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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

New Threat to Community-based Anatomic Pathology

THERE IS A NEW DEVELOPMENT that may be off the radar screens of **CAP**, **ASCP**, and the various subspecialty pathology associations. It is the requirement for second reviews and subspecialty reviews of certain complex pathology tests as part of the laboratory benefit management program (LBMP) ready to launch in Florida.

Enforcing this requirement for lab tests done on **UnitedHealth** patients in Florida will be **BeaconLBS,** a wholly-owned subsidiary of **Laboratory Corporation of America**. Some alert pathologists have already recognized that a payer requirement for second and subspecialty reviews for complex pathology procedures will work against general practice pathology groups serving community hospitals. In that regard, it can be considered the newest threat to the private pathology practice business model.

You should read our coverage that follows of the UnitedHealth and BeaconLBS prior authorization pilot program to better understand its goals and the role of the second/subspecialist review requirement. *Pathology Blawg*, commenting about the lab benefit management program, had this to say:

> *Basically, the LBMP mandates essentially all malignant and pre-malignant diagnoses must have a second review in order for the claim to be paid [by UNH], and in many instances it requires a sub-specialist to perform the second review.*
>
> *Board-certified anatomic pathologists will no longer be permitted to sign out [under the UnitedHealth LBMP] any malignant cytology or derm cases, or any lymphoma specimens (both nodal and extra nodal), without a second read by a pathologist who is board-certified or board-eligible in that sub-specialty.*
>
> *In addition, any labs which sign out bone marrow studies must have sub-specialty certification in hematopathology.*

Pathology Blawg goes on to say, this "will most definitely be a significant hardship on small pathology groups and hospitals, especially those in underserved areas, that rely on pathologists with only AP or AP/CP certification."

Do pathology associations want a payer (possibly influenced by its national lab collaborator that competes with local pathology groups) to establish a requirement for lab payment that goes beyond today's accepted standard of clinical care? And would that payer exclude properly trained and licensed pathologists from providing the current level of patient care that they do? Community pathologists may want to alert their professional associations to this development. TDR

Test Utilization Targeted by UnitedHealth, LabCorp

In Florida, LabCorp subsidiary will handle test prior authorization for UnitedHealth patients

CEO SUMMARY: Many independent laboratories serving patients in Florida are unhappy about the decision by UnitedHealth (UNH) to initiate a pilot program that calls for LabCorp's BeaconLBS subsidiary to handle prior authorization for certain lab tests. UNH's laboratory benefit management program will commence on October 1, 2014. Just 13 laboratories are currently listed as network labs on the UNH website and five of those 13 labs are owned by LabCorp.

INDEPENDENT LABS ACROSS THE UNITED STATES should watch a unique managed care contracting strategy that will be unfolding in Florida over the next 60 days. If successful, this strategy has the potential to disadvantage local labs in their attempts to retain provider status with health insurers and access to patients in their communities.

Clinical laboratories and pathology groups in Florida will be first to feel the sting of a new scheme that is nominally about managing the utilization of laboratory tests. It involves **UnitedHealthcare** (UNH) and **Laboratory Corporation of America's BeaconLBS** subsidiary.

UNH's Laboratory Benefit Management Program commences on October 1, 2014. On its website, UNH says "The pilot launch is for our fully insured commercial members in Florida, excluding Neighborhood Health Partnership members." In Florida, UNH is the second largest insurer with 544,000 enrollees and a 14% market share. **Blue Cross Blue Shield of Florida** has 1 million lives and a 30% market share.

Earlier this year, officials from UNH and from BeaconLBS contacted laboratories serving patients in Florida to inform them about the program and encourage them to become a contracted laboratory provider. Similar to BeaconLBS's efforts in past years, this latest recruiting program failed to win over many lab executives from competing labs.

The proof of this meager response can be seen in the fact that, just weeks away from the official launch of the UNH laboratory benefit management program, only 13 laboratories are listed on the UNH

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website as "Laboratories of Choice." Moreover, LabCorp and its wholly-owned lab divisions make up five of those 13 labs. Three labs on the panel are toxicology labs, a fourth is a dermatopathology lab, and three are anatomic pathology laboratories. Outside of LabCorp, there are just two local clinical laboratories in the "Laboratories of Choice" network at this time.

Who Will Get Test Orders?

On the surface, this assessment of UNH's 13-lab panel for the benefit management program would indicate that LabCorp is well-positioned to get a large share of the tests that are ordered by physicians serving UNH patients throughout Florida. At least that's what many executives from other lab companies in Florida believe will be the outcome from UNH's pilot program that has the stated goal of controlling lab test utilization through prior authorization or advanced notification. *(See pages 7-9 for reactions from lab managers in Florida.)*

Pathologists and lab managers interested in learning more about the details of the UnitedHealth/BeaconLBS program can visit UnitedHealthcare's website. *(*URL is*: http://tinyurl.com/p633fm8.)* Information distributed by UNH and BeaconLBS explains that, starting on October 1, each time a physician wants to order one of 82 lab tests currently on the "Decision Support List," he or she will be required to order using UNH's electronic ordering system.

Utilization Review Process

After passing through the utilization review process, the physician will "print the Outcome Summary and place it with the specimen or give to the member, as it is required by laboratories before they proceed with testing," notes UNH on its website.

UNH further states that, when any lab submits a claim for any test on the decision support list, there must be a prior authorization requested. An "outcome summary" will be issued with a notification number and UNH says that "If notification was not received, the claim will be denied as a laboratory liability."

In their descriptions about the goals and value of the laboratory benefit management program, both UnitedHealth and LabCorp's BeaconLBS paint a rosy picture. In a letter to physicians, UnitedHealth wrote that it is "to help improve quality of care and manage appropriate utilization for outpatient laboratory services."

LabCorp says that BeaconLBS will: 1) deliver decision support tools that guide the selection of a lab provider and the lab test; 2) give physicians access to a high-quality lab-of-choice network; and 3) work from a clinical and administrative rules engine that supports the claim adjudication process.

Not The Original Vision

It is important for pathologists and lab managers to understand that this pilot program about to be implemented by UnitedHealth is not what LabCorp executives envisioned when they created BeaconLBS in early 2011. At that time, LabCorp believed that it could assemble a network of laboratories on the provider side, then sell that extended laboratory network to multiple health insurers.

This would be the proverbial win-win. LabCorp executives believed that labs would want to participate in the BeaconLBS network in order to become a network provider for multiple health insurers under one agreement. Similarly, numerous health insurers would find it attractive to sign one agreement and gain access to a network of laboratories.

However, the strategy has not worked out that way for BeaconLBS. During the first three years, despite constant wooing by representatives of BeaconLBS, it is believed that no significant laboratory organizations committed to be part of the BeaconLBS network. That being the case,

Physicians Face Financial and Other Sanctions Should They Not Use Decision Order Support

BeaconLBS® Lab Benefit Solutions

UNITEDHEALTH SENDS A CLEAR MESSAGE to physicians about the need to follow prior authorization and advanced notification requirements when ordering tests on the "Decision Support List." Here is language from the UNH website.

PHYSICIANS:

If you do not use physician decision support to order decision support tests within 90 days after the laboratory benefit management program effective date, you may be subject to one or more of the following administrative actions:

- A decreased fee schedule.
- Termination of your agreement with us.

If your practice performs and bills for laboratory tests that are not Clinical Laboratory Improvement Amendments (CLIA)-waived, you must also register as a laboratory.

UnitedHealth or BeaconLBS may contact you if you:

- Order tests from a non-network provider.
- Order decision support tests from a network provider who isn't authorized to perform the test.
- Order decision support tests using an ordering system that is not integrated with physician decision support.

PATIENTS:

You will be financially responsible if the service performed is not covered or does not meet UnitedHealth Medical Policy.

INCLUDED ON THE UNITEDHEALTH LIST of "laboratories of choice" for Florida and participating in LabCorp's BeaconLBS are the following 13 lab organizations:

- Laboratory Corporation of America
  - Dianon Pathology, LabCorp Specialty Testing Group
  - Integrated Genetics, LabCorp Specialty Testing Group
  - Integrated Oncology, LabCorp Specialty Testing Group
  - MEDTOX Laboratories, LabCorp Specialty Testing Group
- Broward Health
- Clarient Diagnostic Services, Inc., GE Healthcare
- Dominion Diagnostics, LLC
- Granite Diagnostic Laboratories
- Gulf Coast Dermatopathology Laboratory
- Ketchum, Wood & Burgert Pathology Associates
- Millennium Laboratories, LLC
- The Meditrend Group, Inc.

reps from BeaconLBS were having difficulty selling managed care companies to enter into agreements with BeaconLBS.

Lab executives in Florida have told THE DARK REPORT that, in order to serve UNH members in Florida, labs need to register with the BeaconLBS program. By registering, those labs become part of the BeaconLBS network and must match their tests to the tests that BeaconLBS will cover.

The requirements for participating in BeaconLBS are onerous and difficult to complete, the lab executives said. What's more, simply registering to participate does not guarantee that a lab will be a laboratory of choice.

The letter from UHC said to labs, "Please follow the steps below to prepare for the laboratory benefit management program: By May 31, 2014, register with

BeaconLBS and consider participation as a laboratory of choice. As part of the registration process, you will provide quality criteria, map test information, and prepare to submit your laboratory test identifier on claims."

Extra Payment Required

Becoming a "laboratory of choice," would require an extra payment, one lab executive told THE DARK REPORT. The payment is based on the test volume a lab would generate. *(See pages 7-9.)*

Any lab that does not become a laboratory of choice would be difficult to find on the UNH web site. However, any laboratory chosen to be a laboratory of choice would be listed on UNH's and BeaconLBS' websites, the executives said.

For a physician seeking to choose a laboratory that is not a lab of choice, he or she would need to click beyond the front page to find his or her laboratory from a list of labs that are not on the 'Laboratory of Choice' list, the lab executives said.

Getting Paid By UNH

Another interesting insight was offered by an anonymous poster on the *Pathology Blawg* website. The poster wrote that: "The information from UnitedHealth indicates physicians do not need to register with BeaconLBS if they order electronically from LabCorp. It also indicates that the advance notification requirement must be completed within 10 days of the specimen collection date, otherwise the lab won't be paid for their services. So if a physician orders from LabCorp but fails to complete the advance notification requirement, will UnitedHealth withhold payment from LabCorp?"

If the answer is that UNH would pay LabCorp in such a situation—but not pay a laboratory of choice—that would seem to raise interesting questions about anti-competitive business practices. TDR

—Joseph Burns

Is BeaconLBS a Way for LabCorp to Be Paid?

WILL LABCORP MAKE MONEY with BeaconLBS? In the company's second quarter conference call with Wall Street analysts last week, David P. King, Chairman and CEO of LabCorp, touted his company's pilot program with UnitedHealth in Florida.

BeaconLBS Lab Benefit Solutions offers physicians, "the assistance they need to select the appropriate tests for their patients," declared King. Also, "payers need help in managing the utilization of expensive diagnostic testing," he added. Therefore, the BeaconLBS decision support tool, "helps our clients choose the right test at the right time and helps payers thoughtfully address concerns about both unit cost and trend."

The BeaconLBS division of LabCorp was formed in 2011, he said. It operates as a laboratory benefit management company, similar in nature to pharmacy benefit managers. Instead of managing the pharmacy benefit, however, BeaconLBS serves as a gatekeeper for physicians ordering laboratory tests.

LabCorp expects to benefit from the UnitedHealth/BeaconLBS relationship by getting paid for more tests. King told analysts that "...the idea behind BeaconLBS is just to let the physicians know at the point of service, [whether] the testing is not going to be covered or is not going to be paid for; and to let the labs know at the point of service that testing is not going to be covered or paid for."

King further stated that, "So, we actually have a tool that will allow payers to implement these policies in an appropriate way at the front end as opposed to the lab performing the service and then simply getting a denial and not being paid at the back end."

"...We remain very much committed to resolving MoPath, either consensually with the payers and, if not, then by explaining to the physician community that we can't continue to do significant amounts of high-value testing that we're not going to be paid for," said King.

Labs Wary of BeaconLBS, Express Major Concerns

Lab execs say they worry about having a lab competitor's company run United's network

CEO SUMMARY: Lab executives asked to join UnitedHealth's new BeaconLBS lab benefit management system soon to launch in Florida have multiple and serious concerns. The primary issue is that BeaconLBS is a subsidiary of LabCorp—their major competitor. These executives understand why a payer wants to implement a prior authorization program for expensive lab tests. But they can also see how they would be at risk for performing tests and not getting paid because of the flaws in this program's design.

FLORIDA IS ABOUT TO BECOME the testing ground for a new managed care contracting arrangement. News of this development has caused consternation among clinical labs and pathology groups that currently provide lab testing services to patients in the Sunshine State.

As described in the intelligence briefing on pages 3-6, a laboratory benefits management program will be instituted in Florida on October 1, 2014, by **UnitedHealthcare** (UNH). What makes this program noteworthy is that UNH will hand over two responsibilities to **BeaconLBS**, a wholly-owned subsidiary of **Laboratory Corporation of America**.

The first responsibility is to develop a network of labs that meet certain criteria to be on the "laboratory of choice" panel for the lab benefits management program. All of these labs compete against LabCorp in providing testing services to patients in Florida.

The second responsibility is to manage the prior authorization and advance notification requirements when a physician orders any of the tests on the "decision support" list. This program puts BeaconLBS—owned by a national lab company—in charge of handling the lab test authorizations for orders placed by physicians treating UNH patients.

The full description of UnitedHealth's laboratory benefits management program and the BeaconLBS service can be found on their respective websites. (For UNH: *http://tinyurl.com/p633fm8*. For BeaconLBS: *http://beaconlbs.com*.)

Beacon Reps Visited Labs

For some months now, representatives of BeaconLBS have been contacting national and local labs that provide testing to patients in Florida. Their goal was to recruit labs to become part of the laboratory-of-choice panel.

Discussions across the lab industry during past months have reflected general unhappiness with the UNH pilot program involving prior authorization. The major source of this unhappiness is not the concept of pre-authorization for designated tests. Most pathologists and lab administrators understand why payers would want to institute such a function.

Rather, the dissatisfaction is rooted in the recognition that a company owned by a competing laboratory will manage both the lab network and the prior authorization activities of UNH's pilot lab benefit management program.

THE DARK REPORT has tracked these developments. There are some lab companies on the laboratory of choice panel that are satisfied with their inclusion and their expected role in the program. That is not true for most of the lab organizations that declined to be part of UNH's laboratory benefits management program.

Their executives consider this to be not only a poorly-designed scheme for lab test pre-authorization, but also to have elements of anticompetitive business behavior. Their comments are presented below. All of the executives interviewed asked not to be named.

One Obvious Concern

The most obvious concern mentioned by lab executives about BeaconLBS is that it is a subsidiary of LabCorp. Additionally, LabCorp is well represented in this network of 13 preferred labs, which BeaconLBS calls 'laboratories of choice,' according to the list of labs currently posted on the UNH website. Of those 13 labs, one is LabCorp and four are subsidiaries of LabCorp.

Another concern is that, for a lab to join the BeaconLBS network, it must map its tests to the BeaconLBS test menu. Another requirement to be in the network includes developing new information system links to BeaconLBS, lab executives said.

"Our position is that Beacon is not of any benefit to anyone except Beacon and LabCorp," declared one executive. "That's true for the short term and it's true for the long term. We see Beacon as a mechanism to steer lots of lab testing to LabCorp. It's as simple as that."

Another lab executive said, "It's obviously geared so that LabCorp is the primary lab in the network because of the range of testing that LabCorp has that correlates to the 82 tests on the prior authorization list.

Fears Of 'Test Skimming'

"We believe that some labs will do routine testing and LabCorp will skim the high-cost and esoteric testing," she continued. "Our lab team here studied the lab test panels established by BeaconLBS. It's our opinion that these were arranged so that your lab may not have the right kinds of tests in your test panels. Therefore, as a result, some of the most high-priced work will go to LabCorp."

This executive also made the same comment about the targeted tests being "geared so that LabCorp is the primary lab in the network because of the range of testing that LabCorp does."

Labs already serving UNH commercial members in Florida find it difficult to see an advantage in joining the BeaconLBS network, noted several lab executives. Executives for labs that already contract with United said they would not sign with Beacon. "Like us, many of our competitors with existing agreements with United are reluctant to sign with Beacon. Why would we?" asked an executive. "There's no advantage."

Lab executives agreed there could be benefits for health plans to use benefit management companies but such companies would need to be independent of any laboratory company, they said. Otherwise, the question of bias would color any negotiations and labs would fear that lab work that should go to them would be steered to the lab company that owns the benefit manager.

Labs Required To Pay A Fee

A related concern is that some labs have been told they can become a preferred lab if they pay a management fee to BeaconLBS, said one lab executive. "If you're a preferred lab, your lab will be

Design of UnitedHealth and BeaconLBS Program Is Likely to Confuse Both Physicians and Patients

MUCH NEW GROUND WILL BE BROKEN as UnitedHealthcare moves forward with what may be the nation's first serious attempt by a major health insurer to mandate that physicians use a decision support system when ordering certain laboratory tests.

In conversations with lab executives who were presented with details of the pilot program and read the contracts of UnitedHealth's laboratory benefits management program, they see numerous hurdles and the potential for plenty of patient unhappiness that could bedevil implementation of the program when it begins on October 1.

Several Hurdles Identified

Hurdles mentioned were the elaborate system that labs must follow when ordering most of the more than 80 tests on the decision support list.

Labs must process test orders and results electronically. In addition, labs need to meet certain quality criteria, including CLIA certification and CAP accreditation. That was not considered difficult, but what did raise eyebrows was the requirement of a secondary review and a sub-specialist review for certain complex pathology tests.

If a lab does not follow all of these steps, it will not get paid. The most difficult of these provisions is the secondary and sub-specialist reviews for certain complex tests, lab executives said. Another issue centered on decision support.

"The decision support—as it is designed—does not mirror the reality of the ordering process for physicians in a practice," observed a pathologist. "What happens in most practices is that about 30% of the ordering is done on a script which the physician fills out and hands to the patient. The patient takes the script to the lab.

"We asked the Beacon rep what happens if a patient shows up at a patient service center with a test script that hasn't gone through the decision support system," continued the pathologists. "The answer was that it would be the lab's responsibility to decide whether to run the test or not. If your lab does the test and payment is denied, as a member of the lab network panel, you are basically agreeing to eat the cost without reimbursement. You might not get paid even on appeal."

"Most physicians don't know what it means when they're told to use BeaconLBS," stated a lab administrator. "So, we asked what happens when a doctor is not personally placing the order? No one could answer that question satisfactorily.

"We all know that often it is a nurse or office staff who actually orders the test," he said. "It's unrealistic to expect a doctor to sit at the computer and click through the lab requisition to ensure that the clinical documentation required by BeaconLBS is in place. We expect that the decision support procedures that physicians must follow will create confusion."

listed on the front page of their computerized support tool," one executive commented. "But if you don't pay that management fee, your lab would be listed on the second or third page." [Only one lab mentioned this management fee.]

The cost of complying with the requirements of BeaconLBS was seen as a deterrent by most executives willing to discuss the program. "We have to map our test menu to the Beacon system and our staff says doing that could take several weeks," one executive said. "In addition, we need to program our billing systems so that we can bill in accordance with the logic that BeaconLBS is using."

"All this preparation means that we would need to spend a lot of administrative time and incur costs labs don't usually incur just to get started," he added. "If you do all that and then BeaconLBS steers most of the lab test volume away from you, what good is it?" TDR

—Joseph Burns

Lab CEO Has Five "New School" Rules of Success

Dealing with Realities of Changing Market for Laboratory Testing

CEO SUMMARY: Swift transformation of the American healthcare system is causing financial challenges for those clinical labs and pathology groups that have been slow to react to these developments. At NorDx Laboratories in Scarborough, Maine, the team is following the classic five rules for laboratory success. However, as NorDx CEO Stan Schofield said in his presentation at the Executive War College in April, in today's more competitive marketplace, it is essential to drop the "old school" execution of these essential rules and adopt "new school" approaches to be successful.

PART ONE OF TWO PARTS

WHAT ARE THE RULES FOR SUCCESS in today's changing and challenging financial environment for clinical laboratories? One lab executive says that the five classic rules for clinical and financial success still work—but labs must address these rules in new ways.

"Think of it as old school versus new school," explained Stan Schofield during his presentation at the *Executive War College* in New Orleans in April. "Traditional ways of managing a lab and developing the business are less effective in today's rapidly changing healthcare system. That is why the new school approach is necessary to be successful."

Schofield is President of **NorDx Laboratories** in Scarborough, Maine; Senior Vice President of **MaineHealth**; and Co-Founder and Managing Principal of **The Compass Group**.

NorDx is a comprehensive clinical laboratory providing clinical diagnostics services to hospitals, physicians, other laboratories, and managed care providers throughout New England. MaineHealth is the largest health system in the state. The Compass Group is an organization of not-for-profit IDN System Laboratory leaders from 23 of the largest integrated delivery systems in the United States.

"One secret of successful management is to keep things simple," observed Schofield. "That is true of these five rules. Pathologists and lab directors will recognize them as the same time-honored rules that labs have followed for many years. What is different today, however, is the need to be innovative in order to use these rules successfully."

In part one of this two-part series, THE DARK REPORT will present Schofield's observations about the first three rules. Part two will address the remaining two rules.

Schofield's five rules for successful laboratories are:

1. Add clients
2. Keep clients
3. Create revenue opportunities
4. Get paid
5. Reduce expenses

RULE 1 | Add Clients

"The old school method of adding clients was to do the classic steps of lab outreach," noted Schofield. "Labs would build their clients by concentrating on adding physicians, hospitals, and other laboratories; and serving nursing homes.

"We've all done this work because every lab—just like any business—needs to increase the number of customers," he said. "The old school approach was to do outreach in the traditional manner.

"Your lab team worked with the providers you knew," continued Schofield. "You had couriers serve a few doctors in the neighborhood and the two or three nursing homes in your vicinity. We do that today at NorDx by supporting 110 nursing homes for lab services even though it's difficult and expensive.

"But the new school way of operating, at least for us at MaineHealth, is to do hospital integrations as well," he stated. "NorDx currently manages 10 hospital laboratories.

➤ Integration Of Hospital Labs

"Our model is to do outreach to those hospitals, but also to integrate those hospital laboratories into our lab process and standardized workflow," commented Schofield. "Through these hospital integrations, we've become a lead organization for the health system. That's because our laboratory is first to do clinical integrations in these hospitals.

"This is the new school approach to adding clients," he noted. "Today, more hospitals are becoming integrated and affiliating with larger hospital and health systems as a way to get contracts from payers.

"In turn, payers want those health systems to prove that they're clinically integrated and that, by being integrated, they can cut costs and improve quality," observed Schofield. "In the lab, we are the trailblazers for that clinical integration on behalf of MaineHealth, our parent system.

"As part of its integration with our health system, the hospital outsources its lab staff, equipment, and services to NorDx," he added. "By doing that, we often generate substantial savings to the hospital.

"Let me emphasize that we are not simply chasing test volume," continued Schofield. "We're providing a high-quality lab testing service at the lowest possible cost point and we're doing that for a smaller and perhaps rural hospital that could never achieve that level of quality or such low prices on its own.

"During the integration process, there is often a long, drawn-out discussion about control of the processes and fear that some people might lose their jobs," he said. "The problem is that the money is going away. Reimbursement for services in small hospitals and long-term care facilities is declining and what we see today is only the first wave.

➤ High-Quality Lab Testing

"When I started working in Maine almost 20 years ago, we would talk with small hospitals about the advantages of clinical laboratory integration and they all said, 'We don't need do that,'" he stated. "By contrast, today, hospitals are contacting NorDx to explore cost savings and to enhance lab test services to help them improve patient care while better meeting today's financial challenges.

"To make this integration work, we contract with these hospitals to do all their lab testing," noted Schofield. "We cut the expenses, standardize the equipment, and tune up the staff. The hospital pays us and it does all the billing for inpatient and outpatient and retains that revenue."

RULE 2 | Keep Clients

"For MaineHealth, this method of clinical integration with hospitals and other providers allows us to keep our clients," observed Schofield. "This is the goal today because you do not want to lose any client *ever*! And, yet, clients are leaving for many reasons that you cannot control.

"We all remember how, in the past, retaining clients was easy," he continued. "The old school approach was to have an account rep buy the client lunch, and do an annual business review of volume and costs. Then you added information system connectivity. If the office staff was happy, it was an account in good standing. All these are standard patient-retention strategies.

"It used to be that good labs produced timely and accurate lab results," added Schofield. "That doesn't cut it any longer. Today, as a new school lab, we have a tailored metrics program for clients because hospitals want data from labs.

"The new school approach is for our lab to transform and take on a new role," he said. "NorDx must step up and meet the needs of today and tomorrow. We can do that by becoming lab data management experts.

"Our new school strategy for Rule 2 is to offer a tailored metrics program for each hospital," said Schofield. "All the doctors have report cards now and hospitals and health systems have report cards as well.

"Labs benefit from report cards too because lab managers need these metrics," he noted. "More specifically, lab managers need to perform in the areas of clinical quality, service, and finance as documented by objective, measurable data. If your lab doesn't, you'll be handicapped in the marketplace because your competition is already doing that.

"Patient satisfaction or patient experience reports are just one example," noted Schofield. "You have to measure how each patient feels about his or her experience.

"Hospitals live and die on HCAHPS scores," he added. "The HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey is a national, standardized, publicly available assessment of patients' perspectives on care. They are used by hospitals throughout the nation, just as the Picker survey from the **National Research Corporation** is used.

"In this new school approach for keeping clients, we track the patients' experience with the lab," stated Schofield. "We've designed versions of Picker surveys that complement those report formats.

"That way, when a hospital reports to a federal or state payer, to accountable care organizations, or to health plans, these entities understand how well the lab is doing in terms of patient experience. Our reports have a lot more detail than most labs deliver because they are customized for the lab experience.

"As an example, we had to custom-build our surveys so that they are specific for phlebotomy," he added. "That's because hospitals were using the HCAHPS or Picker outpatient surveys and applying them to the lab. Well, of course, the lab scores were abysmal because these surveys were not asking questions specific to the lab.

"Now we can show, for example, how patients feel about their phlebotomy experience in our 22 patient service centers and 10 hospitals," observed Schofield. "The survey asks about cleanliness, quietness, overall rating, facilities, and pain management.

"Our lab team spent a year developing this survey product," added Schofield. "Now Picker has that lab module and makes it available to labs."

RULE 3 | Create Revenue Opportunities

A number of old school strategies are available to comply with the third rule: create revenue opportunities. "Your lab can add new tests or you can bring back

Schofield's First Three Rules of Lab Business

IN HIS PRESENTATION at the *Executive War College* in April, Stan Schofield, CEO of NorDx Laboratories, presented his five classic rules of the laboratory business. He described the "old school" approaches, then discussed how labs should pursue "new school" strategies to meet today's healthcare challenges.

Rule 1 | Add Clients

OLD SCHOOL

- Outreach
- Providers
- Nursing homes

NEW SCHOOL

- Hospital integrations–10 at NorDx to date
- Health system–clinical integrations

Rule 2 | Keep Clients

OLD SCHOOL

- Add a new test occasionally
- Add local clients
- Clinical trials sometimes

NEW SCHOOL

- Hospital management agreements
- Contract with point-of-service health plans
- Method, equipment validation on contract
- More highly complex testing-KRAS, BRAF, viral loads, broad molecular menu

Rule 3 | Create Revenue Opportunities

OLD SCHOOL

- Account rep visits, lunches
- Annual business review
- IT connectivity
- Keep the office staff happy

NEW SCHOOL

- Tailored metrics for quality and services
- Report cards for clients – quality/quarterly
- Patient experience monitoring
- Continual improvement
- Participate in all payer agreements

tests you once sent out," advised Schofield. "Along with adding new clients to boost revenue, if your lab is creative and cutting edge with its test menu and technologies, you might add clinical trials or a drug study with local doctors. Those are tried and true and may still work but your lab will probably need others.

Revenue Opportunities

"At MaineHealth, our new school approach to creating revenue opportunities is to do more management arrangements," noted Schofield. "For example, hospital management agreements are now 70% of our business.

"This strategy is a lot more lucrative than chasing doctors for a few test referrals," he said. "Even better, if you manage the hospital's lab testing needs well and that hospital is a strategic asset to your health system, you enhance your value as the lab operator.

"In today's new school environment, it is essential that your lab participate in all your hospital or health system's payer agreements," recommended Schofield. "If you don't participate, you will be excluded by payers and then your lab probably won't get back into the network. Yes, it may be painful when rates from some health plans are Medicare, minus 20% or minus 15%, but it's necessary.

"Certainly geography can help a hospital if it is the only such facility within 50 miles of its community," he continued. "But we saw the example of a hospital where the administrators, thinking their geography was an asset, refused to accept deep discounts for lab work. That was enough to get the hospital excluded from several payer networks.

Substantial Loss of Revenue

"Three years later, the facility had lost substantial revenue," recalled Schofield. "Currently, this hospital can't get back into these important payer networks.

"Here's a related strategy for creating revenue opportunities to the new school way: Contract with point-of-service insurance programs," he said. "Patients who have a point-of-service (POS) plan can choose a provider in the narrow network. Your lab must pursue that POS business, because—as painful as the pricing may be—insurers will cut you out due to national contracting if you don't participate.

"The question is: How do you participate?" noted Schofield. "To answer that question, you need data on your lab's performance that will allow you to sit at the table with the big labs. Then you can show that you are just as good as they are, that you have the quality, and significantly, that you are local.

"This is one of the single most important new school strategies for success today," he emphasized. "If your lab has enough of the right kind of performance data, you will be better able to succeed. Of equal importance, you will be preparing your lab for what's to happen in the next two to four years."

Benefits of High-Value Tests

Next, Schofield addressed the benefits of adding high-value tests. "Your lab can generate revenue by offering highly complex tests such as KRAS and BRAF," he said. "Doing these tests demonstrates the value of your lab. If oncologists see you delivering results within a day, they will appreciate that turnaround time.

"With cancer testing, time is of the essence," noted Schofield. "Thus, with your lab right there in the community, it means the patient and the physician won't have to wait a week for these results.

"However, this work is a double-edged sword," he said. "Your lab must do this work well and you must be cost-effective. Otherwise, this expensive testing will eat into your lab's financial performance."

Another new school approach to create revenue opportunities is to validate equipment for the manufacturers of clinical labo-

Benchmarking and Other Useful Steps to Demonstrate the Effectiveness of Your Laboratory to Administration

"HERE IS A LITTLE PEARL OF INFORMATION to keep in mind about performance data," offered Stan Schofield, CEO of NorDx Laboratories. "No matter how good you think your lab is, you're probably not that good.

"Remember the saying that 'no one has an ugly baby?'" he asked. "It is this aspect of human nature which makes it helpful to call in an outside expert to validate your lab's true level of performance.

"In particular, that outside expert can help your lab team benchmark your lab against the best in the lab industry," noted Schofield. "In turn, that has credibility with hospital administration, particularly when your lab needs additional capital and resources to add more value to clinicians and improve patient care.

"This is why it is important to be metrics-driven when creating revenue opportunities in the new school manner," explained Schofield. "NorDx is a metrics-driven organization. In our health system, not only does our lab report about its costs, quality, and turnaround times, but—for each of these operational functions—we must measure ourselves against our competitors. The only way to do that is to benchmark."

Schofield recommended a series of steps that labs should take when initiating a benchmarking program. "For step one, benchmark against yourself," he said. "Start by comparing one year or one quarter against a previous year or a previous quarter.

"For step two, benchmark against your friends, such as affiliated labs," he explained. "A third step is to benchmark against the competition and the entire lab industry.

"One issue we track meticulously is our finances," stated Schofield. "We have always thought that our billing operation was a strong performer.

"But benchmarking is the additional step you take to prove it," he noted. "Thus, we brought in a consultant who understands the lab business and who has a good database to use as a comparison. This consultant showed that our operation was very good when our performance metrics were compared with that of other labs.

"Apply this example to your own lab's situation," he continued. "Should someone in your healthcare system suggest taking over your billing operation and replacing it with centralized billing, you will have an answer that is grounded in the metrics that document your lab's performance.

"You can demonstrate how having anyone else perform this function would weaken the lab operation," observed Schofield. "You can show that your lab is demonstrably as good as any in the industry. That's the value that benchmarking delivers to your laboratory."

ratory systems. "If your lab is well run and consistently produces quality results, then it has the capability to validate the new analyzers and diagnostic systems for the *in vitro* diagnostics manufacturers," he advised.

"Some companies making cutting-edge molecular, next-generation sequencing devices have come to us for method validation," said Schofield. "One advantage to such arrangements is that our lab gets the equipment just for making sure it works well.

"We are also paid for doing that validation work," he added. "As reimbursement for clinical testing drops dramatically, your lab must pursue every revenue-generating opportunity."

In part two of this two-part series, Schofield will explain the old school versus new school applications of rule 4: "Get paid" and rule 5: "Reduce expenses." TDR

—Joseph Burns

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At Mid-Year, Labs Struggle To Get Paid for Many Tests

➤Nationwide, pathology groups report that three trends are reducing revenue during 2014

➤➤CEO SUMMARY: At a recent coding and billing conference, pathology and lab clients of one of the nation's largest revenue management companies agreed that three trends have caused lower revenues since the start of 2014. One trend seen by labs involves higher deductibles and copayments from patients. Another is the exclusion of local labs from health plan networks. The third trend is an increase in the number of claims either denied outright or unpaid for some types of molecular and esoteric tests. Even IHC claims are getting tougher scrutiny.

ONCE AGAIN THIS YEAR, CLINICAL laboratories are struggling to get paid. That was the consensus opinion of labs participating in a recent conference on pathology and laboratory test billing and collections.

The conference was a strategic meeting for the lab and pathology clients of **McKesson's Business Performance Services** division. Participants from across the nation identified three significant trends making it difficult for labs to collect money from payers since the start of the year.

Trend number one is the sizeable increase in the deductibles and copays for which a patient is responsible. Trend number two involves payers both narrowing their networks and refusing to pay claims from out-of-network labs. Trend number three is the actions by many payers that make it harder for labs to be paid for certain types of molecular and genetic tests.

"The first trend involves the effect of the sharp increase in the number of health plans that offer patients high-deductibles and high copayments under the Affordable Care Act," stated Eddie Miller, Vice President of Pathology Operations for McKesson. "The design of these plans makes it difficult for labs to get paid. Moreover, these labs say that the little they do get paid is coming in at a much slower rate than they have ever experienced."

➤Narrow Networks

The second trend labs are experiencing is a narrowing of managed care networks. "Many labs and pathology groups report to us that they being denied network contracts with health insurers," stated Leigh Polk, a reimbursement specialist with McKesson. Being denied network participation was a problem for the largest number of labs that participated in McKesson's strategic conference.

"It was reported that a growing number of health insurers are closing their networks to most regional, independent, and local labs," explained Polk. "Instead, these payers are contracting only with the largest national laboratories and a select number of regional laboratories.

"Florida is an example of this trend,"

she said. "In that state, payers are taking steps to narrow their networks. A sizeable number of labs report being denied contracts with **UnitedHealthcare** and other health plans in Florida.

"Similarly, across the nation, all Blues plans are making it harder for labs to get into their networks because of changes to the Blue Card program," continued Polk. "Independent labs are being denied contracts if they do not currently have a presence in the state. These Blue Cross plans say, 'our network is closed to out-of-state labs at this time.' This development is particularly concerning to smaller and startup laboratory organizations."

Out-of-Network Changes

Polk noted that another new factor in the lab testing market is compounding the negative financial impact of payers' narrowing their networks. "In past years, there were certain advantages to being out of network with some payers," she stated.

"In particular, if a lab was out of network, it might often be paid more for most lab tests than if it was a network provider operating under a fee schedule with a payer," said Polk.

"Until recently, this was because out-of-network payments were mostly based on the fact that employer groups did not want their employees and family members to be forced to pay high deductibles and high copayments simply because they used an out-of-network lab," she explained. "Most employer group policies were structured so that their employees would not to be financially disadvantaged by the use of out-of-network diagnostic services when the patient historically could not control where physicians referred their blood work or specimens."

"That situation has changed dramatically," noted Miller. "An increased number of health plans are now narrowing their networks, and—at the same time—requiring higher deductibles, higher coinsurance, and outright denial of benefits for out-of-network services."

Medicare Proposed Rules For 2015 Published by CMS

EARLIER THIS MONTH, the federal **Centers for Medicare & Medicaid Services** published its proposed rules for the CY 2015 Physician Fee Schedule.

The proposed rules can be found in the July 3, 2014, issue of the *Federal Register*. For pathologists and lab executives interested in providing comments to CMS about the proposed rules, CMS has announced a deadline of September 2, 2014. It is expected that CMS will announce the final rules in November.

In its comments about the proposed rules for 2015, the **College of American Pathologists** (CAP) called attention to several proposed changes.

For prostate biopsy pathology services, CMS proposes use of a single code (G0416) for all cases, independent of the number of specimens. Additionally, CMS says it believes this service is potentially misvalued for 2015. It is soliciting public comments on what payment level would be appropriate in 2015.

When it comes to the overall impact on pathology independent laboratories, CAP noted that "CMS estimates that the initiatives included in the 2015 proposed physician fee schedule would increase overall payment to pathologists by 1% due to changes in the practice expense, which impact primarily global and technical component services. Independent laboratories would see a 3% increase in their Medicare physician reimbursement due to these changes."

In its proposed rules for the 2015 Physician Fee Schedule, CMS does not appear to be targeting clinical laboratory and anatomic pathology services as aggressively as it has in past years. In particular, several rule changes proposed in 2013 by CMS for the 2014 Physician Fee Schedule would have represented significant reductions to payments for lab services had those rules been implemented as proposed.

"As a result of these changes by many health insurance plans, it may no longer be an advantage to be out of network anymore," emphasized Polk. "As noted earlier, in the past, a lab would be paid a higher rate if it were an out-of-network lab. But now, out-of-network labs are telling us that they are not being paid at all."

Competitive Lab Test Prices

Sandy Laudenslayer, Marketing Director for McKesson's Business Performance Services, said that client pathology groups and clinical labs concerned about the consequences of payers narrowing their networks may want to reassess their lab test pricing. "If your lab has a contracted fee schedule that is higher than that of your competitors in that market, then that sole fact could lead to payers excluding your lab from their networks," she said.

"In order for pathology groups and labs to remain competitive from a price perspective and remain financially viable, it is essential for them to continually evaluate their cost structure," added Laudenslayer. "To reduce their costs, we see more labs using Lean and Six Sigma methods to redesign workflows and to trim costs. This is a response to narrow networks and the need to accept lower prices from government and private payers."

Payment For Gene Tests

The third trend involves the actions of payers to pay less for certain molecular and genetic tests. "During our conference, labs reported that, since the beginning of the year, it was noticeably more difficult for them to get their claims paid for many types of esoteric, molecular tests," stated Polk.

"Another new issue centers on the changes recently announced regarding payment for immunohistochemistry work," she said. "These new requirements are one reason why payers are either denying or not paying these claims.

"One example has been the introduction of HCPCS codes, including the Z codes for molecular tests and G codes for prostate biopsies for IHC stains," continued Polk. "Laboratories and health plans are only now becoming familiar with how to work with those codes.

"Also, labs are struggling to get paid as a result of inconsistencies in how health plans deal with test payment under the NCCI edits," she added. "Health plans are inconsistent in how they approve payments because each one has a different method for approving payment.

"Plans are following the NCCI edits but they use multiple types of editing software that define test bundling differently," Polk explained. "This lack of standardization among multiple health plans is a major problem for labs seeking reimbursement."

More Denials Of IHC Claims

To demonstrate this point, McKesson told THE DARK REPORT that, for IHC claims, their client billing data confirms that denials as a percentage of claims have gone up measurably. These denials create a greater level of difficulty when labs and pathology groups initiate the appeals process with payers.

Additionally, McKesson noted that, as a result of cuts from Medicare and confusion about payment among insurers, pathology groups have lost an average of 62% of their IHC revenue just since the beginning of the year. This 62% is a national average across the more than 375 clients served by McKesson.

"Not only are labs getting lower reimbursement, but payment of these smaller amounts of money is taking longer based an increased need to appeal denials," observed Miller. "It used to be that when a lab submitted a bill it got paid. Now labs submit bills and payment is denied. Then, labs must appeal the denial. Eventually they get a smaller payment than they once received." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Consolidation of private pathology group practices continues. On July 8, **NeoGenomics** of Fort Myers, Florida, announced that it had acquired **Path Logic** of Sacramento. Then, one day later, **Incyte Diagnostics** of Spokane, Washington, disclosed that it was buying **Accupath Pathology Services, Inc.**, of Seattle, Washington. Path Logic was founded by Peter Kolbek, M.D., in 1999 as a niche renal biopsy service and expanded to nine pathologists in multiple subspecialties. It attracted private equity capital from **Mainsail Partners** in 2010. Accupath Laboratory Services was founded in 1981. It was owned by Robert Hasselbrack, M.D., and has six pathologists on staff.

MORE ON: *Pathology Group Consolidation*

No region of the United States seems to be consolidating pathology groups faster than Washington State. In recent months, a spate of pathology group practice acquisitions has been announced. At the forefront have been Incyte Diagnostics and **CellNetix** (based in Seattle). In the month of May, Incyte and CellNetix acquired a private pathology group practice located in Washington state. *(See TDR, May 19, 2014.)*

ACCREDITATION OF PROFICIENCY TEST PROVIDERS

In the field of proficiency testing, the bar is being raised. Last month, seven accreditation bodies from six nations were inaugural signatories to the APLAC Mutual Recognition Agreement for the accreditation of proficiency testing providers (PTPs). APLAC is the **Asia Pacific Laboratory Accreditation Cooperation**. The signatories are accredited to "the international standard ISO/IEC 17043: Conformity assessment—General requirements for proficiency testing to accredit PTPs." The **Association for Laboratory Accreditation** (A2LA) from the United States is a signatory to the APLAC mutual recognition agreement. The seven signatories have agreed to recognize the cross-border accreditations of each other.

TRANSITIONS

- **Ativa Medical Corp.** of St. Paul, Minnesota, announced the appointment of James M. McNalley, Ph.D., as President and CEO. McNalley has held positions at **Quest Diagnostics Incorporated**, **Bio-Imaging Research**, and **Picker International**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 11, 2014.