Volume XVIII, Number 11 Monday, August 15, 2011

Specialized Information Publishers Foundation
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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

Consequences of Underfunding Lab Test Services

HOW LONG CAN IT TAKE FOR A HEALTHCARE SYSTEM to underfund clinical lab testing and anatomic pathology services before this ongoing financial erosion becomes visible in the form of systemic quality problems with lab tests?

I believe the United States is now on the path to learning the answer to this question. As you will read on pages 3-5, within the federal government, the Joint Select Committee on Deficit Reduction is mandated to recommend $1.5 trillion in specific cuts. It is known that Medicare Part B lab testing fees are one prime target for major spending cutbacks by this committee. Meanwhile, the normal budget process in the House and Senate has also put laboratory testing in the budget-cutting cross hairs. In both cases, restoration of a patient co-pay or coinsurance for Medicare Part B lab tests is under consideration.

It is a well-established fact that Medicare pays less today for laboratory tests, in inflation-adjusted dollars, than it did in 1984! I don't believe any other medical service has seen a similar sustained erosion in the purchasing power of its Medicare reimbursement over this same period of time.

To this ongoing reduction in reimbursement, one must add the lab test funding cutbacks that were part of the ObamaCare legislation of 2010. The Patient Protection and Affordable Care Act (PPACA) mandates that, for a five-year period beginning in fiscal 2011, there will be a yearly, across-the-board 1.75% fee cut to the Medicare Part B laboratory fee schedule. And don't forget to add the impact of the 2.3% federal tax on medical devices that takes effect on January 1, 2013, and which is expected to cover *in vitro* diagnostic analyzers and laboratory equipment. *(See TDR, March 29, 2010.)*

The point here is that the nation's medical testing laboratories have not seen fees and reimbursement keep pace with inflation over a multi-decade period. Thus, is the time approaching when the most financially-squeezed laboratory organizations will be discovered to have produced inaccurate lab tests for some period of time, causing patients to be misdiagnosed?

This is not an idle question. It is often asked in Canada now. *(See pages 16-18.)* Problems in anatomic pathology testing in several provinces in recent years have put a spotlight on the issue of adequate funding for laboratory tests in those provinces. Given the ongoing erosion in laboratory reimbursement in this country during the past 25 years, will this current round of cost-cutting be what tips the quality scales for lab testing in the United States? TDR

Congress Again Considers Co-Insurance for Lab Tests

Potential Bad News Looms: Congress May Restore Patient Co-Pay for Medicare Part B Laboratory Tests

CEO SUMMARY: Congressional cost-cutters are putting the 20% patient co-pay/coinsurance requirement for lab testing back on the table. The added complication this year is that the new Joint Select Committee on Deficit Reduction is mandated to produce its own list of cuts to the Medicare program. This is in addition to the normal budget cycle that occurs each year in the House and Senate. One estimate is that reinstituting coinsurance for lab tests could produce savings of $8.5 billion to $16 billion over 10 years.

BY NOW, MOST PATHOLOGISTS AND LAB ADMINISTRATORS know about the legislation that raised the federal debt ceiling. But few in the lab industry realize that one component of this new law has the potential to significantly reduce Medicare reimbursement for lab testing services.

That component is the possibility that the 12-member congressional Joint Select Committee on Deficit Reduction could implement cost sharing for laboratory services in Medicare. This cost sharing would probably come in the form of requiring laboratories to collect a 20% patient co-pay or coinsurance for Medicare Part B laboratory tests.

This is major bad news for the laboratory testing industry. Moreover, the possibility of implementing cost sharing for lab services in the Medicare program is actually being discussed in two separate sets of budget negotiation talks.

First is the Joint Select Committee. The Budget Control Act of 2011 mandates that this committee identify $1.5 trillion in spending cuts for the years 2012 through 2021. Second is the normal budget process now unfolding in both houses of Congress.

It is expected that the Joint Select Committee will work from a list of 27 specific sources of spending cuts from the Medicare program that was prepared during negotiations conducted prior to passage of the federal debt ceiling bill. It was back on July 15 when *DarkDaily.com* was the first lab industry news source to publish the contents of these leaked briefing papers.

In these leaked documents, restoration of the Medicare patient co-pay for

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

clinical laboratory tests was identified as generating between $8.5 billion to $16 billion in savings over 10 years.

That put the lab test co-pay as the sixth largest source of cost savings among the 27 specific ideas on the list. Those top six items represented $283 billion in potential savings. By contrast, all 27 items totaled between $334 billion to $353 billion in Medicare savings over 10 years.

Large Spending Cuts Sought

The point here is that, should members of the Joint Select Committee (known as the Super Committee) decide to include substantial cuts to Medicare in whatever final package of budget cuts and new taxes it recommends to Congress, there is a high probability that the 20% patient co-pay or some form of cost sharing will be included. At $8.5 billion to $16 billion, the 20% lab test co-pay represents too much in cost savings for the negotiators to ignore.

The second set of discussions involving the lab test co-pay is taking place within Congress as part of the regular yearly budget process. The **American Clinical Laboratory Association** (ACLA) is concerned about an option raised by the Congressional Budget Office (CBO) and the National Commission on Fiscal Responsibility and Reform to change cost-sharing structures for Medicare beneficiaries. This includes the addition of a new 20% coinsurance requirement for laboratory services.

In response to these legislative proposals, ACLA, the **American Association of Bioanalysts** (AAB), the **National Independent Laboratory Association** (NILA), and members of the Clinical Laboratory Coalition are educating lawmakers about the problems associated with imposing a coinsurance requirement on Medicare Part B laboratory testing services.

Further, it is important for laboratory administrators and pathologists to recognize that this year's budget battles in Congress are extraordinarily different than those of recent years. Currently, the federal government borrows 40¢ of every dollar it spends.

That single fact has energized politics in Washington, DC, this year with an intensity that exceeds even the debate over passage of the Accountable Care Act (ACA) in 2010. It is also a reason why both the Democrats and Republicans may be motivated to have Medicare patients pay some form of coinsurance for laboratory testing and use those cost savings to spend money for other purposes.

"We have been on the Hill and talked with officials at the White House," stated ACLA President Alan Mertz. "In addition to holding dozens of meetings on the Hill with members of Congress, the heads of the lab companies have been meeting members of Congress as well.

"Contact with members of Congress over this issue has been more intense in a short period of time than we have had over any issue in eight years," noted Mertz. "ACLA members have sent more than 10,000 letters to members of Congress about this issue."

In a briefing paper it sent to its members earlier this month, ACLA said that this coinsurance option would cut Medicare reimbursement for clinical laboratory services by 20%. It would also require laboratories to attempt to collect the coinsurance from beneficiaries. ACLA said that, in connection with the debt ceiling extension negotiations, a variation of this option surfaced. This proposal would impose a flat copayment of $1 to $2 per laboratory test.

Considering Coinsurance

"Both of these options would have the same negative consequences for patients and the providers that perform their laboratory testing, and represent a virtually unworkable policy for laboratory services," said ACLA. "Over the past nearly three decades, coinsurance or co-pays on laboratory services have been considered

and rejected numerous times by independent outside organizations, government agencies, and Congress.

The proposals have been rejected for essentially the same reasons each time: laboratories are unique among all providers in several very important respects."

Five Reasons Cited

The ACLA cited five specific reasons that co-pays or coinsurance for Medicare Part B laboratory tests are unworkable, as follows:

- **First,** the amount of the coinsurance or co-pay is so small in comparison to the cost of collection that the average coinsurance billed would be only $6.20, and the average co-pay billed would be $3 to $6, depending on whether negotiators add $1 or $2 co-pay per test. Yet, the collection costs are estimated to be at least $3.50 per bill, and could be higher if repeated collection attempts were needed.
- **Second,** most laboratories do not have face-to-face, personal relationships with beneficiaries, as do all other providers who bill patients. "This lack of a face-to-face relationship or billing relationship will make collection extremely expensive, difficult, and, in many cases, impossible," said ACLA.
- **Third,** many small labs tend to be the sole providers of lab services to Medicare's most vulnerable beneficiaries in nursing homes and other such settings. For these labs, the coinsurance or co-pay proposals could be economically devastating.
- **Fourth,** any cost sharing requirements for laboratory services do not save the healthcare system money because they shift billions in costs from the government to the nation's most vulnerable seniors without affecting utilization. Cost sharing would thus dramatically increase seniors' out-of-pocket healthcare costs and administrative costs for providers. According to the **Institute of Medicine** (IOM), this would hit the sickest and poorest seniors the hardest.
- **Fifth,** and perhaps most important, imposing coinsurance on seniors for laboratory services conflicts with congressional intent to encourage more prevention and early detection of chronic diseases such as diabetes, heart disease, kidney disease, and cancer. Lab tests help physicians detect these conditions early and prescribe preventive care.

THE DARK REPORT observes that the Super Committee must issue its recommendations by November 23. It should be expected that cuts to Medicare providers, including laboratories, will be included in the committee's proposals. TDR

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Budget Cuts Hit Labs Hardest, ACLA Says

IN A BRIEFING PAPER ABOUT PROPOSALS TO REINSTATE COINSURANCE, the American Clinical Laboratory Association (ACLA) pointed out that such a step would financially undermine the ability of many laboratories to continue serving Medicare's vulnerable patients.

Independent clinical laboratories that serve rural communities or nursing homes often have 80% or more of their patients on Medicare. The effective reduction in Medicare reimbursement from reinstating coinsurance would threaten their viability.

Also, over the past 20 years, Medicare payments for clinical laboratory services have been reduced by 40% in real (inflation-adjusted) terms, ACLA said. This financial erosion is compounded by the Affordable Care Act (ACA), which mandated an annual cut of 1.75% to the Medicare Clinical Laboratory Fee Schedule for five years. ACLA noted that this cumulative 9% cut is the largest cut among all Medicare Part B providers.

Another provision of the ACA legislation specifies that clinical laboratories take a permanent cut through the productivity adjustment. For labs, this adjustment took effect this year and will result in an additional 11% cut in Medicare reimbursement over the next 10 years.

Bostwick Laboratories Puts Facilities on Market

➤National anatomic pathology company lists lab facilities in several states for sale or for lease

➤➤CEO SUMMARY: Events are unfolding rapidly at Bostwick Laboratories, Inc., of Glen Allen, Virginia. In recent months, the company has listed its facilities in Arizona, Tennessee, New York, and Virginia for sale or lease. In July, it agreed to pay a civil fine of $129,000 to settle a consent judgement involving hazardous waste violations at its lab in Tempe, Arizona. Also in July, Bostwick Laboratories obtained a new line of credit that totals $43 million.

FROM ITS FOUNDING IN 1999, it was almost a full decade of high-flying growth for **Bostwick Laboratories, Inc.**, based in Glen Allen, Virginia. By the end of 2007, the privately-held pathology lab company reported $102.7 million in annual sales. In early 2008, it filed documents for an initial public offering (IPO).

However, Bostwick Labs has had its share of business woes during the past 30 months. Last month, it was reported that Bostwick Labs paid a $129,000 civil penalty in connection with hazardous waste violations in Arizona.

➤Facilities Put On The Market

The previous month, in June, the *Richmond BizSense*, a newspaper in Richmond, Virginia, reported that the pathology lab company's laboratory facilities in Tempe, Arizona; Uniondale, New York; and Nashville, Tennessee, were all on the market.

The newspaper also reported that Bostwick Laboratories was scheduled to vacate one of its two locations in Richmond in October 2011, and that the company's 65,000 square foot corporate headquarters in Innsbrook, Virginia, was put on the market in June. The lease for this property ends on December 31, 2011.

If the company follows through with the closure of its facilities in Tempe, Uniondale, Nashville, and Richmond, as reported by local newspapers in these cities, then it would be a sign that Bostwick Laboratories is undergoing a significant corporate restructuring.

THE DARK REPORT contacted Bostwick Laboratories' corporate office with requests for an interview. However, as of press time, no official from Bostwick Laboratories had responded.

On the money front, Bostwick Laboratories appears to be equally busy. It recently tapped a source of capital to help it in this next business phase. On July 7, 2011, Bostwick Laboratories issued a press release and disclosed that it had obtained a $43 million commitment from the **Healthcare Finance Group, LLC**, of New York. In the press release, Bostwick labs said these funds would be used to refinance existing capital, for term loans, and to fund an interest rate swap.

Of the total, Healthcare Finance Group (HFG) will make $20 million available in a revolving line of credit. Bostwick Laboratories will take the remaining $23 million in the form of senior secured term loans.

Putting Credit Line To Work

Gregory Geisz, Bostwick's Vice President of Finance, said, "The continued growth of our company requires a lender that understands our current and future needs for capital, the healthcare regulatory environment, and the surrounding issues that accompany the growth we expect."

The fact that Bostwick has borrowed this money and not accepted an equity investment could mean that David G. Bostwick, M.D., MBA, the company's Founder and CEO, wants to maintain maximum control over his company.

It was in March, 2008, when Bostwick Laboratories filed the documents necessary to sell its stock to the public. However the company never followed through with its proposed IPO. *(See TDR, March 24, 2008.)*

Another growth strategy was to grab pathologists from the **Armed Forces Institute of Pathology** (AFIP) as this organization was reorganized as mandated by the Base Realignment and Closing Act (BRCA) of 2005. In the fall of 2009, Bostwick Labs hired as many as 25 former pathologists from AFIP and opened a new laboratory facility in Silver Spring, Maryland, and named it **American International Pathology Laboratories** (AIPL). *(See TDR, August 31, 2009.)*

Future Plans For Bostwick

It is unclear how Bostwick Laboratories plans to consolidate its laboratory testing activities, given the news reports that it has listed several facilities for sale or for lease. Armed with a substantial new line of credit, the pathology lab company is positioned to execute any of several different business strategies. TDR

Bostwick Labs Pays Fine in Arizona

AS RESOLUTION TO CERTAIN ISSUES, on July 8, 2011, the **Arizona Department of Environmental Quality** (ADEQ) and Arizona Attorney General Tom Horne announced a settlement with Bostwick Laboratories.

Bostwick Labs agreed to pay a $129,900 civil penalty under a consent judgment for hazardous waste violations. In February 2010, ADEQ's hazardous waste inspectors found a number of violations at the company's lab in Tempe. ADEQ said the pathology lab company:

- Did not put decontamination equipment in one storage area.
- Had not made local police and fire officials and area hospitals familiar with its emergency procedures.
- Had incomplete inspection logs.
- Did not have contingency emergency plans or an emergency coordinator.
- Lacked training records for hazardous waste storage personnel.
- Did not mark "Hazardous Waste" on 5-gallon containers.
- Shipped hazardous waste without obtaining the required identification number from the U.S. Environmental Protection Agency.
- Did not register with ADEQ, pay annual registration or hazardous waste generation fees, or submit annual reports since beginning operations in 2006.

"This lack of management of hazardous waste put employees and the community at risk," stated ADEQ Director Henry Darwin about the case. "Agreeing to pay this sizeable penalty is an acknowledgement of the severity of the situation."

Lab Law Update

Myriad Wins Federal Appeal In Important Gene Patent Suit

Clinical labs and pathology groups that hold licenses from Myriad will continue to pay

IN THE CLOSELY-WATCHED COURT CHALLENGE involving gene patents, **Myriad Genetics, Inc.**, of Salt Lake City, Utah, recently won a favorable decision from the federal appeals court. However, legal experts believe that the plaintiffs are likely to ask the Supreme Court to review the case.

It was July 29 when the United States Court of Appeals, the appellate court which oversees patent issues, released its ruling. The decision is not directly favorable to clinical labs and pathologists.

"Many labs are licensees of patents that Myriad holds and those labs do not benefit from this decision because the patents were found to be valid," explained David B. Cupar, an attorney with **McDonald Hopkins** who is Co-Chair of the firm's patent law practice. "The appeals court decision means that labs must pay the Myriad royalties on those tests."

However, Cupar says that this recent court decision lacks clarity. That's because the three-judge panel split on how to resolve the issues involved in evaluating the patentability of genetic material.

"Given that the federal appeals court judges themselves did not agree to a standard, it means clinical and pathology labs will face the big issue about where to draw the line on what's patentable and what's not," he commented.

"Fundamentally, the issue of patentability of genetic material will be difficult for everyone involved, including pathologists," continued Cupar. "It will be necessary to determine whether they should pay a license on something that is patentable by definition."

The federal circuit court sided with Myriad when the three-judge panel declared that Myriad's "composition of matter" claims covering isolated DNA and cDNA of the BRCA1 and BRCA2 genes are patent-eligible under Section 101 of the United States Patent Act.

Also, the court ruled that five of the company's six method claims in question did not satisfy Section 101. But Myriad has 237 method claims for its BRACAnalysis product that were unaffected by the court's ruling. Therefore, these method claims remain in full force and company officials say this provides Myriad with strong patent protection.

Even the Judges Disagree

This federal appeals court ruling reverses the decision of March 29, 2010, by the United States District Court for the Southern District of New York. In that case, the court ruled that Myriad's patents on the BRCA1 and BRCA2 genes are invalid.

Because the federal appeals court reversed the lower court's ruling, this case, which is known as the *The Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, may eventually end up at the U.S. Supreme Court. But there is uncertainty as to whether the nation's highest court will decide to review this case, noted Cupar.

"What's murky is the standard that should be used to judge the patentability of genetic materials and tests," noted Cupar. "In the decision itself, there is a disagreement among the three appeals court judges about what the standard should be with regard to the patentability of genetic material.

"Specifically, the judges disagreed on where a line should be drawn in terms of what is considered actual manipulation or work on genetic material versus something that occurs naturally," Cupar explained. "If it's naturally occurring, it's not patentable. But if something is done to purify it, for example, or if additional steps are taken to change it in some way, then there tends to be agreement about patentability. But where is that line exactly?

"Myriad argued that it worked on a gene outside the body to develop its BRACAnalysis test," he continued. "Therefore, by purifying the gene, Myriad said it created a diagnostic test out of that purified form of the gene. In a nutshell, that is Myriad's argument."

Myriad's BRACAnalysis product is a molecular diagnostic test that analyzes the BRCA1 and BRCA2 genes to assess a woman's risk for hereditary breast and ovarian cancer. Seeking to invalidate these patents, several plaintiffs filed suit against the U.S. Patent and Trademark Office, Myriad Genetics, and the **University of Utah Research Foundation**, which hold the patents on the genes, BRCA1 and BRCA2.

The plaintiffs claimed that patents on human genes violate the First Amendment and patent law. In their lawsuit, the plaintiffs said that, as "products of nature," genes cannot be patented.

Peter Meldrum, Myriad's President and CEO, told *The Wall Street Journal* that Myriad discovered the genes through research it conducted with the **National Institutes of Health** (NIH) and the **University of Utah**. As the patent holder, the university licensed them to Myriad Genetics, he added.

"For clinical labs and pathologists, the decision of the federal appeals court means each patent will have to be tested based on unclear standards," observed Cupar. "This promises to create ambiguity for both the patent owners and licensees.

"What happens next in this lawsuit is difficult to predict," he added. "There are other cases involving gene patents that could impact this decision, such as the Prometheus case."

It was in June when the U.S. Supreme Court said it would review the case of *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, and consider whether companies should be able to patent medical diagnostic tests. Mayo is challenging two Prometheus patents, saying Prometheus is claiming a monopoly right to observe a natural phenomenon.

Is Supreme Court Next?

As to the Myriad lawsuit, Cupar said it is unclear whether the Supreme Court will choose to hear this case. "The Supreme Court heard a case similar to the Myriad case, but it involved patents in the computer science field and the justices tend not to hear similar cases back-to-back in successive years," Cupar explained. "But if some justices see the issue of patents on human genes as a big enough question, they could take it up in the next session.

"In the meantime, researchers that develop tests which utilize genes that are patented by others may need legal advice before bringing such clinical laboratory tests to market," he said. "Each new genetic test will have to stand on its own."

Swift advances in the use of genetic and molecular technologies are allowing biotech companies and medical laboratories to develop useful new diagnostic tests. As this happens, the need for test developers to obtain a license and pay royalties to use patented genes in these assays is now a growing problem. TDR

Contact David B. Cupar, 216-430-2036 or dcupar@mcdonaldhopkins.com.

CEO SUMMARY: Last summer, InCyte Pathology in Spokane, Washington, found itself facing demand letters from the recovery audit contractor (RAC) responsible for that region. The RAC auditor was questioning claims for technical component (TC) services and seeking repayment from InCyte Pathology. It took three months and plenty of dogged determination for the InCyte team to challenge the audit demands and prevail with its position. InCyte's CFO shares several important lessons learned.

Recovery audit contractors (RAC) are visiting pathology labs and groups

How One Pathology Group Survived Its First RAC Audit

WHEN THE MAILROOM started delivering boxes of mail to Tom Rehwald's office, the Chief Financial Officer (CFO) of **InCyte Pathology Inc.**, in Spokane, Washington, took immediate notice. The boxes contained letters about Medicare claims sent by a recovery audit contractor (RAC).

Rehwald recognized that the recovery audit contractor was acting on the authority of the federal **Centers for Medicare & Medicaid Services** (CMS). RAC auditors are empowered to conduct audits of Medicare claims submitted by hospitals, physicians' groups, and other providers, including pathology group practices and clinical laboratories.

The RAC auditor looks for both overpayments and underpayments. It is allowed to keep a percentage of the money that Medicare recovers or pays out as a result of the audit.

In the case of InCyte Pathology, each letter from the RAC auditor was an inquiry about a Medicare payment for technical component (TC) services that it said had been improperly billed by Incyte Pathology. Beginning in July last year, the letters from the RAC auditor came in bunches, one for each questionable payment.

The letters were the first inkling that a RAC audit was underway. These letters also marked the beginning of three months of telephone calls and communications from InCyte Pathology in Spokane to the RAC auditor, **Health Data Insights** (HDI) in Las Vegas, Nevada.

HDI is Medicare's exclusive Recovery Audit Contractor in 17 western states and three U.S. territories. Also involved was InCyte's Medicare carrier, **Noridian Administrative Services, LLC**, in Fargo, North Dakota, which erroneously took $50,000 from InCyte's current Medicare payments as a result of the RAC audit.

This money was eventually repaid to InCyte. However, it required substantial time and effort from Rehwald and his staff to properly respond and document the accuracy of the Medicare claims questioned by the RAC auditor.

Contingency Fee Payments

"One factor that drives RAC auditors is that they are paid on a contingency fee basis," observed Rehwald. "The fee ranges from 9% to 12.5%, depending on the region of the country involved."

Some experts have criticized this method of payment, but Rehwald believes it is useful, "Paying the RAC auditor in this way is good because it provides them with an incentive to prioritize where they think the most egregious practices are and where our taxpayer dollars may be improperly paid," he commented.

"One issue we faced from the RAC was that we billed globally to Medicare, but the RAC said the TC claim should have been bundled back to a skilled nursing facility (SNF)," Rehwald explained. "This area is tricky.

"For us to bill the SNF in this example, the Medicare patient needs a Medicare-qualifying stay in a hospital and the patient needs to be in a Medicare-level of care in the SNF for us to bill the SNF," he noted. "Otherwise, these patients are probably receiving Medicaid level of services in which we can bill globally. Nursing homes don't always do a great job of notifying us on the requisition whether it's a Medicare or non-Medicare bed.

"In the summer of 2010, we started receiving letters—initially in dribbles and later in boxloads," recalled Rehwald. "The number eventually totaled 402 demand letters from our RAC. They all related to two hospitals that we had been billing under the grandfather rule.

"At the time, we had 12 hospitals that we were billing under the grandfather rule and the RAC focused only on two," observed Rehwald. "So our exposure was not just 402 accounts, but it was perhaps more than 2,500 accounts. For the accounts under

audit by the RAC contractor, our total exposure from these 400+ accounts was probably about $75,000.

Allegations In The Letters

"The letters alleged that we didn't have the right to bill globally for those services and that we had to bill the hospitals," he explained. "Our contention was that these two facilities were grandfathered and had been since 1999."

During the three months that InCyte disputed the charges, Noridian prematurely recouped $50,000 in disputed payments. "I'm not sure why they recouped this amount," noted Rehwald. "It might have been an error on their part."

Not having prior experience with RAC audits and the appeals process, Rehwald and his team worked diligently to address each claim in question. By September, 2010, the matter was resolved and the case was officially closed. However, InCyte did not recover all the payments that had been prematurely recouped by Noridian until October 2010.

InCyte Pathology is a regional pathology super practice of 22 pathologists. It operates its own technical laboratory and contracts with 23 hospitals in Washington and Idaho. In April, it acquired **Davis, Sameh, Meeker Laboratory** (DSM) of Walla Walla, Washington, a three-pathologist practice *(see TDR, April 11, 2011)*.

Hire an Expert

For pathologists and lab directors, the story of how InCyte Pathology survived the RAC audit is instructive. As RAC auditors seek to recover payments from pathology groups, pathologists will want to be aware of the steps Rehwald took in response to this challenge and the lessons the pathologists learned. Rehwald offered these lessons learned:

- Hire a lawyer or someone knowledgeable to challenge the RAC audit findings.
- Know the issues in question.
- Recognize that you may know more than the RAC auditor knows.
- Listen closely and be respectful.

Even though Rehwald notes in his first lesson that labs and pathology groups should hire a lawyer, InCyte did not. "We felt we could handle this challenge because in the past, I worked as a healthcare compliance officer and also I worked directly with a Medicare carrier fraud unit on a provider issue," he explained.

"Because of this experience, I had a good sense of how this process works," added Rehwald. "I stand by the recommendation that labs or pathology groups should always consider getting an attorney or a capable billing expert involved. Our situation was different than most.

Letters Came In Waves

"It was last summer [in 2010] when the first letters arrived from the RAC auditor," Rehwald said in an interview with THE DARK REPORT. "At first, the letters seemed to dribble in slowly. Then they came in waves.

"When the mail room needed another box just for my mail from the RAC auditor, I knew something was amiss," he continued. "About 400 letters arrived, approximately one for each instance of our use of the technical component (TC) for billing. Sometimes, there were multiple accounts attached to each letter, but mostly there were individual letters addressed to the compliance officer or chief financial officer.

"In addition, for each Medicare claim challenged by the RAC auditor, there was a five-page demand letter," recalled Rehwald. "The demand letter included detailed explanations about the RAC process and a termination notice, which, if brought to the ultimate conclusion, would have excluded us from the Medicare program.

"The demand letter was basically boilerplate material identifying the RAC auditor's role and responsibilities," he said. "It also explained our appeal rights and then

Lawyer Explains Why It's Best for Path Groups To Respond Quickly to RAC Audit Letters

RESPONDING QUICKLY IS ESSENTIAL when a pathology group challenges the findings of a Medicare RAC (recovery audit contractor). That's the advice of Jane Pine Wood, an attorney with **McDonald Hopkins**, a national law firm. Wood spoke during an audio conference about RAC audits produced last month by **THE DARK REPORT**.

"Speed is essential to prevent or minimize offsets," stated Wood. "An offset is when the lab's Medicare carrier responds to the RAC auditor's findings and begins to deduct what the RAC auditor believes the lab owes to the Medicare program. Offsets usually begin 41 days after the date of the RAC letter.

"It's instructive to know that RAC audit contractors are paid a percentage of recoveries and a percentage of identified underpayments," she noted. "This is their financial incentive to identify Medicare claims that resulted in an overpayment or underpayment to the provider. Because the RAC auditors have an incentive to make as many overpayment determinations as possible, it is important to understand your appeal rights.

Know the Issue Thoroughly

"Acting swiftly in response to demand letters from the RAC is key from a legal standpoint," Wood continued. "If a pathology group misses any time period with respect to an appropriate appeal of a RAC audit, that group has no further recourse.

"When a RAC letter arrives at your pathology group, it can be very confusing," she observed. "That's because the format of the letters is not clear, particularly about what steps your group must take to contest the audit findings. However, there are at least two parallel paths to follow, and they run in tandem.

"The first level of appeal is to ask for a redetermination," explained Wood. "This must be in writing and it must be delivered to the Medicare Part A carrier.

Redetermination Request

"In order to stop the recoupment of the alleged overpayments, this request for a redetermination must be received within 30 days after the RAC audit letter. A copy should also be sent to the RAC contractor," she added.

The tandem path is with the RAC. "Your option with the RAC is called a discussion period," said Wood. "Basically, it gives you 40 days to talk to the RAC informally. It allows you to discuss the Medicare claims in question and explain why you think the determination is wrong. When you make this call, take good notes, including the name of the person with whom you spoke, the date and time of the call, and what was said.

"If, as a result of these discussions, you get a sense that the RAC contractor may issue a letter that will revise the audit, or possibly even revoke the audit, don't relax and wait for that letter to arrive," advised Wood. "That's because the 'offset clock' is ticking against your pathology group.

"On day 41 after the date of the RAC audit overpayment determination letter, your Medicare carrier may begin deducting offsets from your pathology group's Medicare payments," Wood said. "In order to stop those offsets from occurring, it is essential that your request for a redetermination is filed prior and within 30 days."

presented the details of the audit, in a manner that looks like remittance advice. The audit detail delineates where the RAC auditor thinks the error is, what the claim is, and how much is due back to the Medicare program."

InCyte determined that most of the TC charges in question involved the so-called "technical component grandfather clause." Under this clause, Medicare has permitted independent laboratories to bill and receive direct payments from Medicare for both specimen preparation (the technical component, or TC, of the service) and the diagnosis (the professional component or PC) of hospital patient specimens.

Extension Of The Provision

Over the past several years, CMS has sought to discontinue paying labs separately for the TC, but Congress has repeatedly extended the provision. By extending the provision, Congress may have created some confusion about how RAC auditors should apply the rule.

"As soon as we realized there was an issue involving TC, we contacted HDI by phone to make sure we understood the issues," Rehwald said. "We had been billing under the grandfather rule for 11 years. Thus, to be hit with improper billing charges for TC claims caught us off guard.

"I pulled out the regulations and anything we could get that would support us in how we billed for TC," he stated. "Once we had all our supporting information, we called the RAC auditor back to discuss these issues in detail.

"It took two or three different phone calls before I reached someone at the recovery audit contractor who could articulate the actual concern," continued Rehwald. "Now, at this point, our discussions with representatives of the RAC auditor became very granular and detailed."

Rehwald said that one key issue was that InCyte Pathology should be treated under CMS designation 70, which is a group practice. There is another term, designation 69, which is for independent laboratories.

"For the past 11 years, if you were an independent lab or a pathology practice, it didn't matter whether you were designation 69 or 70," he explained. "Every pathologist who could use the grandfather rule did so. The rule affects hospitals, not the pathology provider.

"Therefore, once I finally found someone at HDI who was knowledgeable about the regulations governing groups and independent laboratories, I was able to help him recognize that InCyte Pathology is a group 70 designation," noted Rehwald. "The regulations used by HDI to audit our TC claims apply only to independent laboratories with a designation 69.

"In our research of the regulations, it became apparent why this problem occurred," added Rehwald. "In its regulations, CMS has no definition for independent laboratory versus physician practice. By never defining it for 10 years, CMS basically had an oversight in its own regulations.

"Whenever a RAC auditor goes back retrospectively and says a pathology group like ours should not have billed the TC in this way, it is a difficult position for them to defend," observed Rehwald. "Knowing all this, we saw that the terminology actually supported our position.

Superior Level of Knowledge

"This was lesson number two: recognize that you may know more about the regulations than the RAC auditor knows," Rehwald said. "For 10 years, there was no distinction between a pathology group and an independent laboratory in the Medicare regulations.

"During this same 10 years, Medicare paid these claims," he explained. "So it is quite harsh and inequitable to provide clarification retrospectively. If Medicare wanted to handle it prospectively, I have no issue with that. But going back any number of years and saying we should have known there was a distinction seems wrong.

"That was our argument and we were confident that we would prevail given our

understanding of the issues, but we had to persuade the RAC auditor," he continued. "During all the back and forth over the phone from July to September, Noridian start taking money out of our current claims payments. We recognized that taking money from our current payments was the result of a failure in communication between HDI and Noridian.

"This was lesson number two: recognize that you may know more about the regulations than the RAC auditor knows," Rehwald said.

"As a result of how we responded to the RAC letters—and after considerable time and effort on our part—virtually all money demanded by HDI was reversed, except a very small amount that we just wrote off," he said. "This was a difficult process and required perseverance on our part.

"Ultimately, HDI closed the case, not only because of push-back from us, but from other pathology groups that HDI had audited in this region," he added.

"Early on, as we began to challenge the demand letters issued by the recovery audit contractor, we hoped nothing would be recouped and that only interest would be tacked on until the issue was resolved," Rehwald explained. "But ultimately we had to do a considerable amount of research and documentation, along with a vigilant tracking of our records to be sure we got the recoupment reversed. We used a spreadsheet to track every recoupment and the recovery of each one.

"One final lesson I would add involves being an attentive listener," offered Rehwald. "In private practice pathology, we use certain terms and we know what we mean when we use those terms.

"However, although RAC auditors are experts in healthcare, they are not likely to be experts in pathology or in the operation of pathology laboratories," he continued. "We cannot expect them to understand the vernacular we use.

"This does cut the other way, as well," noted Rehwald. "RAC auditors might think they are communicating clearly with us, but we often don't recognize the terms they use. This is pervasive in healthcare."

Rehwald emphasized that this "language gap" played a role in conversations his team had with the individual auditors at HDI. "In our case, the primary issue involved what we in pathology call the 'grandfather rule,'" observed Rehwald. "However, the recovery audit contractor might have no idea what that means.

"Additionally, there may be 20 different grandfather rules that apply in other medical specialties," he said. "But because pathology has only one, that's the only one we know.

"This is an example of why it is beneficial for you and your laboratory staff to be patient, persistent, and respectful to make sure each party is on the same page," observed Rehwald. "And related to this point is this: It doesn't help to be disrespectful.

Respect the Process

"As a former compliance officer, I know there is no mileage to be gained from getting defensive," commented Rehwald. "RAC auditors are trying to discharge this case and they don't need a reason to keep you on their radar."

THE DARK REPORT observes that Rehwald might be the perfect person to offer advice on how to survive a RAC audit. His background as a compliance officer and his work with a Medicare carrier fraud unit provided him with an insider's perspective on the most effective ways to settle this audit in a professional manner. TDR

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Why Canada Has Growing Shortage of Pathologists

➤Canadian Journal of Pathology published a study of factors affecting supply and demand

➤➤CEO SUMMARY: In Canada, it is known that the supply of pathologists and laboratory physicians has diminished since 1998. Further, a federal program that measures patient wait times for certain surgical and imaging procedures does not measure how long patients wait for anatomic pathology test results. Authors of a recent study point out that—lacking data on patient wait times for laboratory test reports—government funders may be inclined to steer funding to other clinical specialties.

IN MANY DEVELOPED COUNTRIES, the supply of pathologists already falls short of meeting the demand. This situation is expected to become more acute because of cutbacks in medical training positions and as more pathologists reach retirement age.

In Canada, these shortages are exacerbated by disincentives to create attractive positions within the controlled healthcare market. As a consequence, the shortage of pathologists is already severe in some places. For example, Saskatoon, Saskatchewan, has seen reporting delays for anatomic pathology tests due to an inadequate number of pathologists in the region.

Currently, the Saskatoon region has openings for four pathologists, a shortage that caused a backlog of 992 specimens in July and a turnaround time (TAT) of seven days or more. In March, the backlog was 1,300 specimens and the average TAT for reports was 12 days, according to the *Canadian Medical Association Journal* (CMAJ). The **College of American Pathologists** says the standard report time should be two days for rush biopsies and five days for complex surgical cases.

Canada's national government analyzes how long patients wait for certain procedures. However, pathology wait times are not evaluated, said Terence J. Colgan, M.D., Head of Gynaecological Pathology, Pathology & Laboratory Medicine, at **Mount Sinai Hospital** in Toronto. Recently, Colgan and his colleagues studied the supply of pathologists and laboratory physicians and published their results in an article, "Canadian Laboratory Physician Supply: Falling Behind," in the *Canadian Journal of Pathology*.

➤Fewer Pathologists

Researchers determined that, across Canada, the number of pathologists and/or laboratory physicians has diminished in the past decade, relative to the size of the population and also relative to the number of clinical physicians and radiation oncologists in practice. There is also variation in the supply of pathologists and laboratory physicians by province.

More significantly, researchers concluded that the number of pathologists

Pathologist Supply/Demand Experience Varies Across the Different Provinces in Canada

FOR AN ARTICLE IN THE *Canadian Journal of Pathology,* researchers reviewed physician supply data from 1998 through 2008 from the **Canadian Institute for Health Information** (CIHI).

The researchers defined and then calculated three measures of laboratory physician or pathologist supply as follows:

- Population-to-laboratory physician ratio and population-to-pathologist ratio;
- Clinical physician-to-laboratory physician ratio; and
- Comparison of population-to-pathologist ratio and population-to-radiation oncologist ratio.

Under each of these parameters, the supply of laboratory physicians or pathologists in Canada has diminished in the past decade, relative to: total population; number of clinical physicians; and number of radiation oncologists, said the researchers. The number of family practitioners and clinical medical specialists in Canada each increased by more than 6% over this 20-year period. By contrast, the number of pathologists and laboratory physicians decreased by 1.4% and 1.8%, respectively. Supply trends varied by province and parameter, but the supply of laboratory physicians relative to clinical physicians fell in most provinces.

The researchers who conducted this study were: Aaron F. Pollett, M.D., and Terence J. Colgan, M.D., of the Department of Pathology and Laboratory Medicine, Mount Sinai Hospital, University of Toronto, in Toronto, Ontario; and Ginette Lajoie, M.D., a member of the Department of Laboratory Medicine, at **Brampton Civic Hospital**, **William Osler Health System**, in Brampton, Ontario.

Pollett, Colgan, and Lajoie concluded that if the current trends in staffing of pathologists and laboratory physicians continue into the future, an adverse effect on Canadian healthcare can be expected.

and/or laboratory physicians relative to the number of clinical physicians fell in most provinces. This finding is inauspicious for the future of anatomic pathology services in Canada.

"The study clearly showed, that by the three parameters we used, the supply of pathologists is shrinking," Colgan said in an interview with THE DARK REPORT. "The reasons are difficult to identify. However, we know that there are two demographic waves occurring simultaneously.

"First, the pathologist population is aging, and we are uncertain whether there are enough new graduates to replace the older ones going out," explained Colgan. "Second, demographics of our aging population in Canada contribute to an increasing number of cancer cases each year. This means more work in cancer screening, diagnosis, and prognostication—even as the available supply of pathologists and laboratory physicians declines."

Less Interest In Pathology

Compounding the problem is what Dr. Martin Trotter, Vice President of the **Canadian Association of Pathologists**, said is low interest in pathology among medical graduates, primarily as a result of changes in medical school curricula in the past decade. In a CMAJ article, Trotter wrote that medical students no longer take second-year pathology courses. Instead, they are expected to choose specialties in their second or third year. Thus, in their second year, these students lack knowledge of pathology and laboratory medicine.

"I concur with Dr. Trotter's comments that physicians in training are not

exposed to pathology and medical laboratory training," stated Colgan. "Until recent years, pathology was an identified discipline within medicine. But changes in curriculum meant that undergraduate schools in this country tend to teach conceptual courses which don't identify pathology or lab medicine as a discipline.

Single-Payer Health System

"There is another reason for the potential shortage of pathologists," he added. "In Canada, the number of physicians available for training—and ultimately the total number of physician positions within the regional health authorities—are controlled by the single-payer health system.

"Under this type of healthcare system, a strong argument can be made that there is a significant disincentive for the regional health authorities and hospitals to create new pathology positions when money is tight and needed in other areas in healthcare," observed Colgan.

"For example, our federal government, in conjunction with the provinces, established a patient wait-times strategy," he continued. "They monitor how long it takes to get specific, important procedures done, such as hip replacement, cancer treatment, or an MRI.

"However, currently no laboratory medicine or pathology procedures are on that list," Colgan said. "Thus, funders have an incentive to spend money to shorten the patient wait-times for certain surgical and radiologic procedures. But funders have no incentive to fund pathology procedures.

"What compounds the negative impact these policies have on anatomic pathology is that Canada does not have accepted national parameters to measure quality in pathology," observed Colgan. "That leaves us with a health system where funders direct money away from laboratories as a consequence of the waiting-times strategy. And, because we lack a method to measure lab quality, that puts the laboratory testing profession in a very tough spot."

Colgan is aware of long wait times for pathology reports in Saskatoon. "Certainly in some cases, not having specimens reported out in an appropriate length of time will impair patient care," he said. "This is particularly true if there is a significant and unexpected finding.

"Also, the decision to do follow-on molecular testing can be made only after an initial pathologist review," he noted. "However, if the tissue sits in formalin too long, it's no longer possible to undertake such testing. In either of these situations, the standard of care for the patient is not met.

"The issue of turnaround time is important for other reasons as well," Colgan continued. "Prolonged TAT indirectly increases clinical costs, but this impact is often not appreciated. Pathology test turnaround time can also serve as the 'canary in the coal mine.' Should TAT for a tissue specimen become extended, then often the development and monitoring of other quality parameters may not happen.

Pathology Test TAT

"Similarly, longer turnaround times for pathology testing often detract from the development and introduction of the latest clinical practices in molecular pathology or personalized medicine because the lab is struggling with this single parameter," observed Colgan. "So, not only should pathology test TAT be of concern by itself, but it can also be a red flag about the actual state of quality in pathology in 2011, compared with where it should be."

THE DARK REPORT observes that this latest published survey of pathology staffing shortages in certain provinces of Canada can be instructive to both pathologists and health policy makers in other developed countries. How each province in Canada meets the challenges of expanding the supply of pathologists or investing to shorten turnaround times for anatomic pathology testing will teach important lessons. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last Friday, the acquisition of **Southern Diagnostic Laboratories, Inc.**, of Birmingham, Alabama, was announced by **Solstas Lab Partners** of Greensboro, North Carolina. Steve Boyd, who is the Founder and CEO of Southern Diagnostics, will become a Senior Vice President at Solstas. Revenues at privately-held Southern Diagnostics were reported to be $18.9 million in 2009.

MORE ON: *Solstas*

Solstas Lab Partners has been on a buying spree lately. In July it announced the acquisition of two laboratory companies based in Wilmington, Delaware. One of the two labs is **Wilmington Nextwave Diagnostic Labs**, which is a clinical laboratory organized to serve office-based physicians and nursing homes. The other lab company was **Wilmington Pathology Labs**, which is the histology and cytology laboratory formerly owned by **Wilmington Pathology Associates**. Revenue at Solstas Lab Partners is believed to be about $400 million per year.

NEW STUDY FINDS MOST WOMEN ACT UPON GENE TEST FINDINGS

In a recent study published in the medical journal *Cancer*, researchers reported that a high proportion of women who get a positive result of a genetic mutation when tested for the BRCA1 and BRCA2 genes will take action based on these results. The study involved 465 women who were tested for mutations in the genes BRACA1 and BRACA2 and the researchers contacted them at a mean of 5.3 years after they had been tested. It was determined that 80% of the women who test positive for mutations in these genes will take some sort of action. These actions typically involved prophylactic surgery to remove their breasts, ovaries, or both.

ADD TO: *Gene Tests*

"There's been a perception that risk-reducing surgery, especially risk-reducing mastectomy, was not something most mutation carriers would choose," stated Marc D. Schwartz, M.D., of the **Lombardi Comprehensive Cancer Center** in Washington, DC. He was the lead reseacher. The findings of this study suggest that most informed patients will take action based on the information provided by genetic testing.

TRANSITIONS

• Mara Aspinall was appointed as President of **Ventana Medical Systems, Inc.**, a division of **Roche Holdings**. Aspinall has held executive positions at **On-Q-ity**, and **Genzyme Corporation**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, September 6, 2011.