G2 INTELLIGENCE
A Bloomberg BNA Business
Bloomberg BNA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 35th Year of Publication

Vol. 14, Iss. 18, October 9, 2014

INSIDE *NIR*

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Lab Execs Air Concerns Over FDA Regulation of LDTs

The U.S. Food and Drug Administration (FDA) late last week officially issued its draft framework for how the agency plans to regulate laboratory-developed tests (LDTs).

The 41-page framework, which was released on Oct. 3 and is now subject to a 120-day public comment period that will extend into the middle of next February, is expected to shape the final rules the agency is expected to issue next year.

Most medical devices currently require some form of approval for the agency and vetting for safety and effectiveness before they can be sold to providers and members of the public. Tests that are sold in kit form to doctors or directly to consumers already require FDA approval.

The FDA announced last July that it intended to regulate LDTs in much the same way as it does medical devices, saying it was required to ensure patient safety, and rejecting the long-held tradition of analytically testing LDTs per CLIA regulations as no longer satisfactory. It noted that laboratory tests have grown more complicated over the

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Labs Briefed on Prepping for Potential Ebola Cases

The Ebola virus, once a curiosity Americans gratefully glimpsed from afar, has landed on U.S. shores and could soon create a quandary for hospital and standalone laboratories.

Not only have victims of the disease with U.S. citizenship been transported here to receive care far advanced in comparison to what is available in western Africa, but a resident of Dallas was recently diagnosed with the disease after initially being sent home as the result of a misdiagnosis. And many Ebola victims have been providers of health care services to previous victims.

That Ebola is in the United States and could strike again has raised anxieties. Some politicians and commentators have called for restricting entry to travelers from certain African countries. But whether or not such restrictions occur, laboratories are on the front line of diagnosing cases of the disease. What will they have to do in order to be both properly prepared and protect their personnel from contamination?

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Lab Execs Air Concerns Over FDA Regulation Of LDTs, *from p. 1*

decade and that the playing field was unbalanced, pitting some tests that had been submitted for FDA approval against those that had not. Altogether, the FDA estimated that there are some 11,000 LDTs on the market that have been created by more than 2,000 different labs. Many of those tests, it noted, were marketed nationwide, and some globally.

The draft framework has allowed for a modest number of operational exemptions from the FDA's plan to regulate LDTs based on their potential risk to patient safety. The FDA does not consider a test to be an LDT if:

- An entity that owns several clinical laboratories creates a test that is then transferred to another lab within its network;
- An academic institution develops a test that it then licenses to a private venture that owns a CLIA-certified laboratory, which then begins manufacturing and distributing the test; and
- An entity that creates LDTs and medical devices will continue to follow the existing regulations for medical devices.

Also exempted are any assays that screen for serious diseases or medical conditions in a patient who is asymptomatic and does not have access to any other test to confirm a diagnosis.

The guidance also places LDTs into three classifications, with the highest-risk assays, Class III, and the more moderate-risk Class II LDTs requiring FDA premarket approval and reporting of adverse patient events.

> *"It is going to have a chilling effect on our ability to get tests approved."*
> *—Edward Ashwood, M.D., Chief Executive Officer, ARUP Laboratories*

Filing and adverse-risk reporting of lower-risk Class I LDTs is mostly optional. The FDA plans to use a "public process" and advisory boards to determine the classification of new LDTs, although details were not provided in the document.

Labs developing LDTs have to begin notifying the FDA about tests they are developing and adverse events six months after the final guidework goes into effect, and begin filing for premarket reviews one year afterward. Some of the more arcane parts of the guidework will be phased in over the better part of a decade.

Lab Officials Are Concerned

Despite the exemptions and the stretched-out periods for the requirements, laboratory sector officials are concerned that the impact on their businesses could be profound.

"It is going to have a chilling effect on our ability to continue offering all the tests we currently offer," said Edward Ashwood, M.D., chief executive officer of Salt Lake City-based ARUP Laboratories. According to Ashwood, ARUP has nearly 1,400 LDTs. Sixty-one are considered high-risk tests and another 584 are classified as moderate-risk tests.

Francisco Velázquez, M.D., chief executive officer of PAML, the large Spokane, Wash.-based laboratory, believes that if the validations the FDA requires for medical devices are replicated for LDTs, it could become burdensome to certify many tests.

"We already do validations for LDTs, as good practice, but if we have to go beyond that, with prospective validation studies, or with larger numbers of subjects, or extend the temperature ranges for the tests or its reagents, that will be an impact, and it could become quite cumbersome," he said.

Altogether, PAML has about 250 LDTs on its menu, including 100 that focus on mass spectrometry and another 150 in broader areas of application, such as chemistry, hematology, and infectious diseases.

Smaller Labs May Be Disproportionately Impacted

Somewhat ironically, Velázquez believes the regulations could become burdensome for smaller labs, many of which have used their LDTs to try to maintain an edge in the health care market.

"This will be limiting to particularly smaller labs, hospitals, and clinics and others, and they may not have the resources to comply. Facilities with less resources are going to be less likely to go off-label," he said. "This will favor some of the bigger labs and players, and that is a paradox."

But even the larger labs may be challenged by the rules. ARUP's Ashwood noted that a large number of the lab's validation studies date back 25 years or more and were conducted by an employee who is now deceased, making appropriate submissions to the FDA unlikely if they are required. He estimates that ARUP could wind up abandoning as many as 400 of its LDTs. These abandoned tests are not ordered frequently and therefore don't have the margin to cover the cost of preparing premarket submissions.

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Ashwood also noted that one popular high-risk LDT of ARUP's, a genotyping test for hepatitis C, would require a premarket approval study and a clinical trial. The test competes with a kit manufactured by medical device giant Abbott, according to Ashwood. ARUP would not be able to complete a clinical trial in the time specified by the draft guidance and may be forced to pull the LDT and offer the Abbott kit instead.

By contrast, Ashwood noted that tests for glucose and creatinine levels—which could lead to significant health problems to a patient if misapplied—are considered to be moderate-risk LDTs.

The laboratory sector as a whole has also voiced its own concerns.

"Diagnostic innovation has thrived under the current regulatory framework and there is great concern in the lab community that additional and duplicative regulation will hamper the ability of researchers and scientists to continue their groundbreaking work," said Alan Mertz, president of the American Clinical Laboratory Association (ACLA).

The College of American Pathologists (CAP) struck a slightly more conciliatory tone than the ACLA. "The [College] will work to ensure LDT oversight assures quality laboratory testing for patients in a manner that is consistent with principles outlined by the CAP," said association President Gene Herbek, M.D. The proposed FDA guidance embodies a number of those key principles. Where there are differences, the CAP will work with stakeholders so requirements do not impede innovation or increase administrative burden on laboratories. The CAP will provide its recommendations and propose changes to improve the guidance during the public hearing and comment period.

As an alternative to FDA regulation, Mertz and the ACLA have advocated for changing and tightening up CLIA regulations in order to properly address the vetting and marketing of LDTs.

Velázquez believes that the CAP could also play a role in supervising LDTs.

"CAP has evolved their process and checklists over the past 30 years for the advance of new technology, and I think most laboratorians would be amenable of evolution instead of a whole new process," he said.

Alberto Gutierrez, the FDA's director of the Office of In Vitro Diagnostics, did not respond to a request seeking comment for this article.

Meanwhile, lab executives such as Ashwood said they will be advocating on their own, particularly as the public comment period moves along.

"I am going to try and rally this industry on the importance of this issue and write lengthy comments on the public draft guidance," Ashwood said. "We really have to dissect out the guidance and give feedback."

Takeaway: The FDA's move to regulate laboratory-developed tests will continue to receive ongoing pushback from the industry as the agency moves toward developing final rules.

Michael J. Fox Foundation Sues New Jersey Laboratory Over Storage Issues

A charitable foundation that funds research for Parkinson's disease founded by a famous actor has filed suit against a New Jersey research laboratory for allegedly destroying huge numbers of specimens through neglect.

The suit filed in U.S. District Court in Camden, N.J., earlier this month by the Michael J. Fox Foundation alleges that the Coriell Institute for Medical Research had inadvertently left a freezer open within the facility last spring, accidentally thawing more than 29,000 blood and cerebrospinal fluid specimens from Parkinson's patients that had been collected for scientific study.

According to the suit, the specimens were supposed to be stored at a temperature of more than 100 degrees below zero Fahrenheit, but Coriell breached that agreement when a freezer door was left open for an unknown length of time. The foundation entered into a $4.3 million contract with Coriell in 2011 to store the specimens.

"We take seriously our obligation to recoup financial costs associated with this sample loss," said foundation Chief Executive Officer Todd Sherer in a statement. The suit claims at least $150,000 in damages.

Michael J. Fox, who is best known for roles on the 1980s television comedy *Family Ties* and the *Back to the Future* movie franchise, was diagnosed with Parkinson's in the early 1990s. He created the foundation that bears his name in 2000, and it has become the largest nonprofit funder of research into the disease in the world.

The Coriell Institute said in a statement that it intends to vigorously defend itself against the suit.

Takeaway: Negligence issues in laboratories can arise from something as simple as allegedly leaving a door ajar.

Labs Briefed on Prepping for Potential Ebola Cases, *from p. 1*

That was the topic explored at a webinar held earlier this week by the American Association for Clinical Chemistry. The speakers were Nancy E. Cornish, M.D., a medical officer with the division of laboratory science and standards at the Centers for Disease Control and Prevention (CDC), and Sheldon Campbell, M.D., director of laboratories at the VA Connecticut Health System and an associate professor of laboratory medicine at the Yale University School of Medicine.

Indeed, Ebola anxiety has already reached into what are everyday practices for laboratory operations. According to Campbell, the Emory Healthcare system in Atlanta, which treated some victims transported from Africa, could only send its lab specimens to the nearby CDC headquarters. "Emory ran into shipping problems, and we're not entirely sure where in Connecticut we could transport a specimen to test it," he said.

Although Cornish noted that few viruses spread in the way of Ebola, commonsense measures should be in place, including the use of lab gowns, respirators, and eye protections for everyone operating in the lab. Campbell also ruled out the use of pneumatic tubes for deliveries. Containers should be rigid with capacity to retain any spills. Pathologists may also want to consider covering their slides during examinations in order to ensure the virus does not spread, although Cornish noted that such occurrences are unlikely.

When work is completed, there should also be a comprehensive plan in place for the safe disposal of biowaste. All surfaces should be cleaned with an Environmental Protection Agency-level hospital disinfectant.

Cornish suggested working at a biosafety level of four and that laboratorians follow the detailed guidelines issued by the CDC in 2007 for isolation precautions.

"It's not quick reading," she said of the 225-page document. "But it's well-written and evidence-based."

Campbell suggested that when it comes to Ebola, laboratorians should follow three steps suggested by a mentor, Joseph Bove, M.D., a professor emeritus of laboratory medicine at Yale: Protect the patient. Protect the lab. Protect the provider.

That is best accomplished by ensuring that the laboratory's plan is integrated into the plan of the entire facility, whether it is a hospital-based lab (likely the front line of Ebola diagnoses), standalone, or at the site of another provider, he said.

Moreover, Campbell also advocated clear routes of communication between the hospital and its laboratory.

"'Tell the lab' should be right at the top of the lists of things to do when a rule-out [a patient suspected of an Ebola infection whose status needs to be confirmed or denied] arrives at your institution . . . because none of your preparation will do any good otherwise," he said, adding that the work the lab is planning to do in such a situation should match what the hospital plans to do if they receive an Ebola case.

Planning, for the moment, should not be overly ambitious. "We may have to plan for large number of cases down the line, but we should plan for what we have now,"

Campbell said. That means the likelihood of dealing with more than one patient at a time is highly unlikely.

"A simple plan that is well implemented is better than a complex plan that is implemented badly," he observed.

Although Campbell acknowledged that lab personnel are no doubt a little anxious about the possibility of encountering Ebola, he was also quick to downplay the likelihood of them contracting the virus. He noted that it is more contagious than HIV but far less contagious than the flu. And proper precautions all but eliminate the risk of contraction. "No one who has worn proper [personal protective equipment] has ever caught Ebola," he said.

But that does not mean that even after taking proper precautions that lab personnel should assume that everything will be safe.

"Don't get nihilistic about [planning]," Campbell said. "But zero risk is not attainable."

Takeaway: Laboratories may have to take extra steps in order to be prepared to assist in diagnosing Ebola victims while safeguarding their staff.

UnitedHealth Group Launches Pathology Preauthorization Pilot in Florida

Laboratories are seeing a beacon in Florida. It is not coming from a lighthouse. It is related to UnitedHealth Group using LabCorp's Beacon management system to start a preauthorization program for pathology and lab services in the Sunshine State. The Minnesota-based health insurance giant launched a pilot program in Florida on Oct. 1. BeaconLBS is a LabCorp subsidiary that focuses on laboratory and medical practice consulting. Its software system had previously been marketed toward smaller and medium-sized labs to better manage their workflow and business operations.

In announcing the program earlier this year to its provider network in Florida, UnitedHealth said it was "to help improve quality of care and manage appropriate utilization for outpatient laboratory services." It will cover UnitedHealth's commercial lives, but not its large Medicare Advantage population or other books of business.

UnitedHealth spokesperson Tracey Lempner said in an e-mail that "any potential expansion of the program will be based off what we learn from the pilot." However, Lempner also noted that "any claim impacts related to the program will not go into effect until Jan. 1, 2015. This allows additional time for providers to acclimate to the program."

The preauthorization is fairly extensive. Physicians will have to submit requests for more than 80 different tests through the Beacon platform for payment approval. They include fairly basic tests, such as thyroid and urine panels and virtually all anatomic pathology assays.

But UnitedHealth's program does not stop at determining medical necessity. Many pathology assays require that the clinician have certification from the College of

American Pathologists. Some premalignant and malignant diagnoses may also require review by a second appropriately certified pathologist. That requirement pretty much applies to all cytopathology, dermatopathology, and hematopathology cases.

Pathologists have been reluctant to go on the record to discuss the pilot program, likely given that UnitedHealth covers 70 million lives nationwide and is estimated to book $130 billion in revenues this year—10 times the combined revenue of LabCorp and Quest Diagnostics.

"Wall Street doesn't care who does your read."
—Mick Raich, Chief Executive Officer, Vachette Pathology

However, there have been worries and grumblings about the program, particularly given that most pathologists have already been under financial pressure due to ongoing reimbursement cuts from the Medicare program and many payers using the relatively low Medicare rates as a baseline for commercial rates. Many pathologists have also been practicing for decades, and there is a belief among them that they can perform a large bulk of the hematopathology and other ancillary diagnoses without having to call in someone with additional specialty training.

Mick Raich, chief executive officer of Vachette Pathology, a Michigan-based pathology practice consulting firm, had a straightforward take on the situation: "United wants to pay the least amount they can; they will deliver any system in order to achieve that," he said.

Raich said that the Beacon system will be deployed by UnitedHealth as a "control usage tool," and that the demand for precertification will almost certainly drive down utilization immediately.

"Precertification is very unique. It is common in the radiology world (where a routine test can often cost four figures), but it is not common for a lab test to be precertified," he said.

On top of that, Raich noted that UnitedHealth will also likely pressure pathology practices and labs to continue to accept deescalating rates of reimbursement.

"United's a publicly traded company. If they can make 5 percent more cutting lab costs, they will," he said.

As for LabCorp's decision to license out its own software to cut down utilization—something that could wind up pressuring its own test volumes down the line—bottom-line considerations also likely played a role, according to Raich.

Eventually, Raich speculated, the overall plan among the payer community is to commoditize lab testing and reduce the skill factor of the pathologists hunching over the slides to render an opinion.

"Wall Street doesn't care who does your read," he said.

Takeaway: UnitedHealth Group is creating what could be the beginning of a comprehensive preauthorization program that could impact thousands of pathologists and laboratories throughout the United States. G2

Wrongful Termination Suit Claims Pennsylvania Hospital Lab Engaged in Medicare, Medicaid Fraud

Did the laboratory at Abington Memorial Hospital in Pennsylvania commit Medicare and Medicaid fraud?

That may eventually become a question for a jury to decide, as a former longtime employee has filed a suit against Abington, claiming its lab had been bilking the government by changing the way tests were being conducted and fired her when she complained.

The suit is not a qui tam, or whistleblower suit, which are filed under seal and usually are not made public unless the U.S. or state governments join such litigation. Instead, it accuses Abington of retaliating against an employee who tried to seek redress when she claimed other employees had been engaging in violating the federal False Claims Act.

Joanne Cleighton, Abington's patient access manager, had been with the hospital for more than 26 years when she was fired last March. Her most recent job performance evaluation was above the 90 percentile, according to the suit.

Where the two sides have butted heads are over Cleighton and Abington's management of outpatient blood tests and their reimbursement. Cleighton managed the staff who inputted blood test laboratory data. Tests for Keystone Blue Cross's Medicare Advantage and Medicaid managed care programs were outsourced to another lab, which apparently was part of their provider network.

According to the lawsuit, Cleighton had discovered last year that lab employees began systematically labeling routine Medicare and Medicaid blood work in a way that they received emergency or "stat" turnaround at Abington, which would receive the payments under those circumstances. Stat orders required a written order from a physician in order to be approved, and the suit alleges that lab staff were revising orders to suggest that the physicians had signed off on them.

Cleighton attended several meetings with lab staff where it had been acknowledged that such mislabeling was going on, but it apparently was not stopped, according to the suit. When Cleighton tried to meet with Abington's compliance officer, she claimed the lab staff began acting in a hostile manner toward her and that she was retaliated against, eventually being accused of violating patient privacy laws and using a racial slur in front of an employee. An internal human resources investigation later determined neither had occurred.

Cleighton was asked to resign not long after, her employer citing what was considered an inappropriate e-mail that had apparently been sent months earlier. She refused to and was fired instead on the same day she had been scheduled to meet with the hospital's compliance officer.

In a statement, Abington said it has not committed any wrongdoing and that it would vigorously defend against the allegations in court.

Takeaway: Can an unsealed wrongful termination suit play the same role as the traditional whistleblower litigation?

 National Intelligence Report (ISSN 2332-1458) is published by G2 Intelligence, 24 Railroad Street, Keene NH 03431-3744 USA. Tel: 800-531-1026 or +1 603-357-8101. Fax: +1 603-357-8111. Web site: www.G2Intelligence.com.

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