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It's Here!

Final Rule for PAMA Market Price Reporting

Our assessment of the rule's potential to create new winners and losers among clinical labs. *SEE PAGE 3.*

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

Is CMS about to Create New Lab Winners, Losers?

FROM ITS INCEPTION IN 1966, THE MEDICARE PROGRAM WAS DESIGNED to give beneficiaries easy access to healthcare services while allowing any qualified provider to provide those clinical services. That is about to change for the worse for many patients and the clinical laboratories that serve them in communities throughout the United States.

That bold statement is based on how the federal **Centers for Medicare & Medicaid Services** is moving to implement lab test market price reporting as mandated under the Protecting Access to Medicare Act (PAMA). Simply said, CMS has crafted a rule that will produce significant cost savings from the Part B Clinical Laboratory Fee Schedule, but at the expense of many community labs.

Assuming that the final rule, as issued by CMS on June 17, is implemented without change, then Medicare officials will have put in place a scheme that will favor certain types of clinical labs while having a punitive financial effect on other types of clinical labs. This is inevitable, given the economics of lab testing. Labs with small volumes of specimens have a higher cost per test than labs with high volumes of specimens. Yet, these smaller labs serve smaller communities and rural towns that larger lab companies consider uneconomical. Thus, smaller labs have an essential role in the American healthcare system by providing both physicians and Medicare beneficiaries with access that otherwise does not exist in their towns—at a price that has always been considered reasonable.

Both the PAMA law itself and the final rule on lab test market price reporting issued are examples of that oft-quoted insight by Otto von Bismark, the Chancellor of Germany from 1862 to 1890. He once said, "Laws are like sausages, it is better not to see them being made." His point was that lawmakers and bureaucrats are subject to vested interests and complicated negotiations when lawmaking.

These factors have been in play, both during the time when Congress was writing the PAMA law and when CMS was interpreting the statute as it crafted the rules needed to implement the law. At every step in the process, different vested interests in the clinical lab industry have attempted to shape the law in ways that favor their interests. Now, with a final market price reporting rule, the clinical lab industry is about to journey into an unknown using a flawed process that some expect to create new lab winners and losers. TDR

PAMA Final Rule Issued, CMS to Cut Rates by 5.6%

New Medicare rates take effect Jan. 1, 2018, after labs report price data from private insurers

CEO SUMMARY: CMS issued its final rule for implementing the laboratory payment reform included in the Protecting Access to Medicare Act of 2014 (PAMA) on June 17. All labs will see significant reductions to the Medicare Part B Clinical Laboratory Fee Schedule that becomes effective on Jan. 1, 2018. That same section of PAMA requires certain labs that perform clinical lab tests to report to CMS what private insurers pay them for laboratory tests. CMS will use the rates from private payers to calculate Medicare payment rates.

IT'S NOW OFFICIAL! Jan. 1, 2017, is the date that the federal **Centers for Medicare & Medicaid Services** will require certain clinical laboratories to report what private insurers pay labs for diagnostic tests. Then CMS will use that market price data to set prices for the Medicare Part B Clinical Laboratory Fee Schedule, beginning on Jan. 1, 2018.

The new rates will be set according to the final rule to implement a section of the Protecting Access to Medicare Act of 2014 (PAMA). *(See TDR, April 7, 2014.)* The CMS final rule also includes language to address payment for advanced diagnostic laboratory tests (ADLTs), as required by PAMA.

However, there is little mystery about the size of the cuts in clinical laboratory test prices that Medicare officials expect to result from market price reporting. During the first year (2018), savings to CMS of $390 million are expected.

That represents significant fee cuts from the $7 billion that CMS currently pays for clinical laboratory tests each year. For the first 10 years, savings from the PAMA private payer rebasing are expected to be $3.93 billion, according to CMS.

From the start, the laboratory test payment reform section of the PAMA legislation, which was crafted to generate savings as an offset for the spending needed to temporarily patch the Medicare physician pay formula, has been unpopular with the **National Independent Laboratory Association**.

There are several reasons clinical lab professionals are concerned with the new PAMA reimbursement system. Small laboratories, in particular, see implementation

of this mandate as a financial hammer blow that will cause them to sell or shut their doors. This is equally true of those independent labs that primarily serve Medicare patients in nursing homes and similar care settings.

How To Collect Price Data

Another criticism is that few labs are equipped to determine how much each health insurance plan has paid the lab for each type of lab test during a calendar year. Thus, many labs consider the data gathering to be a huge burden on all labs—whether large or small. The cost and the staff resources required to produce this information will be immense.

The third major criticism of the PAMA market price reporting requirement, as originally written, is that it will not give CMS an accurate picture of the true average price all insurers—big or little—pay to all labs, ranging from physician office labs to independent labs and hospital outreach labs. Thus, critics said, CMS will base its pricing decisions on a biased sample of pricing data, data dominated by the large national laboratories that perform a substantial proportion of Medicare Part B lab test volume.

The proposed rule excluded many higher-cost labs from the reporting requirement. For example, hospital laboratory outreach programs, which are generally paid more by private insurers for their services, would have been excluded from submitting market price data to CMS.

CMS Knows Much Already

THE DARK REPORT observes that CMS officials understand this fact about hospital laboratory outreach programs. Even without specific market price data from different sizes and types of medical laboratories, CMS understands generally which categories of labs are being paid higher reimbursement from private payers.

For this reason, critics of the agency's PAMA rulemaking argue that CMS is gaming the system to generate larger cuts to laboratory payments and greater savings for Medicare. However, in comments it published in the *Federal Register*, CMS included statements about the final rule that it believes rebuts this criticism.

As defined in the final rule issued on June 17, clinical labs that get at least $12,500 in Medicare revenue from laboratory services paid under the clinical laboratory fee schedule and more than 50% of Medicare revenue from laboratory or physician services will report their private payer rates for test services performed.

This provision requires laboratories performing clinical laboratory tests to report what each private insurer pays them for each type of lab test, along with the volume of tests the insurer covered. Medicare will use the rates from private insurers to calculate Medicare payment rates for laboratory tests paid under the clinical laboratory fee schedule (CLFS) beginning Jan. 1, 2018.

OIG: CMS Pays Too Much

As noted earlier, the rule is expected to save $390 million in 2018 and $3.93 billion over 10 years. Writing for clients of **William Blair & Co.**, Analyst Amanda Murphy said CMS' savings estimates are based on the broad assumption that Medicare pays 20% more than private payers pay.

This 20% figure came from a 2013 study by the federal **Department of Health and Human Services** (HHS) Office of Inspector General that published an analysis of what Medicare spent in 2010 on clinical lab tests. The OIG analysis showed that CMS could have saved about 20% if it paid the lowest price for 20 tests that the state Medicaid programs and Federal Employee Health Benefits Plans (FEHBPs) paid for in 2010. *(See TDR, June 17, 2013.)*

Highly efficient labs will likely benefit from the final rule, Murphy reported. Labs with the lowest cost structure will be best positioned to succeed under PAMA and may benefit by acquiring smaller labs that could struggle financially, she wrote. In

Final PAMA Rule Defines which Labs Must Report, Provides Basic Timeline, But Lacks Specifics

BY PUBLISHING THE FINAL RULE for implementing laboratory payment reform that is part of the PAMA law in the *Federal Register*, CMS has initiated a process that will have profound effect on the entire clinical laboratory industry.

The final rule describes the laboratories that must report their market price data for lab tests and provides some, but not all, details about the reporting process. Here are some key elements of the final rule:

- "Applicable laboratory" will bill Medicare Part B under its own National Provider Identifier (NPI); in a data collection period, it receives more than 50% of its Medicare revenue, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of several sources.
- "Applicable information" to be reported is the payment rate that was paid to the laboratory by each private payer for each CDLT and the volume of such tests for each such payer for the data collection period.
- Payment rate reported by a laboratory must reflect all discounts, rebates, coupons, and other price concessions. Per the PAMA statute, tests reimbursed by capitated pricing are excluded from reporting.
- Where an applicable laboratory has more than one payment rate for the same payer for the same test, or more than one payment rate for different payers for the same test, each such payment rate and the volume for the test at each such rate must be reported.
- "Private payer" is defined as a health insurance issuer and a group health plan (as such terms are defined in section 2791 of the Public Health Service Act), a Medicare Advantage plan under Medicare Part C, or a Medicaid managed care organization.
- In cases where the Secretary determines that an applicable laboratory has failed to report, or made a misrepresentation or omission in reporting, applicable information under section 1834A(a) of the Act for a CDLT… The Secretary may apply a CMP in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission.

CMS stated that this final rule incorporated public input, "We received approximately 1,300 public comments from individuals, healthcare providers, corporations, government agencies, trade associations, and major laboratory organizations," it said.

addition, Murphy believes the final rule will be favorable for smaller labs that offer proprietary assays because private payers pay more for these tests.

Alan Mertz, president of the **American Clinical Laboratory Association**, said that ACLA applauded the change in the implementation date from Jan. 1, 2017, to Jan. 1, 2018. He said ACLA and others had requested the delay.

NILA, however, had requested a two-year delay to allow for activities that support laboratory compliance with a new reporting system.

Continuing with his comments, Mertz said, "While none of us in the lab community want to see cuts, the establishment of a market-based system for determining Medicare reimbursement for laboratory services was clearly preferable to the alter-

natives we faced in 2014—immediate unlimited cuts to payment rates by CMS through its technological changes authority and immediate across-the-board reductions to the CLFS by Congress."

Some Improvement By CMS

ACLA also commented on how CMS defines labs that will report private insurance payment data in the final rule. "On the issue of which labs this rule affects, this is an area that CMS made some improvement over what was in the proposed rule," he said.

"In the proposed rule CMS suggested the labs that would need to report market price data would be determined by their tax ID numbers," added Mertz. "That meant very few hospital labs would report because it's the rare hospital lab that has its own tax ID number.

"ACLA asked CMS to change from the taxpayer ID number to the CLIA number so that the lab would look at just Medicare revenue," continued Mertz. "That would have included virtually all hospital labs that met the volume threshold.

"Instead, CMS moved from taxpayer ID numbers to the National Provider Identifier (NPI)," he noted. "That means more outreach hospital labs will report than in the proposed rule. However, we don't know how many more at this time."

Excluded From Reporting

Not all labs will be required to report what private insurers pay them because the final rule sets the minimum level of Medicare lab revenue at $12,500. CMS estimates that about 95% of all physician office laboratories and about half of independent laboratories will not need to report private payer prices.

Under the rule, laboratories required to report will collect private payer data from Jan. 1, 2016, through June 30, 2016. These labs must submit that data to CMS in the first three months of 2017.

"The problem with this timeline is there are still too many unknowns," stated Julie Scott Allen, vice president of the **District Policy Group** and representing the **National Independent Laboratory Association**.

Using the data labs report, CMS will calculate new Medicare rates based on the weighted median of private payer rates for each test by early November 2017 and the new rates will be effective on Jan. 1, 2018. Again, Allen cautioned, CMS has not explained how it will calculate the weighted median private payer rates.

The final rule differs from the proposed rule that CMS issued last fall in that CMS moved the implementation date from Jan. 1, 2017, to Jan. 1, 2018. CMS said this move allows labs time to develop the data systems needed to collect, review, and verify payment data from private payers.

Do Labs Have Enough Time?

"However, the new implementation date simply reflects the agency's delinquency in issuing a final rule one year beyond the statutory deadline," Allen said. "It is not the delay requested by laboratories for additional time to implement the new payment collection and reporting requirements."

Moving the implementation date allows CMS to validate the data and test the systems it will use for labs to report the data. The added time also gives CMS a chance to do end-to-end testing of its data-collection systems, CMS said.

In the final rule that CMS published, it also addressed Advanced Diagnostic Laboratory Tests (ADLTs). This section of the rule will be analyzed in an upcoming issue of THE DARK REPORT. TDR

—Joseph Burns

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PAMA Final Rule a Threat To Community Lab Survival

Excluding small lab payments means CMS may set lower rates that favor only larger labs

CEO SUMMARY: Will implementation of the final PAMA private payment rate reporting rule for labs put smaller, community labs at financial risk? Yes, says the National Independent Laboratory Association (NILA). By deliberately setting a standard to exclude private payer payment data from hospital outpatient and outreach labs that receive payments off the CLFS, CMS will base its new fee schedule primarily on the data the biggest labs provide, a NILA representative said.

MANY COMMUNITY CLINICAL laboratories may be forced to close or sell to other larger clinical labs under the final rule for market price reporting that the federal **Centers for Medicare & Medicaid Services** issued June 17. CMS will use the rule to set new, lower payment rates for clinical laboratory tests.

"The rule's approach supports the interests of the largest publicly traded lab companies," stated Julie S. Allen, who represents the **National Independent Laboratory Association** (NILA) and is Vice President of the **District Policy Group**. "It does so because CMS will collect data from the commercial discounted rates paid to the largest publicly-traded labs. This data will dominate since those labs generate the biggest volume of Medicare Part B lab testing.

"The rule will result in the exclusion of most of the higher private payment rates currently paid to hospital laboratories," added Allen. "By excluding private payment data from hospital labs, CMS will set the new Medicare Part B rates at levels that do not reflect the costs of providing testing in the community laboratory setting that often are the only local laboratories serving Medicare patients in their coverage areas.

"From NILA's perspective, we see very little improvement from what CMS outlined in the PAMA proposed rule," she says. "That is why we view the final rule as being significantly damaging.

Slow Death For Some Labs?

"How is this final rule any better than proposing to cut lab test payments on an arbitrary basis based on technology, which CMS proposed in 2013?" Allen asked. "For those who espouse support for the PAMA rule, I'd love an explanation on how PAMA is any different than what labs would have faced under a competitive bidding model?

"This final rule is just as bad as these other approaches to cutting Medicare Part B lab test payments," she continued. "It's just a slower death for community laboratories instead of an immediate death. What is unfortunate is that Medicare beneficiaries in many communities are at risk of losing access to the local lab testing services they have relied on for years.

"For these and other reasons, NILA is considering a legal challenge to the rule under federal administrative law and will press members of Congress to require CMS to change the final rule," she said.

Organizations that represent large clinical laboratory companies have praised CMS' decision to delay the implementation of the new clinical lab rates as a victory for laboratories. That's in part because laboratories complained last fall that they would not have time to collect the data CMS needs to set the rates nor would they have time to implement the new rates.

"But a delay in implementation was inevitable anyway, and the one-year delay CMS provided is still insufficient," explained Allen. "Under the terms of the regulation, labs actually have less than six months to collect and report the data.

Fair Market Evaluation

"The delay is secondary to the more important fact that CMS did not address the concerns that NILA presented after CMS issued the proposed PAMA rule last fall," Allen said. "The primary issue for NILA is that CMS is not proposing to conduct a fair market evaluation.

"Instead CMS is establishing a biased and deliberately-skewed market evaluation that is based on the portion of the lab test market with the lowest payment rates," she said.

"CMS opted to define what it calls 'applicable labs'—meaning those that have to report what private payers pay for labs tests—in such a way that the data from the largest publicly-traded laboratories will dominate the calculations, and data from the highest-paying sector of the market will be excluded," she explains.

"If the key to doing a fair market examination is to ensure that all segments of the laboratory market are represented in a statistically relevant way, then it doesn't make sense to exclude hospital laboratories," she argued. "Yet, CMS has succeeded in ensuring that the majority of hospital laboratories will be exempt from reporting by setting a definition for 'applicable laboratories' that CMS knows will not capture hospital laboratories.

'Applicable Labs' Definition

"CMS defines 'applicable laboratories' as those that have an NPI number and that receive 50% or more of their Medicare revenue from either the CLFS or the PFS," Allen explained. "In the proposed rule, CMS said it would use the tax identification number (TIN) as the standard to identify laboratories that would not participate. At that time, CMS argued that different entities may own many laboratories, so CMS should examine that 50% threshold across an entity's Medicare revenue.

"But the PAMA statute is clear that the standard for the 50% threshold is 50% in laboratory revenue, not 50% of the entity's revenue," she said. "Therefore, it's inappropriate and in violation of the statute to examine the 50% threshold based on comparing laboratory Medicare revenue against all of an entity's other sources of Medicare revenue.

CMS Formula For Pricing

"Doing it that way deliberately minimizes the laboratory's revenue," Allen added. "The statute is clear: CMS should examine the 50% threshold for laboratory revenue, not the entity's (meaning the hospital's) revenue.

"The point is that if you use the NPI as the applicable factor, you have to determine if each laboratory has its own NPI," Allen commented. "CMS has no idea how many hospital outreach laboratories have their own NPI, nevermind whether a statistically relevant number of hospitals do.

"In all of the documentation from CMS, including fact sheets, press releases, and the rule itself, CMS officials clearly outline statistics in terms of the percentage of physician-owned and independent laboratories they expect to capture based

By Failing to Analyze All Segments of Lab Market, Test Price Reporting Results Will Skew in CMS' Favor

FOR THE FEDERAL CENTERS FOR MEDICARE & MEDICAID SERVICES, the fairest way to analyze the clinical laboratory testing marketplace is to include all segments of the market.

Doing so is difficult, however, because some segments are too small to provide meaningful data and others are difficult to analyze because of the way CMS bundles payments for tests in those segments.

The next best method is to include all the relevant segments of the market, suggested Julie S. Allen, a Vice President with the District Policy Group who represents the National Independent Laboratory Association (NILA).

"The Protecting Access to Medicare Act requires that laboratories report what private insurers pay for their laboratory tests in the volume associated for each of those rates," she explained. "In a pie chart of the laboratory market examining Medicare test volume, you could eliminate the segments of the pie that represent hospitals and physicians. But then you'd be left with only that piece of pie that represents the independent laboratory test market.

"Within that piece of the pie, we know that two companies dominate the test volume in the independent laboratory marketplace," Allen noted. "Those two companies are **Laboratory Corporation of America** and **Quest Diagnostics Incorporated.** Together, they provide over 52% of Medicare's independent laboratory test market.

"We know that LabCorp and Quest arrange for sole-source contracts with private payers by grossly discounting rates for traditional testing," she explained. "That discounting is used to capture market share by excluding competitors.

"In CMS' market analysis, these discounted rates for Clinical Diagnostic Laboratory Tests (CDLTs) will be reported to CMS at high volume," she says. "That's the biggest factor driving what prices CMS will set for most CDLTs. By eliminating most of the hospital laboratory data, CMS has taken higher-priced private payer rates out of the equation, thus allowing the lowest reimbursement rates to dominate the data and, therefore, also dominate the new Medicare price calculation.

"That skews the data results to the lowest levels," Allen continued. "And because CMS significantly favors lowering the clinical laboratory fee schedule (CLFS), many have asked if CMS' market analysis was designed deliberately to skew the results in this way. And many believe the answer is, 'yes,' to achieve the goal of securing savings in Medicare by paying labs much less than now.

"The end result is that CMS officials are describing the market analysis as if they were painting a picture of the whole market," she explained. "But it's not the whole market. It's only part of the market—the part with the lowest private payer rates.

Potential Legal Challenges

"For these reasons, NILA is examining every angle to address this regulation," she says. "There are potential legal challenges and legislative angles to pursue. Among the legal areas we are investigating is whether CMS' market analysis deliberately violates the statute.

"Also it's set up so that laboratories cannot possibly comply by Jan. 1, 2017, to report the data from private health insurers," she added. "CMS' rule is absent any details on which codes laboratories will report on, and laboratories don't know where or how they will report their data.

"Also the final PAMA rule doesn't provide any information on what data collection and reporting systems laboratories must comply with," Allen concluded. "In addition, we don't have a timetable from CMS on when to expect the subregulatory guidance that laboratories will need to collect and report this information."

on the formula they've set forward," she explained. "But nowhere do they give a percentage of hospital laboratories captured from this formula.

"Another issue CMS officials make clear in the final rule is they believe it was not Congress' intent to include private payer data from hospital laboratories, but they received many comments from Congress and others to the contrary," Allen said.

"CMS focuses the bulk of its discussion in the rule about hospital laboratories on the point that they do not believe the statute meant to include hospital inpatient or outpatient laboratories," she added. "CMS officials agree that hospital outreach laboratory data will be included, and if an outreach laboratory does not currently have an NPI, it can request one.

Time Required To Obtain NPI

"So that begs the question: If CMS is rushing to put a data gathering and reporting system into place, can a hospital outreach laboratory request an NPI in time for the first reporting period, which begins Jan. 1, 2017?" Allen asked. "And, if a hospital outreach laboratory requests an NPI, could that laboratory have the NPI applied retroactively to the 2016 data the laboratory is required to report?

"How does a laboratory get an NPI after July 1, 2016, but somehow link that NPI to the payment data it already collected from Jan. 1 to June 30, 2016? The answer is—and CMS officials know this—hospitals that would like to get a separate NPI for the purposes of reporting data to CMS for the first reporting cycle are unable to do so, and if they did, it wouldn't matter because the NPI cannot be applied retroactively to the claims data.

"Hospital inpatient laboratories are excluded under the PAMA statute because inpatient laboratory tests are paid under a DRG model, not under the Part B Clinical Laboratory Fee Schedule or the Physician Fee Schedule," Allen concluded. "Outpatient tests are paid primarily under a bundle, but sometimes not. But hospital outreach tests are paid under the CLFS or PFS as non-hospital patient tests." TDR

—Joseph Burns

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PAMA Law Itself Has Issues that Divide Labs

ACROSS THE NATION, clinical lab executives and pathologists must now pay attention to the final PAMA private payment rate reporting rule that CMS published on June 17.

For some, their lab will be required to report market price data to CMS. And other labs must prepare for the negative financial consequences of lower Medicare Part B clinical laboratory test prices, beginning on Jan. 1, 2018, just 18 months from now.

The PAMA law has the potential to bring about the greatest realignment in the clinical laboratory testing market seen since the emergence of big, multi-regional public lab companies in the 1970s. PAMA will do this in several ways. One way is how the law defines the ground rules for CMS to establish new Part B clinical laboratory test fees.

For example, what is not being discussed about the final rule CMS published is the fact that lab tests paid under capitation are excluded. That exclusion is written into the PAMA law. Thus, CMS will not collect the highly-discounted capitated pricing data the private payers enjoy from larger national lab companies.

Therefore, if the original goal of Congress was to conduct a fair and accurate survey of what private payers pay for lab tests (and use that data to reset Part B CLFS fees), then why was this language excluding capitated pricing put in the PAMA law? Which class of labs benefits from this price reporting exemption?

Lab IT Update

McKesson, Change Healthcare Decide to Create New Company

McKesson's units for pathology billing/collections, advanced diagnostics management are involved

ACROSS THE NATION, the hundreds of pathology groups and clinical labs that use **McKesson Technology Solutions** for their billing and collections, along with labs that use the Advanced Diagnostics Solutions group, should pay attention to a major corporate deal announced June 28.

On June 28, **McKesson Corporation** of New York and **Change Healthcare** (formerly **Emdeon**) of Nashville, announced a deal whereby a new company will be formed by merging nearly all of McKesson's businesses in its Health Technology Solutions group with Change Healthcare. The company is expected to have annual revenue of $3.4 billion.

Two of the McKesson business units in the MTS group serve pathology groups and clinical laboratories and are believed to be included in this transaction. One is the McKesson Revenue Management Solutions division that provides billing and collection services to hundreds of pathology groups and clinical laboratories nationwide.

The second is McKesson's Advanced Diagnostics Solutions group, familiar to labs doing molecular and genetic testing as the business unit that manages the McKesson Diagnostics Exchange that provides the database labs use to obtain Z-codes when registering proprietary molecular and genetic tests for coverage decisions by government and private health plans.

Change Healthcare is best-known as one of the nation's biggest transaction clearinghouses that connects payers, providers, and patients. It also offers revenue and payment cycle management and clinical information exchange solutions.

Many labs know that Change Healthcare has a laboratory interface built into more than 40 EHR systems to support electronic lab test ordering/reporting. This is one more way that the proposed transaction could trigger changes that affect labs that use Change's EHR interface to connect with their client physicians.

New Owners And Managers

Clinical lab and pathology group customers of the two McKesson service and product lines that are involved in this deal will want to stay informed about how the changes in ownership affect the management of these business divisions. McKesson, Change Healthcare, and the **Blackstone Group** (a private equity group that holds a majority interest in Change) plan a two-step process for this transaction.

In step one, a new company will be created that is comprised of McKesson's HTS group and Change Healthcare. Once that is accomplished during the first half of 2017, McKesson will own 70% and Change will own the remaining 30%.

Step two comes after the merger and integration of the different businesses is completed. The owners of the new company, subject to market conditions, intend to go public by conducting an initial

public offering (IPO). Once the IPO is done, McKesson has stated that it "expects to exit its investment in the new company in a tax-efficient manner."

A name for the new business was not announced. The deal is expected to close in the first half of 2017 and is subject to antitrust clearance and an audit of financial statements from the MTS businesses.

Big dollars are involved in this transaction. The new company has commitments of $6.1 billion in funded debt. The new company will use those funds to retire approximately $2.7 billion of Change Healthcare debt; pay $1.25 billion to McKesson in cash; and pay $1.75 billion to Change Healthcare's stockholders, also in cash. The remaining $400 million will cover expenses related to the transaction, the companies said.

New Health IT Company

At a press conference discussing the transaction, McKesson executives identified these businesses within McKesson Technology Solutions as moving to the new company:

- McKesson Health Solutions
- Connected Care and Analytics (excluding RelayHealth Pharmacy Imaging and Workflow Solutions)
- Business Performance Services (BPS)

Although the RelayHealth Pharmacy and the Enterprise Information Solutions (EIS) division of MTS will stay with McKesson, in a separate press release also issued on June 28, the company said it is "exploring strategic alternatives for its Enterprise Information Solutions (EIS) business, a division of McKesson that provides core hospital information systems."

This division includes McKesson Lab, the laboratory information system (LIS) that is used by several hundred hospitals and labs throughout the United States. Thus, McKesson is signaling its interest to divest those service lines if it can find the right buyers or venture partners.

What do these developments mean for clinical laboratories and pathology groups—whether they are a McKesson customer or not?

How Lab Market May Change

First, it shows that consolidation is ongoing in healthcare. In the proposed transaction, Change Healthcare is becoming significantly bigger as it takes on the business units from McKesson.

Second, pathology groups and clinical labs that use McKesson Revenue Management Solutions for billing and collections may see some interesting synergies once Change Healthcare has full operating control of that business. Among other things, Change Healthcare's clearinghouse service may help labs collect more claims faster. Also, its EHR interface service may make it easier for client labs to bring on new physician clients and support electronic test ordering and reporting.

Three, McKesson disclosed its interest in "exploring strategic options" for the Enterprise Information Solutions business and this may have two consequences for McKesson Lab, its LIS product. On one hand, it will probably become more difficult for the McKesson sales team to win new LIS clients in coming months. On the other hand, LIS competitors will emphasize to McKesson Lab customers that, given the uncertainty about the future of that business division and the LIS product, their clinical laboratory would be best served by switching to another LIS.

Closely Monitor Events

For these reasons, lab executives and pathologists using the McKesson services involved in this transaction will want to monitor developments. This is particularly true because it may involve the McKesson team that handles their labs' billing and collections. TDR

—Joseph Burns

FL Path Group Lost Volume After BeaconLBS Started

Group saw specimen volume decline 20% and that work has yet to return 15 months later

CEO SUMMARY: A 22-physician pathology group in Tampa has complied with rules for lab test ordering that UnitedHealthcare and BeaconLBS established, yet has experienced a steep decline in the volume of specimens it receives. Physicians told the pathologists that other labs were not using the BeaconLBS system or were not asking their clients to use it. Clients also told the Tampa pathology group that it was the only laboratory asking that their medical group use the decision support system, the lab director said.

In the spring and summer of 2015, **Reliance Pathology Partners** lost 20% of its business from referring physicians in Florida as the result of a new and onerous laboratory benefit management service that **UnitedHealthcare** introduced in the Sunshine State.

Since then, the 22 pathologists at Reliance have not seen that volume return, said Joseph Raiano, Director of Operations for the physician-owned, CAP-accredited practice in Tampa and the Interim Lab Director for **Ruffolo Hooper & Associates**, a pathology group.

UnitedHealthcare partnered with **Beacon Laboratory Benefit Solutions**, a division of **Laboratory Corporation of America**, to launch the lab benefit management service. Some physicians say it is onerous and time-consuming, causing many to refuse to use it to obtain pre-authorization or pre-notification when ordering certain medical lab tests. Other physicians have stopped taking UHC patients to avoid having to use the laboratory benefit management system. *(See TDRs, July 21, 2014, and Feb. 17, 2015.)*

For pathologists and laboratory directors, the design and operation of BeaconLBS raises troubling issues. They ask: How can a lab benefit management service—BeaconLBS—be allowed to steer specimens to clinical labs its parent company (LabCorp) owns?

Questions Left Unanswered

UHC launched the program in October 2014, but did not require physicians to use the system until April 15, 2015. On that date, BeaconLBS started to use the system to adjudicate claims for some 89 clinical laboratory tests and anatomic pathology specimens for UHC's commercial HMO patients in Florida. For Reliance Pathology Partners, that was the date the pathologists started to lose some of UHC's referral business, Raiano told The Dark Report.

Founded in 2004, Reliance is an independent lab that contracts with Ruffolo Hooper & Associates to read its cases. A 19-physician pathology and laboratory medicine practice in Tampa, Ruffolo Hooper was founded in 1965.

"We went live when the UHC mandate happened in April 2015 and we went to all of our clients to make sure they were registered to use BeaconLBS," Raiano explained. "We got a lot of pushback because many of our client physicians weren't aware of it and some outright refused to use it.

Some Labs Just Say, 'No'

"Other clients were open to it, not because they felt it was relevant to their practice or that it would benefit them in any way," added Raiano, "but because we had a relationship with them and if they did not use the BeaconLBS system for their UHC patients, we explained that we would not be reimbursed.

"The feedback we got from many client physicians was that other labs either were not using the Beacon system or were not required to use the Beacon system," he explained. "It seemed like we were the only lab in the market actually trying to use the BeaconLBS system and abide by the rules that UnitedHealthcare established.

"That's why we lost business. Our clients got tired of having us contact them regarding the BeaconLBS system," Raiano recounted. "I would say we lost about 20% of our business as a result of the BeaconLBS system. It was a huge number.

"Since then, we've been working to get a lot of business back," he added. "It's just that Florida is saturated with independent labs. It's almost like running a pizzeria in New York City: You know there's always another one down the street.

"Plus, we constantly compete with LabCorp and **Quest Diagnostics**. They dominate the market because they have most of the insurance contracts," stated Raiano. "That level of dominance is bad because a lot of providers don't want to use the big lab companies. They'd rather use small, independent labs where they get better quality and faster service.

"I've talked to some practitioners who have stopped taking UnitedHealthcare patients altogether," Raiano explained. "Recently, one group practice I know said that they were no longer accepting patients with UHC health plans.

"But it's hard to blame the physicians because we were saying they had to use this lab test ordering system while other labs were saying, 'Don't bother with BeaconLBS. We'll handle it for you.' Why would clinicians use the Beacon system then?" he asked. "These physicians want to make their office staff happy and they don't get penalized by UHC or BeaconLBS if they don't use it. So, in reality, they couldn't care less about using the Beacon system.

"From our perspective, BeaconLBS is kind of a broken system because in their own marketing literature they say biopsies should be taken for certain patients," noted Raiano. "But if that's the case, then why is the clinician not penalized if that physician does not use this system that they claim is so terrific?

"If this program is supposed to benefit the patient and help United monitor overutilization, then the clinician should get penalized and not the laboratory," he reasoned. "It makes no sense to penalize the laboratory when we have no control over what the physician does when ordering lab tests for UHC patients.

Is This a Conflict of Interest?

"To me, the BeaconLBS system is a compliance issue because an independent laboratory company owns BeaconLBS and the whole point of the software is to dictate when and where a biopsy should be sent once it's collected," declared Raiano.

"In addition to the burden that doctors face when using the BeaconLBS lab ordering system, the pathologists in my group have questions about possible legal and ethical aspects of this arrangement," he continued. "Essentially, LabCorp, the owner of BeaconLBS, benefits when any of its lab businesses receive a biopsy from a referring physician. So how is this national lab company able to create a business that manages the lab test

Why Did BeaconLBS Design Its Web Ordering Portal In Ways that Make It Difficult for Physicians to Use?

DEVELOPERS OF ANY SOFTWARE OR WEBSITE, always emphasize the need for ease of use. Therefore, when a program or website is difficult to use, it leads to questions about why.

Joseph Raiano, the Director of Operations for Reliance Pathology Partners in Tampa, found the BeaconLBS site particularly difficult to use, especially for any client physician who wanted to order lab tests from Reliance, he said.

"When you look at the software on their web portal, it's very difficult for clinicians to use," stated Raiano. "For instance, when entering the BeaconLBS site, there are two areas: one for preferred lab providers and the other for participating lab providers who are not preferred.

"The preferred providers get listed on this nice long list of laboratories, most of which are LabCorp locations," he noted. "Further, for preferred lab providers, BeaconLBS pays a reimbursement rate that is not the same as the UnitedHealthcare fee schedule," he said.

Knowing Where to Look

"If you are a participating lab provider—but not a preferred provider [a lab of choice]—you are in some back-end area of the BeaconLBS website that is difficult for the client to find," continued Raiano, "Actually, the physician must know where to look in order to find this list of labs, then he or she must click through a number of different links to get to the list of participating lab providers, where our lab is listed.

"When we saw that, we went to our clients to explain how to find our lab on the BeaconLBS site," he added. "We told them we were not on the first page. Otherwise they would never find us on the correct list and wouldn't know we are a participating provider.

"Plus, we couldn't send them a link because, for each type of lab test, BeaconLBS shows the physician a different list of labs at the time he/she orders that test," stated Raiano. "That's why we went out to our physician clients to show them how it works and how to find our lab on the list.

"Another problem for some of our client physicians was the difficulty in implementing the BeaconLBS system into their workflow," stated Raiano. "Some practices had to answer only one or two questions to order certain tests. For others it would take many questions and a long time. Each practice had to find its own method of implementing the BeaconLBS ordering processes into their workflow.

"What's strange is that, if the goal is to reduce costs, this BeaconLBS system is not helping to do that—at least for some physician practices," Raiano explained. "It actually increases the cost because some practices had to hire additional staff just to use the BeaconLBS system to order lab tests.

"We talked about this issue with representatives from BeaconLBS," he said. "They told us that physicians are required to justify the need for labs to get paid for each test. But we said that, in pathology the justification for getting paid is based on our report. If our pathologists document everything they do and explain why it was done and include the clinical history of the patient, there should be no ambiguity over why everything was done.

"To me, it seems UHC is trying to save as much as possible because if a client physician doesn't submit the claim for our test within 10 days, we don't get paid," he concluded. "Even if the physician submits that information on day 11, our lab still cannot get paid. Moreover, our lab has no recourse because, if the physician submits it late, it is rejected and we can't resubmit the claim or appeal."

Tampa Path Lab, when Listed as Preferred Provider, Finds BeaconLBS Payment Rates to Be Quite Low

FOR RELIANCE PATHOLOGY PARTNERS in Tampa, becoming a preferred laboratory provider [a laboratory of choice] in the UnitedHealthcare laboratory benefit management program was unattractive, in part because of its low payment per specimen, said Joseph Raiano, Reliance's Director of Operations.

"The terms they offered to become a preferred provider would have forced us to take a huge hit on what our pathology lab would be paid per specimen compared to our normal charges for UnitedHealthcare patients," explained Raiano.

"If your lab wants to become a preferred provider and get onto the list of what BeaconLBS calls Laboratories of Choice, you must agree to take a lower percentage of what UnitedHealthcare would normally pay," he continued. "The statement BeaconLBS made to us was that our lab would be paid 'a little bit less but you would be on the preferred provider list!' But compared to what our pathology lab is paid under our current UHC contract, the BeaconLBS payment range was substantially lower than what we would normally get under our current UnitedHealthcare contract.

"It's almost like they've put a gun to your head if you want to get your lab onto the laboratory of choice provider list and potentially not lose any business," Raiano commented.

"To be a preferred lab provider, you'd get the BeaconLBS rate that was a significant reduction off the prevailing UHC rate and your lab wouldn't send claims to UnitedHealthcare anymore," he said. "Instead, your lab would send claims to BeaconLBS. Given that disparity in payment rates, it would be easy for a lab to decide it would be better off financially by being out of network rather than being a preferred provider on the BeaconLBS lab panel.

"The only advantage to being a preferred provider is your lab would be listed on that main list on the first ordering page and then you could hope that clinicians don't pass you by during the ordering process," added Raiano. "This is why we are simply a participating provider because it was beneficial for us not to take that financial hit in terms of payment. This decision also required us to do a work-around by educating our clients about how to find our lab in their system when they were obtaining pre-notification or pre-authorization for a laboratory test."

ordering process for a health insurer—in this case, UnitedHealthcare—that includes a system that determines which lab is to get the specimen that the ordering physician wants to be tested? Wouldn't an arrangement like this border on inducement?

"When it comes to inducements and kickbacks, Florida is a strict state with a lot of laboratory guidelines they use to enforce laws governing kickbacks, inducements, and similar schemes," noted Raiano. "Well, then, how can this system for determining which lab will get the specimen referral be legal under Florida law when other areas of lab rules are not? I have no idea.

"Isn't it true that it's illegal for a pathologist to have a vested interest in a medical practice? So how is it not illegal for a laboratory—via a third-party company it owns—to dictate to a clinician about the specific laboratory where that clinician should send a specimen?" asked Raiano.

In preparing this story, THE DARK REPORT asked UnitedHealthcare for comment on the question of whether it's legal for a laboratory company to establish a business subsidiary that has a benefit management system that requires clinicians—when ordering lab tests—to send specimens to laboratories that the lab company owns. To date, UnitedHealthcare has not responded. TDR

—Joseph Burns

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Direct Payment Update

California Lab Company Offers Genetic Tests with Low Prices

ONE BY ONE, A HANDFUL OF PROGRESSIVE LAB COMPANIES is finding financial success with a strategy of pricing genetic tests at levels that are affordable and attractive to the general public. These labs report an added benefit: they find it easier to get health insurers to pay their genetic test claims.

This reflects one new reality in healthcare. Under the old model of care delivery, a clinical lab could set a high price on its assays. It would then negotiate managed care contracts, knowing that insurers would pay only a percentage of the lab's bills. Under the new model, high-deductible health plans (HDHPs) make that process obsolete and financially unsustainable for clinical labs.

Patient-Friendly Test Prices

In the new healthcare model, clinical labs focus on meeting each patient's needs while setting test prices at consumer-friendly levels. Keeping prices high no longer works, for two reasons. First, payers are rebelling against the high prices many genetic testing labs charge. Second, tens of millions of patients must now meet high deductibles and they become angry or frustrated or both at having to pay what they consider to be exorbitant prices for genetic tests and other healthcare services.

Another common patient complaint related to these points is the lack of transparency around pricing. It is difficult for a patient to get the simple answer to this question: "How much will this test cost?"

Recognizing these new dynamics, one lab company has adopted a consumer-centric approach to meet and exceed patient's expectations. It is **Color Genomics**, a startup lab in Milbrae, Calif.

The company was founded last year by tech entrepreneurs Elad Gil, PhD, and Othman Laraki, along with Taylor Sittler, MD, and Nish Bhat. The initial goal was to offer affordable genetic breast and ovarian cancer screening to women.

Previously, Gil and Laraki built some of the top products at **Google**. They next created and sold a company called **Mixer Labs** to **Twitter**, then worked at Twitter as the social media company grew rapidly. Their work in consumer products and social media is visible in Color's approach to consumer-friendly payment.

The privately-held, venture-capital-backed genetic test company has not sought reimbursement from health insurance companies, though it may in the future.

Last year, Color Genomics launched a physician-ordered breast and ovarian cancer risk test analyzing 19-genes, including BRCA1 and BRCA2, for $249. In April, Color Genomics expanded the number of genes it analyzed by offering a 30-gene panel for testing men and women for risk of developing eight of the most common hereditary cancers and kept the price at $249.

"From day one, we have adopted a simple, direct-pay model," Laraki said in an interview with THE DARK REPORT. "We did not put a lot of effort into pursuing insurance payment because our focus has always been on improving patient access to these genetic tests.

"For consumers, the $249 price is dramatically lower than the $1,000 to $4,000 that many labs ask for similar tests," noted Laraki. "This comparison is somewhat

unfair, of course, because those labs priced tests at thousands of dollars with the idea that only a subset of patients qualify for an insurer to pay that amount.

"We don't have any aversion to insurance," Laraki conceded. "From the start, we thought the most direct route to make our genetic test accessible to patients through their physicians was to offer it at a low price. We thought that was a better business decision rather than attempting to get insurance coverage and then going back into direct pay if insurance payment failed.

"It is also why our strategy was to design our genetic tests to be a high-quality and physician-ordered product that is offered a price point that is not a barrier for people," he explained. "That's how we started. We intend to continue striving for simplicity and transparency in pricing."

So far, Color's methods have been successful. "Much of the attention we get is organic, in part because of the many challenges involving access to genetic testing," Laraki explained. "Physicians and their patients have been interested in getting these tests for a long time. And since we launched, we've had continuing strong interest from patients and their doctors.

Payer Guidelines Are Barrier

"Not only was the cost of genetic testing an issue, but the payer guidelines around who could get reimbursed for a test created a barrier as well," he said. "Patients were required to demonstrate an extensive personal or family history of cancer. This is despite the fact that a number of published papers have found that about 50% of carriers of BRCA1 and BRCA2 don't have enough evidence in their family history that would enable them to get tested.

"And those papers make sense from this perspective," noted Laraki. "For example, half of women with mutations in BRCA1 or BRCA2 inherit the mutation from their fathers. For that reason, that part of the family history doesn't jump out as starkly as it does when it comes down the female line."

Physicians interested in ordering the test from Color can do so online and track their orders through its online provider platform. Consumers can also purchase a test online and indicate a physician's name who would place the order and review the results. The test analyzes genes for the most common hereditary cancers, including breast, ovarian, colon, and pancreatic cancer. The $249 cost includes genetic counseling to help consumers understand their results and next steps.

CLIA-Certified Lab

Once Color receives payment, it sends a kit to collect a spit sample. The patient follows the directions and returns the specimen to Color's CLIA-certified, CAP-accredited automated lab in Burlingame. There, Color uses next-generation sequencing (NGS) systems, including the **Agilent** SureSelect method and **Illumina**'s NextSeq 500.

"Even though Color Genomics works with consumers in addition to physicians, it does not consider itself a direct-to-consumer company," said Laraki. "We are more of a traditional clinical lab, the difference being that we use direct pay and include genetic counseling as part of the test.

"Using the direct pay model has saved us the substantial cost and effort that would normally go into billing payers," he continued. "Instead, we have a simple payment funnel that allowed us to launch and be financially sustainable.

"As the business grows, we would consider working with insurance companies," noted Laraki. "But in our start-up mode, we found that beginning with direct pay made our lives and the lives of our patients much easier. It's a straightforward and simple payment model." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

More developments have happened at **Theranos, Inc.**, the beleaguered clinical lab company based in Palo Alto, California. On June 24, Brook Buchanan, Vice President of Communications at Theranos, resigned, giving personal reasons for the decision. Buchanan was hired in November 2015, just seven months earlier. Meanwhile, the press conference that was scheduled for Elizabeth Holmes following her scientific presentation at the **American Association of Clinical Chemistry** meeting in Philadelphia on August 1 has been cancelled. Press reports state that Holmes was advised that it would not be in her best interests to field questions from journalists at a time when the company is under a criminal investigation by the **Department of Justice**, along with a probe by the **Securities and Exchange Commission**.

MORE ON: *Theranos*

After **Walgreens** terminated its agreement with Theranos on June 12, the lab company announced that it would be opening its own patient service centers in order to continue its lab testing activities in Phoenix. Theranos says it currently operates six PSCs.

DOC GUILTY IN BIO-DIAGNOSTIC LAB FRAUD CASE

One more physician has pled guilty in the Medicare fraud case involving **Bio-Diagnostic Laboratory Services** of Parsippany, New Jersey. Last Thursday, Juan Espindola, MD, a pulmonologist in Clifton, pled guilty to bribery charges. He becomes the 27th doctor convicted of accepting inducements from BDLS in violation of federal anti-kickback laws. Espindola received about $1,500 per month in "consulting fee" payments from BDLS, totaling about $15,000 in 2011 and 2012. In exchange, he referred $65,000 in blood tests to BDLS, according to U.S. Attorney Paul J. Fishman.

TRANSITIONS

• **RainDance Technologies** has appointed Kathy Ordoñez as CEO. Previously, she held executive positions at **Quest Diagnostics Incorporated**, **Celera**, and **Hoffman-La-Roche**, including **Roche Molecular Systems**.

• Mario Morken is the new Director of Business Development at **Exsome Diagnostics.** Formerly, he worked at **Bio-Rad Laboratories**, **ThermoFisher Scientific**, and **National Institutes of Health**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 25, 2016.

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