Volume XX, Number 12 Monday, September 9, 2013

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

Medicare's Latest Attack on Lab Test Prices

MANY OF YOU KNOW ABOUT THE PROPOSED NEW MEDICARE RULE by the **Centers for Medicare & Medicaid Services** (CMS) that it would use to initiate a review of the prices it pays for 1,250 clinical laboratory tests under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS).

However, I'll bet that most of you are unaware of the other two proposed new rules that CMS also published in July. For services covered by the Physician Fee Schedule (PFS), the agency proposes to lower the price paid for non-hospital services to no more than the hospital outpatient department rates. A number of pathology services would see a fee reduction of between 4% and 80% if this rule is implemented as currently written.

The third rule involves the Hospital Outpatient Department Prospective Payment System (OPPS). The proposed rule would allow CMS to bundle both clinical laboratory tests and pathology services into the payments the agency makes to hospital outpatient departments. This is causing great concern because of fears that CMS will not use a transparent process and will not engage the industry as it proceeds to establish the prices of the bundles for individual outpatient services.

In this issue of THE DARK REPORT, we provide you a clearer picture of these proposed new rules and the negative financial impact they may have if implemented as currently written. In particular, the fact that these actions by CMS may be a challenge to the authority of Congress and its power to establish the budgets for the Medicare program—including Part B clinical lab test fees—is something that you will not read anywhere else.

Further, this information is actionable business intelligence you can use. Whether you decide to become more involved in your lab association, college or society; or whether you decide its time to contact your elected officials in Congress, the insights and analyses provided on the pages that follow can help you make your points with clarity and vigor.

What comes next is anyone's guess. CMS closed the comment period on the proposed rules last Friday. In coming weeks, there is certain to be intense discussions in Washington involving Medicare officials and lab and pathology leaders. Not until CMS publishes its final rules for 2014 in early November will anyone know if these unprecedented proposals will take effect on January 1, 2014. TDR

CMS Ready to Hack Away At Cost of Lab Testing

If proposed rules take effect on January 1, clinical labs and pathologists will see prices fall

CEO SUMMARY: In July, the federal Centers for Medicare & Medicaid Services (CMS) published three proposed rules which would allow it to act independently of Congress to set prices for clinical laboratory testing and pathology services. Analyses of these proposed rules indicate that they would substantially reduce reimbursement paid to labs and pathologists under existing arrangements. Some industry attorneys point out that these rules are likely to go beyond the agency's existing legal authority.

THERE IS AN INTERESTING TUG-OF-WAR unfolding between Congress and Medicare officials over who should have the authority to set prices for clinical laboratory testing.

This tug-of-war is a high-stakes contest for the clinical laboratory industry. Since the launch of the Medicare program in 1966, Congress has reserved for itself the power to establish funding levels for Part B Clinical Laboratory Testing.

Now, however, officials at the federal **Centers for Medicare & Medicaid Services** (CMS) appear ready to challenge that authority. In July, CMS published three proposed rules as part of the 2014 updates to the different Medicare fee schedules. CMS would claim additional power to determine coverage guidelines and prices for clinical lab tests and pathology services.

Implementation of these proposed new rules would be a significant change with deep ramifications for the clinical laboratory industry. If the primary power to set Part B lab test prices and funding shifts from Congress to CMS, it would dramatically change the interaction clinical lab professionals have with the federal government.

In particular, it would take lab test funding decisions out of the political arena and put them into the hands of regulators. That would upend a 47-year old process.

Two questions are being widely asked. First, why are CMS officials proposing these rules that would give them more authority to change the reimbursement for lab and pathology testing services? Second, why are they doing this now—and not earlier or later?

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

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 $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

NO PART of this Intelligence Document may be printed without written permission. Intelligence and information contained in this Report are carefully gathered from sources we believe to be reliable, but we cannot guarantee the accuracy of all information.

visit: www.darkreport.com • ©The Dark Group, Inc. 2013 • All Rights Reserved

Two recent events within CMS provide solid clues into how the agency is thinking about the cost of clinical laboratory testing. In May 2012, a study favorable to national competitive bidding for Part B clinical laboratory testing was published in the *Medicare & Medicaid Research Review* (MMRR, 2012: Volume 2, Number 2). The study was titled "The National Market for Medicare Clinical Laboratory Testing: Implications for Payment Reform." *(See TDR, September 17, 2012.)*

How To Save $910 Million

Early this year, on June 11, the **Office of the Inspector General** (OIG) issued a report titled "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings." It stated that the Medicare program could save $910 million per year on Part B clinical lab testing.

Essentially, the OIG concluded that, if the Medicare program would set its price for each lab test at the lowest price paid somewhere in the United States by a state Medicaid program, it would pay $910 million per year less than it currently pays for these lab tests. *(See TDR, June 17, 2013.)*

More has happened since these two federal studies dealing with how to save money on Part B clinical lab tests were made public. The deep cut to CPT code 88305-TC was enacted. And the entire lab industry is still dealing with the botched implementation of the 114 new molecular CPT codes that became effective on January 1, 2013.

All of these developments fit a pattern. Officials at CMS seem to have decided that there is a problem with the existing Medicare Part B Clinical Laboratory Test Fee Schedule and they intend to fix it, now!

If one assumes that this conclusion is true, then clear battle lines will soon emerge. For one, the anatomic pathology profession and the clinical laboratory industry will each oppose CMS actions they deem to be outside the law.

They may have a good legal basis to support their opposition. As you will read in this issue of THE DARK REPORT, a number of lab industry attorneys and associations believe that CMS does not have the basis in existing laws and regulations to assert the authority to allow it to change the prices for lab testing as described in the three proposed rules.

Next, Congress itself may weigh in on this issue. On pages 11-14, you will read how events are unfolding in Washington, D.C., along with observations about why Congress would want to be in control of Medicare lab test budgets so it can use any cost cuts as offsets to support other budget priorities.

Simply said, CMS has set a new game in motion when it proposed the three new rules in July that it wants to use to establish different prices for lab and pathology testing services. There will be members of Congress fighting CMS over aspects of these new rules.

At the same time, it can be expected that the different lab and pathology associations, societies, and organizations will step forward with their opposition to implementing these proposed rules as currently written. Early analysis of the impact of these new rules shows that they can be financially devastating to all lab organizations, whether large or small.

CMS Has The Next Move

Now that CMS has closed the comment period as of last Friday, the next move is up to the agency. It must respond to the comments and publicly release its final rules. This typically happens early in November.

With fee cuts of 4% to 80% estimated to result from implementation of the proposed new rules as currently written, it is reasonable to expect tough opposition from the laboratory medicine profession. One thing will be clear to any lab executive who studies these proposals: deep reimbursement cuts lie ahead if these rules are implemented as written. TDR

CMS Proposes Yet More Cuts for 2014, Beyond

Medicare unveiled three proposals that will result in lower payments for lab tests

CEO SUMMARY: In July, CMS proposed rules to cut payments under the Hospital Outpatient Prospective Payment System, the Physician Fee Schedule, and the Clinical Laboratory Fee Schedule. Under each program, the proposed payment cuts could have a significant and negative effect on the amount of payments that laboratories receive from Medicare. Two of the proposals may go into effect on January 1, 2014, and the other proposal won't become effective until 2015 at the earliest.

YET AGAIN, MEDICARE OFFICIALS are proposing new rules with the goal of further reducing what the federal health program pays for clinical laboratory tests and anatomic pathology services. These rules may become effective on January 1, 2014.

First news of this development came on July 6, when the federal **Centers for Medicare & Medicaid Services** (CMS) announced its 2014 Medicare Physician Fee Update. Each summer, CMS uses this vehicle to propose specific changes in how it will administer the Medicare program for the coming years.

The bad financial news for the pathology profession and the clinical laboratory industry can be found in the proposed rules that would change the following three Medicare payment systems:

- Physician Fee Schedule (PFS)
- Clinical Laboratory Fee Schedule (CLFS)
- Hospital Outpatient Prospective Payment System (OPPS)

The payment cuts under each of these programs could be significant, but are only proposed. The comment period ended Friday, September 6. CMS must now consider the comments it received from clinical lab administrators, pathologists, and their representatives. The final rules will likely be issued in November.

For an explanation of these changes and how they might affect clinical laboratories, THE DARK REPORT interviewed Paul Radensky, M.D., J.D., a partner in the law firm of **McDermott Will & Emery LLP** in Washington, D.C. He has analyzed the proposed changes.

No Consideration of Value

"In July, CMS published three proposals in the *Federal Register*," stated Radensky. "Each proposed rule is based on faulty assumptions and none of the proposals involves a consideration of the value of the information that results from lab tests.

"What's been overlooked in each of these proposals is the importance of considering what a prudent actor would pay for the value of the information that is generated from these laboratory and pathology tests," he observed. "Nothing in these proposed rules reflects that CMS is

considering the value of the information to patients and physicians.

"In the first proposal, CMS would limit payments for non-facility based services under the Physician Fee Schedule to the amount paid when the service is performed in the facility setting," explained Radensky. "CMS estimates that this proposal will reduce payments to laboratories by approximately 25% starting January 1.

CMS To Review 1,250 Tests

"The second proposal involves conducting a systematic examination of payment amounts for tests on the Clinical Laboratory Fee Schedule that have undergone 'technological changes' affecting the price of the test," he said. "In this process, CMS will review 1,250 of the most common clinical laboratory tests over five years. The review will begin in 2014 for rates effective in 2015.

"The third proposal involves bundling clinical laboratory payments into the Hospital Outpatient Prospective Payment System," he added. "This would start on January 1, 2014."

Relative to the PFS, the first proposal would cap payments based on the hospital Outpatient Prospective Payment System. Radensky explained the details. "CMS said that, in cases where a physician pathology payment for a service provided in non-hospital settings is higher than the same service provided in hospital settings, it would reduce that payment in the non-hospital setting to the same level as the hospital setting," he noted.

"In some ways, this may not appear unreasonable," Radensky observed. "Any purchaser would argue that—when the same item found in two stores is cheaper in one than it is in the other—he or she should buy the cheaper one if all other factors are equal.

"But applying the same logic to physician pathology testing services—whether in a hospital or non-hospital setting—assumes that the data that determine payment rates for testing in the hospital outpatient setting is more accurate than the data that determine rates for the non-hospital setting," stated Radensky. "Many organizations inside and outside of CMS have said that CMS should not assume that payments under the OPPS represent the actual cost of the service delivered.

"Under the OPPS, hospital labs know that, overall, payments are part of a zero sum game in which they may lose money on some tests and make it up on other tests so that they can break even overall," he continued. "But with this proposed rule, CMS is picking out the items in the lowest-paid settings and saying these are the ideal prices.

"For CMS to view costs in this way is simplistic," said Radensky. "That's because costs in the OPPS come from hospital charges for individual services and cost reports that reflect the costs of laboratory services in the hospital as a whole.

"But these data do not represent the actual costs of individual services, since every charge reflects a mark up from costs and CMS is making the assumption that everything gets marked up uniformly," he added. "Thus, if one item is marked up four times, then the approach proposed by CMS assumes that everything is marked up four times. But that's not true.

Calculating Overhead Costs

"Take the example of overhead costs added to every medication dispensed in a pharmacy," continued Radensky. "If the pharmacy adds $5 to every pill it dispenses, then a 10¢ aspirin will cost $5.10 and a $100 medication will cost $105," he stated. "Thus, the items with the lowest cost generally have the highest mark-up and higher-cost items have a lower mark-up.

"This principal is equally true in the lab," he said. "Therefore, for CMS to assume that each laboratory test has a uniform mark up is incorrect. This point has been discussed many times before with CMS.

"It will be a major problem if CMS makes this incorrect assumption and it results in a reduction in payment for laboratory testing services," Radensky noted. "It is possible that the reduction in fees for outpatient clinical laboratory test services could be as much as 25% lower than what Medicare currently pays. For individual tests, cuts in excess of 50%, 60%, or even 70% may occur."

Radensky saw a similar problem with the second proposal that involves the Clinical Laboratory Fee Schedule. "CMS says it intends to do a systematic five-year examination of payments for about 1,250 clinical laboratory tests under the CLFS," he stated. "CMS said it wants to identify those tests that have undergone 'technological changes' that affect the resources required for a laboratory to perform these tests."

Increased Test Utilization

In an article it published on the changes, McDermott Will & Emery wrote: "The reason for this proposal is that CMS has seen increased use of point-of-care testing, genetic and genomic testing, and laboratory-developed tests (LDTs). CMS defines a technological change as any change to the tools, machines, supplies, labor, instruments, skills, techniques and devices that results in changes to the resources required to perform the test, the types of personnel required to perform the test or the volume, frequency, and site of service of the testing."

"There are several problems with this second proposal," Radensky said. "First, unlike payments to physicians and payments for inpatients, the CLFS is not a resource-based fee schedule. This is significant, because charges—not costs—are the basis for existing prices on the CLFS.

"Historically, the CLFS has been charge based," he continued. "In its proposal, CMS is not clear on how it would adjust fees on the basis of costs.

"Further, there is very little detail in the second proposed rule about how it

ACLA's Comments to CMS Document Past Lab Cuts

WHEN IT MADE ITS COMMENTS to the federal Centers for Medicare & Medicaid Services, the **American Clinical Laboratory Association** (ACLA) pointed out many problems with the design of the three proposed rules the agency published in July.

Notably, ACLA reminded CMS that it is overlooking the fact that Medicare reimbursement for clinical laboratory testing services has failed to keep pace with inflation, reaching back as far as 1984.

On this point, ACLA wrote that "CMS makes a cursory mention of adjustments based on changes in the CPI-U, productivity adjustments, and 'adjustments required by statute.' These adjustments have not been insignificant and should not be dismissed lightly. Taken together, these have been substantial payment adjustments—almost uniformly downward—for the [laboratory testing] services that ACLA's members provide." ACLA then noted the following:

- In at least 19 of the years from 1984 through 2011, laboratories received no fee increase or did not receive the full amount of the Consumer Price Increase (CPI) increase that the statute otherwise would have required. In a few years, the fees actually decreased.
- There also have been seven reductions in the National Limitation Amounts ("NLAs") for laboratory services. The net result is that a laboratory test that was reimbursed in 1984 at $10.00 was reimbursed at $8.71 in 2011, a 13% downward adjustment before inflation.
- A provision in the health reform law applied a 1.75% annual downward adjustment for laboratory tests on the CLFS for each of the years 2011 through 2015.
- A law passed in 2012 called for a 2% rebasing of the CLFS in 2013.

will identify tests covered by the CLFS for review," observed Radensky. "CMS said it will start with the oldest tests or the highest-volume tests. But what steps will CMS then take to identify specific technological changes that have changed how laboratories perform each of these assays?

Faulty Logic

"What makes this CMS proposal troubling," he continued, "is that there appears to be an assumption that—whenever a lab system or analyzer is simpler to operate—it can be automatically concluded the test is now cheaper and so labs using the automated system should be paid less. But, again, this is faulty logic.

"The lab industry has two major concerns about this second proposed rule," he explained "First, it takes a considerable amount of research and development costs to design and manufacture a point-of-care (POC) testing system. Thus, maybe there is less lab labor to run these POC tests, but the supply costs may be higher.

"Second—and of equal significance—is the heavy regulatory burden that must be met by every lab test manufacturer and by clinical laboratories as well," added Radensky. "The cost of obtaining regulatory clearance to bring an assay to market, and keep it compliant, is built into the supply cost of the POC test. Once again, we have an incorrect assumption that it's cheaper to develop a test that takes fewer people to produce a result.

Equally Troubling Problem

"Should CMS look only at the unit cost for a laboratory to perform a lab test result, there will be an equally troubling problem," he stated. "Under this approach, there will be no innovation because no one is calculating the cost of the innovation. Assume a company invests $10 million to develop and validate a test and the cost to perform the test runs $100 per test.

"Were CMS to pay only the $100 cost for performance of this test, how can a company recover the $10 million it invested in development costs?" he asked. "Many in the clinical laboratory and medical device industries have voiced this specific objection many times."

Under the third proposal, CMS wants to bundle clinical laboratory payments into the Hospital Outpatient Prospective Payment System (OPPS). This would become effective on January 1, 2014.

"It appears that CMS is looking to have more global payment in the outpatient setting just as it does on the inpatient side with DRGs," commented Radensky.

"The problem is that the outpatient prospective payment system is not designed like the inpatient DRG system, where CMS has developed appropriate groupings over the past 30 years," he noted. "The OPPS is a fee-schedule system designed to pay for procedures. It's not a diagnosis or patient-encounter based system.

Labs Could Face Problems

"The concern with this proposal is the hospital will get an increase in payment but labs could face problems because the hospital may no longer want to run all tests that patients may need," noted Radensky. "Hospitals may suggest patients get some tests outside of the hospital in order to control costs. Then hospitals might not have a record of those tests. Alternatively, the patient might not bother to get those tests because doing so outside of the hospital may be more costly or time consuming or both for the patient.

"With Medicare no longer paying the hospital lab directly for these outpatient tests, the result for hospital-based laboratories will be fewer tests for these patients and a new way to account for payment for these tests," stated Radensky. "Either way, this proposal could result in a loss of revenue and a drop in sample testing volume in hospital-based clinical laboratories." TDR

—By Joseph Burns

Contact Paul Radensky at 202-756-8794 or pradensky@mwe.com.

Attorneys for CAP Say CMS Fee Proposals Illegal

CMS lacks statutory authority to change resource-based pricing, CAP letter says

CEO SUMMARY: In its comments about a proposal to change the way CMS pays for clinical laboratory and pathology services, the College of American Pathologists (CAP) said that CMS is using faulty assumptions. CAP further commented that the CMS proposal to cap physician fee schedule payments at the level of hospital outpatient department rates violates a statutory Medicare requirement that physician expenses should be resource-based. The comment period ended on September 6.

LAST FRIDAY WAS THE DEADLINE for submitting comments in response to the proposed new Medicare rules published in July by the federal **Centers for Medicare & Medicaid Services** (CMS).

In its comments submitted to the federal agency, the **College of American Pathologists** (CAP) stated that the proposed rule that would link payment for pathology services on the Physician Fee Schedule (PFS) to lower rates paid under Medicare's Hospital Outpatient Prospective Payment System (OPPS) violates the statutory requirement that Medicare practice expenses be resource-based.

Contrary To Law, Regulation

In the opinion for CAP, lawyers from the law firm of **Sidley Austin LLP** said the proposal from CMS "does not reflect actual resource costs in the non-facility setting—contrary to law and regulation and CMS' stated policies and past practices." The proposal also "relies on faulty assumptions and inapplicable facility resource data," CAP said in a statement released Friday (September 6).

In a 96-page letter to CMS Administrator Marilyn Tavenner, CAP urged CMS to withdraw the proposed rules CMS issued on July 8. CAP said the proposals could threaten patient access to pathology services.

In an interview with THE DARK REPORT, Richard C. Friedberg, M.D., Ph.D., Chair of CAP's Council on Government and Professional Affairs, said, "We have a legal opinion that clearly shows that the Medicare proposed rule linking the PFS to lower rates paid under the OPPS violates the statutory rules regarding practice expenses." Friedberg also is Chairman of the Department of Pathology at **Baystate Health** in Springfield, Massachusetts.

Asked if CAP would file a legal challenge against CMS if the agency pursued these proposals when it issues a final rule in November, Friedberg said he could not be certain what course of action CAP might take. "That's not what we're focused on right now," he stated. "CAP has provided its comments and legal analysis to CMS and just because the com-

ment period has ended, that doesn't mean this campaign will end.

"CAP members have been—and will continue to be—in touch with their members of Congress about these concerns," emphasized Friedberg. "We expect members of Congress to engage with CMS on these issues.

"Keep in mind that there is much time between now and November 1, when the final rules will come out," he observed. "During this time, we expect to have many discussions about these proposed rules."

Concerns About New Rules

In its letter to Tavenner, CAP not only focused on the issues CMS raised about the PFS, but it also listed other concerns the college has with two other proposed rules. One rule deals with the bundling of payment under the OPPS. The other rule would establish a review of lab tests that are reimbursed under the Clinical Laboratory Fee Schedule (CLFS).

CAP pointed out that the proposed rule to lower PFS payments to no more than the hospital outpatient department rates, would, "if finalized as proposed, ...reduce the technical component (TC) and global payment of 39 pathology services billed for non-hospital patients by as little as 4% and as much as 80% depending on the service."

In its comments about the proposed rule to change the Hospital Outpatient Prospective Payment System, CAP advocated "for the withdrawal of CMS' Hospital Outpatient Prospective Payment Proposed Rule (CMS-1601-P), which attempts to bundle pathology physician services and nearly all clinical laboratory tests into Medicare's payments to hospital outpatient departments."

The college noted that "CMS proposes three packaging policies in the OPPS proposed rule that create serious concerns and questions for CAP members: packaging physician pathology services into 'primary procedures;' packaging certain 'add-on' codes; and packaging nearly all clinical diagnostic laboratory tests (except molecular pathology.)"

In particular, CAP noted that "CMS' proposal to 'bundle' over 1,000 clinical laboratory tests into the payments for hospital outpatient procedures could create financial disincentives to perform medically necessary testing, or shift testing from outpatient settings to hospital settings, creating new burdens for patients and higher costs for the healthcare system."

CAP additionally commented that "Within the proposal, CMS proposes to conditionally package over 280 physician services, including over 80 pathology physician services, without any assurance that they will be reimbursed adequately. As pathology practices may receive referrals of specimens from multiple hospitals and physician practices, keeping track of when tests should be paid separately vs. packaged into a hospital service will create enormous administrative burdens."

Wary Of Rule About CLFS

The college was equally wary of the proposed rule involving the Clinical Laboratory Fee Schedule. It wrote that, "With respect to CMS' proposed review of technological changes that may affect the cost of performing some laboratory tests, the CAP urges CMS to proceed with great caution. In reviewing these technological changes, it is essential that all parties—CMS, the laboratory community, and other interested members of the public—be involved in the development and refinement of the review process."

All pathologists and clinical lab administrators should take note of the fact that each of the three proposed rules, if implemented as written, would have a substantially negative impact on the finances on virtually all of the nation's labs. TDR

—By Joseph Burns

Contact Richard Friedberg, M.D., Ph.D., at Richard.Friedberg@BaystateHealth.org.

CMS' Proposed Lab Rules May Not Fly with Congress

In Washington today, elected officials want control over cost cuts due to budget pressures

CEO SUMMARY: Many clinical lab administrators have noticed the new activism at the federal Centers for Medicare & Medicaid Services (CMS) when it comes to control of establishing prices for clinical laboratory tests. In this exclusive interview, two long-time advocates for the National Independent Laboratory Association discuss several of the issues associated with the three proposed Medicare rules that CMS intends to use to more directly set lab test prices.

IN MANY WAYS, MEDICARE OFFICIALS have become more activist in their approach to managing clinical laboratory testing and establishing prices for individual tests.

This increased activism was most obvious in the three proposed rules that the federal **Centers for Medicare & Medicaid Services** (CMS) published in July. Each proposal, if enacted, can be expected to substantially reduce what the Medicare program pays for clinical laboratory tests in coming years. *(See pages 2-10.)*

In turn, these three proposals must be understood in the context of several federal studies made public over the past 18 months. In response to these studies, the three proposals announced by CMS in July would enact:

A) significant cuts to pathology services (via the Physician Fee Schedule–PFS);

B) bundling for laboratory services in hospitals (via the Outpatient Prospective Payment System–OPPS); and,

C) reassessing payment rates under the Clinical Laboratory Fee Schedule–CLFS.

To help lab administrators and pathologists understand why CMS officials have become more assertive in their efforts to control the prices of clinical lab testing, THE DARK REPORT turned to two individuals who regularly have conversations with members of Congress and their staffs, administration officials, and officials at CMS.

For a number of years, Julie Scott Allen, Government Relations Director, and Erin Will Morton, Senior Government Relations Manager, for **Drinker Biddle & Reath LLP**, in Washington, D.C., have represented the **National Independent Laboratory Association** (NILA). They have helped independent lab owners who are members of NILA educate lawmakers and agency officials about the impact these decisions have on community labs.

What Medicare Should Pay

Allen and Morton have important insights about how the thinking of lawmakers and government administrators has evolved in recent years. This information can help lab professionals better respond to the events now unfolding in Washington.

The first point that Allen and Morton made is that every health program is being scrutinized based on costs—laboratories included. They noted that the thinking within CMS as it pertains to clinical laboratory test fee schedules has evolved. They believe that the agency wants to assert a greater level of control over how Medicare reimbursement for clinical laboratory tests are established.

More Control Over Lab Fees

"This desire to have more control over clinical lab test fees is based on the ability that CMS has to set prices in other areas of the Medicare program," explained Morton. "When you look at how CMS works, it has greater control over the physician fee schedule (PFS) and the hospital inpatient and outpatient payment schedules (IPPS/OPPS). For these fee schedules, CMS uses formulas to set rates.

"That is not true for the Clinical Laboratory Fee Schedule," she continued. "The agency does not have such a formula for clinical lab reimbursement rates.

"What we have heard in our discussions with members of Congress and their staff on the hill," stated Allen, "is that officials from CMS have been making a lot of statements about their frustration over not having any control over what Medicare pays for laboratory services and how such payment rates are derived."

Take the observations of Allen and Morton at face value and THE DARK REPORT can argue that a series of actions taken by CMS over the past 24 months can be interpreted to be consistent with the agency's desire to claim it has the authority to establish clinical laboratory test prices with some degree of independence from Congress.

"For a while, we have suspected that CMS wanted greater control over lab rates but its officials have struggled with both how to do it and whether they have the legal authority to do it," explained Allen. "We now have studies being produced by agencies like the **U.S. Office of Inspector General** (OIG) that we believe make inaccurate comparisons between what Medicare pays for laboratory tests versus other payers."

"Adding to that frustration is the legal question about whether CMS has the ability to set rates for clinical laboratory tests," interjected Morton. "For years, this question about statutory authority was mentioned in the reports from the Office of Inspector General and others who said CMS does not have the authority to set rates for clinical laboratory tests."

In fact, CMS has been criticized on exactly this point after it published its three proposed rules in July, each designed to allow it more control over setting the prices for clinical laboratory testing. Critics ask, "Does the agency have the authority to administer these aspects of the Medicare program as it proposes?"

Another Twist In The Story

There is another fascinating twist in the story about CMS' efforts to assert itself more aggressively into the price-setting process for clinical laboratory testing. By taking these steps, CMS may be challenging a power that Congress has reserved for itself. That could set off a fight that involves both politics and who keeps the economic power in these matters.

To further complicate things, the sequester and issues associated with the debt ceiling limit have Congress on high alert for opportunities to cut costs in every possible way as part of its own budgeting process. This includes the Medicare program and the fees for clinical laboratory testing—which brings the CMS proposals into conflict with the needs of Congress, at least in this regard.

In their analysis, Allen and Morton have factored in the issues associated with the federal budget and how cuts are made in one area to offset increased spending in other areas. Morton explained that the three proposals introduced by CMS in

Medicare Program's Three Proposals to Control Lab Test Prices Are Challenge for Lab Industry

EACH OF THE THREE PROPOSED RULES published in July by the federal Centers for Medicare & Medicaid Services (CMS) represents a serious threat to existing patient access to lab testing and the financial stability of clinical laboratory organizations across the entire United States.

However, it will not be simple for the lab industry to educate government officials and members of Congress about the negative impact these proposed rules can have. That's the opinion of two experienced advocates representing the National Independent Clinical Laboratory Association (NILA) and employed by Drinker Biddle & Reath LLP, in Washington, D.C.

Challenge Facing Labs

Julie Scott Allen, Government Relations Director, and Erin Will Morton, Senior Government Relations Manager, described the challenge now facing the lab industry and its professional associations. "The problem with having three different proposed cuts from CMS—each of which is significant—is they become complicated for all of us to talk about with elected officials and policymakers," stated Morton.

"Changes are proposed in three different Medicare fee schedules and each change affects a different segment of the clinical laboratory industry," she added. "It is a problem that no one is looking at these cuts collectively and how they could have an effect at unraveling a well-performing medical laboratory testing infrastructure in the United States."

"With these three proposals, CMS is effectively changing the market in how lab testing services are delivered," noted Allen. "Yet, prior to issuing these proposed rules—which are on track to possibly be finalized this fall—CMS did not engage stakeholders, ranging from members of Congress to clinical lab associations, patients, and sectors of healthcare that will be affected by the downstream consequences of these proposed rules.

"Policymakers tend to look for easy answers, meaning they sometimes look at profit margins and other metrics to evaluate the success of the industry," Allen continued. "Washington sometimes has a spreadsheet mentality that has nothing to do with fundamentally addressing policy reforms to improve healthcare delivery and address long-term cost concerns. For example, Congress is more interested in finding short term 'pay-fors' or offsets to achieve financial goals and labs have suffered in recent years as a result."

"These are just some of the issues that make the latest proposals so frustrating," concluded Morton. "This new effort from CMS has great significance and consequence. But there was no discussion with the community prior to the announcement of these proposed new rules."

July came just as Congress was talking about conducting negotiations over increasing the debt ceiling.

That means Congress will be looking for savings from all providers, including, once again, clinical labs. "The hill is looking for savings that it can put into its package of changes designed to revise the sustainable growth rate (SGR)," noted Morton. "Yet each of the three proposals announced by

CMS in July essentially takes these savings away from Congress."

Two Approaches To Spending

There are two approaches to cutting spending, Allen explained. One is political and one is philosophical. "On the political front, there is the battle of the offsets," she stated. "The obvious example involves the sustainable growth rate (SGR), when lab spending gets cut as part of the overall spending cuts Congress needs to offset the funding for the SGR fix.

"For political reasons, Congress wants flexibility to cut spending on lab tests when money is needed for the debt ceiling, SGR, or entitlement reform," added Allen. "But on the philosophical side, some in Congress believe Medicare should never pay more than what the private sector pays for lab tests.

"The question over what goes into the actual cost of laboratory testing services is complicated, yet CMS and Congress seem to be seeking simplistic answers," noted Allen. "To compare Medicare spending to private sector spending is not an apples-to-apples comparison."

"The challenge in discussing all of these issues in Washington is explaining clearly what truly goes into the cost of providing each type of lab testing service," explained Morton. "For example, the cost of labor and transport have all gone up.

Delivering More Care

"Our healthcare system is also delivering more care to an older population with chronic health issues," she said. "These issues affect costs for all providers, including labs. Elected officials and policymakers need to be educated about these costs.

"At the same time, it is essential that these decision makers understand two points," concluded Morton. "The first point is how proper utilization of laboratory testing contributes to lower costs within the Medicare program. The second point is what will happen if labs were no longer available to provide these services." TDR

—Joseph Burns

Contact Julie Allen at 202-230-5126 or Julie.Allen@dbr.com; Erin Morton at Erin.Morton@dbr.com or 202-230-5634.

What's at Stake with Three CMS Proposed Rules

TWO THINGS MAKE IT DIFFICULT for the lab industry to respond to the three proposed rules published by the federal Centers for Medicare & Medicaid Services (CMS) in July that address lab testing.

First, each proposed rule deals with a different schedule of fees within the Medicare program. A different process is used to develop coverage and reimbursement guidelines for each of the three fee schedules.

Second, a different sector of laboratory medicine is directly affected under each proposed rule. Thus, when educating lawmakers and their staffs about the consequences of each of the three rules, it can become quite complicated. It also makes it tougher for a single coalition of medical laboratory interests to speak with one voice about the three proposed rules.

The three payment schedules involved in the three proposed rules are:

- **Clinical Laboratory Fee Schedule (CLFS)–**This Part B schedule is well-known to most clinical labs. CMS estimates that it will review prices for 1,250 clinical lab tests.
- **Hospital Outpatient Prospective Payment System (OPPS)–**involves bundling clinical laboratory payments.
- **Physician Fee Schedule (PFS)–**for pathology services, would limit pathology payments when they are higher in nonhospital settings than the payment for in-hospital settings.

Hospitals Recognize Need For Uniform Lab Test Data

To operate ACOs and deliver integrated care, hospitals want standardized test data in their EHRs

CEO SUMMARY: Hospitals may soon insist that payers allow their in-house labs to provide outpatient testing regardless of exclusive managed care contracts with national lab companies. The migration to accountable care organizations (ACOs) and medical homes makes it essential that physicians have access to lab data across the entire continuum of care. Standardization of reporting formats and reference ranges are needed to allow meaningful tracking and trending of patient data within the electronic health record.

FOR DECADES, HOSPITAL ADMINISTRATORS have failed to recognize the potential value of clinical laboratory testing. This failure is about to change—and fast!

Hospital administrators are waking up to the new reality. Whether the setting is inpatient or outreach, their physicians need real time access to standardized lab test data to support integrated clinical care and improved patient outcomes. A fragmented or incomplete record of a patient's lab test data can no longer be tolerated.

If this premise is true, then big changes are ahead for two competing sectors of the lab testing industry. Hospital and health system laboratories may benefit at the expense of the national lab companies.

THE DARK REPORT is learning about how progressive hospitals and health systems are responding to the different needs required to participate in an integrated care delivery organization. This is true whether it is an ACO, a medical home, or another business model of integrated care.

Administrators in hospitals and health systems that are part of ACOs have two distinct clinical and operational needs—each of which utilizes clinical lab testing in essential ways. One need is to improve the care delivered to inpatients to meet payer requirements for value-based payment. This requires populating the electronic health record with lab test data that has standardized reporting formats and standardized reference ranges. Both are required to allow physicians to track and trend patient data in a meaningful way.

Access To More Specimens

The second need of hospitals and health systems is to have access to increased volumes of lab test specimens that can be processed on their existing lab automation systems. This supports inpatient testing and generates a lower average cost per test for the hospital (and the ACO in which it participates).

The other important benefit is that, by integrating lab test data across the inpatient and outpatient environments, the ACO or medical home can track patient progress and avoid costly duplication of testing.

These are the reasons why, during planning sessions, the conversation quickly turns to laboratory testing. As hospital administrators work to improve inpatient services and integrate care within their ACOS, it becomes obvious that clinical lab test data is needed at the point of care so that physicians can track patients' progress from one setting to another. As noted earlier, that also avoids costly and duplicative testing.

Longitudinal Data Needed

This fact is well-known to pathologists and clinical lab managers. Longitudinal data on patient care must be available if any integrated model of care delivery—such as ACOs or patient-centered medical homes—is to be successful.

Another element that has the full attention of hospital administrators is healthcare's new reimbursement models. In ACOs and medical homes, physicians and hospitals often operate under shared-savings contracts. Each party can share in the savings produced by reducing healthcare costs. The opposite is also true, as ACO providers operating under shared-risk contracts must cover any costs above a budgeted amount.

Administrators of ACOs recognize that their organizations must do more to prevent illness while also keeping costs low. That is why, in strategy discussions across the country, the value of laboratory testing is gaining new recognition.

At the same time, hospitals and health systems find themselves dealing with a number of serious problems. In some manner, each problem involves either how lab testing is performed or whether an accurate and complete history of a patient's lab test data is available in the electronic health record (EHR).

Problems occur when hospitals and health systems cannot get a complete record of all the lab test data generated by their patients during previous visits. Similarly, when the patient shows up in the hospital, physicians there benefit by having access to lab test data generated during the patient's visits to office-based physicians.

For example, the ACO's providers struggle to manage care efficiently if either the hospital or the primary care clinic cannot get the patient's lab test data it needs at the point of care. Similarly, if the lab test data is not in a readable format in the physician's electronic health record system or hospital's EHR, that also interrupts timely and accurate care.

THE DARK REPORT is hearing that multiple hospitals are dealing with these same issues. These are early-adopters that own one or more primary care physician groups. Under hospital ownership, most of these primary care groups run clinics where they have phlebotomists who collect lab specimens.

In such arrangements, a longstanding lab industry practice creates a problem for the hospital attempting to develop an integrated clinical delivery organization. Once the primary care clinic collects the specimens, the clinic must then separate the specimens and send them to different laboratory providers.

Some specimens go to the hospital's in-house clinical laboratory. Other specimens are sent to the large national labs because of managed care contracts that exclude the parent hospital's laboratory as a provider. The federal Medicare program doesn't have exclusive contracts with the national labs and so the hospitals can do that testing for the primary care clinics.

Lack-Of-Continuity Problem

As ACO administrators meet to discuss how to move forward with integrated care, they recognize that having multiple laboratories provide test data for the same patient creates a lack-of-continuity problem. That directly impedes the efforts of physicians to achieve improved patient outcomes while lowering the overall cost of care.

Market May Encourage Different Strategies For ACOs to Achieve Uniform Lab Test Data

WHEN MANAGED CARE CONTRACTS require the primary care clinics owned and managed by hospitals participating in accountable care organizations (ACOs) to send most of their clinical laboratory testing to the large national laboratories, it confounds the ability of the ACOs to deliver integrated care.

However, the shift to hospital-owned physician practices might help to change the contracting practices involving clinical lab testing services. Typically, a physician practice has contracts with managed care organizations for the patient services that they provide. These contracts direct the physician practice to use the payer's network laboratories. Too often, these networks exclude hospital laboratories as providers.

As a strategy, the hospitals that own physician practices can actually take advantage of these contracts. They can do this by having the physician practice continue to bill for testing while the parent hospital laboratory owner provides the actual testing through an internal transfer fee arrangement.

The benefit of this strategy is that the the hospital or health system is positioned to secure patient testing across the care continuum with integrated reporting and with an economic incentive.

Working With National Labs

A second strategy is for a hospital or health system to work with the national laboratories to be recognized as one of their lab testing sites. The national laboratories call this "reverse testing" and it is a rare arrangement at this time. What may change this situation is the pressure a hospital brings to bear to gain an integrated patient laboratory data record.

Because many hospitals and health systems utilize the national laboratories as their reference laboratory providers for the esoteric testing that is not on their in-house test menu, national laboratories may be interested in stronger partnering arrangements with their customers. That is why a reverse testing program could help to solidify those business relationships.

The third strategy is for hospitals and health systems to negotiate directly with health insurers. Once payers recognize the importance of having standardized lab test data that is fully integrated within the patient's electronic medical record, it will be harder for the payer to continue supporting a non-integrated model of lab testing.

Need To Educate Payers

For this strategy to succeed, hospitals will need to educate payers about the value of lab test data. It means that the managed care negotiators at hospitals must first understand the value that their in-house labs can contribute to improved patient outcomes and reduced cost of care.

This strategy also helps hospitals meet another important challenge. That is the sizeable co-pays and deductibles that health insurers levy on patients when out-of-network laboratories perform testing. Payers commonly won't require patients to pay large deductibles if the testing is done by one of the national lab companies contracted by the payers.

Hospital administrators are beginning to realize that, if the outreach patients being seen by their primary care clinics are to avoid having to pay these high deductibles for lab testing, then they must convince payers to add their hospital laboratories to the provider networks.

Collectively, these developments in the healthcare marketplace indicate that a long-standing status quo in the lab testing outreach market may be poised for an interesting transformation.

It means that physicians must sort through different lab test methodologies, different names for the same tests, and different reference ranges.

If the hospital laboratory was to provide testing for inpatient, outpatient, and outreach services, it would create a unified patient record that is available in the physicians' EHR, and the hospital's EHR.

There are also financial issues caused by having multiple laboratories serve the patient population of an ACO. For example, if the hospital retained the specimen volume originating in the physicians' offices, it would see a substantial reduction in the average cost per test within its in-house laboratory.

Administrators at certain hospitals are telling lab management consultants that they are concerned about their inability to track patients' lab test data so that they can show trends over time. Cancer is a good example. To treat cancer patients, physicians must be able to track patient lab test data over many months.

Where Patients Are Treated

But tracking an individual patient is a challenge because cancer patients often move from one location to another. In the fee-for-service model of healthcare, when the patient moves from a clinic to a hospital for treatment, there is no continuity of care data on that patient. That makes it difficult for physicians to access the results of tumor marker testing and other relevant lab test data.

Here is where the evolution of healthcare may bring about a fascinating change in the relationships between hospitals, managed care companies, and the national laboratories. It is being reported to THE DARK REPORT that hospital administrators are becoming frustrated at the fact that the national labs actually exacerbate this problem of continuity in patient data.

Frequently the national lab companies cannot transmit their lab test results to the hospitals in the same format that the in-house hospital labs use. Also, methodologies and the reference ranges used by the national lab companies are different than the test menu of the hospital's laboratory.

Such a situation makes it nearly impossible for the hospitals to do effective tracking and trending of lab data for its patients. But it is something they could easily do if those lab tests from the primary care clinics they owned were performed by the hospital lab.

Managed Care Lab Contracts

And here is where the lab test contracting practices of health insurers contribute to this problem. If health insurers require hospitals and their primary care clinics participating in an ACO to separate the components of the lab work, how can the hospital provide integrated services to patients?

This is why a small number of first-mover hospitals are developing strategies and—if necessary—preparing to engage the health insurers and the national lab companies. Their goal is to find a solution that provides them with a patient health record that includes complete and standardized test data.

What may add urgency to changing the status quo in the clinical lab testing marketplace is that a sizeable number of ACOs are already delivering integrated care. Participating hospitals stand to earn performance incentives if they can improve patient outcomes and reduce healthcare costs by a significant amount in a contract year.

Tracking and Trending

Simply said, these institutions need to have standardized lab test data as soon as possible. It is an issue that must be resolved if the hospital and the ACO are to deliver improved patient outcomes while controlling costs.

For that reason alone, THE DARK REPORT predicts that hospital administrators will become much more forceful in their negotiations with managed care companies about including their laboratories in provider networks. TDR

—By Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

bioMérieux is on the move. Last week it announced that it would pay $450 million to purchase privately-held **BioFire Diagnostics** of Salt Lake City, Utah. BioFire has a solid technology base in molecular diagnostics. It developed and currently markets its FilmArray product, which it describes as a multiplex PCR system. BioFire also designed the LightCycler system which it licensed to **Roche Diagnostics**. bioMérieux says that the acquisition of BioFire will help it expand its products for infectious disease testing.

MORE ON: *bioMérieux*

The acquisition of BioFire comes in the wake of other important news for bioMérieux. On August 23, the company issued a press release about FDA clearance of its VITEK MS. The company says that this is "the first clinical mass spectrometry MALDI-TOF-based system available in the U.S. for rapid identification of disease-causing bacteria and yeast." The availability of this system shows the rapid advances that *in vitro* diagnostic manufacturers are making in the design of mass spectrometry systems that offer more automation, consistent analytical quality, and faster time to answer.

J&J READY TO SELL ORTHO-CLINICAL DIAGNOSTICS

Late on Friday, *Reuters* reported that **Johnson & Johnson Co.** had launched a sales process to sell its **Ortho-Clinical Diagnostics** (OCD) business. *Reuters* also reported that the business has annual sales of about $2 billion and may sell for as much as $5 billion. It has been known for some time that J&J executives were considering a sale of the OCD business.

XIFIN MAKES INC.'S FASTEST-GROWING LIST OF FIRMS

XIFIN, Inc., of San Diego, California, has extended to seven years its inclusion on *Inc. Magazine's* annual list of the 5,000 Fastest-Growing Private Companies in the United States. For 2012, XIFIN ranked 2,887 and posted a three-year growth rate of 118%. The company says it processes more than 200 million claims per year, primarily in clinical laboratory and pathology. Its revenue cycle management services are anchored by a cloud-based technology platform.

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...

...**Laboratory Corporation of America's** purchase of **MuirLabs**, the lab outreach business of **John Muir Health** of Walnut Creek, California. Announced on September 4, health system officials said about 450 lab employees will be laid off. No price was disclosed.

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, September 30, 2013.

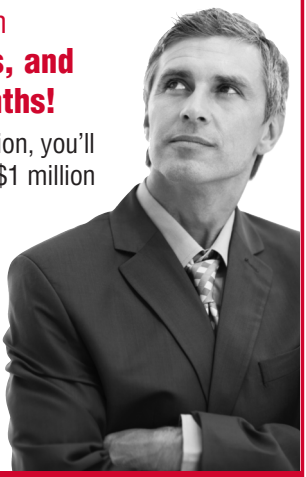
Register Now!

Lab Quality Confab

October 1-2, 2013 • Astor Crowne Plaza Hotel • New Orleans, LA

Leo Serrano of Broward Health on

Using Test Formularies, Algorithms, and CPOE to Save $871,000 in 12 Months!



Pick your cost cutting target! In this powerful session, you'll learn how the lab at Broward Health saved almost $1 million in just 12 months. Esoteric and send-out testing savings were $362,000. Platelet waste reduction saved $220,000. Projects to address blood products generated reduced costs of $212,000 in use of red blood cells. Learn how you can do the same in your own laboratory. Register today and guarantee your place!

Register today to guarantee your place!

For updates and program details, visit www.labqualityconfab.com

UPCOMING...

- **Even Amidst Uncertainty, Demand Strong For Lab Managers with Leadership Skills**
- **New Twist on Whistleblowers: Doctor Sues Lab for Offering Him an Inducement... and Wins!**
- **Strategies for Smaller Pathology Practices: Is It Time to Merge, Consolidate, or Sell?**

For more information, visit:

www.darkreport.com

Sign Up for our FREE News Service!

Delivered directly to your desktop, ***DARK Daily*** is news, analysis, and more.

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends