Volume XXVI, Number 6 Monday, April 29, 2019

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

"I'm from the Government, and I'm here to help."

ACROSS THE NATION, CLINICAL LABORATORIES STRUGGLE to correctly interpret and follow the new National Correct Coding Initiative (NCCI) guidelines that took effect on Jan. 1. A financial disaster lies ahead for many labs.

As you will read on pages 7-10, "The denials are very high right now and those denials are nationwide," stated Kyle Fetter, Executive Vice President and General Manager of Diagnostic Services for San Diego-based **XIFIN**. "Even if we consider only molecular tests in tier 1 and tier 2, there are many labs that are not getting paid for these tests. I would estimate that the effect of the changes NCCI made is anywhere from 40% to 100% of the revenue for these clinical labs."

This negative development is not getting wide play in the lab industry. It is one more financial hit to clinical labs. Moreover, this is one more example of federal government ham-handedness in how it handles coding/billing and reimbursement for clinical lab tests. Many of you know about these past events:

- Jan. 1, 2013: New molecular test CPT codes are introduced. Medicare administrative contractors (MACs) were unprepared to process claims. Some labs got no payments for these tests until May and June of 2013. *(See TDR, Apr. 15, 2013.)*
- Apr. 1, 2014: The Protecting Access to Medicare Act (PAMA) includes specific steps CMS is to take to grant coverage for new advanced diagnostic laboratory tests (ADLTs) and establish a market price. Effective steps to implement this section of PAMA and timely action have often been lacking.
- 2017-18: First PAMA-mandated reporting of private payer lab test price data. Critics charge that CMS created a final rule that games the incoming data so as to skew the results in a manner that would generate a much lower Medicare Part B Clinical Lab Fee Schedule than would result from a true and accurate market study consistent with the language of the PAMA law.
- Jan. 1, 2019: New NCCI guidelines that are confusing and conflict with existing federal laws/regulations and coding requirements of the American Medical Association.

Maybe this is what President Ronald Reagan meant when he often said, "The nine most terrifying words in the English language are, 'I'm from the government, and I'm here to help.'" TDR

UHC Sets July 1 Launch for New Preferred Network

UnitedHealthcare gives "preferred" status to seven large lab firms while retaining 300 in-network labs

CEO SUMMARY: UnitedHealthcare will launch a new preferred laboratory network with seven lab companies on July 1. In an April 22 announcement, UHC said physicians and consumers may continue to use its existing network of more than 300 labs currently in-network. One goal is to give patients a choice of labs based on price with preferred labs offering the lowest costs. Another goal is to have clinical laboratories and anatomic pathology groups support the triple aim of improving patients' experience and population health, while reducing cost of care.

SEEKING LOWER COSTS, SHORTER WAIT TIMES, AND IMPROVED PATIENT OUTCOMES from clinical laboratories and anatomic pathology groups, **UnitedHealthcare** (UHC) named seven laboratories to a new preferred lab network. In an announcement on April 22, the nation's largest health insurer also said physicians and consumers may continue to use its network of more than 300 legacy clinical laboratory providers.

Saying it wants "more affordable procedure costs, shorter wait times, and higher quality" from its providers, UHC will ask the preferred labs to follow the triple aim of improving the patient experience of care and the health of populations and reducing the per capita cost of care.

"The preferred lab network is an advanced way for us to work with selected lab partners to deliver on UnitedHealthcare's triple aim in the lab space," said Linda Simmons, UHC's Vice-President, National Lab Program.

"By following the triple aim, we aim to improve healthcare value by making healthcare more affordable, and by improving patient outcomes and satisfaction for our patients and their physicians," commented Simmons. *(See sidebar, "Triple Aim Established to Drive Improvement," page 6.)*

In a departure from the way most health insurers contract with clinical labs and anatomic pathology groups, UHC will track patient outcomes among those members who use the preferred laboratories to understand how labs can improve patient outcomes. Doing so will take several years, Simmons said.

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

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

In its news release announcing the preferred lab network (PLN), UHC said, "The creation of the PLN is an advanced way to work with selected lab providers to deliver care that places a greater emphasis on patient outcomes and the total cost of a person's care." *(See sidebar, "Seeking Improvements in Patient Outcomes, UnitedHealthcare Will Monitor Labs' Data," page 5.)*

Rigorous Quality Criteria

The seven preferred laboratories were selected based on a "rigorous quality review process," UHC said. The seven labs that will begin serving UHC members on July 1 are:

- **AmeriPath/DermPath** (a subsidiary of **Quest Diagnostics**),
- **BioReference Laboratories**,
- **GeneDx** (a subsidiary of BioReference Laboratories),
- **Invitae**,
- **Laboratory Corporation of America**,
- **Mayo Clinic Laboratories**, and
- **Quest Diagnostics**.

For consumers, UHC said there is no change in lab access because members can continue to use any of the more than 300 laboratories currently in its network of legacy labs. Depending on which lab a member chooses, costs may increase as follows:

- Preferred labs (seven) are the lowest cost labs.
- In-network (or legacy) labs (more than 300 nationwide) cost a bit more.
- Out-of-network labs (thousands nationwide) cost the most.

UHC explained that the cost of testing will differ for each type of laboratory a consumer would use, noting that preferred labs will have shorter wait times, online scheduling at patient service centers, higher quality of care, and lower costs.

"Services accessed through the PLN are at a lower average cost than other lab providers," UHC said. "For example, pathology services for a biopsy in the PLN would cost about $90. Consumers could still choose a lab not in the PLN, but the cost would increase to about $150. An out-of-network lab would cost even more."

By including all of the more than 300 of its in-network labs along with the preferred labs, UHC aims to serve all members, Simmons said. "Regarding access to testing, we're looking for each laboratory to be able to provide services to all of our members in all lines of business with an emphasis on convenience," she added.

Those physicians who refer patients to a preferred lab should expect to see improved service, the health insurer said. Physicians will "notice prompt turnaround times for lab results, ease-of-use when ordering lab [tests] electronically, as well as easy access to physician-to-lab medical director consultations to support patient care," UHC added.

"[Physicians] will not need to do anything different to access services from these providers. The seven labs participating in the PLN will be designated as such in UnitedHealthcare's provider directories," said UHC.

UHC wants physicians to choose labs based on quality and costs. Physicians often order clinical laboratory tests based on habit or historical practice and may not realize that more affordable and higher quality options are available, UHC said.

Choosing Among Labs

In the interview, Simmons offered some detail about how UHC selected the labs for the PLN. "The preferred lab network is based on differentiated criteria for access, cost, and quality," she said. "Also, it serves as a way for us to differentiate among the many labs in our network, including the more than 300 labs that are currently in network nationwide. We invited those laboratories to apply to be in the preferred lab network, and of those 300, we received more than 90 applications."

Many of the in-network legacy labs are independent laboratories and several are based in hospitals and health systems,

Seeking Improvements in Patient Outcomes, UnitedHealthcare Will Monitor Labs' Data

ONE FACTOR TO WATCH CLOSELY IN THE COMING YEARS is how well UnitedHealthcare's preferred laboratory network succeeds in tracking patient outcomes with the goal of improving them. This aspect of the network separates what UHC is doing with clinical laboratories from what most health insurers do when contracting for clinical and anatomic pathology testing.

"In the preferred laboratory network, we will be measuring back to the goals of the triple aim," said Linda Simmons UHC's Vice-President, National Lab Program. "This will be done by assessing how preferred labs impact service and by measuring the impact on patient outcomes.

"The information on patient outcomes will take a few years to collect in order to actually demonstrate improvements or changes in outcomes," Simmons added.

By asking the preferred network labs to focus on the triple aim, they will be required to take a holistic approach to patient care, Simmons commented. "The laboratory is a key component in helping physicians to provide evidence-based care," she said.

"This preferred laboratory network is less about cutting lab test utilization and more about supporting and enhancing a patient care model that includes following certain care pathways, so that physicians and consumers have the right information at the right time," noted Simmons.

"In the preferred lab network, we will collect data to ensure compliance with the triple aim and will measure the impact on the patient outcomes," she added. "Then, we will share that data with our external constituents, such as employers and other purchasers."

although Simmons would not say how many are in each category.

Each clinical laboratory seeking to participate in the PLN needed to complete a proprietary application that UHC prepared. "From those 90 applications, we then applied the criteria we used to select the labs for the PLN," she said. "To be clear, those applicants that weren't selected still remain in network. In fact, any in-network lab that didn't apply still remains in network.

"That's because we wanted to continue to offer our preferred lab network and our broad base of in-network labs," she noted. "At the same time, we also wanted a way to differentiate within the network those providers that have met the higher standards UnitedHealthcare set for preferred laboratory providers.

"This is important for consumers for several reasons," continued Simmons. "First, there is no change in lab access for our members. Everyone still has access to all of the network laboratories that we have, and we want it that way.

"Second, for our members, there should be broad access, but also, we can now highlight those lab providers that meet the additional criteria to be preferred laboratories, because using one of those labs can lead to a better experience for consumer service, online scheduling for patient service centers, and we have other higher quality service standards as well," added Simmons, "In addition, labs in the PLN will offer lower average costs than other lab providers," she said.

Quarterly Reports Required

Each quarter, UHC will require the preferred labs to report performance data. "All participants in the PLN will be measured annually on their performance to ensure our doctors and patients receive great care at the lowest cost," UHC said.

Simmons explained in general terms what data UHC wants from the PLN

labs. "We will do an annual evaluation for labs in the preferred lab network," she commented. "For that evaluation, quarterly reporting of certain measures will be required to ensure that preferred labs meet UHC's standards.

"Laboratories in the PLN will be required to submit various pieces of information about access, quality, and service," stated Simmons. "There are criteria in each of those areas.

"Regarding access, we're looking for the preferred labs, and all in-network labs, to provide services to all of our members in all lines of business and to have an emphasis on convenience," she added.

Saying its standards are proprietary, Simmons declined to elaborate on what data preferred labs would need to submit to demonstrate compliance with UHC's standards. She did add, however, that the standards are designed "to create a more efficient user-oriented service model. In addition, we look for enhanced member protection through different standards that measure clinical, financial, and data quality."

Performance Reports

One reason to submit the data UHC wants each quarter is to ensure that patients and physicians get what they want from the preferred labs. "For physicians, we expect the labs will focus on the quality and service standards of the triple aim," Simmons commented. "For physicians using the preferred labs, we want them to get prompt turnaround time, ease of use when using preferred labs, and direct consultation with a lab medical director for patient care."

In addition, UHC has standards the preferred labs will need to meet to help the health insurer to improve patient care through enhanced data sharing, she explained.

UHC is not focused so much on reducing test utilization as it is on ensuring patients get the appropriate care for their needs. "Our patient care model is actually not about just reducing lab test utilization," she said. "It's about ensuring that, for selected care pathways, each member gets the appropriate care at the appropriate time and for that, laboratory test results are very valuable. Lab test results drive so many of the diagnostic decisions that physicians use for patient management and to develop treatment plans."

Although LabCorp is one of the seven preferred labs, UHC did not add LabCorp's subsidiary, **BeaconLBS**, to its preferred network. When asked about BeaconLBS, Simmons said only that it remains in place serving physicians and patients in Florida. TDR

—Joseph Burns

Contact Linda Simmons at 952-979-6690 or linda_m_simmons@uhc.com.

Triple Aim Established to Drive Improvement

In 2007, the Institute for Healthcare Improvement (IHI) in Cambridge, Mass., established the triple aim. The idea was to pursue the goals of improving the patient care experience while also improving patient outcomes and lowering healthcare costs.

To achieve these goals, the institute challenged hospitals, physicians, and other providers to develop new ways to deliver care to pursue three dimensions of care simultaneously. Those aims are:

1. Improve the patient experience of care (including quality and satisfaction),
2. Improve the health of populations,
3. Reduce the per capita cost of care.

Providers should use "a change process that includes: identification of target populations; definition of system aims and measures; development of a portfolio of project work that is sufficiently strong to move system-level results along with rapid testing, and scale up that is adapted to local needs and conditions," the institute said.

Labs Get High Denial Rates Under New NCCI Rules

Billing expert says guidelines affect labs running molecular tests and assays requiring multiple steps

CEO SUMMARY: Under guidelines the National Correct Coding Initiative issued last year, many clinical laboratories are not getting paid for some tests. The rates of denial for labs running mostly molecular tests could range from 40% to 100% of revenue, one billing expert said. Implemented Jan. 1, the guidelines apply to labs running tests in multiple steps on one patient sample, including next-gen sequencing assays and routine lab testing for Medicare and Medicaid beneficiaries.

MANY CLINICAL LABORATORIES REPORT high rates of denials for lab tests ordered on behalf of Medicare and Medicaid patients as a result of changes the **National Correct Coding Initiative** (NCCI) made late last year, according to Kyle Fetter, Executive Vice President and General Manager of Diagnostic Services for **XIFIN**.

The new NCCI guidelines were issued three weeks before they took effect on Jan. 1 and were implemented without notice to or comment from stakeholder labs. Since then, the guidelines have been problematic for labs running clinical and molecular tests because they conflict with previous NCCI policy manual instructions and with coding guidance from the AMA. *(See TDR, April 8, 2019.)*

In an effort to resolve these conflicts, the **American Clinical Laboratory Association** (ACLA) and eight other lab industry associations sent a letter to the federal **Centers for Medicare and Medicaid Services** (CMS) urging the agency to withdraw the NCCI guidelines and work with labs to address the problems. In the letter, the associations said the NCCI guidelines are confusing for labs submitting claims for such tests to Medicaid and to any of the nation's Medicare Administrative Contractors (MACs).

In a separate letter, ACLA raised similar complaints with NCCI. *(See "ACLA: NCCI Guidelines Are a 'Step Backwards'," page 11.)* As of April 24, ACLA had not received a formal response from NCCI or CMS in regard to the issues raised in the letters.

Labs Have Three Concerns

In an interview with THE DARK REPORT, Fetter said clinical laboratories that run molecular and other tests in multiple steps have three areas of concern regarding the new NCCI guidelines. They are:

1. Labs are not getting paid for many procedures when multiple lab procedures are performed on one patient specimen for one date of service and laboratories do not know how to bill for the tests even though they are covered under existing NCCI guidelines or other applicable association guidelines.
2. The changes will degrade the information that Medicare collects on these medical laboratory tests.

3. Private payers could make similar changes.

Among these concerns, the last one may be the most significant. "Now that Medicare has made this change to the NCCI guidelines, one of the problems that could result is that all commercial payers could do the same thing," warned Fetter.

"In other words, this problem could spread industrywide, meaning laboratory and genetic services that are the standard of care for many different types of patients are no longer payable without extensive efforts from the provider and patient," he added. "Even the use of modifiers and other tools that are available to providers to manage these edits aren't going to work at some point."

As of early April, XIFIN did not have data showing that other payers were following Medicare's lead, but XIFIN's cross-industry analysts were monitoring payment trends and watching for denials from other payers, Fetter said.

"For large laboratories that do a lot of molecular testing and for those labs that do molecular testing only, this change could affect a significant source—or all—of their revenue," continued Fetter. "Any clinical lab that runs tests in multiple steps—such as next-generation sequencing assays—may need to follow the new guidelines."

Overlapping, Contradictory

Given that the guidance from NCCI and the AMA are overlapping and contradictory, the ACLA said specific requirements for labs remain unclear, and so ACLA has urged CMS to provide clarification.

For clinical labs and pathologists, payment denials and delays are significant concerns. "The denials are very high right now and those denials are nationwide," Fetter commented. "Even if we consider only molecular tests in tier 1 and tier 2, there are many laboratories that are not getting paid for these tests. I would estimate that the effect of the changes NCCI made affects anywhere from 40% to 100% of the revenue for these types of specialty clinical labs."

ACLA's Joan Kegerize, JD, was concerned about payment for other lab tests. "In addition to molecular and genetic tests, the NCCI guidelines apply to HCPCS and CPT codes for more routine lab testing that require multiple steps on one patient specimen," said Kegerize, Vice President of Reimbursement and Scientific Affairs. She offered the example of what happens when a physician orders routine creatinine and protein tests. *(See sidebar, "NCCI Guidelines Affect Even Routine Lab Tests," page 9.)*

Concerns about Other Tests

"The codes apply to a laboratory procedure that produces multiple reportable test results for a single specimen," she explained. "That means that when two or more tests are ordered on the same specimen, the laboratory shall select a code that most accurately describes the test, or the test would have to be submitted as an 'unlisted chemistry procedure' or, in the case of a pair of genetic tests, an 'unlisted molecular pathology procedure.'"

Coding tests as unlisted procedures could cause confusion in lab billing departments, and because many labs may be unclear about how to bill, they cannot file claims with confidence. If they submit claims incorrectly, they might not get paid or the payer could demand repayment months later.

Asked how any lab would know how to comply with these new instructions, Kegerize said, "Individual labs would need to consult their legal and compliance teams. We have urged CMS to provide clarification and not to implement without engaging relevant stakeholders."

Concerns about payment could cause healthcare costs to rise, in part because molecular tests are becoming more widespread every day, Fetter commented.

"Molecular and genetic tests are among the fastest-growing areas of diagnostics,

because we've learned over time that they help identify genes that cause disease and impact how patients respond to different treatments," he added. "And these diseases are extremely costly to the Medicare program and to the entire healthcare system."

In 2018, **Concert Genetics**, a company in Franklin, Tenn., that tracks such testing, estimated that about 75,000 genetic testing products were in use and labs were introducing more than 10 new genetic tests each day. Concert Genetics defines a testing product as an individual gene test or multiple gene panels.

"Many of these tests use next-generation sequencing and these tests are becoming more affordable," Fetter explained. "But now some laboratories are talking about the possibility of going back to different methodologies that they used earlier and those types of tests may be more expensive in some cases.

Use of Misc. Procedure Code

"In addition, physicians order many molecular tests quite often," he added. "Take, for example, EGFR or KRAS tests run for patients with certain types of cancers. A busy oncology practice orders these tests every day and the idea that a lab would need to submit a miscellaneous procedure code to get paid for these tests is a very big problem.

"Today, a growing number of tests are done on next-gen sequencing platforms because they offer a combination of efficiency and reliability, and these machines have become better, faster, and more accurate over time," noted Fetter. As those machines have become more efficient, the cost of such testing has declined, he added.

While some clinical laboratories are not getting paid, others may have a workaround. "We work with many laboratories that have participated in the Medicare MolDx program for several years," Fetter said. "As a result, some of those labs may have miscellaneous codes for some of their procedures already. If they do, then it's likely that they are using those miscellaneous codes and getting paid."

NCCI Guidelines Affect Even Routine Lab Tests

MOST OF THE FOCUS ON THE CHANGES MEDICARE MADE to the National Correct Coding Initiative (NCCI) has been on the effect the changes have on molecular and genetic tests. But the changes also apply to any labs that run more routine tests on one patient specimen, said Joan Kegerize, JD, Vice President of Reimbursement and Scientific Affairs for the American Clinical Laboratory Association.

"The codes apply to a laboratory procedure that produces multiple reportable test results for a single specimen," she explained. "Let's say a senior is having a regular check-up with her primary care doctor, and based on a health evaluation the physician orders and performs a urine protein and creatine test. According to longstanding CPT guidelines, the billing should document the individual tests performed, 82570 (creatinine) and 84156 (protein).

"But, if we are to interpret the new NCCI manual guidelines literally, labs must now bill for an unlisted chemistry code (84999) any time two or more chemistry analytes are ordered at the same time," she added. "Billing this way reduces transparency and places a significant burden on MACs and state Medicaid programs, which will now have to adjudicate a vast number of claims with miscellaneous and unlisted codes."

"Ultimately, this means that patient claims for medically necessary tests may be inappropriately denied," Kegerize said. "It's worrisome that the sweeping new language violates long-standing **American Medical Association** CPT guidance, which dictates that labs should use the most specific codes when billing tests. In our view, these hastily released changes require further clarification from CMS."

MolDx is a classification system that MACs use to identify molecular and genetic tests. Under MolDx, CMS groups tests into tier 1 and tier 2, genomic sequencing procedures, molecular multianalyte assays (MAAA), MAAA administrative codes, and proprietary laboratory analyses.

Lack of Coding Detail

The downside of using miscellaneous codes is a lack of specificity about which tests, or lab procedures, labs are running for patients. That lack of specificity is particularly troubling for any payer collecting data on which tests physicians are ordering for which patients and how much Medicare and Medicaid pay for these tests.

"That use of miscellaneous codes will be particularly troublesome for labs reporting their private payer lab test price data to CMS under the Protecting Access to Medicare Act (PAMA)," said Fetter.

Under PAMA, CMS requires what it calls "applicable labs" to report data on the prices commercial health insurers pay for the tests they run. CMS uses that data to set payment rates. If the data are inaccurate, labs can be fined and CMS' payment rates could be based on bad data.

"Over time, and particularly since CMS introduced the MolDx program, we've developed a coding system for molecular and genetic tests," he said. "But under the NCCI guidelines, those codes have pretty much been completely circumvented. Consider, for instance, testing for lung cancer or colon cancer. The specificity of testing for those diseases is hugely important for any physician trying to decide whether patients will respond to the different therapies that are available.

"Under the new NCCI guidelines, labs are told to use miscellaneous codes to identify what are typical and fairly normal tests and test procedures, which then makes it impossible to identify which specific tests are being used and for which tests Medicare is paying," he added. "That greatly increases the burden on the MACs administering the MolDx program, because now they have to do an assessment on every test that comes through on every claim."

Kegerize agreed. "This troubling change reduces transparency about testing," she wrote in an email. "Using miscellaneous and unlisted codes rather than the individual codes places an unnecessary administrative burden on laboratories, the MACs, and state Medicaid programs.

"It means that when two or more tests are ordered on the same specimen, the laboratory shall select a code that most accurately describes the test, or the test would have to be submitted as an 'unlisted chemistry procedure' or, in the case of a pair of genetic tests, as an 'unlisted molecular pathology procedure,'" she explained.

"This then puts the burden on MACs and state Medicaid programs to adjudicate a vast number of lab test claims with miscellaneous and unlisted codes," continued Kegerize, "which will no doubt require collecting additional documentation, and may lead to medically necessary tests being inappropriately denied."

One way to avoid confusion over what ACLA called contradictory guidance would be for CMS to withdraw the guidelines and work with labs and their associations to address their concerns about billing practices, she said.

More Specificity is Needed

"Insurers, clinical labs, and physicians all argue for more specificity rather than less," concluded Fetter. "In that sense, it seems as if the ramifications of the changes CMS made in the NCCI guidelines were not fully understood."

CMS replied on April 26 to The Dark Report's request for comment. The organization is preparing a response to the concerns lab groups raised, which we will include in a future issue. TDR

—Joseph Burns

Contact Kyle Fetter at KFetter@XIFIN.com or 858-793-5700 or Joan Kegerize at 202-637-9466.

ACLA: NCCI Guidelines Are a 'Step Backwards'

Lab association critiques new rules, identifies multiple problems that confuse labs and create risk

CEO SUMMARY: In a letter to the National Correct Coding Initiative, the American Clinical Laboratory Association (ACLA) raised significant concerns about new language in the policy manuals for Medicare and Medicaid. ACLA said the new NCCI guidelines for molecular and other tests requiring multiple steps for one specimen reduce transparency, increase the administrative burden on clinical laboratories and payers, and contradict long-standing coding guidance from both the AMA and CMS.

Two days after the National Correct Coding Initiative (NCCI) announced changes to the coding guidelines for certain lab tests, the **American Clinical Laboratory Association** (ACLA) charged that the changes would be impossible for clinical laboratories and the Medicare and Medicaid programs to implement.

The ACLA also said the changes would result in less transparency in lab testing, and the guidance would make it difficult to know which lab tests physicians were ordering, labs were performing, and Medicare and Medicaid were covering. *(See "Labs Get High Denial Rates Under New NCCI Rules," page 7.)*

ACLA's Letter to NCCI

In a letter dated Dec. 14 to NCCI's then-Medical Director Niles R. Rosen, MD, Sharon L. West, ACLA's Vice President, Legal and Regulatory Affairs, wrote that the changes were a step backward in transparency about testing, and "...put laboratories in a position of violating long-standing coding guidance set forth plainly in the **American Medical Association** (AMA) CPT Professional Edition codebook, [and also that] the new policies run counter to the way physicians order and laboratories perform analyses."

ACLA sent copies of the letter to executives at the federal **Centers for Medicare and Medicaid Services** (CMS). In the letter, ACLA said NCCI should not implement the changes for several important reasons including:

- The guidelines are confusing and inconsistent in how NCCI uses the word "procedure."
- The molecular pathology section of the guidelines contradicts long-standing coding guidance when clinical laboratories use next-generation sequencing (NGS) to evaluate multiple genes, such as when NCCI said labs should use a single code to report when a "laboratory procedure" produces multiple reportable test results.
- The guidelines are counter to the scientific basis labs use when performing and reporting some tests.

Effective January 1, the new NCCI guidelines have far-reaching effects because they affect lab billing for molecular and genetic tests, and more rou-

tine tests, on one patient specimen for all Medicare and Medicaid beneficiaries, according to Joan Kegerize, JD, ACLA's Vice President of Reimbursement and Scientific Affairs.

Defining a 'Lab Procedure'

How CMS and NCCI define the term "procedure" in the new guidelines lacks clarity, West said. In a clinical and molecular laboratory, a procedure is generally considered any process that requires multiple steps to complete testing on a patient specimen.

"It is imperative—first and foremost—that NCCI explain to stakeholders what is meant by the term 'procedure' in the context of the new language added to the manuals," West wrote in the letter to Rosen. "In common usage, a 'procedure' describes a series of steps taken in a certain order, without regard to results. In the context of NCCI procedure-to-procedure edits, a 'procedure' is represented by a single specific CPT or HCPCS code."

But NCCI's definition is unclear because the word 'procedure' is used differently in different sections of the new NCCI policy manuals for Medicare and Medicaid, she added.

"In one instance, the word appears to be used in the same way as in the procedure-to-procedure edits context (referring to a 'tier 1 or tier 2 molecular pathology procedure CPT code...')," she explained. "In another instance, the meaning is not clear at all," she wrote, citing this wording from the NCCI manuals, "If a laboratory procedure produces multiple reportable test results...."

West added, "For any provider to comply with policies in the NCCI manuals, their meaning must be clear and definitions consistent and not defined in terms of reportable test results."

The NCCI guidance on coding for molecular pathology testing also was problematic. In that section, the NCCI guidelines say, "If one laboratory procedure evaluates multiple genes utilizing a next-generation sequencing procedure, the laboratory shall report only one unit of service of one genomic sequencing procedure, molecular multianalyte assay, multianalyte assay with algorithmic analysis, or proprietary laboratory analysis CPT code.

"If no CPT code accurately describes the procedure performed, the laboratory shall report CPT code 81479 (unlisted molecular pathology procedure) with one unit of service...."

This wording contradicts long-standing coding guidance, West charged, adding that following this wording would increase the administrative burden on labs, Medicare Administrative Contractors (MACs) and state Medicaid agencies, and reduce the information Medicare and Medicaid collect about which tests are being performed for which patients.

CPT Codes for Genetic Tests

Given that the CPT Professional Edition codebook includes CPT codes for individual genes, labs submit claims using those appropriate codes to describe each gene evaluated using NGS, she wrote.

"Requiring a laboratory to bill an unlisted code, rather than use the available CPT codes that describe the specific genes evaluated and the specific analyses performed, runs counter to CPT and CMS guidance and would result in an unnecessary administrative burden for laboratories, the MACs, and state Medicaid programs," she added.

To show how the guidelines could inconvenience patients and potentially increase healthcare costs, West provided an example. "Physicians seeking to determine whether their patient has a variant in a gene must receive both the sequencing and the duplication/deletion analysis," she explained.

"Under the new [NCCI] policy, a physician would be required to bring the patient back for a subsequent office visit to collect a subsequent sample in order to

receive the complete gene analysis," noted West. "This would contribute to hardships and burdens on patients that are surely counter to CMS goals." Although ACLA did not mention it in its letter, having patients return for a subsequent visit to collect a second specimen could incur additional costs to the healthcare system.

Scientific Basis Lacking

At the end of the letter, West addressed changes in the NCCI guidelines regarding procedure-to-procedure edits in which a lab bundles together two tier 1 CPT codes for a molecular pathology procedure. The changes appear to indicate a failure to understand the scientific basis for how labs run molecular tests.

Here is the wording in question from the NCCI guidelines: "Procedure-to-procedure edits bundling two tier 1 molecular pathology procedure CPT codes describe procedures that should not routinely be performed and reported together."

In her letter, West said, "There is no scientific basis for stating that these procedures 'should not routinely be performed and reported together;' rather, they are commonly performed together. And, although ordered and reported together, they are separate and non-overlapping analyses performed by laboratories.

Different Analyses

"These analyses are not subsets of one another, or duplicative; rather sequencing variants and duplication/deletion variants require different analyses to determine their presence," she added.

On April 26, CMS' media relations department responded to a request for comment from THE DARK REPORT, saying it was preparing a response to the issues the lab groups have raised and that it expected to send that response sometime during the week of April 29. We will include CMS' comments in a future issue. TDR

—Joseph Burns

Contact Sharon West at 202-637-9466.

CMS Puts Its Focus on Bundled Lab Tests

TWICE SINCE LAST YEAR, the federal Centers for Medicare and Medicaid Services (CMS) focused closely on bundled tests for clinical and molecular lab testing. And each time, the lab industry questioned the logic behind this focus on bundled tests.

In November, the **Government Accountability Office** (GAO) issued, "Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments." In the report, GAO said CMS stopped paying a bundled-payment rate for certain panel tests that could result in paying as much as $10.3 billion from 2018 through 2020, compared to estimated Medicare expenditures using lower bundled-payment rates for panel tests.

U.S. Senator Chuck Grassley (R-Iowa), Chairman of the Senate Finance Committee, questioned what he said was "the potential for a striking increase in costs to Medicare for laboratory services." *(See, "Senator Asks: Are Lab Test Payments Too High?" TDR, Feb. 4, 2019.)*

To many, the GAO report was puzzling because Medicare's National Correct Coding Initiative (NCCI) requires labs to report the CPT code for a panel (not the individual tests) if the laboratory performs all tests included in the panel, as the American Medical Association (AMA) defines such panels. In fact, labs generally do not unbundle tests included in the AMA's organ and disease testing panels.

In the latest instance of its focus on bundled tests, the NCCI issued changes at year-end to its coding guidelines regarding procedure-to-procedure edits in which a lab bundles together two tier 1 CPT codes for a molecular pathology procedure. The changes appear to indicate a failure to understand the scientific basis for how labs run molecular tests, the ACLA said in a letter it sent to NCCI in December.

Market Update

PAMA Price Cuts Now Delivering One-Two Punch to Labs' Revenue

First punch is less revenue from Medicare; Second punch are Medicaid lab test price cuts

When discussing their earnings with Wall Street analysts in February, executives from both **Laboratory Corporation of America** (LabCorp) and **Quest Diagnostics** explained that the lab test price cuts from the Protecting Access to Medicare Act of 2014 (PAMA) were not only reducing revenue, but that many state Medicaid plans are following Medicare's lead and cutting their lab test prices.

LabCorp executives said they expect the company's lab-testing revenue would be lower this year by about 1.6% as a result of two factors:

1. Lower direct Medicare payments of some $85 million; and,
2. An indirect effect from PAMA will reduce other payments, primarily from Medicaid-related plans, by $30 million.

Medicaid Cuts Lab Prices

Both fee-for-service and managed Medicaid plans have cut what they pay, and the rate reductions were consistent with the cuts Medicare made, LabCorp's executives said,

"This was not anticipated as part of the PAMA statute," commented LabCorp Chairman and CEO David King. "It was not contained within the statutory language, which specifically applied to Medicare. But it has exacerbated the impact of PAMA."

Later, King characterized the reduction in Medicaid payments as "administratively reducing rates," and said, "These are not negotiated rate decreases." As previously reported, the PAMA statute addresses Medicare reimbursement only and does not address the consequences of those cuts in reimbursement from any other payers, including Medicaid.

Executives from Quest also discussed lower payments from Medicaid plans but were less certain if the lower payments resulted from PAMA. Some Medicaid programs have reduced what they pay and those cuts in payment may be related to PAMA, said Quest CFO Mark Guinan.

"It's hard to know whether these Medicaid rates are directly tied to PAMA," he commented. "You can look across all the states, there seems to be potentially some direct relationship. Not all of them have changed the rates."

While lower payments should concern all clinical laboratories, smaller and regional labs may feel the effects most keenly because they tend to get a higher percentage of their revenue from Medicare and Medicaid, the executives commented.

Conversely, large labs have a wider mix of payments from commercial and government payers. They generally do not feel the effects of lower payments as acutely. King said labs under pressure from reduced payments may consider partnering with larger lab companies "or find other ways they can optimize the cost side of their business." TDR

—Joseph Burns

Improve Your AP Group's Financial Performance

Additional revenue can be collected by use of several essential key performance indicators

CEO SUMMARY: Across the nation, health insurers are paying less for anatomic pathology services. This shrinks pathology group revenue and reduces pathologist compensation. Savvy pathology groups are responding to this trend by reviewing long-standing processes in their coding, billing, and collections department. Their goal is to update these billing and collections processes in ways that allow the pathology group to collect more of the money legally due it from payers.

Part Two of a Series

PRIVATE PATHOLOGY GROUPS face their most serious revenue challenges since Medicare introduced diagnosis-related groups in 1983. Since then, the federal **Centers for Medicare and Medicaid Services** and commercial insurers have cut deeply into what they pay pathologists for the technical component and professional component of their services. Therefore, it's imperative that pathology groups pay close attention to coding, billing, and collections.

Get the Most from Billing

Part one of this series about anatomic pathology billing and collections included an overview of how AP groups can get the most from their coding, billing, collections, and financial reporting systems. *(See "Anatomic Pathology Groups Can Protect Both Revenue, Pathologist Compensation," TDR," April 8, 2019.)*

To improve the financial management of any AP practice seeking to maximize revenue and pathologist compensation, Al Sirmon, co-founder along with Chappy Manning, of **Pathology Practice Advisors**, of Columbia, S.C., advise pathologists and their practice administrators to look more closely into the financial performance of their practices to get an inside look at the opportunities for improvement that may not be obvious otherwise.

Using data from a group's billing software, he plugs those numbers into a spreadsheet to identify problems and trends. Among the most useful data are key performance indicators (KPIs) that include net collections, bad debt, and days in accounts receivable (AR).

"Most billing software programs allow easy access to the data we need and have useful analytical tools," Sirmon said.

"One useful function is the ability to download data into a spreadsheet," he noted. "I then create a pivot table from that spreadsheet.

"Once the pathology group puts its data in a pivot table, it can slice and dice the numbers in a variety of ways to gain insight into that particular part of its practice," he explained. "For instance, one KPI is the net collection percentage.

"For decades, we told pathologists that net collections should be above 90% and

bad debt should be less than 10%," he said. "But today, those benchmarks are difficult for pathology groups to reach and sustain.

"In addition, days in AR should be around 40," he added. "But getting AR days to about 40 is more difficult today than ever before because of high-deductible health plans (HDHPs).

High-Deductible Health Plans

"Some patients have deductibles of more than $7,000 a year, which means these people need to be handled like self-pay patients," said Sirmon. "When patients' responsibility levels are high, collection processes slow down and that affects the pathology group's financial targets.

"Not only is it difficult for the typical pathology group to get its AR days to 40, but it's also hard to hit 90% in net collections," he commented. "Currently, we recommend that good targets for collections and bad debt are about 88% and 12%, respectively. For days in AR, we recommend somewhere between 40 and 50. These numbers vary based on payer mix.

"Sometimes, despite considerable billing efforts, it remains difficult for a pathology practice to hit its goals due to the economics of the region," Sirmon said. "But with effort, it's still possible to make worthwhile progress. Recently, we saw a practice that had net collections above 90% because their billing team looked closely at the data before they turned claims over to a collection agency.

Data Mining, Pivot Tables

"When trying to identify the source of problems, data mining and pivot tables can make a big difference to an AP practice," Sirmon suggested. "Many practices look only at their income and expenses on the P&L. If they have enough cash to cover expenses and salaries, then they devote their time to all the many other problems of running a pathology practice.

"But that ignores the opportunity to collect a larger proportion of money legally due the practice," he continued. "I recommend pathology groups go much deeper and do a more complex analysis by looking first at patient revenue in detail.

"This should include a thorough examination of the complete revenue cycle, including gross charges minus contract adjustments (which equals net charges)," explained Sirmon. "Next, review gross collections minus refunds to get net collections, bad debt, and AR.

"We use the same principle with patient revenue," he said. "To do that, we start with the pathology group's beginning-accounts receivable plus gross charges. We then subtract contract adjustments, gross collections, refunds, and bad debt to get to ending-accounts receivable.

Key Performance Indicators

"Once we have these numbers, we can compute the key performance indicators," he said. "That's your pathology group's entire billing cycle simplified down to seven numbers. Those numbers show your pathologists everything that happens in the billing department.

"Remember, each time a pathologist signs out a case, it generates a gross charge," he noted. "That gross charge is paid by the insurance company or the patient. If it's not paid, the group will write it off as a contract adjustment or as a bad debt. If it's not paid and not written off, it remains in your data as a receivable.

"After following all these steps, it then becomes relatively simple to follow the numbers to see if a pathology group has a problem and find the source of that problem," he recommended.

"With these numbers, your pathology group can review all the data on accessions for a month, a quarter, or a year," advised Sirmon. "It is now possible to break this information down by CPT code, by payer, and by place of service—meaning whether the work was done for a hospital inpatient, outpatient, physician's office, or ambulatory surgery center.

To Improve Financials, Pathology Groups Can Use Key Performance Indicators, Benchmarks

PRACTICE CONSULTANTS OFTEN WILL USE the terms "key performance indicators" and "practice benchmarks" interchangeably. But in fact, the two phrases are distinct, according to Al Sirmon, founder of **Pathology Practice Advisors**.

"For any pathology practice, we typically analyze three key performance indicators (KPIs)," he commented. "Sometimes, we refer to these KPIs as external benchmarks because we use them to compare one practice against another.

"One KPI is net collection percentage," he explained. "We compute the net collection percentage by comparing net collections to net charges. Net charges are gross charges minus contract adjustments. Net collections are gross collections minus refunds.

"Once calculated, these metrics tell us how much the pathology group collected, compared to what the practice was allowed to collect—meaning the allowed amount in payer contracts," he said. "At one time, we would shoot for 90% or more in net collections. However, today, patients are responsible for a larger share of bills and so 88% may be more reasonable for net collections.

Bad Debt Percentage

"We calculate the bad debt percentage by dividing bad debt by net charges," he explained. "This number shows how much the pathology group could collect compared with what it actually collected. In past years, we tried to keep this number at 10% or less. Currently, with patient responsibility so high, 12% or less is acceptable.

"At the end of a period—such as a month, quarter, or year—we will review the net collection percentage plus the bad debt percentage. These two numbers should equal 100%," he recommended. "For example, 88% for a net collection percentage, plus 12% in bad debt equals 100% of the allowable."

Another common KPI is days in accounts receivable (AR), which is common in businesses that carry accounts receivable. "We calculate days in AR by dividing AR by average daily sales," he said. "Once again, due to rising levels of patient responsibility, this number has increased. At one time, we targeted around 40 to 45 days as a good number. Now 50 days is the norm.

"These KPIs vary among pathology groups, depending on the payer mix and the economy of the region," he said. "If any KPI is not what we expect, we will then compute that KPI for each health plan, CPT code, location, and place of service. This level of detail helps us identify any issues involving the pathology group's revenue.

Useful Benchmarks

"After KPIs, the following benchmarks also are useful, if used cautiously," added Sirmon. "That's because these KPIs may not be comparable from one pathology group to another," he explained. "In other words, they are most useful as internal benchmarks.

"One is the gross collection percentage, which is gross collections divided by gross charges," he said. "This benchmark is useful to compare results from one period with another. For example, you may compare the gross collection percentage for 2018 to 2017.

"You should not, however, use the gross collection percentage to compare one practice to another because one practice will have different fees (charges per CPT coded) and insurance contract allowables than another," concluded Sirmon.

"It is also useful to break it out by location—meaning which hospital was involved," he added. "Some of our groups have pathologists in multiple hospitals. Once a group follows these steps, it will see problems that need to be addressed.

Pathology Group's Analysis

"Here's an example: We had an assignment for a big practice," he recalled. "For this practice, we placed all their data by accession for the year on a worksheet. We used a pivot table to analyze all the different ways of looking at those numbers.

"Because this pathology practice had so many different locations, we could see how that group might bill each one either globally or for the professional component only," he explained. "For an AP practice, this factor is critical for two reasons. First, you need to know how to bill for each particular hospital patient. Second, you need to know if your group is billing correctly.

"For one hospital, if your group is billing only for the professional component, but instead you bill it globally, then you'll be overpaid," he warned.

"The opposite might be true if your group is supposed to bill for the global amount, but instead you bill only for the professional component. In this second example, the group would be leaving money on the table.

"These reports provide a quick way to identify those different kinds of discrepancies," Sirmon advised. "And, your team can pick any combination it wants to analyze to identify problems that might be impossible to locate otherwise."

Global Billing Approach

Sirmon provided a second example from an AP group that does a considerable volume of cases for two ambulatory surgery centers (ASCs). "The pathology group may need to bill one ASC globally and bill the other ASC for the professional component only," he explained.

"Depending on the payer, it could be either way, which would be complicated for the billing department to know without looking at the payer's contract. Therefore, a well-run pathology group will monitor that data closely to confirm that it is billing correctly.

"In cases where a pathology group's billing company does not provide the data needed for such a deep analysis, the group can download its Medicare accession data in a spreadsheet format from the billing software," he said.

"In this spreadsheet data, there's a column for each of these items: CPT code, payer, pathologist, place of service, and location. There are also columns for the charge, contract adjustment, paid amount, bad debt, and receivable. Using these data, the group can build a pivot table and pick any two or three variables for analysis.

Use of Random Sampling

"A pathology group can analyze all the data from the download, or it can take a random sample of 100 cases—as we do," he said. "When we do this type of analysis, we load the data into a worksheet and then use a pivot table to generate multiple ways to view the data. Whether the sample consists of 100 cases or 100,000 cases, the same principles apply.

"What you'll find is that if your samples are truly random, you will see that even small samples are amazingly accurate," he said.

"Once the analysis is complete, it's important to validate the findings by comparing results for each segment of the pathology group's data to the whole universe of data," he concluded.

"You can do this by adding up each segment of data to see if it totals the whole for the month, quarter, or year. If anything looks out of whack, you'll need look back to see where the analysis may have gone wrong." **TDR**

—Joseph Burns

Contact Al Sirmon at al@pathologypracticeadvisors.com or 843-319-0605; Chappy Manning at chappy@pathologypracticeadvisors.com or 803-553-8717.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Investor interest in digital pathology (DP) and the use of artificial intelligence (AI) to analyze digital pathology images seems to be at a fever pitch recently. In the last three weeks, investors poured almost $85 million of capital into just three digital pathology companies, as noted below. This activity may be a sign that certain DP and AI companies may be close to a product that can obtain FDA clearance for use by pathologists in patient care. The three recipient companies have products and systems that can be used to digitize and analyze pathology images, and identify cancer patients at the time of diagnosis for enrollment in clinical trials.

PATHAI RAISES $60 MILLION

On April 17, Boston-based **PathAI** announced it closed a series B funding of $60 million. Private equity investors were **General Atlantic** and **General Catalyst**. Pathologist, Founder and CEO Andrew H. Beck, MD, PhD, stated these funds would be used to enhance PathAI's existing offerings, improve its platform, and fund ongoing research into new tools and devices. PathAI was founded in 2015 and "supplies AI-powered research tools and services for digitizing and analyzing pathology images."

$14 MILLION GOES TO DEEP LENS

Just two days earlier on April 15, **Deep Lens** of Columbus, Ohio, stated that it had completed a series A financing round that totaled $14 million. Lead investor **Northpond Ventures**. Existing investors **Rev1 Ventures**, **Sierra Ventures**, and **Tamarind-Hill Partners** also participated in the round. Deep Lens has made VIPER, its primary product, "available free-of-charge to pathology groups worldwide, as we work to identify patients at the time of diagnosis for available clinical trials," said T.J. Bowen, PhD, Co-Founder and Chief Science Officer.

ISRAEL-BASED IBEX GETS $11 MILLION

In a press release issued on March 26, **Ibex Medical Analytics** of Tel Aviv-Yafo, Israel, announced the closing of a series A funding round that totaled $11 million. Investors included: **aMoon Fund**, **Kamet Ventures**, **83North**, and **Dell Technologies Capital**. The company's website says it has an "AI-driven diagnostic system which delivers efficient, metric-driven and accurate cancer diagnoses for tissue biopsies. It combines AI, data science, image analysis, and deep-learning technologies, and applies them to cancer diagnostics in digital pathology."

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...findings by researchers at the **University of Nebraska-Lincoln** (UNL) and the **Ocean Road Cancer Institute** in Tanzania that support the possibility that the cervical microbiome could be used by medical laboratories as a biomarker in determining womens' risk for cervical cancer.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 20, 2019.