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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Be Careful Payers, You May Get What You Wish For!

FEW CLINICAL LABORATORY EXECUTIVES AND PATHOLOGISTS would disagree with the assertion that both government and private payers would like to see the prices they pay for medical laboratory testing and the amount of money they spend reimbursing labs to stay flat or shrink from one year to the next.

Certainly the actions taken by Medicare officials and private health insurers in recent years support that assertion. Collectively, the nation's payers have reduced substantially the amount of money they pay laboratories for tests. In this issue of THE DARK REPORT, we feature intelligence briefings on two new developments that mean less reimbursement paid to labs.

The first development is **UnitedHealthcare's** (UHC) new policy—effective May 1—that prohibits a hospital lab from submitting claims for a non-inpatient test to UHC under the hospital's facility participation agreement. *(See pages 3-5.)*

The second development is presented on pages 7-9. We report on the fact that many health insurers refuse to recognize clinical lab test claims submitted with PLA codes (proprietary laboratory analyses) or MAAA codes (multi-analyte assays with algorithmic analyses). This happens even after Medicare may have made a favorable coverage and reimbursement decision for a specific assay. Use of these codes was authorized under the Protecting Access to Medicare Act (PAMA) of 2014.

Government and private payers may see short-term financial benefits in their steady stream of slash-and-burn policies intended to greatly reduce what they reimburse labs for tests. But the collective clinical lab industry is quickly approaching the point where many community labs—including hospital labs that do outreach testing—fail to receive enough revenue to cover the basic costs they must pay to continue operating.

It will happen slowly and without much public notice. But as one community lab after another ceases operation, patients and physicians in those cities will lose access to accurate and speedy testing services. In turn, that will adversely affect physicians' ability to accurately diagnose and select therapies. If these situations cause a deterioration in patient care, that will mean higher medical expenses for payers—likely much more expensive than whatever savings they realized from cutting lab test reimbursement to below the cost of lab testing. Thus, payers may get what they wished for! TDR

New UnitedHealth Policy For Hosp. Reference Tests

Policy prohibits billing for non-inpatient tests under a hospital's facility participation agreement

CEO SUMMARY: Under a new policy UnitedHealthcare will start in May, hospital laboratories will no longer be allowed to bill for reference testing for members who are not hospital patients. The policy is likely to affect clinical lab testing for patients whose testing goes through a hospital's outreach program. UnitedHealthcare would prefer that all outreach lab testing be sent to its preferred network laboratories where payment rates are lower.

One of the nation's largest health insurers is taking decisive action to clamp down on hospital laboratories that submit lab test claims for outpatients and outreach patients using their hospitals' inpatient fee schedule. Starting May 1, **UnitedHealthcare** (UHC) implements a new policy designed to stop those billing arrangements.

Many hospital and health system laboratories have engaged in this practice for decades. After performing tests for outpatients and outreach patients, they submit claims using their hospital's high-priced inpatient price schedule—prices that are often double, triple, or more of what independent labs are paid by health insurers. Payers reimbursed for those claims at the inpatient prices.

Now UnitedHealthcare is taking steps to curb that long-standing practice. To address this issue, in its February network bulletin, it published the new policy, as follows:

> *For claims paid on or after May 1, 2020, hospitals acting as a Reference Laboratory or conducting diagnostic testing for non-patients cannot bill for such non-patient diagnostic laboratory tests under that hospital's Facility Participation Agreement. Hospitals wishing to participate in UnitedHealthcare's commercial network as a Reference Laboratory may apply with UnitedHealthcare to be credentialed and contracted as a Reference Laboratory.*

The new policy was a surprise to many clinical laboratory administrators and managers whose hospitals and health networks serve UHC beneficiaries. The policy is likely to affect clinical lab testing for

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patients in hospital outreach programs and for any testing done in physician office labs, lab consultants said.

"Essentially, this is about leakage," observed Mick Raich, CEO of **Vachette Pathology**, consultants in Sylvania, Ohio. "Any test performed for an outpatient or an outreach patient that is billed at hospital inpatient prices represents leakage out of UHC's reference laboratory network."

Responding to a request for comment from THE DARK REPORT, a UHC spokesperson said, "The information in our network bulletin reiterates that hospitals processing [lab] tests for non-patients need to be contracted with UnitedHealthcare as a reference laboratory."

Patients whose physicians send their blood work and specimens to a hospital reference lab through the hospital's outreach program will be the UHC members that are affected, Raich explained.

"Over the past several years, UHC has cut back on the clinical laboratory tests they cover," he added. "With this rule, they will exclude the highest-priced hospital labs from doing outreach testing on behalf of UHC beneficiaries.

Big Effect on Outreach

"UnitedHealthcare expects testing for these outreach patients will shift to the labs in its reference laboratory network," continued Raich. "These in-network labs do this outreach work for UHC for very low test prices and UHC doesn't want any lab doing this testing for more than that. In effect, via this new policy, UHC is shifting this type of lab work down to the lowest possible rate it can get."

The biggest national labs that are in-network with UHC are **Laboratory Corporation of America** and **Quest Diagnostics**.

If a lab test comes from a hospital in a health system to the core lab in that same system, UHC would pay for that test because it involves a specimen from a patient who's registered within that health system, Raich added. "But if a patient's specimen is coming from outside that health system, then that patient's test would not be covered.

"Let's say that patient specimen comes from an ambulatory surgery center or a doctor's office that's outside the hospital reference lab's health system. Then that would be outreach testing and would not be covered," he said. "Under its contracts, UHC wants that work to go to LabCorp or Quest or one of its network labs so that UHC can get a lower rate on that testing."

Adding Reference Tests

In recent years, many hospital labs have tried to boost revenue by increasing the number of reference tests they run, and much of that testing is done for consumers who are not hospital patients, said Ann Lambrix, Vice President of Client Services for Vachette Pathology in Sylvania, Ohio.

Such testing gets paid at a higher rate than it would generate otherwise simply because it is done in a hospital reference lab and billed using the hospital's inpatient price schedule, she added.

"These labs bill under their hospital contract, so they can get paid a favorable rate for that testing to offset the decrease in reimbursement that labs are experiencing throughout the industry," Lambrix explained. "UHC is saying it will not allow such billing starting in May.

"Instead, any hospital that wants to bill for reference testing will need to get a separate contract with UnitedHealthcare specifically as a reference lab," she advised. "Then, those rates will most likely be lower than what they currently bill.

Preventing Leakage

"In addition, UHC will probably not make it easy for hospitals to get those contracts because UHC would prefer to steer that testing to LabCorp and Quest," added Lambrix. "Clearly, UnitedHealthcare wants to drive lab test volume to its preferred network labs by preventing leakage out of its contracts with the large lab companies."

A Short History of Hospital Laboratory Outreach and the Two Most Common Pricing Strategies

HOSPITALS AND HEALTH SYSTEMS began to see opportunity in outreach laboratory testing during the second half of the 1990s. Two trends encouraged this business strategy.

The first trend was the consolidation of hospital ownership. Between 1994 and the end of 1997, almost 2,000 hospital acquisitions were completed and the number of multi-hospital health systems increased by 50%, from about 400 to more than 600. With between two and 10 hospitals now under single ownership, a logical step was for the health system to create a core lab and concentrate as much testing as possible in that facility.

The second trend involved hospitals purchasing physician practices during the 1990s. With these physicians now employees of the hospital or health system, it was an easy step for hospital administrators to want to capture their lab test referrals. The added benefit was now a single lab was doing all the inpatient, outpatient, and outreach testing for patients treated in these clinics.

Here is where the story gets interesting. Each time a hospital or health system decided to build its outreach business, a decision needed to be made: Should the outreach lab bill payers under the hospital's inpatient contract with payers, or should the outreach lab bill payers using the lower competitive prices offered by commercial lab companies?

Outreach Lab Strategies

Hospital lab outreach programs succeeded with either strategy. Some outreach programs, such as at **PAML** in Spokane, Wash., and **Consolidated Medical Laboratories** of Lake Forest, Ill., flourished while billing with lower, competitive prices.

Similarly, most hospital outreach labs that chose the path of billing with inpatient pricing did fine for decades because their claims were paid. But since 2010, payers began pressuring these programs to move to competitive pricing. That financial pressure was a factor in some hospitals selling their outreach programs. It is also one reason for UnitedHealthcare's new policy.

The new UHC policy may create an additional level of complexity for any health system that operates multiple hospitals and moves some inpatient testing from one hospital to another for testing, according to a healthcare lawyer who consults with clinical labs.

Some states have laws preventing hospitals from holding two CLIA lab licenses for the same lab space and same instruments, he said. That means a health system in those states could not establish a lab to do outreach work as a reference lab, while being a network provider that uses the same lab space that it uses for inpatient testing and bills under its facility participation agreement, he explained.

The UHC policy instructs any hospital that wants to continue as a network lab to contact a UHC network representative to begin the steps required to be credentialed and to contract with UHC as a reference lab. In its comments about the new policy, UnitedHealthcare said that, if the lab does not have such a contract, claims submitted for non-patient diagnostic laboratory tests, or claims for which a hospital is acting as a reference laboratory, will be denied for failure to comply with the new policy if the hospital submits bills under its facility participation agreement. TDR

—Joseph Burns

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Lab Marketplace

Healthcare, Lab Market Trends Central Focus at Exec. War College

POWERFUL FORCES ARE AT WORK transforming the U.S. healthcare system and the clinical laboratories that serve it. These forces will be identified and discussed at the upcoming 25th annual *Executive War College on Lab and Pathology Management*, which takes place on April 28-29 in New Orleans.

"Without question, the one trend that has the full attention of every clinical lab CEO and pathology practice business leader is how payers are slashing what they pay for lab tests," stated Robert L. Michel, Editor-In-Chief of THE DARK REPORT and Producer of the *Executive War College*. "To help labs respond appropriately to these payer actions, there will be experts and sessions dedicated to revenue cycle management, how to submit more clean claims, and ways to make coding/billing/collections more effective, to name a few.

"Plugging the holes in lab revenue caused by the different policies and actions of government and private payers is the immediate priority, but lab leaders also need strategies that align their organizations with the fundamental changes in the delivery of healthcare that are happening today," continued Michel.

Labs Getting Paid for Value

"One important trend is the shift away from fee-for-service payment and toward different models of value-based reimbursement," he said. "Several speakers will lead sessions on how their labs are getting paid for delivering actionable clinical intelligence to physicians and payers in real time, thus creating a new source of revenue."

One learning track at the *Executive War College* will deal with consumers as the drivers of change, informed by transparent prices and easy access to provider outcomes. Another learning track will cover how labs are succeeding with Clinical Lab 2.0 projects, sharing how they engaged payers, ACOs, and others in ways that allowed them to deliver more value—and be paid for that value.

Response to Coronavirus

There will even be a session on how one major health system laboratory responded to the ongoing outbreak of the novel coronavirus. Keeping with this topic, all systems are "go" for the *Executive War College,* for an interesting reason.

"As of this date, lab professionals are registering for the *Executive War College* at or above the level of last year," observed Michel. "We attribute this to a simple fact: Lab managers and pathologists have training and experience in lab medicine which helps them understand that—as the usual end of the flu season arrives by late March—there is a high probability that new cases of influenza and the novel coronavirus will fall to low levels. This was true of the outbreaks of SARS in 2003 and MERS in 2012."

Two optional, one-day workshops will take place at *EWC* on Thursday, April 30 (*www.executivewarcollege.com*). They are:

- Anatomic Pathology Gamechangers: How Digital Pathology, Precision Medicine, and More Can Generate New Revenue Streams and Grow Pathologist Income; and,
- Lessons from Clinical Lab 2.0 Innovators: Creating New Revenue Streams for Your Lab, Ways to Add Value, How to Engage Payers. TDR

Insurers Are Rejecting Many PLA, MAAA Codes

Hope fades for labs expecting to get paid for new PLA, MAAA codes that PAMA authorized

CEO SUMMARY: Clinical labs developing innovative tests face a challenge getting paid. While Medicare may reimburse for these tests, some commercial payers and state Medicaid programs are not paying for new proprietary laboratory analyses (PLA) codes and multianalyte assays with algorithmic analyses (MAAA) codes. For labs running these tests, experts say the codes themselves bias payers against payment.

When the Protecting Access to Medicare Act (PAMA) was enacted in 2014, some clinical laboratory directors expected that the law would improve billing and payment for new proprietary assays and that new codes would make it easier for payers to make coverage decisions for these tests.

But six years later, this little-known element of PAMA worries lab directors seeking payment for proprietary laboratory analyses (PLAs) or multianalyte assays with algorithmic analyses (MAAAs). The PLA codes were added to the current procedural terminology (the CPT code set) that the **American Medical Association** CPT Editorial Panel oversees.

PAMA designated certain tests to be included as PLA and MAAA codes along with:

- Advanced diagnostic laboratory tests,
- Clinical diagnostic laboratory tests,
- Genomic sequencing procedures (GSPs).

PLA codes are alpha-numeric CPT codes and include a description for the test in question, according to the AMA. Tests with PLA codes must be performed on human specimens, and labs that offer these tests must ask the AMA to issue these codes.

In recent months, the PLA and the MAAA codes have been particularly troublesome, according to consultants working with labs running these tests.

New Kinds of Lab Tests

"The PLA and MAAA codes were added because labs and the AMA needed to be specific about the kinds of new tests labs were developing," said an industry expert who asked not to be named. "Previously, too many general categories of tests were lumped together into one category with all the other CPT codes."

The new tests with PLA and MAAA codes came from the MolDx program that McKesson developed. **Palmetto GBA**, a Medicare Administrative Contractor, implemented that program for labs seeking approval for assays that do not fall into the more general categories of tests.

"PLA and MAAA codes were intended to be used to identify new and more unusual tests than Medicare, Medicaid, and commercial insurers may have paid for previously," the expert commented.

"Instead, these new codes now serve as a red flag for insurers who use these codes to identify tests that they label as being experimental, investigational, or for research purposes only.

"So, while the idea of using PAMA to establish more specific codes was a good one, implementation of these codes has become a nightmare for some labs," added the expert. "Labs performing tests billed with these codes may be able to get Medicare to pay for these assays. But often other payers—meaning commercial insurers and state Medicaid plans—reject claims with these codes without doing much to review the validity of these tests. Sometimes, payers don't review the value of these tests at all.

"While Medicare payment is welcome, that action alone does not persuade many commercial insurers or state Medicaid plans to follow suit," they commented. "In fact, many commercial plans don't recognize PLA codes at all. There's a disconnect between the concept of using a new set of codes and implementing that concept. For labs running tests with these codes, the implementation is not going well at all."

PLA, MAAA Codes

Some commercial payers and state Medicaid plans pay for some tests with PLA and MAAA codes, said Scott Liff, President and CEO of **Kellison and Company**, revenue cycle management consultants. "One interesting development is that, although payment for tests with MAAA codes is higher than it is for tests with PLA codes, the overall reimbursement for tests with MAAA codes continues to be much lower than the reimbursement commercial payers and state Medicaid programs pay for clinical lab tests with standard CPT codes," he added.

One problem labs face is that when a physician orders a test with a PLA or an MAAA code, the lab will analyze the specimen and produce a result but then won't get paid, leaving the lab with increased costs and no revenue unless it can appeal the denial successfully.

As a result of a large number of denials for tests with PLA and MAAA codes, innovation is stifled.

Codes Could Help Innovation

"When these codes first came out, labs thought they had an opportunity to develop innovative and creative tests to solve problems that their referring physicians faced when treating patients," the expert explained. "But instead, innovation, creativity, and problem-solving went nowhere because labs couldn't afford to develop new tests if there was no reimbursement for them.

"Even though Medicare may pay for an innovative test, that payment alone is useful but the rest of the market for these tests, meaning the universe of payers, is almost nonexistent," the expert said.

"So, a lab would spend money to develop the test in the innovation stage when there's no revenue yet," he explained. "Then the lab would go through all the steps necessary to validate that test and then it can market the test to physicians treating patients.

"If Medicare approves the test, that lab might generate revenue from that assay but then the lab must spend as much if not more to prove to other payers that it's a useful test," the expert explained. "Doing more studies to produce more evidence of utility costs the lab money, but that work does not generate revenue.

"At the same time, health plans will say they don't have the expertise, or the staff, or other resources to review the validation data for each new test that labs propose for payment," the expert commented. "That may be true or not, but we've seen many payers that simply are not interested in determining if tests with PLA or MAAA codes have any value to their physicians or to members.

"It's almost as if many payers are simply seeking a way to say 'No, we don't pay

For Texas Lab, Medicare Approval for Its Test with a PLA Code Didn't Help with Other Payers

LATE IN 2018, THE FEDERAL CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) agreed to cover a new test that physicians use to monitor patients for compliance with prescriptions for pain medications. After agreeing to cover the test, CMS added it to the 2019 Clinical Laboratory Fee Schedule.

That decision was a milestone for **Firstox**, a toxicology lab in Irving, Texas, that has a blood test called "AssuranceRx Micro Serum" to assess patient compliance with pain medications and opioid prescriptions, according to Firstox CEO M.P. George. Firstox developed this proprietary toxicology test that uses two drops of blood from a fingerstick to assess for the presence of more than 35 pain medications, George said.

Before George could offer the test, he needed to request a proprietary laboratory analysis (PLA) code from the American Medical Association's CPT Editorial Panel. In 2017, he made that request and the test was classified as PLA 0054U, meaning these five digits were tacked onto the CPT code.

Once George had the PLA code, he sought approval and pricing from CMS. When CMS added the test to the 2019 fee schedule, the agency agreed to pay $165 for each use of the test.

While George heralded the CMS approval, obtaining payment from other health plans has been mixed. Some state Medicaid programs pay for the test, but not others. Some insurers refused even to review the evidence from a clinical trial that Firstox conducted comparing AssuranceRx with urine drug testing.

"Some payers recognize the test, including **UnitedHealthcare** and the **Blues** plans in Texas and Illinois," George said in an interview with THE DARK REPORT. "But others do not, such as **Cigna**. And, most state Medicaid plans do not recognize it." Firstox uses an algorithm it developed to indicate the patient's dose compliance for opiates and opioid drugs, he added.

For George, such payment refusals are frustrating because clinical trials are supposed to be the gold standard that insurers say they need for coverage decisions, and the fact that Medicare added the test to the CLFS should send a positive signal to other payers, he said.

"For our company, payment denials from health insurers and state Medicaid programs have cut into lab revenue each month," George explained.

"Our lab has 27 employees and we do 2,000 to 3,000 tests each month, but 90% of the volume is for the AssuranceRx Micro Serum test," he said. "The other 10% is for urine drug tests. Among those 90% of tests, payers reject about 25 requests for payment every day. That number of denials cuts into the lab's revenue by about 10% to 20%."

When asked why some payers might reject requests for payment, pathologist Frederick Kiechle, MD, PhD, a consultant to clinical labs and pathology groups, said that many payers recognize tests with G-codes as a red flag that a test could be suspect. Also, he added, some payers want to hear a fuller explanation of some of George's claims about the validity of the test.

for new tests, especially unusual ones,'" he added.

"In essence, PLA and MAAA codes act like a red flag showing that these tests are innovative and that they may fill a void; however, many labs can't even get payers to evaluate these assays," the expert concluded. "In that way, these new codes are stifling innovation in labs." **TDR**

—Joseph Burns

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Lab Will Have Capacity to Handle Large Volumes of Tests

Northwell Lab Team Validates COVID-19 Test on Fast Timeline

CEO SUMMARY: Clinical labs are working with haste to test for the novel coronavirus, also called nCoV and SARS-CoV-2. Their efforts to prepare for high capacity testing for viral respiratory illness include validating molecular tests for the newly-identified virus and making those tests available for testing patients who may have the COVID-19 illness. At Northwell Health, the lab team has been validating the CDC's manual test and a multi-test panel for respiratory diseases that will include the novel coronavirus.

Following the outbreak of a novel coronavirus in China at the end of December, clinical laboratories have faced multiple significant challenges.

Among the challenges they face are validating a diagnostic test for the virus that has the sensitivity and specificity to make it useful for physicians treating patients and working with public health officials to manage a rapidly evolving epidemic.

Another of these challenges is to develop the ability to perform these tests at high volume levels and with a fast turnaround time for results. While seeking to meet all of these challenges, clinical labs also must comply with federal and state regulations that govern the use of these assays.

In mid-January, scientists in China released the genetic information for this novel virus. At that time, the leaders and staff in the clinical laboratories of **Northwell Health** in Lake Success, N.Y., recognized the need to be able to validate a test that the federal **Centers for Disease Control and Prevention** (CDC) would release, and then be able to run that test in enough numbers to meet an unknown level of demand.

As one of the nation's biggest health systems, Northwell has 23 hospitals and a central reference laboratory serving both Northwell and other hospitals in the greater New York metropolitan area, making Northwell's lab one of the largest in-system clinical laboratories in the United States, according to Stefan Juretschko, PhD, D(ABMM), Northwell's Senior Director of the Division of Infectious Disease Diagnostics. Juretschko is leading the systemwide efforts to increase the labs' capacity for testing for the novel coronavirus that causes the coronavirus disease (COVID-19).

The virus was unknown before late last year when it was identified in patients in Wuhan City, in Hubei Province, China. At the time, the virus was named 2019-nCoV, and by early March it was named SARS-CoV-2, the federal **Food and Drug Administration** (FDA) said. As of the end of the first week of March, the illness had spread to 93 other countries, infected more than 101,927 people (including 80,813 in China), and caused more than 3,486 deaths (including 3,073 in China), according to a **World Health Organization** (WHO) report on March 7.

Shortly after scientists in China made public the genome sequence of the novel coronavirus on Jan. 12, and public health officials began reporting the number of infected patients and deaths, federal and state health authorities began inquiring about the capacity of hospital and health system labs to identify the virus in patients. Such inquiries combined with daily and hourly breaking news about the virus created a dynamic working environment in labs nationwide.

As soon as the test kits arrived from the CDC and from the **New York State Department of Health** (NYSDOH), Juretschko, other lab directors, and the lab staff began the steps required to validate and run the test in Northwell's labs. Also, the lab began acquiring new analyzers, testing supplies, and reagents from vendors nationwide to support their efforts to run large volumes of tests for patients and their physicians.

Working Day and Night

During an interview with The Dark Report on March 4, Juretschko outlined those processes and said he was confident that **Northwell Laboratories** would be capable of testing patients in large numbers by the end of March. Since the middle of January, Juretschko and other lab staff have worked night and day to scale up testing for the virus, he said. During this time, events in other countries and in the United States began to unfold quickly.

For example, on Jan. 21, officials from WHO conducted a field visit to Wuhan, when Chinese scientists released the primers and probes for test kits that labs in other countries would use to detect the virus.

On Feb. 4, Alex Azar, the Secretary of the federal **Department of Health and Human Services**, issued an emergency use authorization (EUA) saying that the coronavirus created a significant potential for a public health emergency that could affect national security or the health and security of U.S. citizens. That same day, the FDA issued an EUA allowing the emergency use of the

CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel.

Under this EUA, testing was limited to qualified, CDC-designated, and CLIA-certified laboratories to perform high-complexity tests. The clinical labs at Northwell Health meet these criteria.

Emergency Use Tests

The FDA then issued two EUAs on Feb. 29. One outlined the policy-specific guidance that public health laboratories needed to follow to contain the public health emergency. The second EUA allowed two public health laboratories in New York to expedite the availability of diagnostic testing. The two public-health, CLIA-certified labs were the **Wadsworth Center** at the NYSDOH and the **New York City Department of Health and Mental Hygiene**, Public Health Laboratories.

"The EUA required labs to follow specific procedures when seeking to produce assays and test kits for identifying the virus, a process that slowed Northwell's efforts," Juretschko said. For individuals who meet the CDC's criteria for such testing, the FDA's instructions called for collecting upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).

Significant Progress

Since then, Northwell's lab staff has made significant progress in drafting plans for the tests, and to have the equipment and supplies in place to test an unknown, but presumably large number of patients.

By March 7, lab leaders were deep into validating the test kits received from the CDC and preparing to validate test platforms from commercial companies such as **GenMark Diagnostics** in Carlsbad, Calif., and **Cepheid** in Sunnyvale, Calif., Juretschko explained. He expected the lab to complete validating multiple platforms for identifying the virus by March 15 or so. "We did all of this preparation work without getting any material or funding whatsoever from the CDC or NIH," Juretschko said.

"But we did get a visit from New York Sen. Chuck Schumer," he noted. "And New York Gov. Andrew Cuomo has promised to make some capital available to us in some fashion. Plus, we learned recently that we will shortly get some quality control material from NYSDOH that is not infectious. It is contrived material that we will use for quantitative analysis.

Testing at Scale

"We are developing a three-pronged approach to do testing on a large scale," Juretschko reported. "The first approach is to implement the original assay that the CDC and all public health laboratories use, along with controls and detailed directions.

"The second approach is to use a device, similar to a commercially-available respiratory pathogen panel to test for the novel coronavirus," he added. "This panel allows for more mobility and flexibility in testing because we can provide the assay directly to the hospital laboratories.

"The ability to apply for an EUA opened up opportunities for labs like ours to do research on how to get these tests running on a larger scale," Juretschko explained. "For example, we used the EUA to have conversations with three vendors to get the tests and the equipment we need to serve our health system.

"The approach would entail an even more automated process for testing on several big-footprint instruments," he continued. "These analyzers are already placed at the core laboratory and can be 'fed' with the original patient samples, processed internally by robot arms, and thus allow for extremely high throughput testing of 1,000 to 2,000 patients per day. The actual assays and reagents have yet to be designed and validated, but we expect to launch those assays and reagents within the next several weeks."

Validation of the COVID-19 Test Requires Lab to Undertake Numerous and Complex Logistics

TO VALIDATE THE CDC'S TEST for the novel coronavirus that causes the coronavirus disease (COVID-19), the lab team at **Northwell Health** found that it "had numerous and complex logistics to work out, such as the positive controls and negative controls, the limit of detection, sensitivity, specificity, and so on," said Stefan Juretschko, PhD, D(ABMM), Northwell's Senior Director of the Division of Infectious Disease Diagnostics.

"As one example, when we look at sensitivity of these tests, we want to know the number of copies of the virus per milliliter of sample," explained Juretschko. "In terms of specificity we want to know if it can actually detect the virus itself or whether it's accidentally detecting something that it shouldn't detect. And here we want really high specificity, such as in the upper 90% or better range.

"Inactivated samples of the virus in different concentrations can be ordered through the CDC and sent to us via courier. We tested those samples side by side with real patient samples here at the core laboratory," he explained. "Those are the technical aspects of the tests, but there are other aspects to be decided about these tests as well.

"For example, how can physicians order the test, who can order it, and is there a restriction on ordering?" he asked. "We need to know if the test detects the one virus—meaning the novel coronavirus—or also detects influenza A and B, RSV, and other viruses. Also, what is the test's negative predictive value?

"We are working with the NYSDOH to have a batch automated test kit. This means we'll be able to run a number of those tests all at once," he reported. "When each test batch is done, we'll load another batch of tests on that same machine, and so on."

Batch processing enables Northwell to test as many patient samples as the number of wells (96) that the machine can handle at one time, he said. Although that batch number is still a limiting factor, this automated processing will vastly increase testing capacity at Northwell Laboratories, he added.

"The test from the CDC is an "old-fashioned," but very reliable and precise polymerase chain reaction (PCR) test, where you have to extract the nucleic acid, which in this case is the RNA," he explained. "A reverse transcriptase will follow along with the actual detection of the virus, which happens in a different instrument.

"Extraction takes place in the first machine, and that process runs for about an hour," he added. "The extracted material is then combined with the testing reagents and run on a different machine for about an hour-and-a-half to two hours. The whole process from start to finish takes about three-and-a-half to four hours.

Core Lab Testing

"This batch test will be done in our core lab, which serves all the hospitals that do not have testing in-house, including affiliated hospitals that use us as a reference lab," he reported. "Our core lab has two instruments for this test and each instrument can test a plate with 96 wells. Every patient sample requires four wells, meaning we can run about 24 patients per batch, thus the two machines can handle 48 samples about every three to four hours.

"We plan to double our capacity by adding two more PCR analyzers. With four machines, we'll be able to run 96 samples every three hours. Then, because these machines will run 24 hours per day, we can analyze up to 768 samples per day at full capacity, which is more than 23,000 samples per month," he said.

Before going into detail about the second approach (using the respiratory pathogen panel), Juretschko outlined the first approach: validating and running the test from the CDC. "The CDC has its own validated assay," he explained. "It's distributing this assay to all departments of public health across the United States. That assay includes all details about probes and primers and the entire standard operating procedure for the test."

During the interview on March 4, Juretschko said the lab team was at the end stage of the validation process to run that test in the lab. Via email, he confirmed that the process was completed on March 7.

While CDC validated the test itself, the Northwell lab staff needed to validate the CDC assay on its own equipment and in the laboratories in which it will run, he said. That validation includes ensuring that physicians can order the tests electronically, and also that the results can go back to ordering physicians.

"Plus, we want to make sure that physicians can read and understand what the results mean," Juretschko added.

Parallel Effort

The lab team's multi-pronged strategy, as Juretschko described, is to scale up the novel coronavirus testing by first using the assay from the CDC. In a parallel effort, the lab will use an automated respiratory pathogen panel from GenMark and other vendors. As Juretschko explained, the work the Northwell lab team is doing to prepare to do high-volume testing for the novel coronavirus provides an excellent example for other labs in hospitals and health systems of the benefits of having a highly-integrated in-system laboratory network.

"Our core lab serves our very large health system and an additional 11 area hospitals as the reference lab," he said. "And in our own system hospitals, the clinical labs are already equipped with the Respiratory Pathogen (RP) Panel from GenMark. This means that, if we successfully validate the GenMark platform, we can deploy such testing throughout the health system, not just at the core lab.

"The RP panel is a sample-to-answer test, which means the sample is put in a cartridge and that cartridge is then put into the analyzer. The operator can walk away and go do something else for 90 minutes or so," he added. "Once the analysis is complete, the results are available without additional labor or input.

"Thanks to the usual needs for respiratory virus testing, we have one of these instruments in every one of our hospitals," Juretschko reported. "In one cartridge, the panel can test for influenza, including influenza A and influenza B, and for respiratory syncytial virus (RSV).

"In addition, we have a more complex panel in some of our largest hospital labs that test for more than 20 targets, including flu A and its subtypes, H3N2 and H1N1; flu B; the four types of coronavirus that were identified in earlier epidemics; the 2009 swine flu; RSV; and others," he said. "About four to six companies make these larger test panels.

"Our immediate goal is to get a test for the novel coronavirus under the EUA, and then work with the NYSDOH and the FDA to add the novel coronavirus testing to the panels these companies already offer," Juretschko explained. "We expect to get validation of the test panels going soon, because they have been designated for research use only (RUO) and some are available for use already.

"It's important to note that the testing reagents in the panel are based on the virus' RNA structure, meaning the tests are similar to what the CDC assay offers," he added. "The key difference is that CDC sent us the primers and probes needed mainly for manual testing, whereas the panel kits enable automated testing.

"Using the panel kits has a lot of advantages," he commented. "First, automated cartridge-based testing provides an answer within 80 to 90 minutes, with very little manpower needed. Second, deploy-

ment to all the hospitals that have that analyzer can be done immediately.

Third, a technologist can run the updated panel with very little in-service training, since they are already familiar with the testing platform," he said. "And, fourth, we can further expand our system capacity by acquiring additional machines.

"We're already talking to the vendor about whether we should buy some of the smaller instruments and put them in all of our hospitals," he added. "We haven't made a decision yet, but that's an approach we're considering."

Instruments in All Hospitals?

"Having full capacity for local hospital testing would shorten turnaround times tremendously because samples would not need to be sent to the core lab for testing," Juretschko explained. "Such rapid resulting—within two hours—would have significant value for managing patients, triaging in emergency departments, and in managing the healthcare workforce."

With sufficient testing capacity, using the complex test panel will give Northwell an important advantage for any patient who goes to a doctor with flu-like symptoms, he said. That patient would be tested for a wide variety of viruses and get an answer quickly. "Many of those patients would be in the clear, and others would learn if they have the novel coronavirus and can take appropriate steps," he noted.

This multi-pronged strategy enables Northwell to achieve a quick launch with the CDC assay, while simultaneously gearing up for high testing capacity using commercially-available automated platforms. Since the end of January, at least two companies announced that they would offer tests for such analyzers.

On Feb. 10, Cepheid said it was developing an automated molecular test for the qualitative detection of the novel coronavirus for its GeneXpert Systems, and that the tests could deliver point-of-care results in about 30 minutes. On March 2, GenMark announced it shipped RUO test kits to detect the SARS-CoV-2 virus and that it would submit an EUA to the FDA for this test.

After working with these vendors and validating the tests, Juretschko predicted that by about the middle of April, Northwell labs would be ready to test large numbers of patients with fully-validated assays.

"By that time, I expect that the whole picture will be turned around so that we're no longer validating and working to get the right equipment and test kits here, but we are at the point of testing a lot of patients quickly and efficiently," he said. TDR

—Joseph Burns

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Origins of the Novel Coronavirus

AT THE CENTERS FOR SYSTEMS SCIENCE AND ENGINEERING (CSSE) AT THE JOHNS HOPKINS WHITING SCHOOL OF ENGINEERING, researchers tracked the novel coronavirus since the pathogen was identified.

On the CSSE site, researchers reported that on Dec, 31, the World Health Organization learned of a case of pneumonia of unknown cause in Wuhan City, Hubei Province, in China. By Jan. 23, there were more than 800 cases of the virus confirmed worldwide, including cases in at least 20 regions in China and nine countries or territories, CSSE reported.

Among the first infected individuals were some who showed symptoms as early as Dec. 8 and were stallholders from the Wuhan South China Seafood Market. That market was closed on Jan 1.

On Jan. 10, gene sequencing showed the pathogen was a new Wuhan coronavirus—2019-nCoV—a betacoronavirus, related to the Middle Eastern Respiratory Syndrome virus (MERS-CoV) and the Severe Acute Respiratory Syndrome virus (SARSCoV), CSSE reported.

COVID-19 Patient? Northwell Has Mobile Phlebotomy App

➤Smartphone app schedules mobile phlebotomist for home draw; useful with coronavirus outbreak

➤➤CEO SUMMARY: What better way to limit the spread of a deadly novel coronavirus than to allow patients who suspect they have the COVID-19 illness to use a mobile phone to book an appointment with a phlebotomist who makes house calls? Northwell Laboratories started this service in November and now views this option as a preferred method of collecting naso-pharyngeal swabs and sputum specimens to test for the virus.

While traveling last year, members of the leadership team at **Northwell Laboratories** used a mobile-phone ride-sharing app to hail a taxi. The routine use of a telephone app to call for a cab prompted a discussion among those lab leaders about the possibility of allowing Northwell patients to use a similar app to call for a mobile phlebotomist.

"Almost immediately, we recognized this was a great idea," said Dwayne Breining, MD, Executive Director of **Northwell Labs**. By the end of the year, Northwell Labs of Lake Success, N.Y., made the app operational across Long Island, throughout Westchester County, and all five boroughs of New York City.

Then, just five months later, the world became transfixed watching news about the outbreak of a novel coronavirus. Northwell's lab team immediately recognized that their smartphone app and mobile phlebotomy service were ideal tools to help Northwell and its patients contain infections from the virus.

Rather than risk patients spreading the illness to members of the public while traveling to a doctor's office, to one of 23 Northwell hospitals, or to other patients in an emergency room or urgent care center, patients who suspect they may be infected can use the app or call Northwell to request a mobile phlebotomy visit, Breining explained.

➤Phlebotomists On-Call

For more than 10 years, Northwell Labs had offered a mobile phlebotomy service for homebound patients on Medicare and Medicaid. Therefore, the mobile app—called LabFly—became a natural extension for patients who would use a credit or debit card for payment, Breining added. Patients can download the app from the app store on their mobile phones.

For patients with commercial health insurance coverage, most payers will cover the cost of the lab test itself, but are unlikely to pay the $20 that Northwell charges to send a mobile phlebotomist to the patient's home, he said.

In November, Northwell introduced the service in Brooklyn, Long Island, Manhattan, and Staten Island. In December, it launched the service in the Bronx and throughout its service area.

By calling for a mobile phlebotomist, patients can skip a visit to the emergency

room or a patient service center for a blood draw and other such specimen collection, such as the nasopharyngeal swabs used to collect samples from patients suspected of having the COVID-19 illness, Breining said.

"Whether it's young children who are anxious about a blood draw, busy professionals, or someone being cared for, this app is a way to help fulfill patients' needs," he commented. Since the app went online last year, some 28,000 people have downloaded it, leading to hundreds of home phlebotomy visits, he added.

"We do a large volume of lab tests for patients in nursing homes and long-term care facilities, so the mobile phlebotomy service is always busy," he said. "I estimate that we do somewhere around 300 or so home phlebotomy visits every day.

"Patients who need mobile phlebotomy are those who are bedbound, or they're being treated at home, or they simply can't leave their house for whatever reason: medical condition or inconvenience," he added. "We already had a staff of mobile phlebotomists who could drive anywhere in our service area to get patients' samples, which means we had the staff and the infrastructure in place.

App for Mobile Phones

"That made it relatively simple to set up the LabFly service," continued Breining. Northwell contracted with a vendor to develop the app for mobile phones. Now it's available from the **Apple** or **Google** store.

"In this way, we've opened up our mobile phlebotomy service to the general public—meaning those who are not classified as 'homebound' by Medicare or Medicaid," he said.

"Before we offered the app, we surveyed patients and tested the concept extensively," Breining reported. "We live in a time when people are using ride-sharing apps, but also they're routinely using apps like **Grubhub** to get take-out meals delivered," he said. "Because they have that experience, they're willing to pay a reasonable extra charge for the additional service.

"Sure enough, our surveys and concept testing showed there was a market—and, in fact, a lot of interest among patients—for having us come to them rather than require that they come to us," he commented. "We already know that no one wants to go to a hospital emergency room or a patient service center if there's a better option."

Phlebotomy App Is Popular

Given that many people today prefer ease of use whenever possible, the Northwell Lab's app for mobile phlebotomy became popular right away.

"Our LabFly app works in much the same way a patient would use a ride-sharing app like **Uber** or **Lyft**," Breining added. "Patients pay a convenience fee to use our app just as they pay a fee for an Uber ride. The patient makes an appointment and enters a location in the same way too. The only difference is the patient needs a prescription or electronic doctor's order for lab testing, but if he or she has that from the doctor, they're all set.

"What surprised us was the satisfaction ratings," he added. "People who used the app rated it overwhelmingly very good or higher. We knew it would be well received among a certain segment of the population. But we've actually been blown away by how positive the feedback has been.

"Thinking back to when the idea was proposed, we considered it to be an obviously good idea," he concluded. "In retrospect, it was an opportunity that was sitting right in front of us since back when we started the mobile phlebotomy service.

"That idea has even more significance given the outbreak of the novel coronavirus," he added. "Our mobile phlebotomists generally do venipunctures and we can train them quickly to do sputum and nasopharyngeal swab collections." TDR

—Joseph Burns

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Lab Compliance

OIG 2020 Plan of Work to Review Billing for Medicare Part B Tests

Since October, the federal **Department of Health and Human Services Office of Inspector General** (OIG) has published two versions of its plan of work for 2020. In both versions, the inspectors highlighted OIG's efforts to review compliance with Medicare Part B billing requirements for clinical laboratory testing.

All clinical labs and pathology groups that bill Medicare should be aware that this area of lab compliance will get scrutiny by the OIG. At the national law firm of **McDonald Hopkins** in Cleveland, lawyers Arielle Lester, Rick Hindmand, and Courtney Tito issued a client advisory about the OIG's 2020 plan of work.

They advised all clinical labs, physician practices, and companies billing for clinical lab services to be aware that two specific claims are on the OIG's radar as enforcement priorities. One involves claims for genetic or urine drug testing and the second involves Medicare lab test claims that use code-pair modifiers.

These clinical laboratory services may be at risk for overpayments, they added, which is why the attorneys recommended that those labs and billing companies should consider conducting self-audits on their billing and coding processes to ensure compliance with billing and other requirements.

"The OIG has warned that it may use the results of these upcoming reviews to identify laboratories and other institutions that routinely submit improper claims," they wrote. "Once identified, such labs or other institutions could be subject to educational audits, fraud and abuse audits, overpayment demands or other reviews and sanctions."

In October, the OIG announced its intent to review Part B payments for urine drug testing (UDT) for Medicare beneficiaries diagnosed with substance-use disorder or a related condition, according to the advisory. "The OIG observed that Medicare fee-for-service data in 2018 showed improper payment rates of almost 30% for laboratory testing, including UDT, and nearly 72% for drug testing involving 22 or more drug classes," the lawyers wrote.

Update to OIG Plan of Work

The second publication came in January when the OIG updated its work plan for this year to add compliance reviews of Medicare Part B payments related to Part B billing standards for ordering and supervising laboratory and other diagnostic tests. In the January work plan, the OIG highlighted a report it issued in February 2018 showing that Medicare overpaid $66.3 million for specimen validity tests billed in combination with UDTs. In that report, the OIG said, Medicare improperly paid 4,480 clinical laboratories because providers did not follow Medicare billing rules and CMS' payment systems did not prevent payment for specimen validity tests billed in combination with UDTs.

The OIG said Medicare payments to healthcare providers are precluded unless, on request, the provider furnishes the information necessary to determine the amounts due. It will review Medicare payments for clinical laboratory testing and may use the results of these reviews to identify laboratories or other institutions that routinely submit improper claims, the OIG added. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Coronavirus, more specifically, the novel coronavirus that causes the COVID-19 disease, currently dominates global news. This is the third novel strain of coronavirus to emerge as a threat to human health in the past two decades. Severe acute respiratory syndrome (SARS) was identified in November 2002 and played out by July 2003. China was first to see SARS and, as of this date, a total of 8,098 SARS cases—resulting in 774 deaths—were reported in 17 countries, for a 9.6% fatality rate. Middle East respiratory syndrome (MERS, also known as camel flu) was another novel coronavirus that triggered concern. It was identified in Saudi Arabia 2012 and most cases have been in the Arabian penninsula. According to **World Health Organization** data, from 2012 through Jan. 2020, a total of 2,506 MERS-CoV cases have been diagnosed. Deaths totaled 862, for a fatality rate of 34%.

BD AND BABSON TO DEVELOP SMALL SAMPLE COLLECTION TECH

BD (**Becton, Dickinson and Company**) of Franklin Lakes, N.J., and **Babson Diagnostics** of Austin, Texas, announced a strategic partnership on Feb. 12. The two companies plan "to bring laboratory-quality, small-volume blood collection to retail pharmacies." In a joint press release, officials from the two companies said that one goal is to support "laboratory-quality tests that do not require venipuncture," but would use capillary blood.

TRANSITIONS

• On Jan. 26, former California Representative Fortney "Pete" Stark, Jr. died at the age of 88. In 1988, he was the first sponsor of legislation to address physician self-referrals. Elements of this physician self-referral law were included in the 1990 budget act and was called the "Stark Law." This legislation specifically prohibited physicians from referring their Medicare patients to a clinical laboratory if the physician and/or his/her family members had a financial interest in that lab. This law became known as Stark I. In 1993, another law was passed that extended Stark I and added other services to the physician self-referral prohibition. This second law is called Stark II.

• **Laboratory for Advanced Medicine** of Irvine, Calif., announced that its new Chief Operating Officer is Benjamin Oyler. Oyler previously held executive positions at **Ancestry.com**, **Design Ink Corporation**, and **Del Sol**.

• **Prelude Corporation**, of Laguna Hills, Calif., appointed Edwin C. Hendrick as Chief Commercial Officer. He earlier served at **GenomeDX Biosciences**, **US Labs**, **Ventana Medical Systems**, and **Abbott Laboratories**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 30, 2020.

SPECIAL SESSION

Northwell Health Lab's Swift Response to Coronavirus Outbreak

James M. Crawford, MD, PhD
Senior Administrative Director, Laboratory Services
Mayo Clinic, Rochester, Minn.

How Clinical Lab 2.0 Clinical Model Puts the Lab Team on the Front Lines Early with Clinicians

Immediately following news of the outbreak of the novel coronavirus, the lab team at Northwell Health saw the opportunity to quickly support the hospitals and physicians it served with diagnostic testing, using the latest technologies and diagnostics.

You'll learn how this large health system laboratory's expertise, equipment, and resources were rapidly organized to validate both a diagnostic test for COVID-19 and a panel that tested for multiple respiratory agents that includes COVID-19. This clinical lab's efforts caught the attention of both the senior Senator from New York as well as the Governor.

This is an energizing story that illustrates how recent advances in molecular and genetic testing, along with new informatics capabilities, make it possible for clinical labs to be nimble and effective in supporting their parent hospitals and referring physicians in response to unexpected health events. Register now to guarantee your place at this important, can't miss presentation!

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UPCOMING...

- ***Lab Experts Critique the Response of CDC, FDA, Other Agencies to the Coronavirus Outbreak.***
- ***Three Patient Deaths at Three Houston Hospitals: How CMS-CLIA Inspections Review the Lab's Role.***
- ***Why Innovative Hospital Labs Can Help Lead in Anti-Microbial Stewardship Program Successes.***