Volume XXII, Number 14 Monday, October 5, 2015

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

Did Some Lab Execs 'Get What They Wished For?'

BY NOW, MOST OF YOU HAVE LEARNED that, just 12 days ago, CMS issued the proposed rule that details how it will handle the private market price reporting mandate of the Protecting Access to Medicare Act of 2014 (PAMA). Almost immediately, critics spoke out about the obvious inequities that will result from implementing the proposed rule.

Let me call your attention to what I think is one huge problem with this proposed rule that will be corrosive to the entire lab industry over the long term, and that includes the two billion-dollar national lab companies.

It is the plan to collect and use private market price data to establish Medicare Part B clinical laboratory test fees beginning in 2017. Set aside, for the moment, that there are so many problems with the language detailing the private marketing reporting requirements to which labs must comply that I don't know if any single news source can describe them all. What I want to drill down on is that CMS itself estimates that the proposed rule will produce $5 billion in savings over 10 years. *(See stories on pages 3-9.)*

Those of you with good memories will recall that, when PAMA was enacted in April 2014, the bill's authors tallied estimated savings of $2.5 billion over 10 years from reduced Part B CLFS fees. Thus, CMS is doubling the amount of CLFS fee cuts that Congress was mandating. Further, you should know that, at an average of $500 million per year for 10 years, **Laboratory Corporation of America and Quest Diagnostics Incorporated** together will be absorbing just $90 million of fee cuts per year. (Together, those labs are paid about 18% of all Medicare Part B fees.)

That leaves the remainder of the lab industry to split $420 million per year in fee cuts. Worse yet, based on a 2013 report by the Office of the Inspector General, only 20 high-volume lab tests represent 56% of all lab test fees paid by Medicare Part B during 2010. Thus, because of this fact, the smallest labs will absorb a disproportionate share of those price cuts.

At the time when PAMA was enacted last year, some lab associations and lab executives praised the legislation and were quick to point out that PAMA would forestall even deeper price cuts planned by CMS, which had announced that it was ready to reform the CLFS and reset prices based on technological advances and similar factors. Given this new proposed rule—which includes bad news for labs offering advanced diagnostic lab tests—might it be said that these same lab executives will now get exactly "what they wished for"? TDR

CMS Releases Draft of PAMA Market Price Rule

Proposed CLFS would result in substantial cuts in lab test prices starting in January 2017

CEO SUMMARY: CMS' proposed rule details how it will collect private market data, then use that data to establish prices for the Medicare Part B Clinical Laboratory Fee Schedule beginning in 2017. The proposed rule will limit data reporting to less than half of independent labs, a minority of hospital labs, and only a small percentage of physician office labs. Community labs fear that CMS will issue potentially lower payment rates that could cause smaller labs to stop serving Medicare patients or go out of business.

LATE ON FRIDAY, SEPTEMBER 25, Medicare officials published a proposed rule to implement the much-anticipated section of the Protecting Access to Medicare Act of 2014 (PAMA) that requires CMS to collect private market data on lab test prices and use that data to set prices on the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) beginning January 2017.

PAMA was passed quickly to avert a significant cut in Medicare physician payments due to the sustainable growth rate formula known as SGR. President Obama signed it into law on April 1, 2014, following quick votes by the House and Senate. This meant that the lab industry had little time to study the language of the bill and address all the potential consequences. *(See TDR, April 7, 2014.)*

What has caused the most concern is the section of the law that requires CMS to gather market price data on lab tests and the associated test volume tied to those prices from some of the laboratories in the market during 2016, then use that data to identify the median and set prices for the CLFS that will become effective on January 1, 2017.

Once they learned about the mandatory market price reporting requirement in PAMA and how the data would be assessed, many pathologists and lab administrators were seriously concerned that the data collection and reporting system would ultimately result in a new fee schedule tied to the private sector rates that the two largest national labs, **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, set. For

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).

years, these labs have negotiated discounts that allow them to establish sole-source contracts with private payers.

Also, pathologists and lab directors worried that other independent labs, much smaller in size from the national labs, would ultimately suffer under this price reassessment model because the large national labs would report lower prices, particularly for the routine tests they run every day simply because they have much higher volume and thus can charge much less than what smaller independent labs can charge.

Broader Market Assessment

Critics charge that, unless the so-called market assessment process under PAMA includes the broader laboratory market—hospital and physician-owned laboratories—any assessment would be skewed toward the very low prices the largest national laboratories offer private payers.

Quest Diagnostics and LabCorp collected about $1.23 billion of the $6.7 billion that Medicare paid for clinical lab tests under Medicare Part B in 2006, according to estimates *GenomeWeb* published. The $1.23 billion represents about 18% of the total that Medicare spent on lab tests that year.

If hospital and physician office laboratories are excluded from these totals however, Quest's and LabCorp's percentage of Medicare Part B laboratory revenue increases dramatically to more than 50%, according to estimates from the **National Independent Laboratory Association**.

When CMS issued the proposed rule it needs to implement PAMA, it outlined a timetable to stay on-track for having laboratories report rates and volumes in January 2016. The release of the rule comes three months after the law's statutory deadline to have a final rule in place by the end of June 2015.

When the law passed, the Congressional Budget Office estimated that the new payment system would save $2.5 billion over 10 years. However, the proposed regulation states that CMS estimates it will save $5.14 billion over 10 years. It is unclear how CMS arrived at this estimate, but the concern is that CMS may be using data from the federal Office of Inspector General, which found, during 2010, that Medicare paid 18% to 30% more than state Medicaid programs paid for some lab tests. *(See TDR, June 17, 2013.)*

Last year, Congress wrote sections of PAMA as a response to earlier statements CMS made that it intended to modernize the CLFS. Now, following the release of the proposed rules for private market pricing, many in the lab industry see the potential for harm that some feared when the language in the PAMA law was made public in 2014. More specifically, many community and regional laboratories believe they will experience significant financial harm should the private market price rule be implemented as currently written.

For example, the definition of which laboratories would need to report payment rates to CMS (called applicable laboratories) is one of the biggest issues of concern. PAMA defines an applicable lab as one that gets more than 50% of its Medicare revenue from the CLFS or the physician fee schedule.

Many Labs Excluded

This definition excludes hospital inpatient and outpatient laboratories from reporting since they are paid under the DRG system and under a bundled outpatient payment system, respectively. The law was not clear about hospital outreach laboratories, but following the law's passage, statements from Senate Finance Committee Chairman Orrin Hatch (R-Utah) made clear that he intended some hospital laboratories to be included.

However, the proposed rules released by CMS do not call for including any hospital laboratories in the reporting process. The proposed rule also sets up a "low expenditure" threshold to exempt from

Big Question for Labs: Is CMS Timeline Realistic to Assess Market Prices and Set CLFS Rates?

AMONG THE MANY QUESTIONS that clinical lab directors and pathologists have about the proposed rule to revise the way labs are paid is how will labs and the federal Centers for Medicare & Medicare Services accomplish all the necessary steps in the timeline defined by the proposed rule.

"How can CMS require labs to start submitting payment data on January 1, when there will be no final rule?" asked Julie Khani, Senior Vice President for the American Clinical Laboratory Association. "With no final rule, it is impossible for any lab to know whether or not it is an 'applicable lab' and thus required to report its market prices.

"And, there is no final rule to tell the labs what specific applicable data they need to provide or what format to use when submitting that data," she continued. "What CMS is requesting from the lab industry is impossible for labs to deliver at this point.

"Under PAMA, CMS was required to issue final regulations by June 2015, yet the agency was unable to issue the proposed rule by then," noted Khani. "Laboratories should not have to meet unrealistic deadlines to make up for CMS missing its statutory deadlines.

"With the current timeline, it is impossible for CMS to meet statutory requirements for issuing a new rule and implementing that rule," noted Khani. "CMS has just now issued a proposed rule to implement PAMA and comments are due before the end of next month. Given the time required for this process, CMS will not be able to issue the final rule this year.

"If the final rule is not issued by the end of this year—and the data collection period begins January 1, 2016, and ends on March 31, 2016—how does that give labs enough time to comply?" asked Khani.

"There are many other questions that labs need to answer to comply with the proposed rule," she added. "How do labs know precisely what data to report? There are unanswered questions about payments under appeal, partial payments, and many other issues. We will work closely with our members and other stakeholders to make sure that CMS implements PAMA in a manner that is consistent with congressional intent and with the statute."

reporting any laboratory that makes $25,000 or less from Medicare in the first six-month reporting period in 2016 or one that makes less than $50,000 from Medicare in subsequent 12-month reporting periods. This threshold largely eliminates reporting by physician-owned laboratories that perform a significant proportion of the nation's lab tests.

Inadequate Timeline

Technically, here's what happened when CMS released its proposed rule under Section 216 of PAMA to establish a new fee schedule. On September 25, the federal **Centers for Medicare & Medicaid Services** released a proposed rule under Section 216 of PAMA that establishes a new payment methodology for determining the Medicare Clinical Laboratory Fee Schedule. It was published in the *Federal Register* on October 1, and sets a deadline of November 24 for public comments.

The proposal says that, as of January 1, 2017, the CLFS payment rate will be derived from a volume-weighted median of private payer rates for lab services, stated Charles Dunham IV, of **Epstein Becker Green**. "To calculate the CLFS rate, PAMA requires an 'applicable laboratory' to report 'applicable information' for a 'data reporting period' to CMS," he wrote.

The proposed rule defines these terms and sets a schedule for collecting and reporting payment information. Experts told THE DARK REPORT that these definitions and schedules are problematic. The proposed rule also defines a new category of assays, called advanced diagnostic laboratory tests (ADLTs), and the proposed

definition for ADLTs is problematic as well, lab experts said. *(See story on ADLTs in the next issue of* THE DARK REPORT.*)*

Fundamentally Flawed Law

"The law itself is fundamentally flawed, as it requires CMS to determine a weighted median of all the test rates and volumes reported by labs in order to set new payment rates," stated Mark Birenbaum, PhD, administrator of the **National Independent Laboratory Association**. "Clearly, the largest players in the laboratory market—the two national publicly-traded laboratories—will drive the test volumes and their rates will dominate CMS' evaluation."

The **American Clinical Laboratory Association**, which represents larger laboratories, also has serious concerns about the definition of applicable labs. ACLA stated that the proposal conflicts with the law and with Congress' intent to establish a market-based payment system because the definition of applicable labs would exclude many laboratories from the data-collection and reporting requirements.

Blood Brothers Favored

Experts outside the clinical laboratory industry agreed. *GenomeWeb* reported that opinion in a note to investors, Michael Cherny, managing director of **Evercore Group LLC,** said the proposal favors the two largest national labs, Quest Diagnostics and LabCorp. By limiting the number of hospital labs reporting, the proposal helps independent labs, and the largest of those independent labs are in a much better position to absorb any price cuts that result from CMS' new, lower rates, he added.

Birenbaum agreed, saying, "The expressed purpose of the law was to establish private market-based rates within Medicare. How can this be a market assessment if only one segment of the lab test market is evaluated and that segment is skewed toward the largest players?

"From what NILA's seen so far, the goal is not to modernize the fee schedule; rather, CMS appears to be setting up a system that threatens to make inappropriate adjustments to Medicare rates in a manner that benefits the two largest publicly traded laboratories at the expense of community and regional laboratories," he explained. "This regulation threatens access to laboratory services for Medicare beneficiaries, who rely on laboratory tests to guide their care and treatment, particularly those living in rural and underserved communities, as well as nursing homes.

Access By Medicare Patients

"NILA never supported the law and now is working to ensure that the regulations do not force community and regional laboratories out of Medicare or perhaps out of business," he declared. "If community labs leave the Medicare program, then only the large labs would be left. This would negatively affect market competition and the access patients have to Medicare laboratory services."

Under the proposal, laboratory reporting would begin January 1, 2016, and end March 31, 2016. However, what further complicates the issue is that comments on the proposal are not due until November 24 of this year. That means a final rule may not be ready by January 1, 2016. Without a final rule, laboratories question how they could comply with a reporting process set to begin on that date.

In the proposal, CMS envisions evaluating the reported data and finalizing new rates by November 2016. It would then make the new Part B Clinical Laboratory Fee Schedule effective on January 1, 2017. Should that happen, it would leave labs with just a few short months to make business adjustments before the new prices are implemented. Lab experts watching these developments generally believe that CMS will use this process to cut lab test prices. **TDR**

—Joseph Burns

Labs Have Questions for CMS on Proposed Rule

CMS will conduct a new market assessment and use it to set prices for Medicare Part B tests

CEO SUMMARY: On September 25, CMS took a long overdue step to issue a proposed rule on how medical laboratories are to report private market prices for lab tests to the Medicare program during 2016. The proposed rule provides insights as to how CMS envisions pricing new tests and advanced diagnostic tests in the coming years. From most sectors of the lab industry, the response to the proposed rule was generally unfavorable and reflected significant concern. Some believe this proposed rule will cause some labs to go out of business.

RELEASE OF THE PROPOSED RULE by the federal **Centers for Medicare & Medicaid Services** to establish a new payment methodology for setting the Part B Clinical Laboratory Fee Schedule has clinical laboratories questioning the wisdom of the proposal.

In the proposal, many issues concern clinical labs. For example, what is the definition of an 'applicable laboratory' that must report what it receives in payment from private health insurers. Also, what is the definition of 'applicable information' in the proposed rule, meaning what pricing data must labs report to CMS?

Short Time Frame For Action

Other issues include the short time CMS has allotted for labs to review the proposal and then the short time frame CMS has built in for issuing the final rule before it is implemented on January 1, 2016.

A particular concern about the inadequate time frame was described by Julie Khani, Senior Vice President at the **American Clinical Laboratory Association**. That concern involves how much time CMS has to collect the payment data in the first quarter of 2016 and then analyze the data in time to set payment rates to begin on January 1, 2017, she said.

But all of these questions are secondary to the much more important issue. "With implementation of this proposed rule as written, CMS is fundamentally changing how it pays clinical laboratories based on a market assessment that is not, in fact, an assessment of the entire clinical laboratory market," stated Julie Scott Allen, Senior Vice President, District Policy Group, **Drinker Biddle & Reath LLP**, who represents the **National Independent Laboratory Association**.

"Because of the way CMS has written the proposed rule, it is a misnomer to characterize it as a 'full market assessment' that fulfills the language of the PAMA statute," she said. "NILA has always said that CMS would not be performing a market assessment if it was evaluating test rates and volume dominated by the biggest players in the market.

Having the biggest players overwhelm that review is not a fair assessment of how the market is pricing lab testing services.

"CMS went further in making it less of a market assessment by finding ways to exclude hospitals and most physician-operated laboratories that perform laboratory tests," added Allen. "The intent in the law was to assess the overall market. Obviously, when it comes to laboratory testing, the overall market is not just independent labs.

A Tilted Playing Field

"PAMA is written in a way that already favors the nation's largest lab companies by establishing a system that threatens to minimize their competition's place in the market," she continued. "Yet again, CMS is tilting the playing field, collecting and reassessing the fee schedule with rates that will be dominated by **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**. Smaller community and regional labs cannot absorb those feared price reductions without dire financial consequences.

"Indeed, CMS makes exactly this point when it says in its proposal that the rule will have a significant impact on a substantial number of small laboratory businesses," Allen explained. "CMS defines these labs as having revenue of $15 million or less in a year for independent laboratories and $11 million or less for physician-owned labs.

"The proposed rule will have a substantial impact even with a reporting exception for laboratories that perform less than $50,000 in Medicare services in a 12-month period," she said. "Of greater significance, the law and the resulting regulations do nothing to address the impact implementation and its associated fee reductions will have on small lab businesses or the patients they serve.

"Another big problem with the data assessment process CMS details in the law is that most small and regional labs are shut out of many private insurer contracts because so many payers make sole-source arrangements with Quest Diagnostics and LabCorp," she continued. "These two labs have such huge volume that they offer private payers low fees that would not cover the cost of services for smaller labs.

"So, how is it appropriate to rewrite the clinical laboratory fee schedule based primarily on market data dominated by those fees?" she asked. "Assume that PAMA results in significant reductions in reimbursement for the tests physicians rely on to manage the chronic care needs of Medicare beneficiaries. Should this happen, only the largest national lab companies could absorb those cuts. Few other labs, particularly small community labs, could take those cuts and financially survive.

"Does Congress and CMS want only two lab companies to serve Medicare beneficiaries?" asked Allen. "What would that mean for Medicare prices over the longer term? I assure you, those prices will rise.

"There is a primary reason PAMA works for the business model of LabCorp and Quest Diagnostics," she said. "Because these two multi-billion dollar lab companies offer larger test menus, they can absorb more price cuts, since they can make up the losses on those tests with higher-priced tests."

Other Issues Of Concern

In the proposed rule issued by CMS, there are other important issues of concern to pathologists and lab administrators. "In addition to setting the parameters for private-payer volume reporting, the rule also addresses other provisions of PAMA, including new coding and payment for tests deemed to be advanced diagnostic tests and for other new tests," explained Allen.

"Congress wrote PAMA as a way to expedite payment for some new tests while allowing labs to be paid the sticker price—at least initially—for advanced diagnostic tests. Later those prices would be adjusted," she noted. "In the proposed rule, however, CMS threw a couple of curve balls.

"The agency put some additional criteria around which tests can be deemed advanced diagnostics," stated Allen. "This criteria will do nothing to help make the crosswalking and gapfilling program any better or more transparent.

An Unwelcome Development

"Therefore, it could be that the large independent labs and those that advocated for passage of this law don't love this proposal either because perhaps it doesn't give them what they thought they would get from PAMA," mused Allen.

"Moreover, let's not forget who endorsed PAMA in 2014 and who gave rave reviews to the law," she said. "Now that high praise will be a challenge because policymakers will say, 'Well, you endorsed the law at the time it was enacted. This law had your blessing.'

"But PAMA never had NILA's blessing," Allen added. "In fact, NILA was vocal in its opposition when this law was forced through as a way to patch the sustainable growth rate.

"Is the promise that PAMA is better than what CMS would have done to lab test prices without it really true?" she asked. "When PAMA was passed, some in the lab industry praised the law because it was scored as saving only $2.5 billion in Part B lab test spending over 10 years, which they claimed was a significantly smaller cut than the lab community would have faced.

$5 Billion In CLFS Fee Cuts

"But now CMS anticipates the savings from the proposed rule [the result of lower lab test prices] will be closer to $5 billion over 10 years," she added. "In effect, CMS proposes to take an ax to clinical lab fees. This is not a surgical approach of judicious cuts here and there. Instead, this is a proposal to make deep and severe cuts in Medicare laboratory payment rates."

There is another way to look at the problem the clinical laboratory industry faces. CMS is proposing cuts of $5 billion over 10 years, or an average of $500 million per year for those 10 years. It is known that LabCorp and Quest Diagnostics represent about 18% of Medicare Part B payments. Thus, the two blood brothers stand to lose $90 million annually from these proposed cuts.

That means the remainder of the clinical lab profession will absorb about $410 million per year in reduced Part B fees. Further, the OIG report of June 2013 identified just 20 high volume tests as representing 47% of volume and 56% of CLFS dollars (totaling $2.72 billion). These are precisely the same tests that make up the major test volume at smaller labs and community labs. Thus, in proportionate terms, Medicare fee cuts to these 20 lab tests will have a much greater financial impact on these labs than they will have on the two blood brothers. TDR

—Joseph Burns

Contact Julie Scott Allen at 202-230-5126 or Julie.Allen@dbr.com and Julie Khani at jkhani@acla.com or 202-637-9466.

PAMA Was Alternative To CMS Lab Fee Cut Plans

WHILE ACKNOWLEDGING that there is much work to be done during the comment period for the proposed rule CMS issued, the American Clinical Laboratory Association pointed out that "it is important to be mindful of the severe cuts that PAMA prevented" by the passage of PAMA.

"In addition to creating a new reimbursement framework, PAMA also includes several important protections for laboratories," said Julie Khani, Senior Vice President at ACLA. "First, the legislation repealed the ability of CMS to slash lab reimbursement based on technological changes.

"That authority placed no limitations on the number of codes—or on the severity of the cuts—that CMS could make to the CLFS," noted Khani. "Second, PAMA includes a cap of 10% annually on cuts to any codes for the first three years. While that would still allow for significant reductions, those cuts pale in comparison to what we would have experienced under the CMS technical authority policy."

Lab team at Henry Ford Health engages clinicians

Hospital Lab Shares Ten Ways to Create Value with Lab Tests

CEO SUMMARY: Across the nation, labs in hospitals and health systems are feeling pressure from shrinking lab budgets and the need to be a contributor to the integration of clinical care. At Henry Ford Health System in Detroit, the clinical laboratory and department of pathology have responded to these trends by identifying 10 ways to add value with lab testing services. In part two of this series, a pathologist at HFHS explains the value-creation steps numbered six through 10 and discusses how the lab collaborated with physicians to deliver measurable improvements in patient care.

Second of Two Parts

IN RESPONSE TO SHRINKING FEE-FOR-SERVICE payments, a handful of innovative clinical laboratories and anatomic pathology departments are looking to cut costs and develop lab testing services that deliver more value to physicians, patients, and payers in anticipation of new payment models, such as bundled payments and budgeted reimbursement.

It should be recognized that the goals of cutting costs and adding value can be pursued simultaneously by clinical labs. For example, cutting costs by reducing the number of medically-unnecessary tests that are ordered also means that patients are not subjected to unnecessary blood collections. That is added value to patients. As well, health insurers also recognize the benefits that accrue from the reduction of unnecessary lab testing.

This duality in cutting costs while adding value can be seen at **Henry Ford Health System** in Detroit, where the clinical laboratory and department of anatomic pathology have identified 10 different ways that labs can add value. In part one of this two-part series, THE DARK REPORT presented the first five ways that labs can add value. *(See TDR, August 24, 2015.)* Here in part two, we present the second five ways to add value and the five most-common barriers clinical labs encounter when implementing these value-creation strategies.

In developing ways for the lab to transition from volume to value, the lab team at HFHS recognized that its lab testing services must also support the goals of their parent health system. "Within our health system, our lab's value will be judged from overall clinical and financial outcomes," explained Gaurav Sharma, MD, Senior Staff Pathologist and Associate Medical Director of the Core Laboratory, Quality Systems and Regulatory Affairs at the Henry Ford Health System. Sharma was speaking at THE DARK REPORT'S Executive War College in May.

Those second five strategies are:

6) Monitor and reduce defects
7) Improve supplier processes
8) Reduce unintended operating room testing
9) Reduce unintended inpatient testing
10) Reduce unintended testing in specialty clinics

6) Monitor and reduce defects

"The sixth strategy for value creation involves standardization throughout the lab organization," stated Sharma. "An important part of this strategy is to work with your lab's suppliers to reduce defects in every area of lab operations.

"Most studies show that about 80% of defects usually originate outside the clinical laboratory," he added. "We devised a system where we have defined more than 100 defect types, covering pre-analytical, analytical and post-analytical aspects of testing.

"We use this classification to systematically capture, classify, track, study, and reduce defects," noted Sharma. "Therefore, if a specimen is hemolyzed, we have a specific code for that as a defect. If there is a problem at registration in the outpatient lab, that defect has a specific code.

"The laboratory should assist its users in identifying and tracking defects created in the pre-analytical phase," noted Sharma. "Doing so reduces waste and improves patient care at the bedside and in the clinic.

Identify Sources Of Defects

"This system means our lab team can identify the most important defects and produce a profile for each business unit in the hospital," said Sharma. "On the inpatient side, in general, we already knew the good players and the not-so-good players. However, we quickly recognized that it was also important to identify the good players and the not-so-good players on the outpa-

tient/outreach side and work collaboratively with them.

"One important lesson we learned was that, even after all the not-so-good players are identified on the outreach side, it is unproductive to try to educate them," he continued. "The lab staff cannot do this.

"Not only are there too many of them, but because they are on the outpatient side, it is difficult for the lab to exert much control over them," explained Sharma. "Thus, our decision was to focus only on the problem units on the inpatient side. We prioritize our efforts by monitoring frequency of defects by units.

> **"Once you bring value (and the data to back it up) into the argument, everyone can recognize that fixing this source of defects not only makes life easier for pathology, but it also makes life easier for rheumatology, surgery, and other clinical services treating the same patients."**

"For example, we had frequent problems entering patient data at registration in the electronic health record system," noted Sharma. "Some patient information was incomplete and some patients were not registered at all.

"The most common source of defects (errors) was incorrect registration of patients in the new EHR system that had been installed by our health system," he explained. "This became our top priority.

"We focused on this issue," he noted. "By identifying and rectifying the causes of these errors, we reduced the rate of defects by more than 50% in three months. Next, we did the same with the middleware-to-EHR transfer defects and those problems have disappeared.

"What's interesting about this effort is that each time we worked with the clinicians or with IT, their response was the same," he recalled. "They would say that fixing any one of these problems would take too much time. They would also say that, 'It's not worth the time and effort.'

"But because our lab team had data from our defect management efforts, we could show the value of fixing these defects," emphasized Sharma. "Once you bring value (and the data to back it up) into the argument, everyone can recognize that fixing this source of defects not only makes life easier for pathology, but it also makes life easier for rheumatology, surgery, and other clinical services treating the same patients.

7) Improve supplier processes

"Identifying and correcting defects in processes is the seventh strategy," stated Sharma. "To address this value opportunity, our lab identified defects in supplier processes, particularly in surgery. When the surgery department implemented the new EHR system, the majority of specimens that came from surgery needed correction during accessioning, regardless of the specimen type involved.

"Sometimes an operating room nurse working with a new system won't know how to correctly identify the specimen," he noted. "Because the EHR system default is 'tissue,' we started getting specimens generically labeled as 'tissue' at our accessioning window.

"Our lab contributed to fixing this situation by using our defect management system," continued Sharma. "The lab team began counting the number of defects in the main hospital and in our community hospitals. As an example, in our main hospital, we identified 187 defects involving patient registration in the EHR in January. Each of those defects requires considerable re-work in both the OR and the lab.

"After counting the defects, the next step in our defect management system is to do a systematic root-cause analysis and

then take corrective actions," he noted. "Each time this was done, we shared the data with the OR.

"When the staff from the OR and the lab met in March, we complimented them because they had already reduced their defects from 187 to 129," said Sharma. "They liked the fact that we had accurate data and it showed improvement. This data demonstrated that they were making the corrections. We did this with each category of defect. Within six months, the EHR defects related to surgical pathology disappeared.

8) Reduce unintended operating room testing

"The operating room is also involved in value-creation strategy number eight," continued Sharma. "I recommend that pathologists or lab directors review the OR order sets at their hospitals and health systems.

"We discovered an opportunity with our order sets because a senior surgeon called me to ask why he had received a high number of acid-fast bacilli (AFB) cultures for his patients. "When we researched the root cause of this error, it was learned that anytime a physician did an incision and drainage, the nurse would ask what testing to do," stated Sharma. "The physician would often say, 'everything' and the nurse would then use an extensive order set for microbiology testing.

Collaboration With OR Staff

"Once the problem was recognized, our lab team started collecting data and asked the OR staff—along with a multidisciplinary team—to collaborate with us to help solve the problem," stated Sharma. "This is an important lesson because it is a reminder that informatics and workflow problems cannot be solved by either the lab or the physician acting alone. It is often necessary to get the EHR staff, the analytics staff, and the finance department involved.

"In studying this source of errors—unintended test orders for AFB—we learned that, after the EHR upgrade to **Epic**, there were multiple preference settings for AFB testing," he recalled. "Our hypothesis is, after the implementation of Epic, the number of orders for AFB cultures increased due to the use of default order sets and 'easy buttons' in the ordering interface. We are still investigating this possibility.

"Our goal was to reduce the number of AFB cultures and stains on surgical specimens so that our lab performs only those that are medically indicated," said Sharma. "To determine an appropriate intervention, we collect data on the built-in ordering options from where these orders originate and the specimen types," he noted. "We do this by speaking with the trauma surgeons and to other specialists.

"In fact, AFB testing could be the tip of a very large iceberg," said Sharma. "We

Henry Ford Lab's 10 Ways for Labs to Add Value

IN THE FIRST OF THIS TWO-PART SERIES, the first five value-creation strategies developed by the lab at Henry Ford Health System were described. *(See TDR, August 24, 2015.)* The 10 ways to create value with lab testing services are presented below:

1) Choose the right technology to reduce length of stay.
2) Question the need for expensive tests.
3) Create an institutional test formulary.
4) Demonstrate the financial efficacy of the lab's interventions.
5) Understand the downstream implications of lab decisions.
6) Monitor and reduce defects.
7) Improve supplier processes.
8) Reduce unintended operating room testing.
9) Reduce unintended IP testing.
10) Reduce unintended special testing.

may find other examples of lab test ordering rules that need review and revision.

9) Reduce unintended inpatient testing

"Our ninth strategy is a broader approach to reduce unintended inpatient testing," explained Sharma. "The lab team began work on inpatient testing after a project to manage our send-outs and molecular tests was completed. *(See the first five ways to deliver lab value in TDR, August 24, 2105.)*

"And, just as with the AFB cultures, we convened a multidisciplinary team," he added. "This team included internists, pathologists, clinical chemists, the EHR and analytics staff, and finance staff.

"Most lab professionals recognize that—because of built-in order sets—there are a substantial number of unnecessary tests ordered for hospital inpatients," pointed out Sharma. "Our laboratory's goal is to decrease the number of unnecessary lab draws for hospital inpatients.

➤Registration Defects

"On this point, our hypothesis is the same as with strategy number eight: The number of unneeded tests is due to the use of default order sets and easy buttons in the ordering interface that residents and providers use," he emphasized.

"To determine an appropriate intervention, we are collecting data on ordering options, locations, and specimen types," he said. "Then the lab team will adjust for patient acuity and study the outliers. We want to encourage mindful ordering among staff and residents to reduce testing volumes and generate relevant results.

"This ninth way to add value is a relatively new strategy for us and it requires us to collect the data needed to identify the different sources of defects," commented Sharma. "Our expectation is that the lab will generate significant positive improvements similar to the results we've produced with our other lab projects to increase value.

10) Reduce unintended testing in specialty clinics

"Our tenth way to add value has much in common with numbers eight and nine," stated Sharma. "It is a useful approach to reduce unintended special testing that originates with allergists and geneticists.

"When the lab team looked at testing in specialty clinics, it found a lack of criteria for advanced ordering options for allergy testing and germline testing," he observed. "As described earlier, the goal of our lab is to reduce inappropriate testing. Thus, we brought together allergists, pathologists, chemists, geneticists, oncologists, the EHR and analytics teams, and representatives from finance.

"Our hypothesis was that esoteric tests often are easy to order but difficult to select in the correct clinical context," explained Sharma. "Also, these lab tests are often ordered as part of a protocol, and they may be frequently redundant. Our aim was to standardize protocols and limit ordering to specialists. We are early in this project and still collecting data on the benefits that will result from smarter use of lab tests by the medical staff.

"Another example involves cystic fibrosis testing," he continued. "In our clinical practice, the pathologists cancel about 15% of cystic fibrosis results because there is no additional benefit of repeating a cystic fibrosis screen if you already know that the expectant mother is either a carrier or not a carrier.

"But it is surprising how many orders are still received because they are part of order sets sent for pregnant patients," continued Sharma. "When these tests are unnecessary, it wastes money and resources in the lab."

Sharma considers all of these efforts to be works-in-progress. "Remember, there is regular turnover in medical staff even as advances in medical knowledge trigger a change in treatment protocols," he said. "There is also the ongoing introduction of new lab tests. Thus, we are constantly challenged to refresh and update our efforts to

When Implementing Lab Test Utilization Programs, Most Labs Will Encounter at Least Five Challenges

INEVITABLY, LABS WILL ENCOUNTER barriers when implementing lab-test utilization management programs, stated Gaurav Sharma, M.D., Associate Medical Director of the Core Laboratory, Quality Systems and Regulatory Affairs at the Henry Ford Health System in Detroit.

"While opportunities abound for improving lab operations and reducing unnecessary use of lab tests, every lab will encounter significant barriers that must be addressed," he said. "Probably five types of challenges are the most prevalent.

"The first challenge is the most common," noted Sharma. "Clinicians will say: 'We have never done this before and the labs are disconnected from patient care.' The way for the lab team to survive this challenge and succeed in engaging clinicians is to first to have a lab test formulary. Then the lab team must deliver a consistent message and ensure that physicians are involved in the process of developing guidelines for standardizing how lab tests are ordered.

"The second challenge is similar," continued Sharma. "Physicians will say, 'What do you know about this? You don't see patients!' They take care of patients while we take care of specimens. But for us the specimen is a patient. Your lab team must deliver this message consistently to your clinical colleagues.

"When making your case, limit your opinions and use data to support your argument," he recommended. "We know which specialties create the most errors. Present that data. Data that shows how patient care can be improved is always powerful in these situations.

"The third challenge involves communication failures," he said. " We keep our message positive and start by telling a physician that a particular test is unnecessary and suggest alternatives. If the clinician disagrees with our recommendation, we share formulary documentation with them and if they still disagree, we offer to escalate their concern by presenting it to the formulary committee. Because we work on well-defined criteria and determinations, we are able to involve and consult with peer providers and administrators.

"To meet the fourth challenge of engagement, we co-lead the formulary committee with our providers, so that the lab test formulary for all of our inpatient, outpatient, and operating room patients is provider-led," he added. "Our lab is a key member, of course. As a result of this structure, they feel empowered and engaged with the formulary. Otherwise, providers will feel disempowered.

"The fifth challenge is the lack of EHR tools to facilitate lab test ordering," stated Sharma. "Physicians need answers to three questions when ordering tests: 'What is the right test? How do I order the test? And where do I get my results?' That's it!

"Our lab is developing ways to help physicians get the right answers to these questions at the moment when they are ready to order lab tests," concluded Sharma. "Not only will this reduce the number of wrong or unnecessary tests that are ordered, but it will also contribute to improvements in the quality of patient care."

deliver more value using the 10 ways that we identified.

"The good news is that as we implement each of these 10 lab value strategies, we are learning that, in a value-reimbursed paradigm, labs and pathologists will be rewarded for the quality of tests—not the quantity of testing," concluded Sharma. **TDR**

—Joseph Burns

Contact Gaurav Sharma, M.D., at Gsharma2@hfhs.org.

Tasso's Device Collects Capillary Blood for Testing

Goal is to provide clinical labs with a device for collecting specimens that is patient-friendly

CEO SUMMARY: In Seattle, Tasso Inc., a start-up company, is developing a device that adheres to the skin and collects capillary blood that can be used for lab testing. Tasso says the device is a less invasive than a venipuncture. At the same time, executives at Tasso recognize that, for many types of lab tests, it has not yet been demonstrated that capillary blood is a comparable specimen to venous blood, which is the current gold standard for lab specimens. Under its current product development timetable, Tasso expects to file for FDA review of its new device in 2017.

One question researchers want to answer is whether clinical laboratories can use capillary blood rather than venous blood for certain tests. If they can use capillary blood, then the collection process becomes simpler and cheaper for labs and easier for consumers.

Recognizing these benefits, several companies are developing technologies to collect capillary blood in such a way that it can be reliably used for medical laboratory testing purposes.

Perhaps the best known company that claims to have technology that allows it to use capillary blood for much of its clinical laboratory testing is **Theranos**, the lab testing company based in Palo Alto, Calif.,

Also in this technology race is Tasso Inc., a start-up company in Seattle that uses a microfluidic blood-draw device called the HemoLink that it hopes can replace venipuncture.

Tasso President Ben Moga described the technology and the company's plans to seek FDA approval for HemoLink. Developed by researchers at the **University of Wisconsin-Madison**, the blood-collection device is about the size of a golf ball.

To collect capillary blood, the HemoLink device is simply placed on a patient's upper arm and left on the arm for two minutes. In that time, the device uses a lance and then draws blood from capillaries beneath the skin via a slight vacuum. Tasso's proprietary open microfluidic network next transports the blood into an attached collection tube. Then the patient or physician can mail the tube to a medical laboratory for analysis.

Utility of Capillary Blood

"First, I should say that we use lancets in the HemoLink because there is no secret way to puncture the skin," stated Moga. "We use the same mechanism everyone uses: a tiny lancet that pokes the skin.

"Second, there's the issue of whether capillary blood is as useful as venous blood," he continued. "Some people have speculated that interstitial fluid is an issue and it can be for some lab tests.

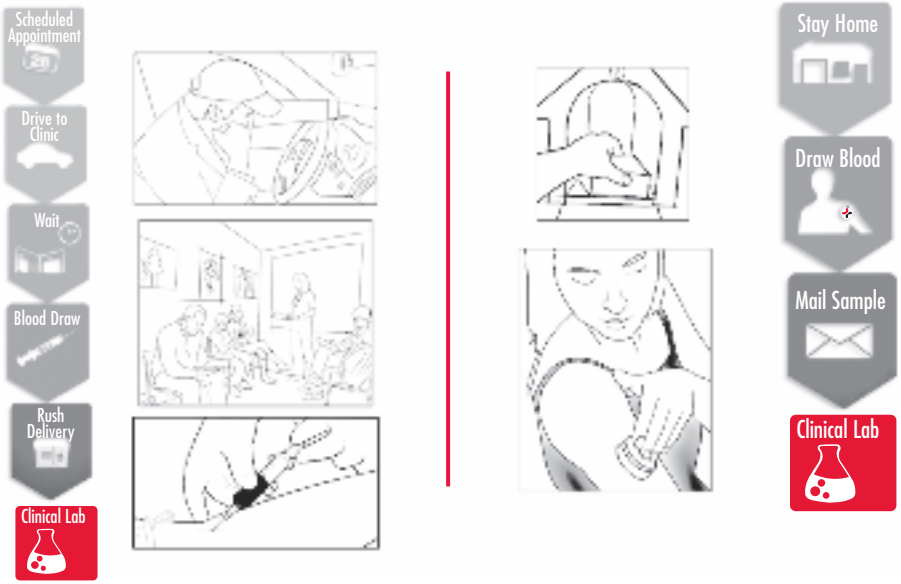
continued on page 18

Using New Technology to Streamline Workflow Involved in Collecting Clinical Lab Specimens

PICTURED AT RIGHT IS THE HEMOLINK DEVICE created by Tasso, Inc., to collect capillary blood for use in clinical laboratory testing and other diagnostic purposes.

HemoLink is designed to be simple to use and to allow patients at home to collect their own specimen. HemoLink is placed on the patient's upper arm. In just two minutes, using lancets and a slight vacuum, the device draws blood from capillaries beneath the skin via a slight vacuum. Using microfluidics, that blood is transported into an attached collection tube. This tube can then be sent to a medical laboratory for analysis.

How HemoLink Might Simplify the Collection and



By designing a capillary blood collection device that can be used by patients at home to collect their own specimens, Tasso may make it possible for medical laboratories to re-engineer the traditional workflow of specimens collected at a patient service center, then transported by couriers to the core laboratory. The above diagram shows how Tasso believes use of its HemoLink device can eliminate two steps in the traditional specimen collection process.

"But the larger issue for clinical labs is whether capillary blood can be compared with venous blood to produce substantially equivalent results from established lab test methodologies," noted Moga. "For decades, venipuncture has been used and as a result it has become the *de facto* gold standard.

Capillary Blood Equivalency

"In recent years, many companies and research teams have been attempting to learn if capillary blood is equivalent to venous blood," he explained. "Point-of-care instruments, for example, use finger sticks to assess A1c. So, we are not alone in asking this question.

"To answer this question, researchers have to go through the normal translational process for every new medical technology," Moga added. "The technology gets vetted to ensure that clinical decisions can be made without errors.

"At Tasso, we are confident that, with the support of our partners, we will make inroads in demonstrating that capillary blood is substantially equivalent to venipuncture," he said.

"Intuitively, we know that biomarkers of interest are present in both capillaries and veins and that they have slightly different properties or are present in different concentrations," he said. "If we identify a biomarker that is not substantially equivalent between venous and capillary blood, then the next question is: can we provide a correction factor that would allow us to normalize the capillary blood so we can compare it to venous blood? This is the point we are at as we prepare for regulatory scrutiny.

"What makes the possibility of using capillary blood so exciting is that there are clear benefits for consumers given that collecting capillary blood via the HemoLink is less traumatic for patients," noted Moga. "This is particularly true for pediatric patients, persons with hard-to-find veins, or those adults who have a history of fainting from a routine blood draw. And, given the density of nerve endings in the tips of our fingers, it is a fact that a finger stick hurts and therefore is particularly problematic for persons with a low pain threshold.

"Because the HemoLink technology has the potential to reduce pain and can be deployed in convenient locations, we are optimistic that it will appeal to consumers today who need or want to have blood drawn," he explained. "Given the more active role that patients are playing in their healthcare—driven largely by increasing out-of-pocket payments—providers are thinking more and more of their patients as consumers. That is why all healthcare providers, including clinical labs, will continue to focus on the consumer's experience.

"We believe that, by collecting blood in the least intrusive way possible and providing samples that result in clinically relevant diagnostic data, the HemoLink will be a disruptive innovation," Moga said.

"At Tasso, our goal is to develop and offer a safe, convenient, and affordable blood draw to the healthcare consumer," he added. "We believe this will be a disruptive innovation for people who value or rely on diagnostic and clinical lab testing as part of their everyday lives.

Development Work

"Much work remains to be done and a successful effort relies on the collaboration of an entire industry," noted Moga. "With that in mind, we want to engineer a solution to make the blood collection front end to be as simple as possible.

"Given the current status of the lead product, our timeline is to submit an application to the FDA for approval in mid-2017," concluded Moga. "The current goal is to obtain regulatory clearance in early 2018." TDR

—Joseph Burns

Contact Ben Moga via email at: info@tassoinc.com, Attention: Ben Moga.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

More venture capital money is moving into the medical laboratory industry in India. In September, **Metropolis Healthcare Ltd** of Mumbai, India, disclosed that **Carlyle**, a private equity company, had purchased a 36.5% ownership interest in the lab company. In April, **Warburg Pincus** sold its 27% in Metropolis to another shareholder, the Sushil Shah family.

MORE ON: *Metropolitan*

Metropolitan Health is a company that operates over 125 laboratories—as well as supporting collection centers—in the countries of India, Sri Lanka, the UAE, South Africa, Kenya, Mauritius, and Ghana. Because of ongoing consolidation of medical laboratory testing companies in India, this sector has attracted the interest of investors from the United States and Europe over the past decade. There is also a shortage of pathologists in India and that is attracting the interest of entrepreneurs in the United States who want to serve the unmet demand for subspecialty anatomic pathology services in India.

NEW GEISINGER LAB HAS 164,000 SQ. FT.

In an official ribbon-cutting ceremony on September 24, **Geisinger Health System** of Danville, Pennsylvania, celebrated the grand opening of its new clinical laboratory facility. In August, all inpatient testing was moved into the 164,000 square feet lab. Built for $64.3 million and designed to be state-of-the-art, it replaces the old lab building that was constructed in 1984. The capital investment and size of this new lab facility demonstrates the importance Geisinger Health places on lab medicine as a necessary resource to support personalized medicine and population management needs.

TRANSITIONS

- **Agendia, Inc.**, of Irvine California, appointed Mark R. Straley as its new CEO. Straley formerly held executive positions at **Thermo Fisher Scientific**, **Metamark Genetics**, **Ortho-Clinical Diagnostics**, **Ausam Biotechnologies**, **Bayer HealthCare**, and **Abbott Diagnostics**.
- Pathologist Eleanor J. Herriman, MD, has assumed the position of Chief Medical Informatics Officer at **Viewics**, with headquarters in Sunnyvale, California. Previously Herriman was employed at **G2 Intelligence**, **Xanapath**, **IC Sciences**, **SmartCells**, **Bain & Company**, and **Neuromedical Systems**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 26, 2015.

It's New!

Lab Quality Confab

and Process Improvement Institute

November 3-4, 2015 • Sheraton Hotel • New Orleans, LA

***Steve Stone**, Managing Director, Argent Global Services:*

Dealing with People, Processes, and Resources to Achieve and Exceed Stretch Goals at Your Lab!

Here are practical insights you can put to immediate use in your lab or pathology group! Steve Stone, a Lean and quality improvement expert, shares the best lessons learned from his experience in helping labs organize their people, processes, and resources in ways that produce impressive results on an accelerated timeline. This is essential knowledge you can apply to energize your lab team and generate substantial gains in every area of lab operations and clinical testing services.

Plan to be with us and guarantee your place by registering today.

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

UPCOMING...

- ***CMS Issues Proposed Rule That Would Cut Prices of Some Advanced Molecular Tests by Up To 91%.***
- ***Creating Added Value in Hematology: Success from Combining Lean, Automation, & Analytics.***
- ***A Second Billion-Dollar Lab Fraud? Wait until You Hear the Rumors about This Lab Company!***

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