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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Congress Raises Stakes in Lab Test Pricing Game

EACH OF YOU READERS KNOW that there is always a story behind the story. This is particularly true in Congress and the federal government, where lobbying and influence can often have their own role in shaping how laws and regulations are written.

Keep that in mind as you learn more about the new law passed by Congress and signed by President Obama last week. Yes, it was a bill to patch the Sustainable Growth Rate formula. But the bill had almost 200 pages of other items that, among other things, mandate major changes in how the Medicare program is to use market-based data to set prices for the Medicare Part B Clinical Laboratory Fee Schedule.

Following passage of the legislation, there have been mixed reviews by different lab industry organizations and associations. Since the language in the bill will affect every laboratory that bills for lab tests under Medicare Part B, there will be some lab winners and some lab losers. Figuring out in advance which lab will be in which category is the challenge.

Since this new law will end up favoring some types of lab organizations over other types of laboratories, it is useful to ask who influenced the thinking of the people who wrote the language in this new federal law. This is not to imply that something nefarious took place. Rather, it is to raise the issue of how key officials within the Senate and House got input from various lab industry groups and whether the specific requirements in this bill will end up giving competitive advantage to one specific group of labs over another.

Please indulge me for considering this aspect of what is probably the single most important piece of federal legislation affecting the lab industry to emerge since passage of the CLIA update bill in 1988. After all, the scope of this federal law establishes a different methodology for pricing all Medicare Part B lab tests, while, at the same time, creating a new set of requirements for how CMS and the MACs are to handle a new lab test when establishing coverage guidelines and determining the price at which that new test will be reimbursed.

This old curmudgeon knows that, anytime you mess with someone's money, there can be much unhappiness. The bill passed by Congress essentially messes with the money paid to every lab which provides lab tests to the Medicare Part B program. Therefore, much dissatisfaction will soon become obvious. TDR

Congress' New SGR Law Has Mixed News for Labs

SGR law initiates lab reporting requirements and multi-year adjustments to lab test prices

CEO SUMMARY: Once again, the lab industry faces a mixed bag following passage of a new law by Congress last week. Besides the one-year fix for the SGR, H.R. 4302 also has language that may defer adjustments to Medicare Part B lab test fees until 2017 and creates a new procedure for Medicare officials to use when pricing new clinical lab tests. At the same time, the law establishes onerous new annual reporting requirements for labs and requires market-based Part B lab fee adjustments in the years 2017-2022.

POTENTIAL NEW CUTS to Medicare lab test fees are causing concern for clinical laboratories. The new pricing will take effect in 2017 under H.R. 4302: Protecting Access to Medicare Act of 2014, the federal law Congress passed last week to patch the sustainable growth rate (SGR) formula.

The bill to extend the SGR creates new requirements for CMS to follow when establishing prices for Medicare Part B clinical laboratory tests. Some in the lab industry predict the law will result in deep cuts in reimbursement. Others in the industry say this law is better than immediate across-the-board cuts and possible unlimited cuts anticipated from CMS next year.

Essentially, the Medicare price cuts for clinical lab tests scheduled to take effect in 2015 will probably not happen. Beginning in 2017, however, CMS will be allowed to adjust prices using lab-reported market data and other factors for all lab tests—except those defined in the law as "new tests" and "advanced diagnostic tests."

Based on what labs report to be "market prices" for lab test codes in the years 2017, 2018, and 2019, Medicare can reduce the price of a lab test by a maximum of 10% in each of three years (a total potential cut of more than 30%). Then, in 2020, 2021, and 2022, CMS can cut lab prices by 15% in each year (an additional total potential cut of more than 45%).

In addition to these potential Draconian price cuts to most of the existing codes on the Medicare Part B Clinical Laboratory Fee Schedule, the SGR law mandates that,

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every three years, labs will report to CMS the prices specific payers pay for each clinical lab test. CMS will use these data to establish prices for lab tests. Lab administrators and pathologists already recognize that it will be impossible for most labs to identify this information in order to report it to CMS in a uniform manner.

Less Revenue for Labs

The two requirements described above will have the most significant effect on revenue. If implemented as currently written, Congress estimates that the lower prices paid by the Medicare program will generate savings of $2.4 billion.

Additional parts of the bill also will affect labs. They spell out how Medicare will establish pricing for new laboratory tests. The language in this section of the law seems to favor new diagnostic tests over traditional lab tests, as Congress permits new pricing for "advanced diagnostics."

Initially, Medicare will pay labs the "list price" for these new tests before CMS evaluates the processes involved in running these tests. If CMS determines the tests have been priced greater than 130% of average market prices, then CMS can recoup the difference.

Reaction by lab industry organizations to this new law is varied. It is likely that few lab industry executives fully understand the complexities of administering the requirements of this law, and few know precisely how it could undermine the finances of local and regional laboratories while favoring the fortunes of the nation's largest lab companies.

Potential Consequences

At the **Association for Molecular Pathology** (AMP), Executive Director Mary Steele Williams, MT(ASCP)SM, said there is concern about potential unintended consequences.

In a letter sent to Senate Majority Leader Harry Reid (D-Nevada) before the Senate vote, AMP stated its concern that labs had no chance to analyze the bill before it was introduced. AMP pointed out that Congress also needs to provide oversight on the effects of the bill. If the effect on labs or patients is detrimental, Congress should repeal the bill, AMP said.

The **National Independent Laboratory Association** (NILA) also criticized the bill. Administrator Mark Birenbaum said, "The SGR patch places an unprecedented unfunded mandate on certain 'applicable' laboratories to begin reporting private commercial payer data to CMS.

"The expressed purpose of the language is to assess laboratory market rates," he stated. "However, as written, the language could exclude a majority of the laboratory market and that could place the burden and risk of significant penalties squarely on regional and community-based laboratories. This new law threatens market competition for clinical laboratory services and access to testing services for Medicare beneficiaries."

Support For The New Law

While AMP and NILA were displeased with the bill the House passed March 27 and the Senate passed on March 31, the **American Clinical Laboratory Association** (ACLA) supported the provisions in the SGR legislation. The law provides a "more rational process for transitioning to changes in reimbursement," the ACLA said.

"These things are never perfect and there are areas in it that we have to work on going forward," stated ACLA President Alan Mertz. "But you have to look at this legislation in the context of what would have happened if this bill did not pass. The lab industry was facing the triple threat of an immediate across-the-board cut, followed by potentially-deep and unlimited-cuts by CMS next year, as well as cuts in future years to pay for the SGR.

"The federal **Centers for Medicare & Medicaid Services** was preparing to make deep cuts in payments for lab tests starting

Laboratory Industry Groups React; One Says SGR Law Favors Independent Labs Over Others

HERE ARE SOME COMMENTS FROM DIFFERENT LAB INDUSTRY ORGANIZATIONS about the passage of H.R. 4302: Protecting Access to Medicare Act of 2014, and its possible consequences.

American Clinical Laboratory Association (ACLA) supported the legislation, saying it:

- Provides a rational process for transitioning to changes in lab test reimbursement.
- Avoids another potential round of indiscriminate, across-the-board payment cuts.
- Brings predictability in lab reimbursement over the next several years and provides more transparency.
- Allows more time for laboratories to prepare for changes in Medicare Part B clinical lab test reimbursement.

The Association for Molecular Pathology (AMP) criticized the law, saying it:

- Disadvantages hospital-based laboratories while favoring independent labs.
- Requires collection of data on costs and test volume that hospital labs may not be able to provide.
- Disregards the CPT code process by establishing a unique identifier system for certain tests.
- Conflicts with current law by designating one or more Medicare Administrative Contractors to set prices for clinical diagnostic laboratory tests.
- Creates confusion among labs by requiring different reporting requirements for different tests.

The National Independent Laboratory Association (NILA) opposed the law, saying it:

- Places an unfunded mandate on community labs to report private payer data, thus assessing only a portion of the lab market by potentially permitting some large labs and an unknown number of other labs to be excluded from the reporting requirement.
- Subjects community-based laboratories to massive fines and the threat of violation of the False Claims Act.
- Threatens serious reductions to Medicare lab test payment rates and provides no overall adjustment to individual test rates for smaller labs with lower test volume.

in January 2015," he noted. "Those would be significant cuts to some high-volume lab test codes under a process that was not transparent and was without limits. We wouldn't know which codes would have been cut or by how much they would be cut.

Facing Across-The-Board Cut

"The lab industry was also facing an across-the-board cut to get savings for the SGR package," continued Mertz. "This was potentially as much as $8 billion—more than three times as much as the new law is estimated to cut.

"On top of that, lab test fees would continue to be subject to being cut in subsequent years each time Congress has to pay for the SGR," he noted. "This is why we faced a triple threat. This law makes those future cuts less likely. Therefore, this was a far better alternative than what we were facing."

Besides the potential of substantial price cuts to lab tests specified in the law for each year from 2017 through 2022, labs will be under new data collection and reporting requirements.

In its comments, AMP observed that, beginning January 1, 2016, labs must report to CMS the payment rate from each non-capitated private payer and the volume of each test for each payer, although CMS can make exemptions for low-volume/low expenditure labs.

"The payment rate reported must reflect all discounts, rebates, coupons, and other price concessions, and an officer of the laboratory must certify the accuracy and completeness of the information reported," AMP said. "Labs that fail to comply face a civil monetary penalty of as much as $10,000 per day for each failure to report, or for misrepresentations or omissions. The information will be confidential and shall not be disclosed to a Medicare Administrative Contractor."

The law also disregards the CPT code process by establishing a new market-based method of setting prices that conflicts with current law because it allows CMS to use only one MAC to establish coverage policies and process claims, AMP said. Also, it creates confusion by establishing different reporting requirements for different types of tests, AMP added.

Labs Must Know Their Costs

"I don't think hospital laboratories have the infrastructure to collect the information they will be required to provide to CMS," Williams said. "We know from the gapfill process last year that labs don't really know what their full costs are to perform an individual test. Likewise, we don't know if labs can readily distinguish between tests that are bundled—for which the bill states they will not have to report—and those lab tests that are not bundled, the payments for which labs must report."

Perhaps the biggest concern, Williams said, is that H.R. 4302 creates an unlevel playing field that favors independent laboratories significantly. "The new weighted median calculations will place a disproportionate burden of reduced payments on hospital-based labs and favor large volume independent laboratories," she said. TDDR

—Joseph Burns

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New Federal Law Directs CMS to Reprice Lab Tests

BOTH PARTIES IN THE HOUSE AND THE SENATE came together on the SGR law to include sections in the law that direct CMS to adopt new approaches to determine the prices that it will pay for clinical laboratory tests. There are six important sections to the law that pertain to clinical lab tests:

- **Setting Prices with Market Data:** Certain labs will be required, beginning on January 1, 2016, to report private payer payment rates and volumes for their tests.
- **New Category: Advanced Diagnostic Tests (ADTs):** For certain tests developed and performed by single laboratories, the initial payment rate for ADTs will be set at the "actual list charge." If the charge exceeds private payer rates by more than 130%, CMS can recoup the overpayment.
- **Setting Prices for New Tests and Expert Advisory Panel:** To ensure transparent and reliable decisions about pay rates and coverage, CMS will assemble a panel of outside advisors, including clinicians and other technical experts. Also, CMS must follow either the crosswalk or gapfill process to determine the initial payment rates and explain, in a transparent manner, how the calculations were made.
- **Changes in How Medicare Codes:** For new lab tests, CMS willl use temporary HCPCS codes to enable payment prior to a permanent HCPCS or CPT code.
- **Coverage Requirements and Decisions:** In support of fair and open coverage decisions for a lab test when a local coverage determination is needed, MACs must now follow a defined development and appeals process.
- **Oversight of Lab Test Pricing and Coverage Process:** Two levels of oversight are written into the law; one by the U.S. Government Accountability Office (GAO), the other by the Office of Inspector General (OIG) of DHHS.

New Federal Law Changes How CMS Sets Lab Prices

CMS and entire laboratory industry to embark on a complex, untried new pricing methodology

CEO SUMMARY: CMS wanted more power to cut the prices it pays for clinical lab testing. A significant part of the lab industry wanted more transparency and consistency in how CMS established coverage guidelines and prices for new lab tests. Congress appears to have attempted to craft a law intended to support both objectives. Now, only the passage of time will reveal whether the new law enacted last week turns out to be something that works for patients, labs, and the Medicare program.

EVERY LABORATORY THAT IS PAID under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) will need to understand the ramifications of the new rules CMS will use to establish prices for clinical laboratory tests.

Passage of a law last week to patch the Sustainable Growth Rate (SGR) formula that was set to expire on March 31, 2014, gave Congress the opportunity to include language to address several other healthcare-related issues. For example, it delayed the implementation of ICD-10 for one year.

The new law is titled: H.R. 4302: Protecting Access to Medicare Act of 2014. What will interest lab executives is "Section 216: Improving Medicare Policies for Clinical Diagnostic Laboratory Tests." This is the portion of the law that includes a dramatic and radical rewriting of the process CMS will use when establishing coverage guidelines and prices for tests on the CLFS.

There are two reasons why Congress included a rewrite of the process for establishing clinical lab test fees in this new law. First, Congress needed to find money to pay for the extension of the SGR formula. Lawmakers estimated that the new rules for pricing lab tests on the Medicare CLFS will reduce the money paid to labs by $2.4 billion.

Second, there was a belief on the Hill that the Medicare program was overpaying for clinical laboratory tests compared to private health insurance plans pay. Two pieces of evidence were seen to support this belief by some officials.

Cheap Lab Test Prices

One piece of evidence is the substantial profits announced each quarter by the two biggest national laboratory companies—along with the knowledge that, for many high-volume tests, these two companies regularly charge below-marginal-cost prices to the national health insurance companies.

The second piece of evidence was a report issued by the OIG in June 2013. It was titled: "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings." Based on its methodology, the OIG wrote that "In 2011, Medicare paid

between 18% and 30% more than other insurers for 20 high-volume and/or high-expenditure lab tests. Medicare could have saved $910 million, or 38%, on these lab tests if it had paid providers at the lowest established rate in each geographic area." *(See TDR, June 17, 2013.)*

Unhappiness In Congress

Several sources have told THE DARK REPORT that, among some members of Congress, there was anger that certain lab companies were reporting substantial profits, even as these same companies were charging private insurers substantially less for lab tests than they charged the Medicare program.

These sources believe that this animus toward the large lab companies by certain members of Congress played a role in how the language of this law was crafted. If this is true, the entire clinical laboratory industry is about to pay for the business behavior of just a handful of big commercial lab companies.

Another aspect to the language in H.R. 4302 is that it attempts to fix a number of issues with clinical laboratory testing that are considered to be problematic by different lab industry sectors and by Medicare program officials. The language of the law that is intended to fix these issues means this law is probably going to produce mixed reactions from labs that see themselves benefiting while other laboratories consider these changes to be a step backward.

New CMS Pricing Method

As one example, CMS will not be allowed to simply rework lab prices as it intended according to a new rule it published in its 2014 Medicare physician fee update. Under that rule, starting in 2015, CMS was going to review all the lab tests on the CLFS with the goal of lowering prices for tests, based on its determination that technology and automation had lowered the cost of performing those tests.

Instead, H.R. 4302 directs CMS to gather market data from labs and, beginning in 2017, it is to use the market data to establish new lab test fees. This is one element of the new law that will produce headaches for Medicare officials and lab managers alike. It is likely to become a point of contention between the lab industry and its government regulator.

In its interpretation of the law's language, attorneys at **Bass, Berry & Sims PLC** in Nashville, Tennessee, wrote that, on the requirement that labs must report private payer pricing: "By June 30, 2015, CMS must publish regulations requiring applicable clinical laboratories to report the payment rate paid by each private payer, including Medicare Advantage and Medicaid managed care plans, along with the applicable volume for each payer."

Hospital Labs Won't Report

The lawyers noted that "hospital laboratories, to the extent they receive the majority of their reimbursement through the outpatient prospective payment system (OPPS), will not be required to report private payer data, but physician-office laboratories will be required to report the data."

Reporting begins January 1, 2016, and is due every three years thereafter. Bass, Berry & Sims further wrote that "the reporting excludes capitated payment arrangements, but is inclusive of all discounts, rebates, coupons, price concessions or any other types of discounts. CMS may impose civil monetary penalties for failure to report or to report accurately of up to $10,000 per day."

Criticisms about this requirement of the law have already surfaced. For example, it is pointed out that few lab organizations have the capability to identify what every payer reimburses for each type of lab test. A typical laboratory may be performing 400 to 800 tests in-house and may be billing dozens of payers. That makes this reporting requirement a sizable burden for every lab, regardless of size.

Second, if a lab does not have to report capitated payment arrangements to CMS, what is to prevent the national labs and the national health insurance corporations from rewriting existing contracts between now and Jan 1, 2016, to convert much of the high-volume lab tests from fee-for-service payment to capitated payment?

Loophole Favors Large Labs

If this happened, CMS would not have data on the very lab companies that are using below-marginal-cost pricing to win exclusive private payer contracts. As well, this loophole would allow the national labs to continue the very pricing practices that angered certain members of Congress. At the same time, the market data that shows their deeply-discounted prices would not be incorporated into CMS' decisions on how to price these tests.

That could mean the prices CMS established for the CLFS would be higher than they would be otherwise. This would benefit the national labs because they would continue to bill Medicare for these tests and be paid at the higher rate—although their costs to perform these tests are lower than the costs of local and regional labs.

All of this is a separate consequence to the expectation that pricing lab tests based on market data will result in much lower prices on the CLFS. If there is any doubt on that point, one has only to read the limits Congress placed on how rapidly CMS can reduce the CLFS price for a lab test from one year to the next.

Attorneys at Bass, Berry & Sims analyzed this section of the law and wrote: "Beginning January 1, 2017, Medicare payment rates for clinical laboratory services will be based on the private payer rates reported during the previous year. The Medicare rate will be the median payment rate, weighted based on volume, of the private payer payment rates [market data] reported in the previous reporting period for each code."

What Will Revenue Impact Be For Clinical Laboratories?

WITH PASSAGE of H.R. 4302: Protecting Access to Medicare Act of 2014, all clinical laboratories in the United States face an uncertain financial future, particularly if Medicare patients make up a significant portion of their specimen volume and revenue.

Language in the new law defines how CMS officials can assess existing laboratory tests using market data, and then, in the years 2017 through 2022, cut prices for specific lab tests by 75% or more.

One way to estimate the financial impact of the new law is to use data provided in the 2013 OIG report titled "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings."

The OIG studied 20 specific lab tests on the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). In 2010, these tests were 47% of the volume and 56% of the expenditures for CLFS lab tests reimbursed by Medicare. That means they made up about $3.7 billion of the $8.3 billion Medicare spent on CLFS tests during 2010.

In its summary, the OIG said that, if the Medicare program paid comparable rates for these 20 lab tests as did selected state Medicaid programs, the Medicare program could have saved $910 million (or 38%).

Assume that, in the years between 2017 and 2022, CMS were to reduce the prices it pays for these 20 high-volume lab tests by 38%, as indicated in the OIG study. That would be $910 million less in annual revenue flowing to all labs in the United States.

For the two largest national labs, the calculations are interesting. Assume that about 15% of their business is Medicare and they do a total of $12.5 billion in yearly revenue. That means Medicare revenue for them both would total about $1.9 billion per year (which also represents approximately 22.9% of what Medicare paid out for CLFS in 2010). A 38% fee cut would reduce their combined income by $722 million per year.

How much can CMS reduce a price for a lab test? "For calendar years 2017 through 2019, any reduction in payment rates based on the new reported medians shall be limited to 10%," wrote the Bass, Berry & Sims team, "and for calendar years 2020 through 2022, any reduction is limited to 15%. The new payment rates will not be subject to budget neutrality adjustment, geographic adjustments, or annual updates, and will apply until the year following the end of the last reporting period. The payment rates will apply to hospital laboratories if the laboratory is not reimbursed under the OPPS."

The law's language allows CMS to cut the price of a single lab test by 30% in the 2017-2019 time period and 45% during the years 2020-2022.

In their analysis of the downstream impact of the new law, some veteran lab executives predict that a wave of small lab closures, bankruptcies, and mergers should be expected after these CMS price cuts kick in during the coming years.

Pathologists and lab administrators should be under no misconception on this issue. CMS will take the 20 to 30 highest volume tests and will drive down the price it pays for these tests in a progressive fashion, starting in 2017.

Since local labs do not have the same specimen volume as the national lab companies, this will be financially-devastating to them. Routine testing is their bread and butter. They don't generate many higher-priced reference and esoteric specimens that could offset the revenue losses from lower prices on the routine work.

In their analysis of the downstream impact of the new law, some veteran lab executives predict that a wave of small lab closures, bankruptcies, and mergers should be expected after these CMS price cuts kick in during the coming years. They also point out that, ironically, as this happens, it will be the two national labs that will benefit, as they will be in a position to pick up those specimens and, with their lower testing costs, probably make a modest profit on those specimens.

Guidelines For New Tests

In a separate area of interest to the laboratory industry, the new law establishes policies to address the problems with developing coverage guidelines and pricing for new tests.

Advocates of this bill within the lab industry point out that it establishes procedures that are more transparent and predictable, both for the lab company introducing the new test and for Medicare officials who must set prices for it.

The attorneys at Bass, Berry & Sims interpreted this section of the new law as follows: "Advanced Diagnostic Laboratory Tests. By January 1, 2016, CMS must assign HCPCS billing codes to all existing advanced diagnostic laboratory tests, which are tests approved or cleared by the FDA that are available from only a single laboratory and analyze multiple biomarkers of DNA, RNA, or proteins to yield a patient-specific result.

Financial Devastation

"For new advanced diagnostic laboratory tests, the initial payment rates will be based on the 'list price' of the offering laboratory," they commented. "Thereafter, the payment rates will be based on the market data reported; however, if the price based on the market data exceeds 130% of the list price, CMS may recoup the excess from the offering laboratory."

This new federal law will have far-reaching consequences. Ultimately, it will be patients who pay the true price should Medicare's price-cutting initiatives cause the nation's network for local and regional labs to disappear in coming years. TDR

CMS Gives Deemed Status To A2LA under CLIA Law

First time in two decades that CMS granted deemed status to a new assessment organization

CEO SUMMARY: Quietly published in the March 25 issue of the Federal Register was a notice that CMS had granted deeming authority for CLIA to the American Association for Laboratory Accreditation (A2LA). This action gives laboratories in the United States a new choice to meet the accreditation requirements of CLIA. Founded in 1978, A2LA is itself recognized as compliant with ISO 17011 and has offered ISO 15189 accreditation services to clinical labs for more than a decade.

THERE'S A NEW PLAYER in CLIA accreditation! Last month, CMS named the **American Association for Laboratory Accreditation** (A2LA) in Frederick, Maryland, as an accreditation organization for clinical laboratories under CLIA for all specialty and subspecialty areas.

This significant announcement was made quietly and was published in the *Federal Register* on March 25. CMS wrote that, "We have determined that the A2LA meets or exceeds the applicable CLIA requirements." The deeming authority is for four years, CMS said.

A2LA now joins a handful of organizations that have deemed status that allows them to accredit labs and inspect the labs in CLIA's stead. This is also the first time in two decades that CMS has granted deemed status to a new organization for CLIA requirements.

"A2LA submitted its application for deemed status to CMS in January 2012, along with several boxes of supporting documents," stated Roxanne Robinson, A2LA's Vice President, COO, and Manager for Medical Accreditation Programs. "CMS was rigorous in assessing our capabilities, particularly as they related to the CLIA requirements addressing complaints, corrective action, and proficiency testing."

A2LA expects quick engagement with clinical laboratories. "We have a number of labs that have indicated their interest in using our services once CMS granted us deemed status," noted Robinson. "Thus, within the next 90 days we expect to have completed our first inspections and assessments of laboratories for CLIA accreditation purposes.

Three Options For Labs

"A2LA has three options," she continued. "Option 1 is CLIA accreditation only and this service is priced competitively compared to existing CLIA deeming authorities.

"Option two is ISO 15189 accreditation only, a service we have offered to labs here in the United States for years," noted Robinson. "ISO 15189 accreditation can

be earned independent of CLIA accreditation requirements.

"Option three is what we call 'Platinum Choice,'" she said. "In one assessment, with one team of assessors, a lab can accredit to CLIA requirements at the same time that it accredits to ISO 15189. In addition to the regular CLIA fees, a surcharge of just $2,500 per year would be added for the ISO 15189 accreditation.

"Platinum Choice gives labs a benefit that they have not had before," emphasized Robinson. "In one assessment cycle, they can earn accreditation to both CLIA and ISO 15189 and what this means is that the laboratory test results they produce will be accepted throughout the United States (under CLIA) and in any of 80+ countries worldwide (under ISO 15189).

"We have to be clear," she added, "that the accreditation under CLIA would be done with regard to the standards from CMS and the accreditation to 15189 would be under ISO (meaning the **International Organization for Standardization**).

Tested Once, Fully Accepted

"What is different is that this dual accreditation helps labs meet a goal we have here at A2LA," continued Robinson, "which is to help testing labs handle specimens and be able to say: 'Tested once—accepted everywhere!'

"Global acceptance of medical lab test results is happening because there is more cross-border movement of medical lab specimens, along with rapid growth in clinical trials testing," she said. "That makes this dual accreditation strategy a worthwhile advantage for labs that want to access these specimens and pursue these opportunities.

"Take this same point up one notch," observed Robinson. "With the dual accreditation to both CLIA and ISO 15189, A2LA helps a laboratory not only say: 'tested once—accepted everywhere;' but, now, for the first time, the lab can also say, 'accredited once—accepted everywhere.'"

In practical terms, the addition of A2LA as a deeming authority gives medical laboratory directors and lab administrators a new choice when it comes time for their lab to meet CLIA requirements. Several traits set A2LA apart from existing deeming authorities.

Accreditation of Labs

First, A2LA has deep experience in the field of accreditation. It is dedicated to the formal recognition of competent testing and calibration laboratories, inspection bodies, proficiency testing providers, and reference material producers. It has served laboratories in a large number of industries since its founding in 1978 as a non-profit, public service membership society.

Second, A2LA can accredit clinical laboratories in the United States to the requirements of ISO 15189 and, because A2LA is a member organization of the **International Laboratory Accreditation Collaboration** (ILAC), the lab test results produced by that laboratory will be accepted in any other country worldwide that is a signatory to ILAC.

Third, A2LA becomes the only organization with CLIA deemed status here in the United States that is, itself, recognized as compliant with ISO 17011: *Conformity assessment–General requirements for accreditation bodies accrediting conformity assessment bodies*. Accreditation to ISO 17011 is a requirement for an accrediting organization to be a member of ILAC.

Complementary Strengths

Fourth, A2LA has broad authority under its deemed status for CLIA. This is also true of the four other groups that have deemed status for CLIA. They are: **COLA**, **College of American Pathologists** (CAP), **The Joint Commission** (TJC), and the **Healthcare Facilities Accreditation Program** (HFAP) offered through the **American Osteopathic Association**.

CMS and Quality Management Systems: Still an Uncertain Path toward Acceptance

AROUND THE WORLD, the quality management system (QMS) known as ISO 9001 has gained wide acceptance. Already in use by tens of thousands of manufacturers, distributors, and service organizations, it is now poised to achieve wider acceptance by hospitals, physicians, and clinical labs globally—despite slow acceptance in the United States.

The QMS of ISO 9001 forms the foundation of ISO 15189 Medical Laboratories, as it does for all the other ISO standards. Here in this country, CMS officials have been slower to warm up to the potential of the QMS of ISO 9001 to underpin both the accreditation process for health providers, as well as to contribute to improved quality, patient safety, and lower overall costs of care.

One reason for this is that the accreditation standards used by the federal Medicare program were originally established in the 1960s and 1970s, following Medicare's creation in 1966. Thus, much of the management principles contained in these standards are now five decades old. Moreover, to change any of these requirements requires both Congressional action and a multi-year rulemaking process.

New Techniques

Meanwhile, over that same 50 years, new management techniques and methods have emerged and undergone continual refinement. Today, rooted in the quality management work done by W. Edwards Deming, Joseph Juran, Taiichi Ohno and others, we have the tools of Lean, Six Sigma, continuous improvement, and system of prevention, to name just a few.

Thus, THE DARK REPORT considered it progress when, in October 2008, CMS granted deeming status to **Det Norske Veritas** (DNV) for Medicare accreditation of hospitals. DNV's value proposition was that it could not only help the hospital meet its Medicare Conditions of Participation (COP), but the hospital could also earn certification to ISO 9001 at the same time. *(See TDR, June 8, 2009 and December 14, 2009.)*

Since that date, DNV has become the accrediting agency for several hundred hospitals in the United States. This shows there is interest among hospital administrators to pursue the advantages that come from implementing the QMS of ISO 9001.

Granted Deemed Status

Now comes the news that, as of last month, CMS has granted deemed status to the American Association of Laboratory Accreditation (A2LA) for accrediting clinical laboratories to the requirements of CLIA. Given that A2LA is itself recognized as compliant with ISO 17011 and already accredits medical laboratories to ISO 15189, this must be seen as another forward step by CMS officials to be supportive of the QMS embodied in ISO 15189.

By the way, these developments did not go unnoticed by other agencies with deemed status. In 2012, The Joint Commission announced the launch of its own program to help hospitals certify to ISO 9001 and several other ISOs. The College of American Pathologists initiated its ISO 15189 accreditation service in 2008.

For previous coverage on the subject of QMS and the accreditation requirements of ISO 15189, these earlier issues of THE DARK REPORT will be helpful: October 12, 2009; November 23, 2009; and April 6, 2010.

"Other accrediting agencies are niche accreditors and have deeming status specific to such disciplines as cytology and blood banking," Robinson said. "It's important to note A2LA now has deemed status for every specialty covered by the CLIA law."

Some lab directors and lab administrators may question why a CLIA-accred-

ited laboratory would also want to earn accreditation to ISO 15189. "When you examine the advantages and disadvantages of both CLIA and 15189, you see that it is quite a good marriage to be accredited to both standards," observed Robinson.

"CLIA is strong in some areas where ISO 15189 is not as strong, and the opposite is true as well. ISO 15189 is strong in areas where CLIA is not as strong," she said. "That's a message we want to get out to clinical labs.

Two Accreditations

"Having both accreditations can strengthen the management operations of a clinical laboratory," continued Robinson. "To date, just a handful of labs in the United States have seen the advantages of pursuing a standard beyond CLIA accreditation. Today, about 40 labs are accredited to ISO 15189 in this country."

"Another significant benefit is the adoption of the quality management system (QMS) that is at the core of ISO 15189," stated Larnell Simpson, A2LA's Director of Marketing and Medical Affairs. "Once a laboratory implements the QMS of ISO 15189 and establishes the operational culture needed to sustain it, the lab gains added capabilities to continuously improve quality while managing costs. This will be a critical success factor going forward as labs find themselves serving integrated care organizations and being paid differently."

Dual Accreditation Option

Now that the decision by CMS officials to grant deeming status to A2LA is official, it will be interesting to see how many medical laboratories will actively use A2LA for either or both accreditations to CLIA and to ISO 15189. TDR

—Joseph Burns

Contact Larnell Simpson at 301-644-3231 or lsimpson@A2LA.org.

A2LA Outlines Standards For Its CLIA Assessors

ONE AREA OF CONCERN for clinical laboratories pursuing CLIA accreditation with an assessment organization is the ability and the experience of the organization's assessors.

The assessors used by American Association for Laboratory Accreditation (A2LA) in Frederick, Maryland, are paid professionals and are not allowed to consult for the laboratories where they perform assessments as part of the accreditation process.

A2LA requires all of its assessors to meet two primary criteria. First, they must have at least 10 years of bench experience in which they were actually performing tests.

Second, the individuals must have several years experience as a laboratory supervisor. "This is the baseline before A2LA will consider an individual for any role as an assessor," noted Roxanne Robinson, A2LA's Vice President and COO. "We use a rigorous process to evaluate and prepare our assessors.

"First, their experience and credentials are reviewed," she said. "Each assessor is then designated to work in certain areas, based on their skills.

"Next, they undergo five days of on-site training and are required to pass an examination," continued Robinson. "We also review their interpersonal skills to ensure that they are fair and unbiased. In some areas, such as pathology and cytology, we select only individuals who are board certified and are medical doctors.

"The next step is to evaluate them on assessments in a technical role," she explained. "During their qualifying as a technical assessor, we send our seasoned assessors along with them to ensure that they are conforming to A2LA standards and CLIA or ISO requirements. Once they are approved as assessors, every three years, we go in the field with them to review their skills."

Quality Management

New ISO 15189 Book Published To Help Clinical Lab Managers

'A Practical Guide to ISO 15189 in Laboratory Medicine' was authored by clinical chemist David Burnett, Ph.D.

THERE IS NOW A COMPREHENSIVE GUIDE for lab executives and lab managers interested in learning more about ISO 15189:2012, the latest version of the quality management system (QMS) for medical laboratories.

It is a book titled: "A Practical Guide to ISO 15189 in Laboratory Medicine" and was published last fall by a division of the **Association of Clinical Biochemistry and Laboratory Medicine** in the United Kingdom.

The book is devoted to the latest update of the QMS, known as ISO 15189: 2012 Medical Laboratories. It was written by David Burnett, OBE, Ph.D., FRCPath of the United Kingdom. He is known to many active members of the **American Association of Clinical Chemistry** for his long service as a Consultant Clinical Biochemist to the **St. Albans and Hemel Hempstead NHs Trust** in England, prior to his recent retirement.

Burnett has produced an information-packed book of 372 pages. It is likely to be considered the definitive guide to ISO 15189: 2012 and will be a comprehensive resource for lab managers wanting to better understand how to earn accreditation to ISO 15189 and then sustain the benefits that it can produce for the medical laboratory.

Here in the United States, few lab managers understand the role that ISO—the **International Organization for Standardization**—has in establishing standards for quality that make it easier for companies and organizations across the globe to get international acceptance for their different products and services. More than 164 countries participate in ISO's Central Secretariat.

Insights Into ISO 15189

In his book, Burnett provides a clear description of ISO, along with how ISO 15189 was created and is updated. He provides clarity on the organization of the various sections of ISO 15189 and how they work together as a comprehensive quality management system within a medical laboratory organization.

It is likely that lab managers and pathologists embarked on the journey to earn ISO 15189 accreditation in their laboratory will find Burnett's book to be a necessary complement to the ISO 15189 standards. His book explains each of the requirements in the standards, providing context and examples.

Burnett is uniquely qualified to author this book. He served on the ISO Technical Committee 2012–Working Group 1 that produced the third version of ISO 15189 that was issued in 2012. This provided him with direct understanding about the revisions and updates that were incorporated into ISO 15189: 2012. **TDR**

For more information and how to order this book, in the USA, visit http://www.aacc.org, Product ID: 8725; in the UK visit http://www.acbstore.org.uk.

Whole Genome Sequencing Is Poised for Clinical Use

After FDA cleared Illumina's gene sequencing system and reagents, two Blood Brothers moved fast

CEO SUMMARY: Pathologists and clinical lab managers interested in following the advances in use of whole human genome sequencing for clinical purposes should follow the money. Within weeks of obtaining FDA clearance for its MiSeqDx system and reagents, Illumina had inked major agreements with Quest Diagnostics Incorporated and Laboratory Corporation of America. Both national lab companies plan to develop and offer next-generation gene sequencing LDTs for clinical use.

FAST-MOVING EVENTS signal that whole human genome sequencing is poised to make a big entry into clinical diagnostics. This has the potential to disrupt the diagnostic standard of care for a growing number of diseases and health conditions.

Much of this activity is happening off the radar screen of clinical lab administrators and pathologists. Yet it is important for them to track these developments because of their potential to disrupt existing lines of clinical lab tests and anatomic pathology services.

Quick Market Response

A simple timeline shows how quickly market players are responding to advances in whole human genome sequencing:

- *November 19, 2013*—FDA clears four of **Illumina Inc.'s** next-generation gene sequencing devices for clinical diagnostic uses. Two clearances are for Illumina's MiSeqDx instrument and its Universal Kit reagents for this instrument. The FDA, in its press release, described these as "the first FDA-regulated test system that allows laboratories to develop and validate sequencing of any part of patient's genome."
- *November 19, 2013*—The **National Institutes of Health** issues a statement by its Director, Francis S. Collins, M.D., Ph.D., about the FDA's action. In part, Collins stated that "In a landmark move that will help to realize the promise of personalized medicine, the U.S. **Food and Drug Administration** (FDA) today announced the first regulatory clearance of a high-throughput DNA sequencing device... Specifically, the FDA authorized broad clinical use of Illumina MiSeq Dx..."
- *January 9, 2014*—Illumina reveals that it has signed a multi-year licensing agreement with **Quest Diagnostics Incorporated** giving the lab company access to Illumina's MiSeqDx instrument and reagents "to develop, validate, and offer molecular laboratory-developed tests... to clinicians in the United States" and for clinical trials testing.

- *January 21, 2014*—Illumina announces a multi-year agreement with **Laboratory Corporation of America** that extends rights to LabCorp to use Illumina's MiSeq DX instrument and reagents "to develop, validate, and introduce laboratory-developed tests to clinicians in the United States and Canada."

Response To FDA Clearance

All of these developments were linked to the FDA's clearance of Illumina's MiSeqDx system and reagents in November. But Quest Diagnostics did not stop there. On January 9, the same day that Quest's agreement with Illumina was announced, another Quest deal was made public.

On that date, **Life Technologies** issued a press release announcing its own multi-year agreement with Quest Diagnostics. This deal gave the lab company rights "to develop molecular tests on the company's Ion Torrent next-generation sequencing platform."

January 9 continued to be a busy day for Quest Diagnostics. In a related development, it issued a press release on that date disclosing that it had entered into a collaboration with the **University of California San Francisco**. In another gene sequencing deal, Quest stated that the two parties "formed a collaboration to accelerate the translation of biomedical research into advanced diagnostics in the field of precision medicine, for improved patient care, treatment and outcomes."

What is noteworthy in these series of events is the speed with which both Quest Diagnostics and LabCorp responded to the FDA's clearance of Illumina's gene sequencing platform and reagents for clinical applications. They will be investing millions of dollars in their respective efforts to use this next-generation gene sequencing technology to develop laboratory-developed tests (LDTs) for clinical use.

In its coverage of the FDA clearance for the MiSeqDx system, the *Los Angeles Times* wrote that the system records "the entire sequence of a person's DNA in a massively parallel fashion, completing the job in a matter of hours. The company intends to market the machine to diagnostic labs, medical centers and private practices, at a price slightly more than $125,000."

Pictured above is the Illumina MiSeqDx, the first next-generation gene sequencing system cleared by the FDA for clinical applications. Sales price is approximately $125,000. (Photo copyright Illumina.)

By contrast, Illumina has priced its HiSeq X Ten instrument system at $10 million. It can generate as much as 3.6 terrabytes of data in six days. Illumina stated that the throughput of this system is 18,000 whole human genomes per year.

At that volume, Illumina says that each whole human genome will cost about $1,000. However, clinical labs will incur additional expenses to assess the resulting gene data and develop a report of clinically-actionable information for physicians who are treating patients.

Assessing Pace of Change

It would be wrong to judge the pace of change in next-generation gene sequencing exclusively on the FDA clearance of the Illumina system, reagents, and tests, in tandem with the speedy response of the national lab companies to acquire these products. That's because Illumina has

plenty of competition and other companies are making their own technology breakthroughs.

After all, **Thermo Fisher Scientific** just paid approximately $13.6 billion, plus the assumption of $1.5 billion in debt, to acquire Life Technologies and its Ion Torrent system. That deal was closed in early February.

Sequencing Costs Shrinking

What is probably most relevant to the interests of pathologists and lab administrators is the fact that the overall cost of sequencing a base pair continues to fall faster than predicted by Moore's Law. This makes it possible for a host of companies in the gene-sequence market to offer systems that are less expensive, more accurate, and simpler to use.

In turn, these more affordable and productive gene sequencing systems will make it easier for clinical laboratories and pathology groups to establish their own sequencing capabilities. However, there is one other factor that comes into play.

That factor is the analysis of the gene sequences and the ability to take that data and convert it into actionable clinical information for the physicians treating patients. None of the press releases announcing the series of events earlier addressed how the buyers and users of these gene sequencing systems intended to take the raw DNA sequence data and produce actionable clinical information.

Sequencing Whole Genomes

Just as the cost of sequencing a base pair is falling at a dramatic pace, there is a comparable geometric increase in the number of whole human sequences that exist in databases across the globe. This will have a separate impact on labs that want to offer gene sequencing services for clinical applications.

Clinical labs and pathology groups developing clinical gene sequencing services will need to have capabilities in capturing the data and analyzing it. This need has been recognized. A growing number of companies are entering the market and offering to process genomic data, annotate it, and identify clinically-relevant mutations.

These are a few of the reasons why it is not quite "prime time" for local labs to enter the whole human genome sequencing arena. Yet, because of the spectacular pace of innovation, all labs should be watching and ready to move when the combination of price and clinical utility makes it feasible to set up and offer these services. TDR

Illumina Jumps into Lead For Market Share, Sales

ONE EXPERT OBSERVER BELIEVES that Illumina, Inc. "has cemented its position as the dominant player in genomics, at what you could call the beginning of the age of genomic medicine."

Luke Timmerman, a journalist, wrote that statement for *xconomy.com*. He noted that, although Illumina currently has annual revenue of $1.42 billion, it has told the investment community that "it sees a total addressable market [for next-generation gene sequencing] ahead of $20 billion." Of this market, a **Goldman Sachs** analyst has told his clients that Illumina is positioned to capture 75% of the market through 2020.

One smart thing that Illumina has done is establish a product line that has a price point for every customer. It has five different "models" available, but only the MiSeqDx has been cleared by the FDA for developing laboratory-developed tests that can be used for clinical purposes.

Illumina, based in San Diego, was founded in 1998 and completed its initial public offering in 2000. Its stock trades on NASDAQ under the symbol: ILMN. In January, 2012, **Hoffmann-La Roche** made an unsolicited bid to buy Illumina for a price per share that would total $5.7 billion. That acquisition attempt was unsuccessful.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In the United Kingdom, the **National Health Service's** (NHS) biggest consolidation of clinical laboratory services is expected to take place in May, after the government's Office of Fair Trading said it will conduct no further investigation into the project. Six health trusts are collaborating on this project and will create a new provider organization to run the consolidated laboratory, which is using the name **The Transforming Pathology Partnership**. Core laboratories will be located in the **Cambridge University Hospitals** and **Ipswich Hospital Trust**. Labs in the four remaining trusts will be organized as stat labs. Those trusts are: **West Suffolk Foundation Trusts**, **Colchester Hospital University Foundation Trust**, **East and North Hertfordshire Trust**, and **Hinchingbrooke Health Care Trust**.

MORE ON: *NHS*

Under pressure to control the cost of healthcare in the United Kingdom, the NHS expects that more consolidation of laboratory testing services can generate cost savings. A separate initiative has local hospital labs bidding to win the lab testing business of primary care trusts located in their service areas. This process is known as "commissioning" in the United Kingdom.

UCSF, WALGREENS TO USE EHRS TO CUT Rx ERRORS

Walgreens and the **University of California, San Francisco** (UCSF) will partner and share EHRs in a project to reduce medication errors when filling prescriptions. Pharmacists and physicians will have joint access to patients' prescription information.

KAISER S. CALIF. TO BUILD NEW LAB

Kaiser Permanente in Southern California plans to build a new laboratory facility in Chino Hills. The building is 137,000 square feet and Kaiser says it will use 90,000 square feet for the laboratory and the balance will be reserved for expansion. The facility will operate 24/7 and will employ 300 people. It is expected that the laboratory facility will open in 2016.

TRANSITIONS

• **Laboratory Corporation of America** has announced that Glenn A. Eisenberg will assume duties as its new Executive Vice President and Chief Financial Officer on June 16, 2014. He has held executive positions outside the lab industry at **The Timken Company** and **United Dominion Industries**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 28, 2014.

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