at least one lab to close and others to cut back on services. Still others are considering making cuts in services, the amicus briefs show.

CMS predicted that under PAMA, its payments to laboratories would decrease by $390 million in 2018, but because the methods CMS used to collect the market-rate data under PAMA were so flawed, reimbursement decreased by $670 million this year, the amicus briefs show.

This amount is about 10% of the $6.8 billion that Medicare paid under Part B for lab tests in 2016, according to the **Office of Inspector General's** report, "HHS OIG Data Brief Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data."

Under PAMA Section 216, CMS was required to modernize how it pays clinical labs under the CLFS. To do so, CMS required labs to report what they received in payment from private payers for laboratory tests and the corresponding test volume. Those rates were the basis for the 2018 CLFS.

Amicus Brief filed by:

NASL
National Association for the Support of Long Term Care

It is notable that the National Association for the Support of Long Term Care submitted an amicus brief in support of ACLA. Nursing homes and skilled nursing facilities (SNFs) are intense users of clinical laboratory testing services.

It is widely-recognized within the clinical laboratory industry that long-term care facilities must constantly have a significant number of medical laboratory tests performed on their patients.

In its brief, NASL said the 2018 Medicare Clinical Laboratory Fee Schedule would cause harm that is "particularly acute and devastating for labs serving nursing homes."

Clinical laboratories serving nursing homes provide critical support to particularly vulnerable patients. In addition, the service model labs use to support nursing home patients is unique because labs require specially-trained employees to travel to patients' bedsides daily or several days each week to draw blood samples and collect other specimens. These patients typically suffer from multiple diseases, meaning their physicians have a pressing need for such tests in order to assess patients' conditions frequently and immediately, the brief said.

Under PAMA, CMS can cut what it pays clinical labs as much as 10% below the prior year's rates for 2018, 2019, and 2020, the association said. "Laboratories that serve nursing home patients would simply be unable to sustain such drastic rate reductions. By 2019—when the cuts would reach a cumulative total of 20%—it would not be profitable for most of these laboratories to stay in business," the brief said.

"If most, if not all, of the specialized laboratories serving this distinct nursing home market were driven out of business, the nursing home population would not be able to satisfy its unique needs for on-site service and prompt test results," stated NASL.

Laboratories serving nursing homes typically are small companies with annual revenues that are much less than those labs that serve patients in other settings, it added. What's more, large labs do not serve this population.

In 2015, the two largest national laboratory companies furnished less than 4% of lab services to the nursing home market, it said. "In many geographic areas, nursing homes are served by only a single specialized laboratory, which may be a local independent laboratory or, in a few areas, a hospital laboratory providing these services at a loss," the brief added.

These labs rely on Medicare payments because they have no alternative revenue base to offset the adverse financial effects of Medicare rate cuts. "On any given day, 78% of individuals receiving care in a skilled nursing care center rely on Medicare or Medicaid to pay for their care," the brief said. In addition, most patients in nursing homes are dually eligible for Medicaid (which pays for their room and board and nursing care) and Medicare (which pays for their physician services, laboratory tests, hospitalization, rehabilitation therapy, and other services).

"This pattern [of patient coverage by both Medicare and Medicaid] is entirely different than the pattern for hospital and physician services, in which private insurance is the majority payer, and can to a certain extent offset adverse effects from Medicare rate cuts," the brief said.

Amicus Brief filed by:

AdvaMed
Advanced Medical Technology Association

In its amicus brief, the Advanced Medical Device Technology Association repeated ACLA's claim that, when implementing PAMA, CMS made significant errors in how it collected the data it used to revise how it paid clinical laboratories and explained how CMS made those errors.

AdvaMed has about 300 member companies that develop medical devices, diagnostic tools, and health information systems. In the AdvaMed brief, attorneys argued that Medicare officials made two significant errors. One involved how CMS defined labs that needed to report private payer rate data. The other was the inadequate time CMS allowed labs to collect the data.

CMS defined each lab that needed to report as an "applicable laboratory," by saying that such a lab would bill Medicare under its National Provider Identification (NPI) number and would receive at least $12,500 of its Medicare revenue from the CLFS, AdvaMed said.

This definition excluded hospital outreach laboratories and physician office laboratories, AdvaMed wrote. These labs generally lack separate NPIs, and most POLs do not get at least $12,500 of their Medicare revenue from the CLFS, the brief said.

In what CMS pays under the CLFS, hospital outreach laboratories get 26%, and POLs get about 18%, the brief explained. "Taken together, these exclusions render the data significantly incomplete and potentially not representative," it added.

"CMS admitted in its executive summary that payment rates were established using data from only 1,942 laboratories," AdvaMed wrote. This figure is lower than the 12,000 labs the OIG estimated in 2016 would be the basis for new payment rates and is less than 1% of the 235,928 labs nationwide.

"Indeed, despite hospital outreach laboratories receiving 26% of the CLFS payments in 2016, only 21 hospital laboratories, representing 1% of the total reported test volume, reported payment rate data in 2017," the brief said.

When debating the PAMA legislation in 2014, Congress agreed that its purpose was to ensure that seniors' access to quality health care was not jeopardized. Yet, ACLA argued in its suit that HHS Secretary Alex M. Azar defeated this purpose by rejecting the statutory definition of the term "applicable laboratory." In so doing, PAMA will "jeopardize the aged and disabled by reducing or eliminating their access to laboratory services," the ACLA lawsuit said.

Amicus Brief filed by:

COLLEGE of AMERICAN PATHOLOGISTS

In its amicus brief, the College of American Pathologists also addressed how CMS defined the term "applicable laboratory." CMS redefined applicable laboratory as a lab plus any other operating units under the same NPI, thus guaranteeing that laboratories functioning within larger healthcare institutions would be excluded from reporting data, CAP said.

"The effect is to leave independent laboratories as the predominant reporting entities," it added.

'A Fraction of the Data'

Thus, the rule captured only a fraction of the needed payment data. "Indeed, in the first round of reporting, fewer than 2,000

HHS Says ACLA Lacks Legal Standing to Challenge Fees Under PAMA Law

IN A COURT FILING, the federal Department of Health and Human Services (HHS) argued that the American Clinical Laboratory Association lacks legal standing to challenge HHS over the 2018 Clinical Laboratory Fee Schedule.

On March 23, HHS filed its answer to ACLA's request for a summary (or quick-resolution) judgment in ACLA's favor by arguing that the court, in fact, should reject ACLA's arguments and rule in HHS' favor. HHS criticized ACLA's arguments regarding how HHS defined the term "applicable laboratories" when it was collecting rate-payment data.

HHS said ACLA's lawsuit "… seeks to enjoin the new fee schedule through a circuitous challenge to the agency's rule-making." The question of how HHS defined the term "applicable laboratories" is at the heart of ACLA's lawsuit.

"Plaintiff further avers that the definition of 'applicable laboratories' caused an insufficient number of hospital laboratories to report their data to the agency," HHS said. "These hospitals purportedly charge more for CDLTs than do other kinds of laboratories, and plaintiff argues that the absence of hospital laboratory data caused the new fee schedule to be lower than it otherwise would have been."

In its filing, HHS said, the ACLA's challenge fails for three reasons. "First, the statute expressly bars any judicial challenge to the 'establishment of payment amounts' in the new fee schedule," HHS argued. "Plaintiff's suit is a direct attack on the Medicare payment amounts established here, and is therefore barred.

"Second, plaintiff lacks standing because it fails to show that the agency's definition of 'applicable laboratory' caused any economic injuries," HHS argued. "Rather, the court is left to speculate as to both the actual cause of any lowered Medicare payments, and whether the sought relief would redress those purported injuries.

"Third, plaintiff has failed to present to the agency a concrete claim for reimbursement and exhaust all administrative remedies, as required for a challenge arising out of the Medicare statute," HHS said. "For each of these reasons, the court should dismiss plaintiff's claims."

'Claims Fail on the Merits'

Then, HHS argued that the ACLA's "claims fail on the merits" when ACLA challenged how HHS interpreted the PAMA statute. "However, the agency logically defined 'applicable laboratory,' in part, as a laboratory that actually receives Medicare revenues by billing under its own National Provider Identifier (NPI) number," HHS argued. "This definition is in lockstep with the statutory directive, which states that an 'applicable laboratory' must be one that receives certain Medicare 'revenues.'"

Also, HHS added, "Plaintiff offers no workable alternative definition, let alone one clearly superior to that in the agency's Final Rule. Plaintiff thus provides no plausible basis for the court to find the agency's actions unreasonable, or arbitrary and capricious, and as a consequence this court should enter judgment for defendant."

laboratories reported as 'applicable laboratories.' This is approximately 3% of the more than 61,000 laboratories that Medicare Part B reimbursed in 2015," CAP wrote. By reducing the number of reporting laboratories, HHS excluded those labs that get higher reimbursement rates, harming all laboratories, it explained.

"The effect of this exclusion is far-reaching. According to 2017 data, hospital laboratories account for 48.2% of laboratory market share by test volume, while independent laboratories account for 29.5%. (**Quest Diagnostics** independently accounts for 9.8% and **LabCorp** 6.7%)," CAP wrote.

21 Hospitals Reported

As other briefs noted, only 21 hospital laboratories defined themselves as applicable laboratories under the secretary's definition, the CAP brief said. The result was that 1% of the reported test volume came from hospital laboratories while independent laboratories reported 90% of the test volume during the first reporting period, and physician office laboratories reported 7.5% of test volume, CAP added. The data the rule generates will therefore predominantly reflect the market for independent laboratory tests, said CAP.

The Effect of Skewed Data

"The impact of this skewed data reporting on the resulting reimbursement rates is profound," CAP explained. "Laboratories have different cost structures based on the types of services they offer and the institutional settings in which they operate. In particular, hospital laboratories have different cost structures than large national independent laboratory chains that are able to benefit from economies of scale and accept lower third-party payer reimbursement rates."

As lab directors and pathologists know, private payers recognize these differences in costs and rates. It is why health insurers reimburse many hospital laboratories at higher rates than they pay competing independent laboratories, it added.

If these arguments fail, Medicare patients will be harmed, the briefs explained. The patients most at risk are those with fewer choices of providers, and where providers are most susceptible to dramatic swings in payment rates, they said. *(See TDR, March 5, 2018.)*

Amicus Brief filed by:

AAB AMERICAN ASSOCIATION OF BIOANALYSTS

Among patients who are most at risk are those in nursing homes and other long-term care settings, those who live in rural areas, and those who are homebound, the American Association of Bioanalysts said in its brief, adding that one laboratory serving nursing homes has already closed and others are reducing or eliminating services because of the Medicare price cuts.

Even before Congress passed PAMA, there was little economic incentive for labs to serve the nursing home population. Serving this market now will become more difficult, AAB argued.

To support its arguments, the AAB brief includes a declaration from Annette Iacono, Vice-President of **Brookside Clinical Laboratory** in Aston, Pa. Brookside has 86 employees and 90% of its business is derived from serving patients in long-term care facilities, particularly nursing homes, Iacono said. Last year, Brookside performed approximately 598,817 clinical lab tests for residents at 90 nursing homes. The lab gets 85% of its revenue from Medicare, parts A and B.

In addition to serving nursing homes, Brookside has, until recently, sent phlebotomists to homebound patients. But, Iacono wrote, "We have already had to make the decision that we cannot afford to continue making home visits to homebound patients, and have started notifying our physicians."

Brookside is one of a few laboratories in an approximately 100-mile radius that serve long-term care facilities. Large independent laboratories typically find the labor costs are too high, profit margins are too low, and facilities tend to be too scattered, particularly in rural areas, for them to serve nursing homes, she added. TDR

—by Joe Burns

Attorney Says Labs Face Increased Legal Liability

New lab test referral arrangements and innovative pricing practices can be problematic

CEO SUMMARY: For many reasons, including cuts to lab test prices that health insurers pay, narrow networks, and more competition for lab test referrals, a significant number of lab companies are seeking ways to increase market share. These methods include the use of new laboratory test arrangements and innovative strategies for pricing lab tests. But an experienced lab industry attorney says that both of these areas can create problems for unwary laboratories.

CLINICAL LABORATORIES face increased risk of rigorous payer audits, legal actions, and more rigorous federal and state regulatory enforcement.

As clinical labs have taken on increased risks, so too have health insurers exerted more scrutiny over lab operations. Most labs are familiar with the pitfalls of developing new test offerings, expanding test menus, or entering new markets. As competition increases and payers shrink networks and reduce lab test prices, however, labs must consider how to reduce the effect of aggressive healthcare reforms and payment structures.

If improperly implemented, popular approaches—such as laboratory referral programs and pricing policies—can create added risk for labs. In a recent webinar for THE DARK REPORT, attorney Jeffrey Sherrin President of the **O'Connell & Aronowitz** law firm in Albany, N.Y., addressed the considerations laboratory directors must keep in mind to limit risk and reduce the chance of payer audits and legal action.

Sherrin's experience spans nearly 35 years representing laboratories and other providers across the country on matters related to fraud, investigations, audits, false claims, and regulatory compliance.

Serious Liability Issues

"In response to all of these financial, payer, and compliance pressures, labs are using a variety of approaches," said Sherrin. "Some approaches are not problematic, such as developing new test offerings. But I want to talk about two that are common and that can be fine, but also present the potential for serious liability issues if not done properly, and which therefore have to be part of every lab's compliance program.

"One approach that can be problematic is the new laboratory test referral arrangements popping up in most states," he noted. "The other issue is the new test pricing policies used by some labs.

"Before going further, I want to point out that there are a variety of federal and state laws that can be implicated, depending on how a laboratory company conducts business," emphasized Sherrin.

"These include:

- "The federal Anti-Kickback Statute, which bars payment for referrals;
- "The federal Stark Law, which forbids physicians from referring to an entity with which they have a financial interest; and,
- "The federal False Claims Act, which generally involves the making of any false statements in the submission of claims.

"Of these statutes, the key tool the government uses is the federal False Claims Act," stated Sherrin. "There are a variety of acts that can trigger a false claim, such as billing for tests that weren't ordered or performed, miscoding or upcoding, violations of regulations, and Anti-Kickback Statute violations.

"Next, labs must be concerned about state laws," he noted. "Many states have fee-splitting laws and their versions of anti-kickback laws. There are also many states with laws addressing fraud and abuse, anti-markup, and direct billing—all of which relate to the questions of whom the lab can bill and how much they can bill. Can you bill the physician? Can you bill an intermediary, or may you only bill the payer?"

Issue of Medical Necessity

At this point, Sherrin wanted to call attention to a new issue associated with allegations of false claims. "There is a growing storm over the lack of medical necessity that is now being used as the basis for alleging submission of false claims," he explained.

"There are currently federal court cases in which the sum and substance of the allegations are that labs have an independent obligation to assure the medical necessity of the tests for which they bill," said Sherrin. "Some payers have been contending that billing for tests that are not medically necessary constitutes a false claim, irrespective of the lab's reliance upon the referring physician's medical determination. That's triggering quite a firestorm and cases are being litigated now over those issues."

Three types of referral arrangements are particularly prone to liability and fraud concerns, Sherrin said. These are:

- Billing pass-through agreements,
- Participation in referral networks, and,
- Laboratory management services arrangements.

Three Types of Agreements

"These are probably the three [types of agreements] of which we currently see the most," said Sherrin. "To be certain that such agreements are in compliance, all participants must carefully vet them with respect to federal and state laws. It is equally true that these agreements must be vetted against the lab's contracts with payers.

"Don't overlook the requirements in the contracts your lab has with health insurers," he continued. "In looking at the transactions and pricing policies covered in your lab's payer contracts, you need to be familiar with what the limitations are on referring out and billing for referenced tests.

"Typically, payer contracts have provisions such that, if your lab will not perform testing, those tests your lab refers out must go to another in-network lab," said Sherrin. "Payer contracts also frequently have anti-assignment language, which says essentially that you can't assign your rights or obligations under the contract to anybody else. There will typically also be limitations on billing for referred services as to who can bill the payer."

Pass-Through Billing

Sherrin discussed the three new types of referral arrangements he identified earlier. "The first is a billing pass-through agreement. It gives rise to potential false claims if there is a misrepresentation as to which lab performed the test, or whether the performing lab was in-network or not," he said.

"Take the example of a billing pass-through agreement where laboratory A is out of network and laboratory B is in network," stated Sherrin. "Lab A performs

the test but has an agreement whereby lab B bills the test to the payer *as if it were done by B, an in-network lab*. Then, laboratory A and laboratory B—by some formula arrangement—share the reimbursement received from the payer.

"This arrangement will give rise to potential false claims if there's a misrepresentation as to which lab performed the test, or whether the performing lab was in network or not," he added. "Also, a payment arrangement involving fee-splitting may trigger anti-kickback concerns. The amount of the payment or the method of payment can also cause anti-kickback concerns."

Referral Network Model

The second type of referral arrangement seen more frequently is the referral network model. "I describe this model as a sponsoring organization, which is not a clinical laboratory, that creates a network whereby the members of that network can refer to other members of that network for tests that either they don't do or for which they are not in-network and thus for which they will not be paid.

"If not properly set up, these arrangements can be problematic," said Sherrin. "While they can also very easily be set up legally, payments to intermediary parties (such as third-party or contract sales representatives) are prone to added scrutiny from payers and regulatory bodies.

"Again, there's nothing necessarily wrong with that," he noted. "The problems usually arise with respect to how the intermediary is paid. Sponsoring organizations of these referral networks can be considered to be arranging or making referrals, such that payments your laboratory makes to those organizations can be considered a payment for a referral.

"Now, it may not be an illegal payment for referral, but it implicates the statute and creates governmental oversight," stated Sherrin. "Problems arise—particularly if the payment to the sponsoring organization is made on a percentage basis—such that your arrangement may trigger compliance issues with fee-splitting statutes or similar government regulations.

"Another consideration is whether or not the payment is in excess of what a fair market value rate would be for the actual linking service that the sponsoring organization performs," he added. "Any payment in excess of what might be a fair market value for that service can be considered an excessive payment and therefore payment for the referrals."

Lab Management Services

This same concern arises with the third arrangement structure Sherrin addressed—laboratory management services. "While common in the laboratory market, the methods by which payments are determined might leave labs susceptible to anti-kickback considerations," he added. "Labs should ask these three questions when considering a laboratory management service arrangement:

- "Are you paying it on a fair market value amount determined in advance, or is there fee-splitting involved?
- "Are there referrals back and forth between the laboratories, which usually is part and parcel of the management agreement?
- "If there are referrals back and forth, is the amount of payment made either for the management services or for the accessioning of the specimens in excess of what a fair market value arrangement would be?"

Sherrin's insights are based on his experience in working directly with client laboratories and other healthcare providers. In this role, he has studied the implications of these three forms of referral arrangements on behalf of labs, or hospitals, or office-based physicians. In a coming issue, Sherrin will discuss new pricing policies that many labs currently use. TDR

—Jon Stone

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Regulatory Update

Response to FDA's Gottlieb on Reducing Regulatory Burden

FDA chief's ideas are positive for labs, but an expert said the details will matter

IN PREPARED REMARKS at a clinical lab industry meeting last month, FDA Commissioner Scott Gottlieb, MD, outlined steps the federal **Food and Drug Administration** would take to reduce the regulatory burden on labs that develop next-generation gene sequencing and lab-developed tests. He also explained some of the ways that the agency could be more flexible in the way it assesses the analytical and clinical validity of new clinical laboratory tests.

THE DARK REPORT presented Gottlieb's key themes in its last issue. *(See "FDA's Gottlieb Favors Flexibility with LDTs, NGS," TDR, Mar. 26, 2018.)*

Concerns About Oversight

At the annual meeting of the **American Clinical Laboratory Association**, Gottlieb described how the FDA was considering efforts to qualify third-party reviewers, such as the **New York State Department of Health**, to help speed reviews and approvals for clinical laboratory tests, including LDTs. He said it also might be possible to exempt from premarket review certain individual tests that meet specific standards when the agency has confidence in the lab's underlying standards.

The clinical laboratory industry is likely to welcome such comments from the commissioner, especially given that, in October 2014, the FDA released draft guidance on a proposal that it called an oversight framework for LDTs and *in vitro* diagnostic tests.

At the time, pathologists, clinical lab directors, and physicians in academic institutions and other settings expressed concerns that the proposed oversight would slow innovation, create a needlessly burdensome and expensive review process, and potentially jeopardize patient care and continuing advances in personalized medicine.

Not all observers opposed the proposal, however. Some medical directors for health insurers, for example, were among those who expressed support for the FDA's oversight framework on LDTs.

In his remarks last month, Gottlieb said he was concerned that the FDA should be able to ensure that regulations keep pace with innovations as they occur in the market.

One reader of THE DARK REPORT responded to the story about Gottlieb's comments and provided a counterpoint. The reader asked not to be named.

The Self-Regulation Question

"Of course, the clinical laboratory industry generally will favor Gottlieb's approach, which is, essentially, self-regulation," the reader wrote. "In and of itself, self-regulation is not a problem, but doing it well and effectively would depend on the industry's willingness to be transparent and self-correcting.

"I would be hard pressed to name any for-profit industry in which self-regulation has worked well," he added. "Consider, for example, the oil and gas, tobacco, compounded drugs, and mortgage banking industries, among others. Clinical laboratories might be different, but, to date, we have no such evidence."

Devil in the Details

On the issue of exempting from pre-market review tests that meet certain standards when the FDA has confidence in the labs' underlying standards, our reader commented: "Regarding this proposal, as with many Gottlieb put forth, the devil is in the details.

"But, let's assume the FDA's proposal would be different from the same basic approach that the **College of American Pathologists** uses for its checklist," he added. "Even if it is different from that, how would the FDA assess and enforce compliance with such standards? Also, how would such standards actually be applied to individual tests?

"As CAP and CLIA demonstrate all too well, assessing the quality of a lab and its practices is certainly not the same as assessing the quality of a specific test from that lab," he wrote.

FDA and LDTs

Another concern involves having third-parties review LDTs. The FDA is considering qualifying the New York State Department of Health as a third-party reviewer, and the agency is seeking to develop what Gottlieb called a "flexible, modern approach to how it reviews next-generation sequencing."

Given that health insurers already struggle to approve many genetic and molecular tests for payment, they are likely to balk at both the idea for third-party review and a more flexible approach to approving NGS tests, our reader commented.

In addition, our reader added, the New York State Department of Health has approved tests that some observers say should not have been approved for analytical or clinical validity and would not have passed FDA's stringent review standards. But, even if the NYSDOH approves a test, such an approval does not guarantee health insurance coverage and payment, he added.

In his comments, Gottlieb frequently described the FDA review and approval process as a burden for lab-test developers. Of course, such review is not designed to be burdensome but rather is a necessary part of ensuring that patient care is not harmed, our reader commented.

The Regulatory 'Burden'

"It's amazing how frequently Gottlieb uses the word 'burden,'" our commenter wrote. "Calling out FDA review as being burdensome is almost counterintuitive. A significant part of the FDA's job is to ensure that tests do what they are designed to do, that they do not harm patients, and that they are analytically and clinically valid.

"How would the commissioner—or anyone—feel if we did away with the agency's review for a lab test that would be used on him or on a family member?" he asked.

In one final point, our reader added that it would be worthwhile to ask the FDA if it has ever retracted marketing authorization for a test once it was on the market.

"I say that because Gottlieb offered this idea about pre-market review but never discussed the need for post-market review," our reader concluded. "Post-market review would work only if the agency is willing and able to remove what might be called 'bad tests' after they have been on the market. Personally, I have little faith that the FDA has done or will do this."

THE DARK REPORT welcomes other opinions and comments on the subject of the FDA's proposals to regulate clinical laboratory tests. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Add Estonia to the growing list of nations that will now provide genetic information to its citizens. On March 20, the government rolled out an initiative that, in its first phase, will generate genetic information for 100,000 of its 1.3 million residents. This data will address an individual's genetic risk for specific diseases. The **University of Tartu's Institute of Genomics** will host the genetic testing service and information will be provided first to the individual's doctor. Genetic counseling will be part of the service.

MORE ON: *Estonia*

Estonia's announcement was not unexpected, as the nation established one of the world's first biobanks back in 2000. Estonia has a reputation for being innovative. The web-based service, *Futurism* says Estonia "was the first nation to ever hold elections via the Internet, the first to offer 'e-residency' for anyone in the world, and among the first to propose a national cryptocurrency."

OSCAR HEALTH RAISES $165 MILLION

Since its launch in 2012 as a new model of a health insurance company, **Oscar Health**, headquartered in New York City, has attracted much attention. Last month, the company announced it had raised $165 million from investors that included **Alphabet, Inc.**, the parent company of **Google**. Oscar says it will expand to 250,000 members in 2018 and has working relationships with several health systems, including the **Cleveland Clinic**.

AURORA ACQUIRES CASCADE PATHOLOGY

On April 9, **Aurora Diagnostics** of Palm Beach Gardens, Fla., announced its acquisition of **Cascade Pathology Services** of Portland, Ore.

TRANSITIONS

- **Cleveland Clinic** named Brian P. Rubin, MD, PhD, as Chair of the **Robert J. Tomsich Pathology and Laboratory Medicine Institute**. Rubin joined the Cleveland Clinic in 2006.

- Chris Callahan was appointed to be the Chief Commercial Officer for **PieranDx**, of St. Louis, Mo. He previously held executive positions at **Sunquest Information Systems**, **QuadraMed**, **Misys Healthcare Systems**, and **Cerner Corporation**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 7, 2018.