Volume XI, Number 10 Monday, July 19, 2004

Special Expanded Issue

Pathology Condo Labs Exposed!

Also... Ex-UroCor Execs Indicted!

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 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Two Blockbuster Stories to Rock the Lab Industry!

WOW! YOU HAVE TWO BLOCKBUSTER STORIES covered in this issue, which expanded into extra pages to bring you all the news and detailed analysis. Our lead story, on the facing page, is first news in the laboratory industry of criminal indictments of three ex-**UroCor** executives for laboratory sales and marketing practices that violated Medicare anti-kickback laws.

However, before knowledge of the federal indictments reached us, we had planned to devote this entire issue, as well as our August 9th issue, to a serious trend: specialist physicians taking active steps to capture revenues from the anatomic pathology services provided to their patients. It's a phenomenon only now getting serious attention within the pathology profession. But, until you read our coverage on this topic in this and our next issue, you probably had no idea about its explosive growth and its potential to threaten the long-term financial stability of hospital-based pathology group practices.

It's unusual for a story to break which "rocks" the entire laboratory industry. In my view, criminal indictments of ex-UroCor executives for using sales and marketing tactics that violated Medicare anti-kickback laws certainly qualifies. The federal attorney hopes to convince a jury, that, among other types of misdeeds, UroCor's use of deeply-discounted lab test pricing and waiving charges for tests done as an out-of-network provider were inducements to certain urologist-clients and thus violated the law. Since lots of labs around the United States commonly offer discounted pricing to some classes of clients, the outcome of this trial may trigger considerable changes in compliance policies and enforcement.

The exploding interest by specialist physicians to bring anatomic pathology revenues in-house is a story which will also "rock" a wide cross section of the pathology profession. You will read our coverage of this trend beginning on page 12. Of particular interest to many will be our exclusive intelligence about a brand new lab scheme adopted by some specialist groups: the anatomic pathology condominium laboratory complex. Such sites are mushrooming in Florida and Texas, attracting specialist group lab owners from states as far away as Missouri and South Carolina. If that sounds odd to you, then you are sure to be surprised about other details of the pathology condominium laboratory scheme! TDR

Ex-UroCor Execs Face Criminal Indictments

Federal prosecutors allege UroCor paid kickbacks & inducements to urologist-clients

CEO SUMMARY: Criminal charges filed against ex-UroCor executives center around several marketing practices that have much in common with marketing strategies used by many laboratories today. These include discounted pricing for non-Medicare specimens, offering to waive charges to payers and patients where UroCor was an "out-of-network" provider, and offering "consulting services" payments to client physicians.

ACROSS THE LABORATORY INDUSTRY in recent years, there have been plenty of complaints about "uneven" compliance practices, the lack of clear regulatory guidelines, and the absence of vigorous federal enforcement of Medicare/Medicaid fraud and abuse statutes.

That situation is about to change dramatically. Federal prosecutors filed criminal charges against three former executives of **UroCor, Inc.** for violations of securities laws and Medicare Fraud and Abuse statutes.

Named in the indictment are William A. Hagstrom (Chairman, President and CEO from 1989 through 1999), Mark G. Dimitroff (employed from 1990 to 1999, Vice President of Sales and Marketing), and Michael N. McDonald (employed 1992 to 1999, Chief Financial Officer). There are hints that other former employees of UroCor may be indicted later.

The indictment was filed on June 16, 2004 in an Oklahoma City federal court by Robert G. McCampbell, United States Attorney for the Western District of Oklahoma. The indictment lists a range of crimes. Most charges center around Medicare fraud and abuse violations and cover activities within UroCor from January 1990 until November 1999.

THE DARK REPORT believes this federal prosecution will turn out to be a milestone event for the clinical laboratory industry and the anatomic pathology profession. At their core, several categories of the alleged

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

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

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

crimes are extreme examples of general sales tactics used daily by many laboratories and pathology group practices to woo new physicians and win their laboratory testing business.

From today forward, every laboratory and pathology group practice will have to weigh this indictment's description of UroCor's criminal actions against their own sales tactics. The indictment's language will complicate the decisions conscientious laboratories make about when and how to offer physicians discounted pricing terms and "waiver of charges to managed care patients."

Invaluable Intelligence

THE DARK REPORT provides a full analysis of this federal indictment in the two stories which follow. The next story provides details about the specific charges contained in the criminal indictment. *(See pages 5-8.)* Following that, an attorney with substantial knowledge about laboratory compliance and business practices shares her views and analysis of the criminal indictment. *(See pages 9-11.)*

This criminal indictment is linked to a Medicare Fraud and Abuse settlement entered into by UroCor in July 2001. At that time, the company paid $9 million to settle allegations that it submitted fraudulent claims to the Medicare program during the years 1992 through 1998.

Serious Financial Woes

Not coincidentally, just three days earlier, on June 28, 2001, UroCor had announced that it would be acquired by **DIANON Systems, Inc.**, based in Stratford, Connecticut. *(See TDR, July 23, 2001.)* Further, by this point in time, UroCor had replaced Hagstrom, Dimitroff, and McDonald. It was UroCor's new executive team which negotiated the Medicare Fraud and Abuse settlement with federal regulators and made the decision to sell UroCor to DIANON Systems.

Combing hindsight with the new revelations in the criminal indictment about UroCor's financial manipulations of its revenues, accounts receivables, and bad debt policies, it appears that UroCor was backed into a financial corner.

It reported revenues of $52.6 million in 2000. Yet it had written off $4.7 million in receivables in late 1998 and the federal indictment says that, around that time, UroCor had over $10 million in receivables aged 150 days or longer. With its net worth falling, UroCor's need to pay $9 million to the Medicare program in 2001 was probably the tipping point in its decision to sell.

DIANON was a willing buyer, because it removed a tough competitors from the urology marketplace. During most of the 1990s, DIANON and UroCor waged intense sales and marketing battles to capture urology clients from one another. It paid $180 million to acquire UroCor.

Did DIANON Overpay?

Again, with the benefit of hindsight gained from the fresh financial revelations in the criminal indictment, a strong argument can be made that DIANON overpaid for UroCor. DIANON paid $180 million for a company with little net worth, $52 million in revenues, and a base of urologists clients who, by the facts laid out in the indictment, were benefiting from test prices discounted to ridiculously low prices and plenty of "waived charges" arrangements.

There was probably an emotional component in DIANON's decision to acquire UroCor. The two companies had each made earlier, hostile attempts to take each other over and DIANON got to remove its toughest competitor from the marketplace.

The speculation that DIANON overpaid is not irrelevant. By October 2002, DIANON had sold itself to **Laboratory Corporation of America** for a price of $598 million. Could UroCor's "financial rot" and the poor margins from its urologist client base have eroded just enough of DIANON's financial margins to encourage its board to accept an aggressive sales offer?

Further speculation could center around the idea that LabCorp may, similarly, have found that DIANON's true operating margins were less than anticipated after it acquired the company. UroCor may have indeed been an expensive prize for two different buyers.

Where Are They Now?

Since leaving UroCor in 1999, William Hagstrom served as Chairman and CEO of **Inoveon Corporation**. In the past 18 months, he moved to a start-up pharmaceutical company, **Selexys Pharmceuticals**, where he is CEO. Both firms are located in Oklahoma City.

Mark Dimitroff, who had worked at DIANON before he started at UroCor, is Vice President of Marketing and Sales at **Resolution Health, Inc.**, based in San Jose, California. This company's information services provide health plans with the health status and risk profiles of its beneficiaries. Michael McDonald is not working in the laboratory business.

Assuming that there are no plea bargain arrangements and this criminal case goes to trial, it will be closely watched by the laboratory business. Laboratory directors and pathologists should be clear about the implications of this criminal case. By filing these indictments, one federal attorney is staking his reputation that he can demonstrate, to the satisfaction of a judge and jury, that UroCor violated various Medicare/Medicaid prohibitions because of the manner in which it used pricing concessions and other forms of "remuneration" [of benefit to the referring physician client] to win new accounts.

This is a new legal case, one without a comparable precedent in the laboratory industry. Even before it goes to jury, it is sure to inject uncertainty into many aspects of laboratory compliance. TDR

UroCor, Inc.
KEY FACTS

- Founded in 1985 in Oklahoma City, Oklahoma as CytoDiagnostics, Inc.
- Files Chapter 11 bankruptcy in 1990. Company reorganizes around a business strategy of providing specialized diagnostics and therapeutics to urologists.
- Revenues hit $2.1 million in 1991.
- Name is changed to UroCor, Inc. in 1994.
- UroCor named to *Inc. Magazine's* "Fastest Growing 500 Companies" list for four consecutive years (1992-95).
- Initial Public Offering (IPO) in 1996, UroCor's revenues are $27 million.
- In October 1998, UroCor writes off $4.7 million of receivables.
- In July 2001, UroCor pays Medicare settlement of $9 million.
- DIANON Systems, Inc. buys UroCor for $180 million in June 2001.
- DIANON Systems is bought by Laboratory Corporation of America in February 2003 for a purchase price of approximately $598 million.
- Criminal indictments against three ex-UroCor executives are filed in federal court in Oklahoma City on June 16, 2004.

UroCor's Sales Tactics Violated Medicare Laws

It's too soon to determine what new legal precedents may develop from this case

CEO SUMMARY: By issuing a multi-count criminal indictment against three former UroCor executives, one federal attorney is creating new legal precedents for the laboratory industry. The criminal charges accuse UroCor of inducing physicians through such gambits as deeply-discounted pricing and "free testing" when not a contracted network laboratory. Labs should review compliance with these types of sales practices.

HAS ONE FEDERAL ATTORNEY thrown down a marker for the laboratory industry and the anatomic pathology profession?

Even if it wasn't meant to be an industry-wide warning, the criminal indictments of three ex-UroCor executives filed last month in an Oklahoma City federal court may have that effect. Competitive sales practices among the nation's laboratories will never be the same if these indictments lead to convictions and lengthy prison sentences.

Two-Parts To Indictment

The federal case against Hagstrom, Dimitroff, and McDonald *(see pages 2-4)* is divided into two sections. The first section deals with "conspiracy to provide kickbacks" in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(A). This is the Medicare/Medicaid anti-kickback law. The second section addresses "conspiracy to commit securities fraud in violation of Title 18, United States Code, Section 371."

It is the first section of the criminal case which should be studied by any laboratory or pathology group practice offering laboratory testing services to physicians and billing Medicare/Medicaid. In this section, the indictment describes three basic types of criminal acts.

The general charge states that from around January 1990 until around November 1999, defendants Hagstrom and Dimitroff did "knowingly and willfully offer and pay remuneration directly and indirectly, overtly and covertly, in cash and in kind to doctors to induce them to refer patient specimens for laboratory testing, the payment for which testing was made in whole or in part under a federal health care program in violation" of the anti-kickback law.

Under this first section, the first criminal act described is "the offer of 'special pricing' discounts." The language describes a fairly common business practice within the laboratory industry: "Hagstrom and Dimitroff and other unindicted co-conspirators encouraged UroCor sales representa-

tives to offer substantially discounted pricing for laboratory tests for non-Medicare patients in return for the referral of Medicare business. Discounted or 'special pricing' was offered to those doctors who the sales representatives determined were 'hard-to-close' accounts and had a significant number of Medicare patients. UroCor priced some laboratory tests substantially below the Medicare reimbursable rate and in some cases below UroCor's own cost of performing the tests."

"UroCor priced some laboratory tests substantially below the Medicare reimbursable rate and in some cases below UroCor's own cost of performing the tests."

The indictment then notes that these arrangements were often predicated on selecting doctors with a specific payer mix "because approval was based on the doctor's ability to refer a significant amount of Medicare business to make the offer of special pricing profitable to UroCor."

Next is a specific mention that the doctors benefited from "special pricing" because, as explained in the indictment, "doctors could then bill the patient or the patient's insurance plan at rates that substantially exceeded the 'special prices' charged by UroCor to the referring doctor, thereby providing financial benefit to the doctors."

Potential Violations

It should be noted that the indictment makes two clear points in the following paragraph. One point is that "The effect of the 'special pricing' program was that no discounts were given to Medicare patients, and UroCor did not inform Medicare of the discounts provided to non-Medicare patients." The other point was that defendants "promoted the offer of 'special pricing' to referring doctors even after being advised by UroCor's legal counsel and employees that the practice could violate Medicare regulations."

THE DARK REPORT interjects here to ask an interesting question. How would many lab managers and sales reps answer questions about their labs' use of discount or "client bill pricing" if they found themselves testifying in front of a grand jury investigating this practice? After all, in many instances, the purpose of discounted pricing is to allow a physician to mark-up the lab test and submit the claim to a payer or patient.

On the surface, a lay observer may see little difference in UroCor's use of discount pricing and that of many laboratories today. This point illustrates one way UroCor's criminal indictment may affect legal opinions and change laboratory compliance programs.

Pricing For PSA Tests

The indictment does provide specific examples of how deeply UroCor was willing to discount its test prices to selected urologists. In one case, the indictment lists the Medicare reimbursable rate for a PSA test in 1994 as $27.33. UroCor offered doctors at H. Urological a PSA rate of $12.00 in 1992 for non-Medicare patients. This rate was lowered to $7.00 in 1994 and further lowered to $5.50 in 1997! UroCor priced PSA tests to another urology client at $2.75 per test.

The second criminal act identified in Part One of the indictment is "the insurance reimbursement assessment (IRA) program." This was a ploy developed by UroCor to address situations where it did not hold managed care contracts. It lasted from 1992 through 1999. "UroCor used the program to induce doctors to send all their

laboratory business to UroCor, including Medicare and out-of-network specimens. This program provided a benefit to doctors by saving staff time that would be spent packaging and sending the specimens to different laboratories as required by their patients' managed care plans."

The indictment continues, "In return for doctors agreeing to send UroCor all their laboratory business during the term of the IRA agreement (including their Medicare business), UroCor agreed to accept as full payment any amount (including a full denial of benefits) paid by managed care organizations to out-of-network providers, such as UroCor, for the patients' laboratory services. In addition, UroCor agreed not to send statements to managed care patients for any balance not paid by the patient's insurance when UroCor was an out-of-network provider. This eliminated doctors' concerns that their patients would be penalized financially as a result of the doctor using an out-of-network lab."

Never Terminated

In describing the impact of this tactic, the indictment makes these points: 1) the IRA agreement forms stated that they were to last 90 to 180 days. In reality, "the agreements remained in effect until the program was terminated in April 1999"; 2) IRA agreements were offered "to doctors whose volume of Medicare business assured profitability to UroCor...Neither the Medicare program nor its patients received any benefit from UroCor under an IRA agreement."

It shouldn't be a surprise to learn that the indictment next states that Hagstrom and Dimitroff were advised, "by legal counsel, government fraud alerts, and UroCor employees" that such IRA agreements needed to be cancelled after the 90- to 180- day expiration to avoid concerns that they were inducements to the doctor in return for referral of Medicare patients. The extent to which UroCor used these agreements is surprising. IRA agreements were approved and in effect for 800 doctors!

Out-Of-Network Provider

As described in the indictment, UroCor's IRA agreements allowed it to get a physicians's account even though it was an out-of-network provider for one or more of the key managed care plans that covered the physicians' patients. UroCor would not charge the managed care plan for the test, nor would the physician or patient get a bill for that test. This arrangement resulted in "free testing." It seems to have close parallels to the "waiver of charges to managed care patients" tactic enabled by the OIG's fraud alert of December 1994 and used in today's lab marketplace by a number of laboratory companies.

Whether used by UroCor between 1992-1999 and by some laboratories today, this lab sales tactic effectively means that the lab is willing to do "free" testing for a portion of the physicians' patients in return for access to in-network specimens and Medicare patients.

New Legal Consensus?

As lab industry lawyers parse through this indictment, it will be interesting to see whether or not there will be consensus on how they interpret the criminal indictment's description of a "free testing" agreement by UroCor. Will there be legal opinions that say, based on the UroCor indictment, any laboratory using the "waiver of charges to managed care patients" tactic might face increased compliance risk?

The third criminal act described in the Medicare Fraud and Abuse section is UroCor's use of "consulting services contracts." The indictment describes a

tactic where, to retain a urologist's business, UroCor would enter into a "consulting services agreement." A sum of money was to be paid to the doctor. The doctor, per the agreement, was to document the consulting services provided to UroCor in monthly reports.

The indictment provides examples of UroCor payments to specific urologists ranging from $36,000 to $75,000 per year. It also notes there is no record that any of these urologists filed a monthly statement that documented consulting services they provided UroCor.

Not Many Examples Today

When UroCor's use of "consulting services contracts" with physicians is compared to current laboratory industry practices, there appears to be little evidence that a comparable practice is common in today's laboratory marketplace. However, because such arrangements are well hidden from sales reps of competing laboratories, it is possible that a laboratory somewhere could be using this tactic.

This completes a summary of the criminal acts described in the first section of the indictment. The second section of the indictment describes how the defendants violated securities laws in a number of ways.

Most of these violations would not be relevant in privately-held laboratories or pathology group practices. The violations include misleading investors when making public statements, withholding information and misleading its public accounting firm during audits, and booking revenues from tests for which it never intended to bill.

This last violation is linked to the IRA "free testing" agreements described earlier. As an out-of-network provider, UroCor would perform tests for which it would never bill the insurer, the physician, or the patient, per terms of its IRA agreement with the physician. Yet it would still book that test as revenue and add the never-to-be-billed charge to accounts receivables (AR).

The indictment identifies this practice as eventually building to a point where UroCor's "allowance for doubtful accounts" was "only $350,000 when the Company's internal reports showed that the accounts receivable balance over 150 days old was nearly $10 million, of which approximately $3 million represented IRA account balances."

This summary of the indictment, which ran to 40 pages, highlights how the federal attorney described and characterized several types of criminal actions which violated the Medicare and Medicaid anti-kickback law. THE DARK REPORT believes that many laboratory executives and pathologists, after reading the federal attorney's descriptions, will want to revisit both their laboratory's compliance program and its sales and marketing practices.

Physicians referring tests who have such arrangements with laboratories should also re-evaluate these arrangements, since they are equally at risk for violations of the anti-kickback law.

May Signal A Policy Shift

This criminal indictment should also be considered alongside last fall's proposal by the Medicare program to change the way a laboratory calculates its usual and customary charges and then bills Medicare. Collectively, these two actions by federal healthcare regulators may be early signs of a major shift in how Medicare will establish reimbursement for laboratory tests and allow laboratories to file claims.

In several ways, the criminal indictment of three ex-UroCor executives will have significant ramifications across the laboratory industry. Their trial may reveal what a fine line separates UroCor's crimes from the everyday practices of many labs. TDR

Lawyer Argues: Urocor Charges Are a Concern

Federal attorney breaks new ground by attacking UroCor's sales practices

CEO SUMMARY: ***Criminal charges in the case against three ex-UroCor executives will likely alter existing compliance practices that affect how a lab offers price discounts to physicians and the way a lab uses "waiver of charges" in situations where it is an out-of-network provider. Attorney Jane Pine Wood was one of the first to see the federal indictment and offers a first assessment of its potential impact.***

ONE LAB INDUSTRY ATTORNEY who's had a careful look at the federal indictment of three ex-UroCor executives believes it creates new concerns regarding the compliance of specific laboratory sales and marketing practices.

"To my knowledge, this is the first time federal investigators have filed criminal charges against laboratory executives for such marketing practices as price discounting and waiving charges to out-of-network managed care patients," declared Jane Pine Wood, Partner at **McDonald Hopkins**, based in Cleveland, Ohio.

Initiate A Legal Review

"The charges listed in these indictments break new ground," she noted. "My recommendation is that every laboratory and pathology group practice should have their legal counsel study the indictment and discuss how it may affect existing sales and marketing practices."

In an exclusive interview with THE DARK REPORT, Wood offered insights about the three types of marketing tactics which the federal attorney claims violated the Medicare and Medicaid anti-kickback law.

"Let's take the easiest one first," she began. "That's the criminal charge involving UroCor's 'consulting service agreements' with certain urologists. This will be relatively simple to prove. If there is no documentation or proof that UroCor received consulting services from the urologists paid under these agreements, then it is a likely the jury will vote to convict.

"However, use of these types of agreements is not common within the laboratory industry," observed Wood. "So this part of the indictment shouldn't have much impact on the laboratory industry.

"Next are the criminal charges based on how UroCor used discounted billing," said Wood. "Laboratories need to do their homework on this topic. This case may establish some new precedents. However, UroCor's willingness to offer very deeply-dis-

counted pricing sets it apart from most laboratories in the United States.

"The indictment lists examples where UroCor discounted laboratory test prices by as much as 90% of the Medicare reimburseable rate. This allowed client urologists to benefit by creating larger mark-ups when they billed those tests to private payers and patients. From the perspective of the federal attorney, there is certainly an argument that UroCor offered these inducements to physicians as a way to gain access to Medicare specimens," explained Wood.

"Are there comparable examples of such deep price discounting to be found among laboratories today?" asked Wood. "I don't think so. But there is a compliance concern.

Price Discounting Issues

"This is one federal attorney who believes that price discounting by laboratories to referring physicians is a violation of Medicare anti-kickback laws. If the jury convicts the ex-UroCor lab executives on this particular charge, then it will force both federal health program investigators and laboratories to determine where the line is now drawn between an acceptable price discount to a physician and a discount level which violates the Medicare anti-kickback law.

"Since no one yet knows what evidence the government will offer, nor what type of defense will be mounted, it is difficult to predict how the eventual decision will change the way Medicare officials view discount pricing for laboratory services. This creates uncertainty for lab managers and pathologists. That's because when federal health officials take enforcement action, they often go back five or more years when identifying the acts which they consider in violation of Medicare regulations and statues. In the case of

What About Indictments Of Urologist-Clients?

WHEN IT COMES to Medicare anti-kickback violations, it takes a party to offer the inducement and a party to accept it. So if UroCor is indicted for paying inducements, why haven't any of its urologist-clients been indicted yet?

"The key word is 'yet'," declared Jane Pine Wood, Partner at McDonald Hopkins, the Cleveland law firm with an extensive national healthcare practice. "It is a two-way street when it comes to anti-kickback law. The law is violated anytime someone either pays or receives the inducement. It would be reasonable to infer that, given the extent of anti-kickback activity covered in the UroCor indictments—which spans nine years—the federal attorney has a list of urologist-clients to also indict on criminal charges.

"The first indictments target UroCor's executives because those are easier cases to prosecute and win," she explained. "It's actually a sound legal strategy.

"Step one is to convince a jury that UroCor's executives paid kickbacks to urologist-clients of that laboratory company," continued Wood. "If the jury votes 'guilty', then the federal attorney goes to the next step. He files criminal charges against those urologist-clients of UroCor who received the kickbacks.

"That gives him a powerful case. He first states to the jury that the Medicare anti-kickback law makes it a crime to pay a kickback and to receive a kickback," she continued. "He next tells the jury that the UroCor executives were convicted by another jury, based on this evidence, of paying kickbacks. Thus, the outcome of the previous trial adds credibility to the evidence that these urologist-clients accepted those kickbacks. That is why the indictments and trials of the ex-UroCor executives comes first. Only after convictions in this trial may we see indictments of UroCor's urologist-clients."

UroCor, this indictment was filed in 2004 for criminal acts spanning the years 1990 through 1999."

Third Marketing Tactic

It is the third marketing tactic which gives Wood the greatest concern. "The issue of waiving test charges for managed care plans with which the laboratory remains out of network can turn into a serious change in compliance policy," she said. "Of all the criminal charges in the indictment, this is the one which most disturbed me.

"There are often times when a smaller laboratory, in order to retain a major client's lab testing business, will agree to handle specimens for which it is an out-of-network provider," commented Wood. "Although it knows it may not be paid for such test claims, the laboratory wants time to negotiate with the payer to become a contract provider, using the physician's account to justify why the payer should agree. In any event, this may be one reason why the OIG issued its fraud alert of December 1994, which defined the circumstances when such a waiver of charges would be appropriate.

Federal Prosecutor's Intent

"What I read into the indictment is a different intent by the federal attorney," she said. "The indictment specifically declares that UroCor offered to waive testing fees when it was out-of-network in situations where the physician's volume of Medicare patients would generate enough revenue to offset the losses of free testing. The attorney describes how the physician would benefit, thus documenting an inducement produced by the arrangement.

"The 'waiver of fees' charges include UroCor acts beginning in 1992 and running through April 1999. This predates the OIG's Fraud Alert of December 1994. My conclusion is that the federal attorney is pursuing a kickback argument: UroCor's offer to waive charges created a benefit to the physician (identified as 'saving staff time that would be spent packaging and sending specimens to different laboratories as required by their patient's managed care plans'). The physician benefit was the inducement and thus a violation of the Medicare anti-kickback law," commented Wood.

Wood believes criminal charges involving "waived fees" will be toughest to prove. "In the case of consulting service agreements and discounted pricing, the obvious inducement is that the urologist-client made money. In general, a waived-fees agreement is not designed to put additional money in the doctors' hands. It may be tougher to convince the jury that this activity violated the Medicare anti-kickback statute."

A Recommendation

From her reading of the indictment, Wood has a recommendation for laboratories and pathology group practices. "Laboratories using any of these marketing tactics should be concerned. This is the first federal prosecution centered around what seems to be UroCor's extreme abuses of these methods," she said. "Any criminal trial or plea agreement is likely to create new compliance requirements and redefine what constitutes an inducement anytime a laboratory and a physician enter into one of these arrangements. Laboratories should have their legal counsel track developments and advise them appropriately."

"My final admonition is to remember that these criminal indictments are breaking new ground," declared Wood. "It may take several years for the full impact of this trial to work its way into Medicare and OIG compliance policies." TDR

Contact Jane Pine Wood at 508-385-5227.

Editor's Perspective

Linking UroCor Indictments With Specialist Doc Pathology

This trial's outcome may influence interest in urology/gastroenterology in-house AP labs

By Robert L. Michel

IS THE TIMING of the criminal indictments of three ex-**UroCor** executives going to be a fortuitous event for the anatomic pathology profession?

I ask this question because the exploding trend of specialist physician groups internalizing anatomic pathology services was slated to be the sole topic for this and the next issue of THE DARK REPORT. Moreover, both issues will be expanded because of the sheer volume of intelligence and information we will present to you.

Over the the nine years that I have written THE DARK REPORT, only once was an entire issue devoted to a single topic. That was our coverage of how 9/11 caused massive disruption to clinical laboratory and blood banking services, and how the lab industry didn't miss a beat in serving the American public.

Trend Toward In-House Path

Why, then, would we plan to devote two entire issues to the sole topic of specialist physician groups and how they are actively bringing anatomic pathology services into their groups? It's because we consider this trend has the potential to be a serious threat to the long-term financial viability of the nation's hospital-based pathology group practices.

These groups are the cornerstone of anatomic pathology services in their communities. If they lose the source of their high volumes of biopsies and other specimens coming from outside the hospital, many of these groups will be deprived of the financial and other resources necessary for them to sustain their important role as the laboratory medicine experts of each community.

I need to stress this point. The increased interest by specialist physicians to capture anatomic pathology revenues generated by their patients, if unchecked by other factors, has the potential to seriously erode the financial well-being of hospital-based pathology group practices. To properly inform and educate our clients about this trend, it will require at least two expanded issues of THE DARK REPORT, plus subsequent intelligent briefings as appropriate.

Clinical laboratory administrators also have a stake in this upcoming marketplace battle. I recommend they closely track the progress the phenomenon of specialist physicians capturing anatomic pathology revenues and its impact on local pathology groups. Remember, the introduction of molecular technologies into clinical diagnostics is going to tear down the traditional "Chinese Walls" that have long separated clinical lab testing operations from anatomic pathology (AP) services.

Instead, the knowledge and expertise of anatomic pathologists will be increasingly integrated with that of clinical

pathologists, clinical chemists, medical technologists, and other skilled laboratory professionals. If a community loses needed expertise in anatomic pathology as a result of this trend, it will be that much more difficult for the local clinical laboratory to set up and offer molecular tests as they become available.

UroCor Indictments

Now that you understand why we are taking the extraordinary step of preparing two expanded issues of THE DARK REPORT on this disturbing trend, I'd like to comment on the criminal indictments facing three ex-UroCor executives. As you may have already read, this is a significant event because it will probably trigger deep-reaching changes to some common laboratory sales and marketing practices.

But I think these criminal indictments may have another impact, one that is not obvious yet to many pathologists. UroCor served a specific market: urology. At its peak, it boasted that it provided diagnostic lab tests and AP services to more than half of the nation's urologists.

As you will read in this issue and the next, of all the specialist physicians eyeing anatomic pathology as a source of ancillary revenue, it is urologists who are fastest at looking at the concept, then taking steps to create their own anatomic pathology laboratory.

These criminal indictments should prove chilling to any urologist who studies them carefully and has a candid discussion with his/her legal counsel. Here is the first instance of a federal attorney charging a laboratory—and its clients—for engaging in such practices as discounted pricing for lab tests and waiving charges to payers and patients if the lab is an out-of-network provider.

If UroCor's activities are judged to be inducements and thus violations of Medicare anti-kickback laws, then some urologist-clients of UroCor during the year 1990-1999 are also guilty.

It is equally important that, for 20 years, Medicare regulators and the OIG have paid close attention to the possibility that laboratories may use a variety of techniques to induce business. The Stark Amendments further attempt to control a physician's opportunity to profit from self-referrals.

A consequence of all this Medicare compliance scrutiny—and the $1 billion dollars paid by laboratory companies in the 1990s to settle allegations of Medicare Fraud and Abuse—is that laboratory executives and pathologists are keenly sensitive to the potential of many types of lab business transactions to cross the line and violate the myriad of Medicare compliance requirements.

It is unlikely that urologists, gastroenterologists, and dermatologists are as keenly attuned to the Medicare compliance pitfalls attached to laboratory testing operations. It might be a safe prediction for me to make that specialist physicians may yet find that operating an anatomic pathology laboratory entails much more risk, and malpractice exposure, than is justified by the profits they may earn from their in-house AP laboratory.

Criminal Case Is A Warning

It is for these reasons that I think the timing of the UroCor criminal indictments may prove to be a most fortuitous event for the anatomic pathology profession. Not only will it more sharply define what types of laboratory marketing practices may be considered inducements, but there is the possibility that some urologists, having received the benefits from UroCor's discounted laboratory test pricing and the like during the 1990s, might in the future face criminal charges themselves, as the recipients of UroCor's inducements. TDR

Urology & GI Physicians Bring Pathology In-House

Erodes long-standing business relationships between local path groups and specialist docs

CEO SUMMARY: Increasing numbers of urology and gastroenterology specialist groups are deciding to bring anatomic pathology services in-house. This phenomenon has gathered speed during the past year and is becoming a threat to the long-term financial and clinical stability of the anatomic pathology profession in the United States. Every pathology group needs a strategy to cope with this trend.

By Robert L. Michel

IN TODAY'S HEALTHCARE MARKETPLACE, growing numbers of specialist physicians are taking active steps to capture pathology revenues by bringing anatomic pathology (AP) services into their group practices.

Leading this charge are urologists, with gastroenterologists and dermatologists not far behind. It is a recent trend. Until one year ago, there were relatively few examples where a specialist group had successfully brought anatomic pathology into its group practice.

In-House Anatomic Path

That is no longer the case. During the past 18 months, THE DARK REPORT estimates that as many as 100 specialist physician groups nationwide have successfully internalized all or part of the anatomic pathology cases generated by their patient populations. A current assessment of this phenomenon leads THE DARK REPORT to predict it will accelerate during the next 24 months—assuming no swift actions to quash this trend are taken by federal healthcare regulators or private payers.

The threat to the profession of anatomic pathology is both real and immediate. Moreover, the long-term negative consequences of this trend on anatomic pathology will directly reduce the availability and quality of pathology services to patients, physicians who use pathology services, and the nation's health insurers—both government and private.

For these reasons, it is important for anatomic pathologists and pathology practice administrators to understand the forces driving this trend and develop effective business and relationship strategies to counter it.

This issue of THE DARK REPORT is devoted exclusively to the subject of specialist practices bringing anatomic pathology services in-house. You will read intelligence, information, and analysis exclusive to THE DARK REPORT and presented in advance of other sources available to you. It's required us to expand and add pages.

We analyze this trend to answer several questions. It will take two special issues of THE DARK REPORT. In this issue, we tackle four questions. First, how do you recognize the movement by specialist physiciains to bring anatomic pathology services in-house? Second, what makes pathology condominium laboratory complexes a new business model?

Third, what different business concerns are raised when a specialist group owns an on-site versus off-site anatomic pathology laboratory? Fourth, why have recent market forces motivated specialist physicians to look at anatomic pathology services as an ancillary revenue source for their group practice?

Who's Behind "Condo Labs"

In the next issue of THE DARK REPORT *(August 9)*, these questions will be answered. One, who are the major organizers of these new and disruptive business models? Two, what type of financial analysis is convincing specialist physicians to make investments in their own pathology lab operations? Three, how does this business model raise concerns about overutilization and possible declines in clinical quality and AP services? Four, which legal and compliance issues make these pathology condo labs a high-risk proposition to their specialist group owners? Five, are there efforts inside Congress, Medicare, and the OIG to address the expected problems from pathology condo labs?

The issue of pathology condominium laboratory complexes requires immediate attention. In both Florida and Texas, the number of pathology condominium complexes is mushrooming. This reflects the speedy response of urology and gastroenterology groups to the financial opportunities of such investments, notwithstanding the considerable compliance and regulatory concerns triggered by such schemes.

I believe that, at this point in time, THE DARK REPORT probably knows more about the national scope of this serious issue than any single individual or entity. One reason this is true is that the executives and physicians organizing many of these pathology laboratory condominium complexes are going to extraordinary lengths to hide their business from the general public. In some cases, their corporate offices and pathology condo lab complexes have unlisted telephone numbers.

I recommend that pathologists and their practice administrators pay close attention to this fact. Why would developers of a new business, particularly one which is attracting the investment dollars of so many prominent urology and gastroenterology groups in multiple states, want to be invisible to the public, the press, and the healthcare profession?

One reasonable conclusion is that they understand their business arrangement skirts extremely close to the bounds of Medicare compliance, physician self-referral, and other serious legal issues. The organizers understand this is a high-risk strategy, one that can quickly trigger the wrath of Medicare/Medicaid investigators, not to mention private payers.

Something To Hide?

The murky, "below-the-radar" aspect of this trend should trouble the pathology profession. Further, it is obvious that the greatest direct legal exposure is to the urologists, gastroenterologists, and dermatologists who participate in a pathology condominium lab scheme. It is these specialist physicians who will pay the biggest price whenever Medicare and Medicaid investigators come calling and decide to declare that pathology condominium laboratories might meet the form of the law, but they fail to meet the full intent of the law. TDR

Contact Robert Michel at 512-264-7013.

Pathology "Condo Labs" Are New Business Ploy

Pathologist doc-in-a-box schemes proliferating, their threat to pathology is still unrecognized

CEO SUMMARY: We call 'em pathology condominium laboratories. Other names are "pod labs" and "salon labs." Whatever name is used, this new scheme by specialist physicians to capture pathology revenues may be the most significant threat to the anatomic pathology profession since the imposition of hospital DRGs more than 20 years ago. Here's our exclusive analysis of this exploding trend.

EVER HEARD of a "pathology condominium laboratory complex?" This is the new business scheme that's causing excitement among specialist physicians, particularly urologists and gastroenterologists.

Essentially, the pathology condominium laboratory is a facility owned by a specialist physician group which is located off site from any of the group's clinical facilities. In some cases, it is located out of state!

The business scheme is simple, but the execution is complex, due to the need to stay just inside various Medicare regulations and laws governing ancillary services, self-referrals, inducements, kickbacks, and other similar prohibitions. As a result, the pathology condominium laboratory complex is different from anything seen in healthcare to date.

The companies developing pathology condo lab complexes approach specialist physician groups to solicit their interest. Let's use urologists as the example. The pitch is straightforward. "If your urology group decides to provide its own anatomic pathology services, here's what we will do for you. We will build you a laboratory in our condo complex. It will be fully equipped.

"Because your urology group may not generate enough specimens to keep a histotechnologist and pathologist busy full time," goes the pitch, "we will arrange for a histotech and pathologist to do your work part-time, on an as-needed basis. You will pay for the technical labor and pathology professional services in proportion to the specimens these individuals handle.

Group Submits Lab Claims

"As general managers of the pathology lab condo complex, we will supervise your laboratory's operation, maintain its license, and advise you on its ongoing needs. Your urology group will submit claims on the pathology procedures, collect the reimbursement, and directly pay the lab labor and pathologist," concludes the pitch.

To make this feasible, the pathology condo lab operator finds a building

with, say 5,000 square feet. It divides the building into 10 equal rooms for individual laboratories (leaving space for reception, administration, and support services). Each laboratory space is owned by a specific urology group, in the same fashion as a residential condominium complex. During the day, the histotechs and pathologists walk down the hall from laboratory to laboratory to process and diagnose each urology group-owner's anatomic pathology specimens.

Hot Idea For Urologists & GIs

The lure of bringing anatomic pathology in-house is powerful. During the past 18 months, as many as 60 specialist physician groups decided to invest in developing their own pathology laboratory condominium, located in a building developed and managed by the lab condo complex general partner.

To date, pathology condo lab complexes are known to be operating or under development in only two states: Florida and Texas. However, this has not prevented specialist groups in other states from acquiring their own pathology condo lab. The business organizers of the pathology condo lab business scheme are recruiting groups across a wide area of the United States.

AP Work Done Out-Of-State

In one example, pathologists in Central Texas tell THE DARK REPORT that one large urology group in San Antonio was sending its anatomic pathology work to a pathology condo laboratory it owned and operated in Florida. During the term of this arrangement, because there was not a Texas-licensed pathologist available to do this work, it was believed that a Florida pathologist was reading the slides, but a Texas urologist was signing out the case to fulfill legal requirements. Since that date, a pathology condominium laboratory complex was built and is now operational in San Antonio, Texas.

In Kansas City, Missouri, **Kansas City Urology Care, PA** (16 urologists) and **Mid-America Gastro-Intestinal Consultants** (11 gastroenterologists) have purchased pathology condominium laboratories. In each case, their laboratory is located in Florida. In Myrtle Beach, South Carolina, **Grand Strand Urology** (six gastroenterologists) owns a pathology condo lab located in Florida.

These examples demonstrate that the pathology condo lab problem is not limited to just Florida and Texas. Specialist groups from several other states have bought into this contrivance and are willing to send their AP specimens across state lines to be processed and diagnosed.

Compliance Surprise Ahead?

Unquestionably, this business scheme carries considerable risk to the urology, gastroenterology, and dermatology groups which decide to own a pathology condo laboratory. Unlike the pathology profession, these specialist physicians do not have extensive and first-hand experience with the range of compliance and regulatory issues familiar to all pathologists and clinical laboratory administrators.

It is impossible to operate a laboratory without full knowledge that Medicare officials and OIG investigators are well-versed about issues such as inducement, self-referral, and ancillary service prohibitions involving lab testing. If specialist physicians have overlooked or underestimated this situation, it may come back to bite them in extremely painful ways.

This is the first public disclosure of the pathology condo lab complex tactic. It demonstrates how fast this business opportunity is attracting specialist group investments from many states. TDR

In-House Versus Off-Site: Different Concerns

How much compliance risk do you want? Each of three options has a downside

CEO SUMMARY: ***Three methods are available to specialist physician groups to capture antomic pathology revenues generated by their patient population. Two methods have been around a long time. The pathology condo lab method is a new ploy. Of the three, one is generally accepted and more easily meets state and federal compliance requirements. But the other two methods come with greater compliance risk.***

THERE ARE THREE BASIC WAYS for specialist physicians to capture some or all of the revenues from anatomic pathology services performed on behalf of their patients.

Two are long-standing methods. The first is to establish an in-house pathology laboratory and bring a pathologist into the group practice, either as an employee or as a physician partner. The second is to negotiate discounted fees on both technical services and professional pathology services provided to a specialist group's patients.

The newest method is to invest in an off-site pathology condominium laboratory. *(See pages 18-19.)* As a new development in the lab services marketplace, this method comes with considerable controversy and will be examined in great detail in the stories to follow. The thrust of this story is to address method one and method two so as to provide context for why method three is controversial.

Across the pathology profession, there is general agreement that whenever a specialist group practice decides to bring anatomic pathology (AP) services in-house, it has the ability to do this if it complies with existing laws. However, over-utililization of the in-house AP services by some or all of the specialists in the group creates compliance risks.

Dermatologists Were First

Dermatologists were probably the first specialists to see value in having a dermatopathologist working within the group practice. During the past decade, there are numerous examples of large dermatology groups which brought dermatopathology services totally in-house.

In the last 18 months, this has also become true of urologists and gastroenterologists. Within both specialties, there is a noticeable increase in the number of groups taking active steps to evaluate the benefits of internalizing anatomic pathology services. However, the economics of an in-house anatomic pathology service requires a substantial volume of specimens. Traditionally, that has meant only very large specialist groups found it financially feasible to bring AP services in-house.

The second method, to negotiate discounted billing arrangements with a local pathology group or national pathology lab company, has been less common in past years. These agreements can be structured in a variety of ways.

Discounted Path Services

One approach is to have the pathology provider provide both the technical services and the professional pathology services. The specialist group does the global billing and pays the pathology group a negotiated, discount rate for the services it provided. Another approach is for the specialist group to build its own pathology laboratory and bill for technical services, but have the pathology group provide professional services at a discounted rate.

Expect lots of public discussion in coming months on the subject of discounted billing arrangements and whether or not they violate various legal and regulatory prohibitions.

Requests by physicians to have pathology groups provide services at a discounted rate is becoming a hot issue in the pathology profession. The **UroCor** indictments that included charges based on deeply-discounted pricing offered to client physicians will affect this debate. Expect lots of public discussion in coming months on the subject of discounted billing arrangements and whether or not they violate various legal and regulatory prohibitions.

Similarly, the arrival of pathology condominium lab complexes triggers issues involving state, federal, and private payer guidelines, prohibitions, and fraud and abuse statutes. For many valid reasons, the debate over pathology condo labs will be heated, intense, and highly-emotional for all parties.

Back to the point of this story, which is to identify the three basic methods currently used by specialist groups to capture revenues from anatomic pathology services provided on behalf of their patients.

Three key points must be stressed. First, in most instances, a specialist group which builds its own pathology laboratory in-house and maintains a full-time pathologist within the group's roster of physicians is probably the most accepted method. There are legal and professional precedents which support this arrangement, so long as the appropriate statutes and guidelines on physician self-referral, inducement, and Medicare Fraud and Abuse are diligently obeyed.

Second, discounted billing arrangements are an established fact in the healthcare marketplace. However, these situations are more likely to expose either or both the specialist group and the pathology group providing the services to potential violations of state and federal healthcare prohibitions.

Third, the swift inroads made by promoters of the pathology condominium lab scheme have introduced a new business option to specialist groups that seek to capture anatomic pathology revenues generated by their patients. Whether or not a condo lab arrangement fully meets both the form and the intent of federal and state laws has yet to be determined.

Big Risk For The Reward

However, even the actions of the pathology condominium laboratory complex organizers to "hide" their businesses indicate they know how closely their scheme skirts the boundary between acceptable and unacceptable compliance behavior. If government healthcare regulators decide in the negative, some specialist physician groups may pay a high price for their attempt to use anatomic pathology as a source of additional revenue. TDR

Changing Economics Motivate Urologists & GIs

Specialist docs turn to anatomic pathology to offset income losses from other sources

CEO SUMMARY: Over the past 18 months, more specialist groups have created their own anatomic pathology laboratories than were created in the past five years. It's a gold rush to tap and capture profits generated by the anatomic pathology services provided to their patient populations. This heightened interest in operating in-house anatomic pathology laboratories is directly linked to income cutbacks.

THERE IS A SINGLE, UNIFYING REASON why urologists and gastroenterologists (GIs) recently gained a heightened interest in bringing anatomic pathology services into their group practices. It is profit!

"Both gastroenterology and urology suffered significant cutbacks in major areas of reimbursement during the past two years," stated Bernie Ness, President of **B.J. Ness & Associates** of Toledo, Ohio. "This loss of revenue and income motivated these physicians to develop other sources of income, including ancillary services like anatomic pathology."

Asking For Proposals

"With 20 sales reps throughout the country visiting physicians' offices every day, we have a good feel for trends in the marketplace," said Ness. "With growing frequency, urologists and GIs are asking our sales reps to offer them discounted fees, develop joint ventures, or help them start their own anatomic pathology laboratory. We have a front-row seat to watch this trend unfold. It's also helped us understand why specialist physicians suddenly got extremely interested in how to capture anatomic pathology revenues within their practice.

"In gastroenterology, Medicare reimbursement cutbacks in key CPT codes happened about two years ago," he explained. "The first response of GI specialty groups was to look for ways to replace the revenue by providing the technical component for their clinical services. This fueled the shift from using hospital facilities to ambulatory surgery centers and in-office endoscopy centers.

"Once gastroenterologists saw how much reimbursement hospitals were earning for use of the surgery suites, it reinforced their interest in building up their own ancillary service capabilities," added Ness. "You could say that, once GIs broke ties with hospitals, the gloves were off in their willingness to capture ancillary service revenues.

"It didn't take long before gastroenterologists began evaluating anatomic pathology services," he continued. "It started in some of the largest

GI groups, because they had enough specimen volume to support the histology laboratory and a full-time pathologist. Once they had a full year of operating experience, they began telling their peers about the money they were making with their pathology laboratory. That got other GI groups interested."

Ness says the heightened interest by urologists and GIs in capturing anatomic revenues is easily visible to his pathology sales reps.

Ness says it is a different story in urology. It started several years ago and is tied to an important change in Medicare policy. "The gold mine for urologists was Lupron®. Patients got one shot per month. The urologist could make $100 over the cost of the drug when it was a Medicare patient," recalled Ness. "In some instances, the drug manufacturer gave free Lupron samples to the physician. After administering the free sample to a patient, the urologists could bill Medicare for up to $550.

Urologists Lost Income

"Medicare responded to this situation with stiff reimbursement requirements. Combined with reimbursement cutbacks in other urology CPT codes, it gave urologists a motive to look for ways to replace this lost income. They are looking at all ancillary services, including anatomic pathology (AP)," he observed.

"Remember the intense battles fought by **UroCor** and **DIANON** for urology biopsies throughout the 1990s?" asked Ness. "This did not go unnoticed by some urologists. They surmised that AP could be profitable. They built their own anatomic pathology laboratories. Once they understood the finances, the news spread quickly among the urology profession."

Ness says the heightened interest by urologists and GIs in capturing anatomic revenues is easily visible to his pathology sales reps. "Here's a good example. In Ohio, the Medicare rate for a primary biopsy is about $90. The private payer rate can be up to $150," he noted. "Two or three years ago, if we approached a urology clinic and offered to bill them at the Medicare rate, so they could then bill at the private rate, there was little interest. That's no longer the case. Today many more urology practices are interested in exploring the details of a discounted pricing arrangement for AP services."

In-House AP Trend

Ness believes his sales reps are seeing a new trend which is establishing deep roots, particularly within urology. "Economics drives this sudden interest in AP. Once a urology or GI group believes that anatomic pathology can be a profit center, it begins taking decisive steps to develop a way to capture those revenues," said Ness.

"I've seen lots of things in the 25 years that I have sold esoteric tests and AP services. In my opinion, this trend is a significant threat to any local pathology group or national anatomic pathology company," he continued. "It is changing the fundamental relationship that anatomic pathologists have as a consultant to the referring physician.

"That is not a positive development," added Ness. "It financially weakens the primary pathology resource in a community, which is the hospital-based pathology group. There is also the potential for specialist physicians to over-utilize AP services when treating their patients. Any response by Medicare to control that problem may prove destructive to the entire pathology profession." TDR

Contact Bernie Ness at 800-280-3785.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

A transfusion of the wrong type of blood may have contributed to the death of a critically ill woman at **Sarasota Memorial Hospital** in Sarasota, Florida last month. The patient died about a day after the transfusion. Following the blood transfusion, a reaction had been observed. Attending physicians do not know if the transfusion of the wrong blood type was the cause of death. Sarasota Memorial publicly acknowledged the medical error. It sent the wrong sample to **Suncoast Communities Blood Bank** to match when it ordered blood for the patient. Someone in the hospital mislabeled the blood sample.

ADD TO: Blood Bank Error

This episode illustrates how significant medical errors within a hospital will be publicized. It is the second serious medical error at Sarasota Memorial Hospital this year. In March, a cardiologist performed a cardiac catheterization procedure on the wrong patient. The man was unharmed by that procedure.

"CONTINUITY OF CARE RECORD" (CCR) WILL PRECEDE EHR

Growing interest in CCR means it is likely to precede the DHR when it comes to medical records. CCR stands for "Continuity of Care Record." EHR is the "Electronic Health Record." What makes CCR different from a EHR is that it is a shorthand form of the EHR. CCR is designed to be a portable and interoperable medical information system that enables the free exchange of data between hospitals, group practices, physicians, and patients. One characteristic of the CCR is that it includes information directly relevant to immediate patient care. Proprietary information, such as billing statements, are stripped out of CCR.

MORE ON: CCR

Vendor and provider interest in CCR solutions is high, because it simplifies many of the barriers still blocking development of a viable EHR capability. CCR is supported by **ASTM**, the **Healthcare Information and Management Society** (HIMS), the **Massachusetts Medical Society**, and other organizations. The 20th annual gathering of the "Toward an Electronic Patient Record" (TEPR) meeting held last May in Fort Lauderdale, attracted a record 4,000 attendees and 160 exhibitors. Enthusiasm for CCR and real-time electronic financial transactions is building, because the path to implementation is much less complex than that of the EHR. Lab managers and pathologists should track the shift in emphasis toward a CCR. It is likely that CCR efforts within a local community health system will be first to tap lab test data bases.

More executive changes at **AmeriPath, Inc.**, which announced on July 1 that Donald E. Steen, who recently became Chairman of the Board of Directors, will also become Chief Executive Officer. The CEO slot had been vacant since the departure of James New earlier this year. AmeriPath also brought two pathologists onto its Board of Directors. They are Clay J. Cockerell, M.D., from the group in Dallas, Texas and Jeffrey Mossler, M.D., from the group in Indianapolis, Indiana.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 9, 2004.