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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

In Medicare Bull's Eye: Lab Test Reimbursement

YOU CAN CONSIDER THIS ISSUE OF **THE DARK REPORT** TO BE an early warning of the escalating effort by public and private payers to rein in the "soaring cost" of clinical laboratory testing and anatomic pathology services.

The intelligence briefings you will read on the following pages address important topics, specifically: 1) a new Medicare policy on how prostate biopsies will be reimbursed; 2) the lab industry's first coverage of a Medicare study that looks at the feasibility of national competitive bidding for Part B clinical laboratory tests; and, 3) the interest of the Senate Finance Committee in having providers share stories of times when RAC (recovery audit contractor) audits went badly, due to auditor overreach, improperly-trained auditors, and similar reasons.

I put the "soaring cost" of laboratory testing in quotes for a reason. Both private and government payers complain about the year-over-year increase in the cost of clinical laboratory testing. They are quick to attribute it to how laboratories may be encouraging inappropriate utilization by physicians. But they are equally slow to acknowledge that expanded use of evidence-based medicine (EBM) guidelines by physicians is a major reason why there are regular increases in the number of lab tests (and associated costs) ordered each year.

As you read the intelligence briefings in this issue of THE DARK REPORT, I recommend that you consider how each story is interrelated. Medicare officials are clamping down on what we can assume they deem to be excessive utilization of prostate biopsies—in particular, those prostate biopsies that generate 12 tissue cores for analysis. National competitive bidding for Medicare Part B has similar elements, in that lower reimbursement per test would be a disincentive for laboratory providers to encourage physicians to order more lab tests if those tests come with a fee-for-service reimbursement that is less than a lab's fully-loaded cost to perform those tests.

As to RAC audits, in many ways, the design and implementation of this program is odious to honest providers. Among other things, it creates economic incentives for private contractors—armed with the power of federal law—to gin up findings that would result in revenue to their pockets, even if the auditors themselves knew their audit findings were based on a faulty reading of Medicare policies. Simply said, these three distinct efforts to control laboratory testing costs point to a tougher financial environment for clinical labs and pathology groups. TDR

Labs Have Questions about Prostate Biopsy Policy

Policies issued by NCCI and Palmetto GBA will reduce some prostate biopsy payments

CEO SUMMARY: How will pathology laboratories respond to the publication of revised policies in how laboratories should file Medicare Part B claims for prostate biopsies? Not only will there be a sharp drop in the reimbursement paid for a 12-core prostate biopsy, but labs may be at increased risk of a RAC audit, along with other potential compliance violations. Experts in pathology coding, billing, and law are advising their client pathologists to review their compliance with the new policies.

THERE IS PLENTY OF CONFUSION surrounding a new Medicare policy that appears to reduce reimbursement for a 12-core prostate biopsy by almost 50%. Along with less reimbursement, experts say that labs should be on the alert for RAC audits and compliance issues associated with this new policy.

The policy change was posted by **Palmetto GBA** on August 7, 2012, for Medicare Regions J1 and J11. Palmetto is the carrier for those areas. For Part B prostate biopsy claims, the new policy directs providers to follow the guidelines issued by the National Correct Coding Initiative (NCCI) that became effective on January 1, 2012.

As detailed by THE DARK REPORT in our August 27 issue, the new policy restricts claims for prostate biopsies. Palmetto wrote that: "Effective January 1, 2012, Medicare has limited the number of prostate biopsies that may be reported for CPT code 88305 to four (4) services. To report five or more prostate biopsies, providers must use G0416 with 1 unit of service."

The revenue impact of this policy will be to cap reimbursement for a 12-core prostate biopsy at about 47% of its former level. This will significantly reduce revenue at those pathology labs handling large volumes of prostate biopsies. This will be particularly true for the in-house pathology labs of urology groups.

An equally important issue associated with this new policy is that pathologists are asking how they can comply with the Palmetto directive and the NCCI manual. As of this date, neither Palmetto nor the **Centers for Medicare & Medicaid**

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

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Services (CMS) has issued further guidance to pathologists.

As you will read in this issue of THE DARK REPORT, a compliance officer with a national pathology billing company and an attorney with extensive experience in compliance issues for a number of the nation's largest laboratories explain that in the absence of such guidance, anatomic pathologists may want to review how they bill for prostate biopsies.

At this moment—and in the absence of further guidance from CMS, Palmetto, and other Medicare carriers—anatomic pathologists submitting claims for prostate biopsies should be aware of two consequences associated with the new policies published in the NCCI manual on January 1, 2012, and the Palmetto directive of August 7, 2012.

First, pathologists may be exposed to a higher risk of a RAC audit. Second, some experts believe that, if policymakers prevail in their assertion that the NCCI policy was in effect as of January 1, labs in the Medicare jurisdictions J1 and J11 may be required to repay the difference for any prostate biopsy claims submitted after that date.

Professional organizations representing laboratories have questioned whether Palmetto and the NCCI followed proper procedures in implementing the changes. There was no prior announcement about the changes and the public was given no opportunity to comment on the changes.

Medicare Regions J1 And J11

Palmetto's new policy affects anatomic pathologists running tests for prostate specimens in Medicare jurisdictions J1 (California, Hawaii, and Nevada) and in J11 (which includes North Carolina, South Carolina, Virginia, and West Virginia). The net effect of this change in policy is estimated to be a decline in revenue of as much as 50% for a 12-core prostate biopsy.

National pathology labs that serve the urology profession will be particularly hard hit by this new policy change. Among the most prominent in this market space are such laboratory companies as **Bostwick Laboratories, Inc.**, in Glen Allen, Virginia, and **Oppenheimer Urologic Reference Laboratory** (OURLab) in Nashville, Tennessee. TDR

—Joseph Burns

Deciphering NCCI, Palmetto Polices on Prostate Biopsies

ON JANUARY 1, 2012, the National Correct Coding Initiative (NCCI) manual became effective. Few pathologists noticed that the manual changed how labs should be reimbursed for prostate biopsies.

The wording in the manual regarding prostate biopsies was unclear, according to **PSA, LLC**, a lab billing company in Florence, South Carolina. PSA, in an announcement to its client labs last month, stated that it believed NCCI was attempting to distinguish between the appropriate use of certain HCPCS codes G0416 through G0419 (called G codes). PSA wrote:

The NCCI manual included ambiguous language which many understood to be another attempt by Medicare to distinguish between the appropriate use of the HCPCS G0416-G0419 codes introduced in 2009 for prostate biopsy specimens collected via the transperineal or 'saturation' biopsy technique (PSB) and the use of CPT 88305 for reporting prostate needle biopsies collected via the traditional transrectal ultrasound (TRUS) technique.

However, a policy update published by Palmetto GBA [on August 7] has shed new light on the curious NCCI language, making it clear that it is Medicare's intent to require the use of these new G-codes for all prostate procedures anytime five or more separate specimens are billed. This new policy effectively caps reimbursement for all prostate biopsy specimens, irrespective of the manner in which they were collected.

Changed Medicare Policy Adds to Regulatory Risk

At the moment, uncertainty reigns in how pathology labs should bill for prostate biopsies

CEO SUMMARY: When Medicare's National Correct Coding Initiative (NCCI) manual took effect on January 1, 2012, it contained a significant change in how prostate biopsy claims are to be coded. This change was widely overlooked by the pathology profession and even dismissed entirely for its ambiguity and inconsistency with previously published guidance on the subject. Now this issue is front and center. Labs are asking for clear guidance on how they should comply when submitting claims for prostate biopsies.

Following the August 7, 2012, issuance of a new policy on prostate biopsy claims by one Medicare carrier, lab directors and anatomic pathologists are looking for detailed guidance in how their labs should comply with the National Correct Coding Initiative (NCCI) manual.

Published on December 1, 2011, and effective on January 1, 2012, the NCCI manual included a little-noticed change in how labs and anatomic pathologists should bill for prostate biopsies. This change cuts in half what labs are reimbursed for a prostate biopsy case with 12 tissue cores. *(See TDR, August 27, 2012.)*

"Back in January, few labs noticed the change in the NCCI manual," stated John R. Outlaw, CHC, Vice President for Regulatory Affairs and Compliance for **PSA, LLC**, a pathology billing company with headquarters in Florence, South Carolina. "Even now, there is uncertainty in how labs need to comply with the manual—in part because there has never been any formal communication of the change by Medicare (outside of the NCCI manual itself), and because the change directly conflicts with previously published guidance from Medicare in the form of the Final Rule implementing the new G-codes in 2009."

On August 7, **Palmetto GBA** issued guidelines for laboratories running prostate biopsy tests. These guidelines were designed to comply with edits in the NCCI manual.

The new guidelines affect claims for Medicare Part B prostate biopsies originating in the Medicare jurisdictions of J1 and J11. The Palmetto guidelines brought attention to the NCCI manual change and raised questions about whether labs in other Medicare jurisdictions may also need to comply, and if so, how they should comply.

Pathologists And Coding

"We dedicate considerable resources to educating our clients on regulatory compliance issues—including correct coding—in order to minimize their risk," stated Outlaw. "Unfortunately, the **Centers for Medicare & Medicaid Services** (CMS) has yet to issue any formal guidance to educate pathologists on the NCCI manual change and how to apply it in light of CMS' previous instructions regarding the use of the G-codes.

"Until it does, pathologists submitting claims for Medicare Part B prostate biopsy claims should understand the risks—of which a RAC audit is just one—were they not to follow the NCCI guidelines of January 1, 2012," advised Outlaw.

"We think there is no choice for pathologists handling cases in the Medicare jurisdictions 1 and 11 adminisitered by Palmetto," he said. "In those seven states—California, Hawaii, Nevada, North Carolina, South Carolina, Virginia, and West Virginia—all labs should follow Palmetto's guidance.

"To this point, Medicare Administrative Contractors (MACs) for other jurisdictions have not published their own policies on the subject," continued Outlaw. "But that does not mean they are not applying the policy as it was originally published in the NCCI manual.

Assessing Potential Risks

"We understand why some pathologists may choose not to apply the Palmetto policy outside of Palmetto's jurisdiction," noted Outlaw. "However, we believe that they must understand that there is some risk in that position, since the NCCI manual represents CMS correct coding policy nationwide.

"We all expect that there will be further guidance from CMS and Palmetto on this issue," he added. "It is likely that there will be challenges by some in the lab industry who believe that various rule-making requirements were not followed properly in this matter. However, that does not reduce compliance risks at this time, given the policy changes enacted by NCCI and Palmetto since early this year."

As this issue of THE DARK REPORT went to press, no statements or additional guidance on this prostate biopsy policy had been provided by CMS or any Medicare carriers. Such guidance is expected and come come at any time. TDR

—By Joseph Burns

Contact Leigh Polk at PSA at 843-629-2941 or psa@psapath.com.

Questions Raised about NCCI's Policy Changes

IN 2009, CMS ISSUED A FINAL RULE on the use of the HCPCs codes for saturation biopsies for prostate specimens. The HCPCs codes are sometimes referred to as G codes.

"The final rule on G codes for saturation biopsies was later published in the National Correct Coding Initiative (NCCI) manual, " explained John R. Outlaw, CHC, VP for Regulatory Affairs and Compliance for PSA, LLC. "Given this background, it is curious that NCCI published guidance in December 2011 that changed the way labs should use G codes for prostate biopsies.

"This latest revision to the NCCI manual on G codes for prostate biopsies contradicts the earlier NCCI rule on G codes," continued Outlaw. "This has led to much confusion among pathologists and their coding and billing experts.

"When NCCI's new guidance became effective on January 1, few pathologists knew about those specific changes in the NCCI manual—and those who did know didn't question the apparent contradiction," he explained.

"Importantly, there was no announcement from CMS about this important change regarding prostate biopsies," said Outlaw. "Usually when CMS makes a change like this, it does so in the physician fee schedule. But there was no transmittal to the carriers announcing this change in policy. The fact that there was no announcement meant that it went almost unnoticed.

"This whole process raises procedural questions because some pathologists have argued that no policy published by CMS can supersede a regulation that has been passed by the rule-making process," concluded Outlaw. "If a policy contradicts what's in the regulation, the regulation has to supersede the policy."

Lawyer Advises on Risk Of Prostate Biopsy Audits

All labs could face federal audits for failing to comply with new rules on prostate biopsies

CEO SUMMARY: For labs currently processing prostate biopsy cases with five or more cores and for those pathologists interpreting those cases, there is a lack of clarity about new Medicare policies. As one example, risk of an audit is significant because of recent guidance issued by one Medicare contractor. Another source of risk for labs and physicians is the new policy for prostate biopsy claims in the National Correct Coding Initiative (NCCI) manual that became effective on January 1, 2012.

LABORATORIES AND PHYSICIAN PRACTICES billing Medicare Part B for prostate biopsy cases that have more than five cores face a new level of audit exposure, according to an attorney for a national law firm.

Any lab in Medicare jurisdictions J1 (California, Hawaii, and Nevada) or J11 (North Carolina, South Carolina, Virginia, and West Virginia) could be subject to audits and recoupment, including a RAC audit, if they have not changed their billing procedures since August 7. "That's the date the Medicare contractor for these two jurisdictions issued new guidelines on billing for prostate biopsies, although it is important to note that the Palmetto GBA notice recites an effective date of January 2012," said Jane Pine Wood, an attorney with the national law firm **McDonald Hopkins**.

Palmetto GBA is the Medicare contractor for labs in J1 and J11. "These new guidelines represent a major change," stated Wood, who warned that "the new guidelines raise a number of serious questions, in addition to audit risk.

"In particular, labs and physician practices in the seven states of Medicare regions J1 and J11 also may be at risk for filing false claims under the federal False Claims Act," added Wood. "There are substantial civil penalties for any provider found guilty of violating the False Claims Act."

But what may be a surprise is Wood's concern that every lab and physician practice that bills Medicare Part B for prostate biopsies—regardless of location—could be at risk. "That's because the Palmetto ruling follows edits made to the CMS National Correct Coding Initiative (NCCI) manual that were effective on January 1, 2012," she explained. "These edits set out new requirements for how providers should bill the Medicare Part B program for prostate biopsies. Palmetto's August 7 policy change was based on those guidelines."

New Prostate Biopsy Policy

When it issued its guidelines on August 7, Palmetto wrote that the reference for its new policy was "NCCI Policy Manual for Medicare Services, effective January 1, 2012, Chapter 10-CPT codes 80000-89999, I. Anatomic Pathology (Cytopathology and Surgical Pathology), 10-HCPCS codes G0416-G0419."

At that time, Palmetto also stated, "Providers who have submitted more than four CPT codes 88305 services for prostate biopsies for dates of service on and after January 1, 2012, may be at risk for overpayment collection."

"The question every provider now asks—regardless of jurisdiction—is whether the NCCI manual is binding," noted Wood said. "As lawyers who advise clients on this issue, we believe it is potentially binding, although in this case, there are some concerns about whether the edits were properly issued, as there was no formal rulemaking involved.

NCCI Policy Questions

"In fact, we have heard that NCCI was asked if its new edit is binding or do the individual Medicare contractors have the discretion to adopt or not adopt the guidelines, as Palmetto did on August 7," she continued. "We understand that the answer from NCCI—which has not been confirmed—was that all providers and Medicare contractors are bound by the NCCI manual. Further, any failure to comply could be addressed in a post-payment audit. In other words, providers who do not comply could be subject to a federal audit.

"We are telling clients in the Palmetto jurisdictions that the Medicare position is clear with the published Palmetto guidance," emphasized Wood. "In J1 and J11, providers must bill according to the guidelines that Palmetto published on August 7." *(Policy at http://tinyurl.com/ck8mwk7.)*

Another issue is how the Medicare program will handle prostate biopsy claims that providers submitted after the January 1, 2102, date when the NCCI manual became effective. "There is uncertainty about what providers should do for claims filed between January 1 and August 7," she added.

"On the one hand, we don't want to tell clients to stop billing the usual CPT codes because there continues to be lobbying and uncertainty about whether CMS may reverse the NCCI edits," she noted. "On the other hand, if providers continue to bill the way they have been, then they have a potential exposure. They should be fully aware of this exposure.

"We are in uncertain territory—particularly about how providers should bill for prostate biopsies since January 1," added Wood. "For that reason, we do not have blanket advice for clients.

"I can discuss each situation individually if a client calls me," she stated. "However, I can't give a statement that applies to all providers because each provider's situation and risk tolerance is different.

"There is another difficult question to answer," continued Wood. "Given that the NCCI manual applies to every jurisdiction, how should providers in the jurisdictions outside of J1 and J11 bill for a prostate biopsy case that has five or more cores?

"We were recently asked this question by a client that is outside of the Palmetto jurisdictions," she said. "The answer we gave to that provider was that, if it continued to bill this year as it had last year for prostate biopsies, it could be subject to action by a federal Recovery Audit Contractor (RAC) or other federal auditor—although no one is certain whether this risk is significant or not."

Wood commented that it is common for pathology practices and labs to take a conservative approach in their billing for a service when policies are unclear and the primary risk is of an audit, but not exposure to charges of filing false claims. "In circumstances where a lab may believe that it has audit exposure, it may set aside some money in a fund to cover that exposure," she noted.

Setting Funds Aside

"This concern applies to providers within the Palmetto jurisdictions and outside of J1 and J11," Wood added. "Some providers may believe it is prudent to put some funds aside—not because I think Palmetto will audit labs, but because a RAC auditor certainly could do so. Every provider should be aware of the potential of a RAC audit.

Much Uncertainty Exists about New Policies

ONE REASON PROVIDERS ARE UNCERTAIN about how to bill for five or more prostate biopsies is that neither Palmetto GBA nor the Centers for Medicare & Medicaid Services (CMS) have issued more detailed guidance on how to comply with recent policy changes.

Anatomic pathologists and lab managers have a long list of questions. For example, how do they comply with the policy issued on August 7 by Palmetto, but that is retroactive to January 1? Should they refile claims filed since January 1 or hope they don't get audited?

"Multiple organizations have asked for guidance from CMS and from Palmetto," stated Jane Pine Wood of the national law firm McDonald Hopkins. "To my knowledge, no further guidance was received.

"Ongoing discussions about how to answer these questions may be taking place within CMS," she noted. "The only positive we can take from the lack of more public guidance is that it supports the idea that CMS does not have a definitive position on the issue.

"Providers that are outside of Palmetto's jurisdictions J1 and J11 may argue that they can continue to bill for prostate biopsies in the same way as they have in the past because CMS does not have a definitive position, although there are no guarantees that any such argument would prevail in a Medicare challenge," speculated Wood. "In addition, the guidance from NCCI is confusing and was done without following the proper rule-making procedures.

"The trouble with these arguments is that they are not iron-clad," said Wood. "Providers could make these arguments and still be liable for a federal audit and repayment penalties. Providers could also be liable for false claims.

"The important point here is that providers should understand that, if they continue to bill Medicare Part B for prostate biopsies as they have in the past, they may have to repay the money," declared Wood. "At the same time, it is true that—at this moment—there is not clarity in how the new NCCI policy is to be followed, along with how CMS intends to monitor compliance with it."

"In this situation, a RAC auditor could audit how a provider billed for each prostate biopsy that had five or more cores, going back to January 1, 2012. What could be easier?" she asked. "The RAC audit issue is worrisome. Even though the NCCI edit is poorly worded, the NCCI manual outlines how providers should bill. All a RAC auditor would need is the NCCI manual and Medicare data on prostate biopsy claims paid since January 1.

"Were a RAC or other auditor to assess an overpayment, the provider could argue that neither NCCI nor Palmetto went through the appropriate rule-making processes when implementing these changes," Wood advised. "Further, providers could argue that CMS hasn't issued guidance about how to comply with the new rule.

"CMS also faces a related issue," commented Wood. "The NCCI manual tells labs to use the G code when submitting five or more prostate biopsies. But in so doing, NCCI is changing a definition of how the G codes have traditionally been used.

"In the context of prostate biopsy procedures, G codes have been used for saturation biopsies," she observed. "However, now NCCI and Palmetto are saying that G codes should be used for prostate biopsies, regardless of biopsy technique.

"In response to this development, observers point out that such a change should have been done through the rule-making process," said Wood. "That process would give CMS time to publish a proposed rule and allow providers to comment. Then CMS could set a date to issue the rule so that providers could prepare for it." TDR

—By Joseph Burns

Contact Jane Pine Wood at 508-385-5227 or jwood@mcdonaldhopkins.com.

Lab Compliance Update

CLMA Asks Labs for Examples of RAC Auditor Overreach

Senate Finance Committee tasked GAO to study Medicare program's audits of healthcare providers

STORIES ABOUT HOW PRIVATE MEDICARE AUDITORS are overreaching in their zeal to identify fraud have caught the attention of the U.S. Senate Finance Committee. It is asking providers to submit examples of overzealous RAC auditors.

For its part, the **Clinical Laboratory Management Association** (CLMA) is collecting examples of recovery audit contractor (RAC) auditors behaving badly when they audit clinical laboratories. CLMA will send the examples to the Finance Committee, said CLMA President Rodney W. Forsman.

Forsman, who is also Assistant Professor Emeritus of Laboratory Medicine and Pathology in the College of Medicine at the **Mayo Clinic**, explained that CLMA has sent a memo to its members requesting such examples. CLMA will forward them to the U.S. Senate Finance Committee.

Examples of Audit Problems

In this memo to members, CLMA said it is seeking examples of: a) poor or unclear writing; b) requests based on inaccurate information; c) typographical errors; d) burdensome requests for information, such as asking for hundreds of records; e) a lack of coordination by contractors, such as when one auditor asks for the same documentation from various sources within a lab; f) a failure to follow proper procedures or current rules; and, g) other examples labs may wish to report.

"The Senate Finance Committee also asked the Government Accountability Office (GAO) to study the audits being conducted in the Medicare program," he added. "The committee has heard a variety of complaints about auditors who work for one of several Medicare auditing programs. CLMA wants to confirm what is so far only hearsay. Hearing a number of stories second hand is not the same as having the providers involved explain the circumstances in their own words.

Are Auditors Inconsistent?

"We heard, for example, that a RAC auditor may be inconsistent in how it cites different laboratories for a violation," he continued. "In one case, if the auditor finds that payment for a certain type of lab test was denied, it may cite another lab for receiving a payment for that same type of lab test. But how is *receiving* that payment from a Medicare carrier evidence of fraud on the lab's part?

"In this example, if the Medicare carrier has applied the rules inconsistently, then the RAC contractor should address that question to the Medicare carrier and not to the lab itself," noted Forsman. "Labs and other providers are invited to share these types of experiences so the Senate committee has real world examples of audits that were poorly conducted." TDR

—Joseph Burns

Contact Rodney Forsman at forsman.rodney@mayo.edu or 507-254-9895.

Competitive Bidding: Once Again, It's Back!

Medicare publishes new study that resurrects idea and looks at feasibility of national bid project

CEO SUMMARY: For the clinical lab industry, the concept of competitive bidding for Medicare Part B Clinical Lab Testing may be like the movie "Groundhog Day." The hero, Bill Murray, kept reliving the same day over and over. So it seems to be with competitive bidding. In the latest replay, RTI Technologies just published a study that looks at the feasibility of conducting a national competitive bidding program. The authors' conclusions will not be welcome, particularly for the nation's largest lab companies.

AS AN IDEA, competitive bidding for Medicare Part B Clinical Laboratory Testing is back! The evidence is contained in a study recently published in the *Medicare & Medicaid Research Review* (MMRR, 2012: Volume 2, Number 2).

The study is titled "The National Market for Medicare Clinical Laboratory Testing: Implications for Payment Reform." It is posted on the Medicare program's website at *http://tinyurl.com/d88fp7d.*

MMRR is an on-line, peer-reviewed journal published by the Center for Strategic Planning (CSP) at the **Centers for Medicare & Medicaid Services** (CMS). MMRR was recently introduced as a replacement for the *Health Care Financing Review* (HCFR) and it is often used to introduce new ideas.

In the study's introduction, authors of the report described the current Medicare payment policy for clinical laboratory testing as "outdated," because, in part, it was designed in the 1980s. The authors wrote:

> *In this study, we conduct an empirical analysis of the national Medicare Part B FFS [fee for service] clinical laboratory market, which could inform future efforts to implement Medicare clinical laboratory competitive bidding or other payment reforms. (Underline by THE DARK REPORT.)*

Bad News For Lab Industry?

For the entire clinical lab testing industry, there are serious implications to the fact that officials at CMS wanted a fresh study of competitive bidding. After all, this was an idea that was believed to be dead after the events of 2008, among which was passage of a federal law that repealed an earlier Congressional mandate to conduct several regional competitive bidding demonstrations for laboratory testing services.

However, if the idea of competitive bidding for Medicare Part B Clinical Laboratory Testing is troubling for the majority of clinical laboratory organizations in the United States, then this new study will be particularly unwelcome to the two blood brothers.

It is unwelcome for **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** because the

two lab companies are singled out by the study's authors. After an analysis of the market for Medicare laboratory testing, the authors wrote:

Quest and LabCorp each have a significant market share of Medicare laboratory testing, and we have shown that they each serve large numbers of Medicare beneficiaries in all parts of the country. This suggests that CMS could consider holding a bidding competition among Quest, LabCorp, and any other organizations that could qualify as "national laboratories" (specific criteria would have to be developed).

The winner(s) of this bidding competition would be designated as "national Medicare laboratories" that are qualified to provide services nationally. The national Medicare business could be periodically re-competed. The primary advantage of bidding on a national basis is that the national firms would have an incentive to bid aggressively, because their entire national Medicare business would be at stake. Also, a single nationwide competition could achieve substantial economies in the bidding and contracting process.

Study Based on 2006 Data

Essentially, the study's authors suggest that a national competitive bidding program for Medicare Part B Clinical Laboratory Testing Services would be feasible. This conclusion is based on the authors' analysis of a data sample made up of 5% of all Medicare laboratory test claims for the year 2006.

The study was conducted by **RTI International Inc.** (RTI), of Research Triangle Park, North Carolina. RTI is a non-profit organization that provides technical services and research to government agencies and private companies.

It is notable that CMS officials selected RTI International as the subcontractor for this study. During the years 1997 to 2008, RTI worked closely with the Medicare program to develop the parameters, then implement the competitive bidding demonstration program for Medicare Part B Clinical Laboratory Testing. *(See TDR, December 31, 2007.)*

Stopped By Judge's Ruling

It was in early 2008 that a ruling by a U.S. District Court judge stopped the first demonstration project in the San Diego MSA (metropolitan statistical area) from proceeding. Later that year, Congress passed a law that repealed the competitive bidding mandate. *(See TDRs, April 14, 2008 and June 16, 2008.)*

However, the San Diego MSA demonstration project had moved far enough forward in 2008 that CMS had collected bidding documents from a number of laboratory organizations, including LabCorp and Quest Diagnostics. At the time, it was recognized by lab industry consultants that these documents would give CMS and RTI an unprecedented look at the range of discounts that individual laboratory organizations were willing to offer for different types of lab tests.

It could be argued that the information contained in these bidding documents provided the motivation for Medicare officials to keep the idea of competitive bidding alive. Certainly, it is reasonable to read that conclusion into the findings presented in the 21-page study that RTI prepared under contract to the Medicare program.

To arrive at these findings, the study authors took a random sample of 5% of the national Medicare claims and enrollment data for the calendar year 2006. Using the Medicare Denominator files, the study identified four categories of patients: 1) Aged; 2) End Stage Renal Disease (ESRD); 3) Disabled; and, 4) Dual-Eligible (Medicare/Medicaid).

The focus of the RTI analysis is "Aged." These are "beneficiaries who qualify for Medicare due to age and do not meet any of the previous conditions" that define the other three patient categories.

Of Medicare's 32.5 million beneficiaries, "Aged" patients number 21 million, or 64.5% of the total.

Using the 2006 data, the study authors determined that national Medicare Part B payments for Clinical Laboratory Test Codes totaled $6.7 billion that year. Of this total, $2.5 billion, or 38.1%, was paid to "independent laboratories."

In looking at the category defined as the top 10 national independent laboratories, the list was topped by Quest Diagnostics and LabCorp. What may be a surprise is which labs ranked number three and number four on this list.

Top Ten In Medicare Payment

In 2006, RTI noted that Quest Diagnostics received $749 million (or 29.5% of the independent lab sector share) in Medicare payments. LabCorp's total was $479 million (18.8% share). Numbers three and four on the list were **Spectra Laboratories**—$124 million and 4.9% share, and **DaVita Laboratory Services**—$96.5 million and 3.8% share, respectively. Sonic Healthcare was number five on the 2006 independent lab ranking, with payments of $45 million (1.8% share).

Together, Quest Diagnostics and LabCorp received 48.5% of all Medicare Part B Clinical Laboratory Testing payments made to independent lab companies during 2006. "Quest and LabCorp clearly dominate the independent laboratory market, as they are responsible for almost 50% of Medicare payments for laboratory tests performed by independent laboratories, and the next largest independent laboratory receives just 5% of payments," noted the study authors.

Look At Hospital Labs

Hospital non-patient payments only totaled $565 million nationally and hospital outpatient payments were $1.8 billion nationally. Together, these represented 36.5% of total Medicare Part B payments for 2006. But no single hospital entity represented more than

Competitive Bidding an Idea With a Three-Decade History

IT WAS BACK IN THE EARLY **1980s** when the first studies of competitive bidding for Medicare Part B Clinical Laboratory Testing were conducted by Medicare program officials. So this is an idea with deep roots.

However, not until the second half of the 1990s did a sequence of events begin that culminated in 2003 with a legislative mandate that directed the Centers for Medicare & Medicaid Services (CMS) to conduct two competitive bidding demonstration projects for Part B Clinical Laboratory Testing in different regions of the United States.

Following a series of public meetings between 2003 and 2007, CMS and its contractor, RTI International, announced that the first demonstration project would take place in the San Diego MSA (metropolitan statistical area). A bidder's meeting was conducted in San Diego in December 2007.

Bid documents were due in February 2008. Under the CMS timetable, winning labs were to be announced in April and the two-year demonstration project would commence on July 1, 2008.

However, several laboratory organizations in the San Diego MSA sued the Secretary of the Department of Health and Human Services (HHS) in federal district court in that city in January 2008. Just months later, in April, the judge ruled in favor of the plaintiff labs and issued a preliminary injunction that effectively stopped the competitive bidding demonstration project from moving forward.

Congress then took up the matter. In the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), passed in June, 2008, it repealed the legislative mandate that the Medicare program conduct competitive bidding demonstration projects for Medicare Part B Clinical Laboratory Testing. That is where the story ended—until June 2012, when RTI's study of the feasibility of a national competitive bidding program was published in the Medicare journal.

$17 million in payments for the non-patient category during that year.

The study next looked at market share by urban and rural regions. It determined that Quest Diagnostics and LabCorp had some market share in almost every market. Notably, the study determined that, with 3,141 counties in the United States, Quest Diagnostics provided Medicare Part B testing services to patients in 3,114 counties during 2006. LabCorp provided Part B testing services to patients in 3,014 counties.

In their assessment of the types of laboratory tests that were performed, the study authors identified that just 10 HCPCS codes represented 50.8% of the total payments during 2006. Further, the top 100 HCPCS codes represent about 90% of total Medicare Part B lab test expenditures.

Simplify The Bidding Process

This is important because it could simplify a national competitive bidding program. "The concentration of the lab market in a small fraction of the tests on CLFS [clinical lab fee schedule] suggests that it may not be necessary or efficient to include the full set of 1,000 plus laboratory test codes in the test menu for competitive bidding," noted the authors in their study.

In commenting on the "implications of laboratory market structure" as it would affect the design of a national competitive bidding program, the RTI researchers noted that the significant market share of Quest Diagnostics and LabCorp, their capability to serve patients throughout the nation, and the concentration of test volume into a handful of HCPCS codes would make such a program manageable.

"The winner(s) of this bidding competition would be designated as 'national Medicare laboratories' that are qualified to provide services nationally," stated the study researchers. "The national Medicare business could be periodically re-competed.

"The primary advantage of bidding on a national basis is that the national firms would have an incentive to bid aggressively, because their entire national Medicare business would be at stake," added the authors. "Also, a single nationwide competition could achieve substantial economies in the bidding and contracting process."

Prices At Marginal Cost Level

An important issue in the study is the reference to the possibility of seeing bids driven down to the level of a lab's marginal cost to perform the test. "...competitive bidding could reduce prices paid by Medicare for laboratory tests to the marginal costs of large national laboratories that can take advantage of economies of scale and perform some tests at lower costs than smaller establishments," predicted the authors.

What would happen to local laboratories under such a scenario? The answer is blunt. The study researchers assume they would send tests to the least-cost lab provider. "In this case, smaller laboratories such as physician office laboratories may minimize losses by outsourcing their laboratory testing to an independent or hospital laboratory instead of providing those tests themselves."

This information is a first alert to lab executives and pathologists that competitive bidding is once again being explored by Medicare officials. It is a concept that continues to be resurrected. At a minimum, it is a sign that one or more powerful individuals within the Department of Health and Human Services and CMS are determined to see the concept of competitive bidding for laboratory testing become a reality.

Simplify The Bidding Process

Further, the money that was spent to pay RTI International to conduct this study should be seen as strong evidence that the idea of competitive bidding remains both alive and credible within the federal government. It is still to be seen how the lab industry responds to this latest effort to lay groundwork for another effort to implement a competitive bidding project for Medicare Part B Clinical Lab Testing. TDR

Dark Index

Sonic Healthcare, Bio-Reference Report Financial Performance

Sonic's fiscal year ended with 10.5% revenue growth; Bio-Reference Labs posted 16% growth for its Q3FY12

IN RECENT WEEKS, two of the nation's larger public laboratory companies issued their earnings reports. In both cases, revenue growth was strong, a distinct difference from the recent financial performance of their two largest lab publiccompany competitors.

It was on August 21, 2012, when **Sonic Healthcare, Ltd.**, of Sydney, Australia, issued its financial performance for its full fiscal year that ended on June 30, 2012. Days later, on August 30, **Bio-Reference Laboratories, Inc.** (BRLI), of Elmwood Park, New Jersey, reported its earnings for its third quarter ending July 30, 2012.

Because they have different fiscal years, the earnings reports of Sonic Healthcare and Bio-Reference Labs don't match up with the reporting cycle common for most public companies. For that reason, the release of their earnings often is not covered with the same attention given to those lab companies that report during the more traditional quarterly earnings season.

Growth In U.S. Operations

Sonic Healthcare is generally considered to be the third largest public laboratory company serving office-based physicians in the United States. It reported revenue from its U.S. lab operations of A$765 million, or about U.S.$803 million. This was an increase of 10.5%, compared to 2011.

Overall, Sonic's total revenue was A$3.3 billion, or approximately U.S.$3.5 billion. This was also an increase of 10.5% over the prior year.

Revenues from its laboratory operations in the United States are important to Sonic Healthcare, and represent 23% of the company's total revenue. By contrast, Sonic generated revenue of U.S.$1.1 billion from its laboratory operations in Australia and revenue of U.S.$870 million in Europe. These divisions represented 30% and 25%, respectively, of Sonic Healthcare's total revenue for FY2012.

Sonic's Annual Growth Rate

Notably, Sonic's annual rate of revenue growth in the U.S. lab division was higher, at 10.5% than its 8.8% revenue growth in its Australian lab division and the 9.6% revenue growth in its European lab division. By contrast, for 2011, the annual revenue growth at **Quest Diagnostics Incorporated** was 3% and for **Laboratory Corporation of America**, it was 10.5.%. *(See TDR, March 12, 2012.)*

During 2011, Sonic Health did not disclose any lab acquisitions in the United States that it considered material. However, Sonic executives continue to state they are interested in purchasing laboratories in the United States that meet their acquisition criteria.

For its third quarter ending on July 30, 2012, Bio-Reference Laboratories posted revenue of $172.3 million, which was a 16% increase over Q3-11 revenue of $148 million. For the first three quarters of

2012, BRLI increased revenue by 19%, to $485.6 million compared to same period revenue of $407.3 million.

This puts Bio-Reference on pace to hit full-year revenue of about $667 million. That is not far behind the $805 million in full-year revenue from lab operations in the United States that was reported by Sonic Healthcare.

Expanding Market Share

The point here is that both Bio-Reference Labs and Sonic Healthcare are quietly expanding their share of the lab testing market in the United States—and doing it at double-digit rates of growth.

One aspect of Bio-Reference that is frequently overlooked is its use of a unique, two-pronged business strategy. On one level, BRLI is a routine lab competing for the referrals of office-based physicians within the New York City metro and surrounding areas.

At the same time, Bio-Reference Labs regularly develops new lines of specialty and esoteric testing capabilities. It then uses a national sales force to offer these assays throughout the United States.

Emphasis On Esoteric Tests

As a laboratory company that started out offering routine testing to office-based physicians, Bio-Reference may be unique in how it has successfully expanded its presence in the reference and esoteric testing marketplace. The numbers tell that story. For Q3-12, BRLI says that its revenue per patient (per requisition) was $85.65. Moreover, BRLI executives point out that esoteric testing is now 61% of the lab company's overall revenue.

For clinical lab managers and pathologists in local lab organizations, the business strategies and the sustained growth rates of Sonic Healthcare, Bio-Reference Labs, and **Neogenomics, Inc.** *(see sidebar at right)*, provide powerful evidence that selling service and value remains an effective way to build market share.

NeoGenomics Posts Double-Digit Growth

HEADQUARTERED IN FT. MEYERS, FLORIDA, Neogenomics, Inc., might be described as "the little lab that could." In recent years, this national cancer testing lab company has sustained an impressive rate of growth in both specimen volume and total revenue.

In its second quarter earnings report, released on July 19, 2012, Neogenomics said it had increased revenue 49%, to $15.6 million, compared to Q2-11. It also reported a 57% increase in specimen volume for the quarter.

Currently, Neogenomics has grown to an annual revenue run rate of about $60 million. What is noteworthy is that the company has done this through a well-executed sales and marketing program. It has not relied on acquiring other labs for growth, nor has it had infusions of venture capital or private equity money in a number of years.

For these reasons, aspects of its business model and success at sustained growth would be instructive for regional laboratories seeking to build market share.

Among other things, Neogenomics is working to bring proprietary molecular tests to market. "We launched 20 new molecular assays thus far in 2012, and expect to launch another 15-20 assays... by year end," noted Douglas Van Ort, CEO and Chairman of Neogenomics. He was quoted in the company's second quarter earnings press release.

Van Ort also noted that Neogenomics was implementing a new digital pathology system and it is one of the few labs in the nation currently offering 10-color flow cytometry services to its clients.

Each of these three lab firms is finding and exploiting market niches that allow them to distinguish themselves in unique ways. Further, each lab company shows how it is still possible to use a professional sales program to achieve sustained growth. TDR

Lab Specimen Transport Eliminates Need for Ice

Technology solution contributes more consistency when shipping units of blood

CEO SUMMARY: Because of its unique design and reliability, a new product for transporting laboratory specimens and units of blood without the use of ice and dry ice is gaining favor with innovative laboratories across the country. Kaiser Permanente of the Mid-Atlantic States uses this ice-free specimen transport solution to move units of blood from the blood bank out to various sites and says the benefits are more consistency and better quality in the movement of blood units.

THERE'S A NEW TECHNOLOGY gaining favor with innovative laboratories that eliminates the need to use ice or dry ice when packing and shipping clinical lab specimens and units of blood.

One user of this technology is **Kaiser Permanente of the Mid-Atlantic States**, based in Rockville, Maryland. It ships blood in transport containers that do not require ice and have built-in data monitors to verify that the units of blood were maintained at proper temperatures. These transport systems are sold by **Gryphes, Inc.**, of Covington, Georgia; and Gaithersburg, Maryland.

"Transporting blood units in these containers provides us with the ability to protect the integrity of blood products while giving us a consistent way to ship blood that doesn't use ice and has built-in data monitors," commented Brian K. Williamson, CT/MT/SBB (ASCP), Kaiser's Quality Systems and Resource Utilization Manager.

Kaiser Permanente has facilities in Maryland, Virginia, and the District of Columbia. These centers vary from small outpatient and urgent care facilities to clinical decision units.

"We like the consistency that this blood transport system provides us," noted Williamson. "Consistency is important for us because our facilities are spread out and we have many hands touching the blood." Since there is only one way to pack these containers, they provide a standardized way to ship blood.

Used To Ship Blood Units

"We send blood from Kaiser's regional lab in Rockville to our Capitol Hill facility, which is downtown D.C., or we will send blood to our facility in Gaithersburg, which is about 15 miles away," Williamson said. "Sometimes, if a transfusion is canceled, they might need to send the blood back to the Rockville Regional Lab. This shipping container helps to ensure that the integrity of the blood is maintained at all times during transport.

"We also like the fact that we no longer have to use ice because that eliminates the problems that occur when ice is used to keep the units of blood at the

proper temperature for transport," continued Williamson. "When you use ice, you have to use a certain number of pounds of ice, and to pack it in a way so that the ice won't compromise the blood. By eliminating the need to use ice, we've eliminated those associated problems.

"Another benefit is the data monitor, that is in the shipping container," Williamson said. "Now we know the temperature of the blood from the moment it's packed until we get it back to our blood bank here in Rockville."

When unpacking the box, the lab tech can see the current temperature on the data monitor. He or she can also download the shipment's temperature history to a computer.

Reliable Data Monitoring

"I have all the data monitors set to record the temperature every five minutes," noted Williamson. "The data is used to ensure that the blood was maintained at the appropriate temperature during transport and to meet regulations and accreditation standards. For transport, blood must be in a range of 1 to 10 degrees Celsius.

"Transport blood outside of this temperature range and it would be a loss," he added. "You don't want to lose any blood because each unit of blood costs about $300—depending on the type of blood and special requirements the physician requested."

Integrity During Transport

When Kaiser started doing its own blood transfusions in April 2011, it began to use the Gryphes system to transport blood.

"Although I cannot tell you about how much money has been saved, or the specific payback for this transport system, I can say this," observed Williamson. "I do know this transport system has met the requirements we had, which were consistency in handling across all sites, no need to use ice, and continuous data monitoring." TDR

Transport Lab Specimens Without Using Ice, Dry Ice

IT WAS A SURVEY of clinical laboratories and blood banks that launched the founders of Gryphes, Inc., on their search to develop a laboratory specimen transport system.

"The need was greatest in protecting the integrity of blood products during transport," recalled Randal H. Miller, MT(ASCP), Chief Technology Officer at Gryphes. "There were three things that blood bankers told us they wanted. One was consistency in storing and shipping blood. Second was to eliminate the need to use ice and third was continuous temperature monitoring."

Since launching its novel, ice-free system for transporting blood products back in 2005, Gryphes has about 100 blood bank customers nationwide. "Transfusing compromised blood is life-threatening and could cause a serious patient care problem," observed Miller. "There is zero tolerance for problems in the blood bank, which is why a transport system that reliably keeps a unit of blood at the correct temperature and includes a continuous data monitor for documented compliance has won favor among our clients.

"The economics of the blood bank also play a role," he continued. Typically, the blood bank is responsible for about 25% of the total hospital laboratory budget. Some hospitals routinely spend $200,000 to $500,000 per month for purchased blood products.

"Haivng an ice-free, reliable transport system that reduces the loss of blood products while at the same time documenting the integrity of the transported units of blood are reasons why this system is finding favor with labs at some of the nation's best-known hospitals and health systems," concluded Miller.

—By Joseph Burns

Contact Brian Williamson at 301-255-4010 or Brian.K.Williamson@kp.org; Randal Miller at 216-570-6614 or randalhmiller@comcast.net.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Exome sequencing testing for cancer patients is now offered by the Cancer Genetics Laboratory at **Baylor College of Medicine (BCM)** in Houston, Texas. This clinical testing will be performed using next-generation gene sequencing technology. Pathologists at Baylor are among the first in the nation to offer exome-based testing services. "Cancer exome sequencing is poised to change the current paradigm of genetic testing for cancer patients," declared Federico Monzon, M.D., in a BCM press release. Monzon is Director of Molecular Pathology at the Cancer Genetics Laboratory.

MORE ON: *Exome Testing at Baylor*

Clinical testing based on the human exome has great potential to improve the accuracy of diagnosing cancer. The human exome is made up of about 180,000 exons, representing 3% of the genome. Yet, on this 3%, which directs protein synthesis, research indicates that most errors can be found that contribute to altered protein function in tumors. THE DARK REPORT wrote about advances in exome testing in its April 2, 2012, issue.

MORE "TRUE CRIME" IN LAB INDUSTRY

It's 27 months of jail time for Linda M. Dessell, formerly office manager of **Alexandria Pathology Laboratory,** based in Alexandria, Louisiana. Dessell pled guilty to charges that she had embezzled $350,000 from her employer between 2006 and 2010. She wrote fraudulent checks to herself and her personal creditors from the pathology compay's checking account. Dessell was also fined $8,000 and ordered to pay $350,000 in restitution.

TRANSITIONS

- At the age of 80, Eloise Sweet, is retiring from her job as a medical technologist at the laboratory of **St. Charles Hospital** in Bend, Oregon. It completes a 55-year career in the clinical laboratory, with more than 37 years of service at St. Charles Hospital.

- **Cleveland HeartLab**, in Cleveland, Ohio, announced the appointment of Deborah H. Sun, Ph.D., as Vice President of Laboratory Operations. Sun was formerly at **South Bend Medical Foundation**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 8, 2012.