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Exclusive!

Specialty Docs Want Anatomic Path Revenues!

New threats and opportunities for pathologists

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

Pathology Clients Now Competing Against Pathologists

THIS ENTIRE ISSUE IS DEVOTED TO A SINGLE TOPIC: the exploding interest by specialist physicians in establishing their own in-practice ancillary service in anatomic pathology (AP). Once again, THE DARK REPORT is first to provide the pathology profession with a concise and insightful assessment of a disruptive trend.

I use the word "disruptive" for good reason. Pathologists are about to confront a business nightmare as a significant segment of their customers —primarily urology and gastroenterology groups—decides to enter the anatomic pathology business themselves. As our editor points out, "anytime a profession's major source of business and revenues decides to compete against its supplier, that's a major development."

So far, this phenomenon is concentrated in certain regions of the United States. For those of you working in those regions, it's likely that you've already seen major urology and gastroenterology clients divert their specimens away from pathology group practices in your community and into their own in-practice ancillary AP service. It's likely that these customer defections have had a serious impact on the financial viability of the pathology practices which lost access to those specimens.

There are still areas of the United States where this trend has yet to surface. For example, a pathology sales manager told me last week that, after making a week's worth of calls on urology offices in Southern California, she had heard no discussion of TC/PC arrangements or in-house AP labs. The situation is exactly the opposite in states like New York and New Jersey, where many urology and GI groups are actively involved in capturing at least some of the revenues generated by their anatomic pathology case referrals.

Even if this trend were to be derailed, because of, say, legislative prohibitions or actions by Medicare and private payers to prevent specialist physicians from submitting claims for anatomic pathology services, I believe the old business models in anatomic pathology are being permanently overturned.

I recommend that your pathologists and practice administrators carefully study the business intelligence presented in this issue, then use it as the basis for a strategic planning session. Timely preparation may help your group save several important client relationships. TDR

Office-Based Docs Want Anatomic Path Revenues

Why specialist physicians are eager to bring anatomic pathology in-house

CEO SUMMARY: Specialist physicians think they've found gold in anatomic pathology services. In different regions of the United States, urologists and gastroenterologists are taking active steps to cut themselves a piece from the anatomic pathology revenue pie. Some physician groups are building their own histology labs and hiring pathologists. Others are entering into TC/PC arrangements as a way to make money.

FACED WITH DECLINING REIMBURSEMENT for many of their important clinical procedures, specialist physicians are looking at anatomic pathology as a lucrative source of replacement revenue.

This is a simple trend, but one with the potential to radically transform the anatomic pathology profession. After all, specialist physicians are a major source of case referrals to local pathology groups and national laboratory companies. By redirecting their specimen referrals, these physicians have the power to create new financial winners and losers in the anatomic pathology profession.

The medical specialties of urology and gastroenterology (GI) are the twin drivers and major factor in this trend—at this time. In certain regions of the country, urology groups and GI groups are moving aggressively to develop business arrangements that allow them to capture revenues generated by the anatomic pathology procedures performed for their patients.

The purpose of this intelligence briefing is to provide an overview of this trend, describe its variations, and assess the likely impact this trend will have on the anatomic pathology profession. Much of this information has never before been published. Some of it builds on information provided by THE DARK REPORT in recent years.

Moreover, three basic types of AP business arrangements have emerged during the past 36 months. One is the anatomic pathology laboratory condo-

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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, $13.65 per week elsewhere (billed semi-annually).

minium complex. The second is a physicians' office laboratory (POL). The third is a split service arrangement, where a laboratory provides technical services to the referring physician group and sends the processed slides back to that group. The group then engages a pathologist to read the slides and the group bills directly for the professional component. TC/PC is the new shorthand to describe this business arrangement. It stands for Technical Component/Professional Component.

Client Billing Is Different

It must be stressed that these business arrangements are different from the longstanding practice in many regions of "client billing." In its simplest form, client billing describes a business relationship where a laboratory agrees to provide testing services at a discounted price to the referring physician or medical group practice.

This client receives a discounted bill from the laboratory provider, which it pays. The referring physician or medical group practice then marks up the laboratory testing services and bills the payer or patient directly. (Of course, because of Medicare laws, the laboratory which performs the test must bill these government programs directly, so the referring physician cannot legally mark up a client bill for a Medicare patient and submit that claim to a Medicare carrier.) There are also nine states with direct billing laws which negate client billing. They are: AZ, CA, IA, LA, MT, NV, NJ, NY, SC and RI.

Services Are Discounted

There are two essential differences between a client billing arrangement and the business models of specialist physicians bringing anatomic pathology services in-house. First, in the client billing scenario, the laboratory or pathology group continues to provide lab testing services to clients, albeit at a discounted price. Second, the laboratory continues to bill directly for Medicare patients.

In the scenarios described above, the referring physician groups are actually bringing pathology technical services and/or pathology professional services into their medical practice. In other words, they are establishing their own pathology labs and bringing their own pathologists into the group, specifically to perform tests on the specimens generated by their own patients, allowing them to file claims with all classes of payers, both private and public.

Therein lies the threat to the existing anatomic pathology establishment. As specialist physicians take steps to bring their pathology work in-house, it denies local pathology groups and national pathology lab companies access to this work—and the revenues associated with this testing.

Three Business Models

Currently, few pathologists understand the differences between the three basic business models of anatomic pathology services now making inroads within the urology and gastroenterology specialties. This is particularly true of TC/PC arrangements, which can be structured in a number of ways. Further, each of these three AP business models have unique compliance issues and implications to the specialist physician group which is the source of the referrals, as well as to any laboratory and/or pathologist providing contracted services to the referring physician group.

It is easy to understand why specialist physicians have a growing interest in setting themselves up in the anatomic pathology business. Like pathologists and clinical laboratories, urologists and GIs have seen ongoing

How Specialty Docs are Entering The Anatomic Pathology Business

WHEN SPECIALTY PHYSICIANS decide to enter the anatomic pathology business, they seem to be choosing from among three basic business models. Each is described below, along with a profile of the type of group which seems to prefer this model.

Business Model 1:

Physicians' Office Laboratory (POL)

Business strategy is in-house ancillary service that allows the physician group to bill globally for anatomic pathology services.

Technical Component: Doctors build their own histology laboratory within the practice and process their own slides.

Professional Component: Doctors have two options, either: 1) bring in a part-time/full-time pathologist as partner or employee to provide professional services; or, 2) negotiate with a local pathology group or national lab company to provide professional services at a competitive rate.

Group Profile: Preferred by larger urology and gastroenterology groups (six or more physicians). GI groups typically want a laboratory connected to their endoscopy center or ambulatory surgery center, where feasible.

Business Model 2:

Physicians' Office Laboratory (POL) in the form of AP Lab Condominium or "Pod Lab"

Business strategy is to use the AP lab condo as an in-house, off-site ancillary service that allows the physician group to bill globally for anatomic pathology services.

TC and PC: Managed by the promoter, the arrangement maximizes labor productivity of the histotechnologists and pathologists for groups with smaller volumes of specimens, but still allows the doctors to bill globally for anatomic pathology services.

Group Profile: Not popular in light of OIG Advisory Opinion 04-17. During 2003 and 2004, was of high interest to urology groups located primarily in Florida and Texas.

Business Model 3:

Business Arrangement that Splits Technical Services & Professional Services

Business strategy is to structure either TC or PC as an in-house ancillary and bill for it.

Option A: No Histology Laboratory

TC: Physician group selects a laboratory to provide technical services and process slides. Lab bills for TC (and sometimes provides TC and PC for Medicare patients for which it sends a global bill).

PC: Physician group either brings a pathologist into the practice, or contracts with outside pathologists to do the work at a discount. Physician group bills private payers for professional services.

Group Profile: Mostly of interest to specialty groups with 2-4 physicians, which lack volume to support an in-house lab.

Option B: In-house Histology Laboratory

TC: Physician group has its own histology lab. It sends processed slides to pathologists. It bills the technical component.

PC: Unlike the POL business model, here the doctors want a discounted billing arrangement with contract pathologists (so they can mark up and bill globally); or, the doctors want to outsource pathology to local pathologists (with whom they've had long-standing relationships) and let these pathologists bill the professional component.

Group Profile: Physician groups with established pathology relationships that they want to continue, even as the physician group keeps TC in-house.

erosion in reimbursement for many of their most important clinical procedures. To replace this lost revenue, these specialist physicians have looked for revenue-generating opportunities in ancillary services.

Anatomic pathology attracted their attention for two reasons. First, because of the volume of specimen referrals they generate, even smaller specialist groups can generate enough business to cover costs and generate a profit from doing their own anatomic pathology.

Second, getting into the anatomic pathology business requires a relatively small amount of capital for the histology laboratory. Staff can be limited to as few as one histotechnologist and a single pathologist who can be engaged, full time or part time, to work only the hours needed.

As a bonus, the complexity of running a histology laboratory is much less than that of a clinical laboratory. That also makes it an attractive ancillary service, because it requires less management effort.

As urologists and GIs got interested in anatomic pathology, three different business models have emerged. First is the anatomic pathology laboratory condominium complexes, dubbed "pod labs" by attorney Jane Pine Wood of **McDonald Hopkins**, the law firm based in Cleveland, Ohio. AP lab condos were a particularly hot item in the urology profession during 2003 and 2004.

Lab Condo Complex

Essentially, a promoter leased or purchased a building of, say, 10,000 square feet. This building would be divided into separate rooms of, say, 1,000 square feet. Then, each room would be built out as a histology laboratory and sold to a physician group. The promoter provides management services for these AP condo labs.

Labor would be provided by a histotechnologist and a pathologist. These individuals would either be part-time employees or independent contractors of each physician group owning a condo laboratory in that complex. During the day, the histotech and the pathologist would walk from laboratory to laboratory to perform the work required by each physician group owner.

THE DARK REPORT covered this development in great detail in the summer of 2004. It published two expanded issues devoted to anatomic pathology laboratory condominium complexes. This coverage won a journalism award from a professional association. It was estimated that, at that time, as many as 60 urology and GI groups had purchased AP lab condos during the previous 24 months. *(See TDRs, July 19, 2004 and August 9, 2004.)*

OIG Advisory Opinion

Within six months of publishing this information, the **Office of the Inspector General** (OIG) issued Advisory Opinion 04-17. In reviewing a proposed AP lab condo business plan, the OIG issued an opinion that was generally negative. Since publication of that opinion in December 2004, sales of new AP lab condos fell off dramatically. *(See TDR, January 3, 2005.)*

The second business model for in-house anatomic pathology services is the basic physicians' office laboratory (POL) arrangement. The doctors create a histology laboratory within their practice. This laboratory is staffed by a histotechnologist who is a full employee of the practice. All pathology technical services are performed in this laboratory.

The pathology professional services can be handled in several ways. First, the group may bring in a pathologist as a partner. Second, the group

may hire a pathologist, either full-time or part-time, as an employee. Third, a pathologist or pathology group practice may provide professional services on a fee-for-service basis.

Traditional POL Model

In the case of a pathologist as partner or employee, the physician group can bill for pathology technical and professional services with a global claim. In this scenario, the group's anatomic pathology laboratory and professional service are identical to the traditional POL business model.

The group can directly bill private payers, Medicare, and Medicaid. The pathology laboratory fully meets all the regulatory requirements for ancillary services. Because POLs are a long-accepted ancillary service model, there are few compliance issues with this arrangement.

There are, however, some interesting variations. Once the specialist physicians build their technical lab, they have the option to contract for the pathology professional services. THE DARK REPORT is aware of several different types of relationships.

Contracted Path Services

In a few cases, the specialty physicians will let a local pathology group perform—and bill for—the professional component. The most common approach is to obtain proposals from local pathology groups to do the professional work on-site. This is perfectly acceptable. It is no different than an independent commercial lab contracting with a local pathology group to provide pathology services on-site.These pathology services are then globally billed to all payers.

If the specialist group has some type of contracting arrangement with outside pathologists, then both parties must be careful to structure this relationship to be in full compliance with appropriate federal and state laws and regulations, which include such items as a written agreement, a term of at least one year, a fixed flat rate on a time period basis (monthly, etc.) or on a unit basis, etc.

The third business model is what is often described as a "TC/PC arrangement." It is a business model where a laboratory agrees to provide the technical services to a physician group. It sends the processed slides to the physician group, which has made its own arrangements for pathology professional services.

Submitting TC/PC Claims

Under this business model, the laboratory provider will submit claims for the technical component of the case. The physician group will bill for the pathology professional component.

In the TC/PC arrangement, care must be taken by all parties to properly comply with federal and state laws and regulations. There is significant potential for compliance violations if the TC/PC relationships are not properly designed and followed diligently by all parties.

In the marketplace today, these are the three types of business arrangements finding favor with specialist physicians. For clarity, we can label them: 1) pathology POLs; 2) AP laboratory condos; 3) TC/PC arrangements.

In the balance of this issue, we provide information about how urology and GI groups learned to use these three business models to enter the anatomic pathology business and we recommend strategies pathology groups can use to respond. That is followed by predictions on how this trend is likely to affect the pathology profession. There is also a letter to the editor concerning the trend of specialist physicians entering the anatomic pathology business. TDR

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Labs Taught Physicians How to Do TC/PC Deals

National pathology companies used TC/PC to capture accounts from physician groups

***CEO SUMMARY:** As many pathology groups discover that their best urology and gastroenterology clients are taking serious steps to do their own anatomic pathology, they ask a basic question: How did their best-referring clients suddenly become motivated to get into the pathology business? The answer is simple: in recent years, other labs have taught specialist docs that anatomic pathology can be highly profitable.*

In selected regions of the country, specialist physicians have acquired a keen interest in arrangements that allow them to capture some or all of the anatomic pathology revenues generated from their patient referrals.

It's a development that doesn't bode well for the long-term financial prospects of local pathology group practices. That's because urology and gastroenterology (GI) groups are at the vanguard of this trend—and they traditionally refer high volumes of specimens to their pathology providers. As these physician groups internalize their pathology referrals, or send the work to other pathology providers, local pathology groups are likely to experience a significant decline in specimen volume and revenues.

In order to respond to this trend, it is important for pathology groups and laboratory companies to understand the market dynamics propelling it forward. It is a young trend, almost unknown at the beginning of this decade. But the spontaneous combustion of two factors caused it to emerge and gain momentum at a surprisingly rapid pace, particularly among urologists and gastroenterologists.

One factor was the substantial reduction in reimbursement for clinical procedures that were a core component of urology and GI revenues in recent years. For example, according to a story published in *Urology Times* in December 2004, "a [urology] practice treating 48 prostate cancer patients receiving hormonal therapy would see gross revenue decline from approximately $132,000 in 2004 to $41,000 in 2005, based on CMS's projected reimbursement rates issued July 26, 2004." *(See TDR, May 30, 2005.)*

Profits From Anatomic Path

Specialist physicians, facing large declines in reimbursement on important clinical procedures, became highly motivated to find ways to offset that revenue, particularly with ancillary services they could offer their own patients. Anatomic pathology is one such ancillary service which caught their attention.

The other factor originated from within the laboratory industry. In

recent years, there has been plenty of trade gossip about TC/PC arrangements between pathology laboratories and specialist physicians. *(See pages 2-6 for a description of the TC/PC business model.)*

In tracking this development, THE DARK REPORT believes that **US Labs, Inc.** was among the first, if not the first, to directly market a TC/PC business arrangement to office-based specialty physicians. This started along the East Coast in early 2002, possibly first in Maryland, but shortly thereafter also in New Jersey and New York.

At that time, US Labs was beginning to expand its test menu and offer pathology services to office-based urologists and gastroenterologists. It had seen the success of **DIANON Systems, Inc.** and wanted to build specimen volume from these sources.

TC/PC In Flow Cytometry

US Labs had been offering a TC/PC arrangement in flow cytometry to its client pathologists. It would process the specimen in its laboratory and then send the flow cytometry data to the referring pathologist. In this arrangement, US Labs would bill for the technical component (TC) and the referring pathologist would diagnose the case and bill for the professional component (PC).

As it launched its sales program to urology and GI groups, US Labs offered a similar arrangement. The sales pitch went something like this: "Send us your specimens. Our laboratory will process them and send the finished slides to your group. We will bill for the technical component. You can hire or contract with a pathologist in your area, at a negotiated rate. You can then mark up the professional component and directly bill private payers.

"Oh, by the way, if you need help finding and contracting with a pathol-

Within Pathology, TC/PC Has a Long History

THERE IS A LONG HISTORY OF TC/PC ARRANGEMENTS WITHIN THE PATHOLOGY PROFESSION. It started years ago when the technical laboratory in hospitals would provide processed slides to the hospital's contracted pathology group.

In these situations, the hospital owned the technical laboratory and it would bill the technical component (TC). Processed slides were sent to the pathologists. They would evaluate the slides, sign out the case, and bill for their professional component (PC).

This sets up an interesting contradiction. For decades, the many pathologists who worked in such a setting–whether employed by the hospital, or an employee or partner in the hospital-based pathology group practice–have generated almost all of their income strictly from the professional component services they provide. They have had no ownership share in a technical laboratory.

One could argue that the TC/PC business model has been widespread and has been good to the pathology profession. It also raises an interesting question. For pathologists who currently practice in such a hospital setting and who bill only for professional component services, is there much difference if they provide these services directly to a urology or gastroenterology group?

After all, they would be performing the same type of work, in almost the same circumstances. Their income would be based on their professional component billings. Whether based in a hospital or a physician group practice, the daily work flow of the two environments are quite similar.

The similarity of the working arrangements in both environments suggests that, if a greater proportion of pathology services were to migrate away from hospital-based pathology and into physician office settings, pathologists are likely to follow that work to its new location.

ogist willing to work at a discounted rate, we will help. And also, because of Medicare regulations, we will do all the TC/PC on your Medicare patients and send a global bill to Medicare."

...for the labs offering these arrangements, they were getting paid full ticket for the TC, plus they were generally getting all the Medicare work, which they would bill globally. So these PC/TC client accounts were profitable...

This sales pitch proved appealing, at least in the Eastern United States. It was of particular interest for smaller urology and GI groups, because, with only two to four physicians, they didn't have the specimen volume needed to financially justify their own histology laboratory. But with US Labs doing the TC, it was simple and profitable to contract out the work to pathologists willing to work at a discount, then mark-up and send a bill to private payers for the professional component.

Over the past four years, this sales pitch was successful enough that competing pathology laboratories responded with their own PC/TC arrangements. For example, **Lakewood Pathology Associates** in Lakewood, New Jersey was among the first to adopt this sales approach with office-based specialist groups.

High Interest In AP

The current high interest in anatomic pathology by specialist physicians is a sign that the TC/PC arrangements offered by US Labs, Lakewood Pathology, and similar pathology companies, contributed significantly to their rapid growth in specimen volume and revenue during the past four years. Along the mid-Atlantic area, many urology and GI groups were willing to participate in a TC/PC business relationship.

It should be noted that, for the labs offering these arrangements, they were getting paid full ticket for the TC, plus they were generally getting all the Medicare work, which they would bill globally. So these PC/TC client accounts were profitable for the laboratory.

Now comes the "shop talk" factor. News began to spread through the urology and gastroenterology communities that there was good money to be made from anatomic pathology services. During 2003 and 2004, stories about the profits from the earliest anatomic pathology laboratory condominiums ("pod labs") were like pouring gasoline on the fire of financial interest.

Full, In-House Capability

Not surprisingly, during the past 30 months, growing numbers of urology and gastroenterology groups have taken active steps to evaluate opportunities in anatomic pathology. And size matters. Groups with eight or more physicians are highly likely to be actively developing a full, in-house anatomic pathology capability.

For smaller groups, particularly those with four or less physicians, a TC/PC arrangement is more typical. Because of the smaller volume of specimens, these groups like the economics of having a laboratory provide the technical services. They will then line up their own pathologist, pay a negotiated rate, then mark-up and submit a claim to private payers for the professional component.

Since specialist physicians have plenty of economic motive to enter the anatomic pathology business, this may prove to be a long-lasting trend. TDR

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Finding Opportunities Within the TC/PC Trend

Despite the short-term loss of significant revenue, pathology groups must consider long-term options

CEO SUMMARY: It is common for a pathology group to simply say "No, we won't help" when it is asked by a specialist physician group for help in establishing its own in-practice ancillary service in anatomic pathology. After all, the pathologists are losing a big chunk of their revenue, and helping a client compete against them. However, here's one pathology executive who recommends a different approach.

CERTAINLY THE TREND of specialist physicians establishing in-house anatomic pathology (AP) services is a threat to the financial well-being of many hospital-based pathology groups. After all, specialist physicians usually refer high volumes of specimens to their local pathology group.

"The economic impact of these events is substantial," stated Bernie Ness, President of **B.J. Ness Consulting Group** of Toledo, Ohio. "For example, **The Urology Group** of Cincinnati, Ohio was referring approximately 65,000 biopsies per year before it opened its own pathology laboratory in recent years. When these specimens stopped flowing to the local pathology providers, their cash flow took a huge hit.

"That is why pathologists become concerned whenever one of their biggest urology or gastroenterology (GI) clients approaches them and asks for help in developing a technical laboratory and assisting in the development of their own anatomic pathology testing program," added Ness. "It is not easy for pathologists to confront the loss of this major revenue source, and at the same time, be motivated to help their clients internalize these case referrals."

Ness has an interesting perspective on the trend of specialist physicians getting into the AP business. His career has been devoted to building laboratory sales programs and helping pathology groups develop growth-oriented business strategies. Because of this experience, in recent years he has been approached by specialty physician groups to help them evaluate their options to develop in-house technical laboratories and pathology professional services.

Both Sides Of The Table

"That means I've seen this issue from both sides of the table," observed Ness. "I've participated in the planning sessions of some very large urology and GI groups. The bigger the group, the savvier they are. These doctors understand the economics of medicine. They are quick to recognize why anatomic pathology can be a profitable ancillary service for their practice.

"The numbers are significant," he added. "For an investment of about $200,000, a GI group with eight or more physicians can realize about $50,000 per partner per year, after expenses, based on the average volume of specimens generated per GI.

Ready To Act And Invest

"These large specialist groups also have another advantage over their pathology peers in the community," continued Ness. "They are entrepreneurial, quick to make business decisions, and ready to invest their capital for any clinical opportunity that gives them a reasonable return on investment.

"By contrast, the typical local pathology group they approach to initiate discussions about some type of collaboration is much more conservative and deliberate in their decision making—particularly about a collaboration which means cannibalizing a significant source of their existing specimen volume and revenues."

Ness acknowledges that this situation is highly stressful to pathologists. "There is no business in the world which wants to hear that a major customer is going to compete against it—and wants help to get started!" exclaimed Ness. "Pathologists have every right to be unhappy about this development.

Basic Business Decision

"That being said, pathologists still must make a fundamental business decision when faced with this situation," he continued. "They have two options. First, they have many good reasons to refuse to collaborate and end the relationship with this client. Few people would blame them for choosing this option.

"Second, they can look past the radical change in their business relationship and decide to help their existing client develop the anatomic pathology program most appropriate to their situation and needs," explained Ness. "In my view, this is the best course of action, because I see opportunity in the long run."

It is a case of making lemonade from the lemons. "By the time these urologists and GIs have decided to talk to their pathology provider about setting up a technical lab or negotiating different prices for professional services, they've already made the basic decision to establish an ancillary service in anatomic pathology," said Ness. "The local pathologists should want to stay involved with this client.

"That's because the future is uncertain and things change," observed Ness. "The best business decision is to maintain the relationship, even if it comes with fewer specimens and less revenue. Think about the risk factors for the physician group.

Things Change Over Time

"First, there are lots of regulatory, compliance, and liability issues which are not fully recognized by specialist physicians," he said. "The lab industry is keenly aware of how quickly coverage and reimbursement changes can alter the economics of lab testing. Look at the recent reduction in flow cytometry reimbursement, for example.

"Next, rapid advances in molecular technology are shifting the economics of many assays," noted Ness. "Not only does that add complexity to the technical laboratory, but these new tests may be under-reimbursed. And don't forget the professional factor. These new tests require more sophisticated knowledge of laboratory medicine. Each of these factors is cumulative over time and can erode the financial attractiveness of running an in-practice pathology laboratory.

"My point is, it is better to have a finger in the pot than to be locked out

of the kitchen," advised Ness. "For that reason, I think local pathology groups should negotiate shrewdly with their clients when approached in this fashion and craft the best possible deal they can, given the circumstances."

A Different Consideration

Ness says that pathologists should analyze the situation from a different economic perspective. "Why not consider providing pathology professional services within the specialty group's offices at a negotiated rate?" he asked. "After all, the pathologist will be paid to read the slide and sign out the case and submit a single bill to the group for services rendered. The specialist group must pay for the office, microscope, AP reporting system, dictation, and the like. They will also bear the time and expense of filing claims.

"Seen from that perspective, simply providing professional services at a negotiated rate, without all the management headaches and overhead, may be a reasonable outcome—given the determination of the specialty group to get into the anatomic pathology business," said Ness.

Strategic Options

Ness has prepared a detailed analysis of the specialist physician AP trend, titled "Pathology Alphabet Soup." In strategic planning sessions with pathology groups, he lays out the business options that are available, and recommends a proactive business development program.

"There are many factors which point to this trend as something which is hot today—but likely to cool off at some future point," said Ness. "It's like the anatomic pathology laboratory condominiums—pod labs. These were hot in 2003 and 2004, particularly in the urology specialty. But the OIG's Advisory Opinion 04-17 put the brakes on this business model.

"Old School" Paths vs. "New School" Paths

CHANGE MEANS OPPORTUNITY and that is true of situations where specialist physician groups decide to launch an in-practice ancillary service in anatomic pathology.

"I see two responses in the pathology community," explained Bernie Ness, President of B.J. Ness Consulting Group of Toledo, Ohio. "One response comes from what I term 'old school pathologists.' These are pathologists with decades of experience who remain comfortable with the traditional business forms of medicine. These pathologists are likely to resist doing any type of revenue-curtting deal with their specialist physician clients.

"The other response comes from 'new school pathologists.' These are younger pathologists who are intrigued by innovative opportunities to provide care," said Ness. "They are often quick to see professional and financial benefits to collaboration with the specialist physicians. Their medical and other training has also exposed them to many non-traditional practice settings. So they have a willingness to be experimental.

"When you recognize the extremes each group represents, then you can see an obvious point of conflict within a pathology group practice that has both "old school' and 'new school' pathologists," he continued. "One group is motivated to preserve the status quo and not loosen preferred professional standards. The other group is open to new professional and business arrangements and is willing to explore these with the specialist physicians."

"That's why a 'do nothing' strategy by local pathology groups is unwise," he advised. "It's better to take what you can get today and stay connected to these physicians. This keeps your group in the game and ready for the next unexpected opportunity." TDR

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TC/PC: Pathology's Barn Door Is Now Wide Open

Lab industry has taught its best customers how to establish their own anatomic path business

CEO SUMMARY: ***There's a degree of irony in the current state of affairs. When a handful of lab companies decided to hit office-based urologists and gastroenterologists with the sales tactic of a TC/PC arrangement several years ago, no one realized the consequences of teaching these high-referring docs that there could be substantial profit in anatomic pathology services. Financial damage to the profession is just beginning.***

By Robert L. Michel

HOW DID SPECIALIST PHYSICIANS become interested in anatomic pathology as an in-practice ancillary service? The answer is that both the education and the impetus were provided by the laboratory industry.

During the past four years, a select and steadily growing handful of laboratory companies pursued a sales strategy of calling on office-based urologists and gastroenterologists (GIs) and convincing them to participate in a TC/PC arrangement. The laboratory would provide the technical component and bill for that service. The lab would help the specialist physicians line up a pathologist who provided professional component (PC) services at a negotiated rate. This was marked up and billed by the specialist physicians.

Not surprisingly, once some of the urologists and GIs understood the operations and finances of anatomic pathology, it was a simple step to cross over and convert their TC/PC pathology arrangement into a full-fledged, in-practice AP ancillary service, allowing them to submit global bills. Then they began to tell their colleagues about this profitable ancillary opportunity.

There is a reason why this entire issue of THE DARK REPORT has been devoted to the subject of specialist physician groups creating an in-practice ancillary service in anatomic pathology.

Losing Your Best Customer

Anytime a profession's major source of business and revenues decides to compete against its supplier, that's a major development—one that challenges the economic stability of the profession. From this perspective, anatomic pathology is now facing a challenge with the potential to be more transformational than any trend seen over the past 25 years.

We all know that urologists and gastroenterologists refer high volumes of specimens for analysis by pathologists. In the preceding story, Bernie Ness mentions that **The Urology Group** of Cincinnati, Ohio generates about 65,000 biopsies per year! A large GI group with

eight or more physicians will refer upwards of 30,000 biopsies per year.

These are the medical group clients which financially sustain many of the hospital-based pathology group practices around the country. That is why it is a financial dilemma of major consequence each time a top-referring specialist group calls its pathology provider and says "We would like you to help us set up our technical laboratory and advise us in developing our own ancillary service in anatomic pathology."

What Happens Next?

I ask you to consider this: what does it mean for the profession of pathology when one of its largest market segments—office-based specialist physicians—begins to take active steps to establish their own in-house anatomic pathology ancillary service?

This trend can only prove disruptive to the status quo. Moreover, it will affect some pathologists more than others. Let me speculate how that may happen, looking at different segments of the pathology marketplace.

For the two blood brothers, this trend is likely to be only a blip. With combined revenues approaching $9 billion, **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** will find a way to serve these types of clients, even if at reduced volumes. Plus, they have their own anatomic pathology strategies. Quest Diagnostics, for example, is said to have a goal of hiring 125 more pathologists during 2006.

Then there are the national and regional pathology companies. Most are organized to serve either or both the urology and gastroenterology specialties. This trend will be quite disruptive to their long-term prospects, since it constricts their access to specimens.

However, these are for-profit companies, often financed by equity investors. They will respond vigorously to market changes and are likely to find some service niche that allows them to remain financially viable, even if their annual rates of growth slow or flatten. Companies in this segment range from **Lakewood Pathology Associates**, **Pathology Partners**, and **GI Pathology Partners** to **CBLPath**, **Bostwick Laboratories**, and **OURLab**.

For hospital-based pathology groups, this trend will prove troublesome. Since most of these pathology groups do not have a dedicated sales force to generate new sources of business, it will be more difficult for them to replace specimens lost when existing specialist physician clients bring their anatomic pathology in-house. The loss of revenues from these sources is likely to cause a direct reduction in partner compensation.

However, that may not be true for consolidated pathology "super groups." Because they have their own technical laboratory, a service and sales force, and multiple hospital contracts, they have a better chance of replacing lost specimen volume and even offering esoteric tests to the urologists and GIs in their service area.

Timely Business Strategies

In each of the intelligence briefings of this special issue of THE DARK REPORT, we've analyzed a different aspect of this growing trend. Our goal is to help pathologists and their practice administrators develop timely and effective strategies. After all, anytime there is change, there is also opportunity.

This issue also highlights the irony of the TC/PC business strategy. It was the lab industry that taught these physicians to appreciate the profits in pathology. A handful of pathology companies opened the barn door—and it is likely to never be closed again! **TDR**

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Letters to the Editor

Technical/Professional Billing Triggers Strong Opinions

IT'S A TREND WHICH IS GAINING THE NOTICE of growing numbers of pathologists. Physician groups are taking steps to directly engage pathologists to diagnose cases.

The term "TC/PC" is often used to describe situations where two different providers provide the technical component (TC) and the professional component (PC) and each bills separately for its work.

The TC/PC trend is unwelcome to the anatomic pathology profession and has generated letters to THE DARK REPORT. Here is the latest, written in response to another letter about TC/PC published on May 22, 2006 by THE DARK REPORT.

Letter To The Editor

Dear Editor,

I describe the letter which appeared in the May 22 issue of THE DARK REPORT regarding TC/PC as one of self-interest and mixing fact with fiction.

But, let me make this crystal clear: I, too, am not a supporter of TC/PC. However, no real purpose is served in mashing TC/PC by mixing facts with fiction.

In recent years, a number of laboratories have approached office-based physicians and proposed a split TC/PC business agreement. The laboratory would provide technical component services, send the slides to the client, and file claims for the TC directly with payers.

It was up to the physician group to make its own arrangements for pathology services. In many states, the physicians have contracted with a pathology provider to read the slides at a discounted fee, then the physician group marks up the fee and bills payers directly for the professional component.

Another type of business arrangement is where the physician group builds its own histology laboratory and performs the technical component in this physician office lab (POL). It can then contract with a pathology provider to read the slides and diagnose the cases. In such situations, the physician group will bill for the technical component. But, depending on how it has contracted for the pathology services, it may or may not be submitting claims for the professional component.

Both of these PC/TC situations have plenty of potential to generate compliance problems. The pathology profession is certainly knowledgeable about the risks and compliance concerns that can result from a poorly-structured business relationship.

Although I agree with potential kickback issues described in the May 22nd letter to the editor, such as providing advisory and consulting services and full-function laboratory software at little or no cost, I believe the following may offer a more unbiased presentation of the facts:

- *Complying with Stark's in-office ancillary exception is not a complex, complicated or bureaucratic process for physician groups. In simplest terms, it is keyed to these points:*
  - *the laboratory must be wholly owned by the practice*
  - *the laboratory can only serve the patients of the practice*
  - *a pathology group is contracted to provide services at market rates*
  - *the pathology group provides services within the practice's laboratory*

This ancillary exception is always tagged with the term "Stark" as to imply that something may be wrong with having an in-office laboratory. Few in the industry realize that there are 106,000 CLIA registered in-office laboratories in the country today!

Granted, the vast majority of these physician office labs (POLs) are clinical rather than anatomic laboratories. It is also reasonable to expect over time that a few of the existing in-office clinical laboratories would expand into anatomic testing and require pathology services. For comparison, there are about 8,600 CLIA registered hospital laboratories and about 5,200 CLIA registered independent laboratories.

It is also important to point out that pathologists' market rates are rates which the pathologists accept for their work. No one should be under the misperception that these are deemed by dictate to be Medicare professional component fees or a multiple of those fees, as some pathologists would wish.

- *Not far behind in stoking the flames of fiction is the notion, in that published letter, that "the patient's best interest is often forgotten "(by not) referring the pathology services to the most qualified pathologist...instead find(ing) a local pathologist willing to work on a part-time basis."*

If those statements in the letter are pondered for a brief moment, many may see the folly in them. Where is the most qualified pathologist found? Should a pathologist who is working part-time automatically be classified as "not qualified?"

Consider this: most tissue diagnoses are done in the hospitals of this country by pathologists in average group sizes of three to four pathologists. Very few tissues are sent out of these hospitals for diagnosis by a "most qualified" pathologist. Does this imply that every one of those hospital pathologists is an expert in all of the tissues diagnosed? Or that all tissue-specific cases go only to the tissue-specific expert in the group? I suspect few believe either scenario is reality.

And, how about the part-time pathologist? In most cases that part-timer is a partner or member in a pathology group at a hospital who goes to the specialty physicians' practice laboratory on a rotating basis to diagnose cases. It may very well be that the same pathology group diagnosed cases for the practice before they installed their own anatomic laboratory or entered into a TC/PC agreement. Implied in the "part-timer" tag is someone unqualified to diagnose cases. Unfortunately, this is woefully wrong.

- *Of course, raising the liability issue is always a good scare tactic to toss into the mix. If attention was paid to the above paragraph on the part-time pathologist, it should be clear that the quality of the diagnoses and, hence, the risk of liability is mitigated. In that*

particular situation the risk is little different than it was prior to entering into a TC/PC relationship or installing an in-office anatomic laboratory. The liability issue is raised because the impression is implied that a part-time pathologist is going to ride into town from somewhere, diagnose the cases and ride out of town that afternoon, maybe never to be heard from again. Mixing these scare tactics with fact does not serve anyone's agenda well.

- *I'm surprised the letter did not go right to the heart of the matter on TC/PC business arrangements between a physician group and pathologists who have agreed to provide professional component services, often at a substantial discount. That is, besides the fact the TC/PC agreement hurts the pathologists who used to have that business (at no discount), no one talks about bringing out the big club to use on specialty physicians and pathologists. That club is found in E-6.10 of the* ***American Medical Association's*** *(AMA) Code of Ethics. It reads as follows:*

  "When services are provided by more than one physician, each physician should submit his or her bill to the patient and be compensated separately, if possible. A physician should not charge a markup, commission, or profit on the services rendered by others." (my underline.)

Simply put, it is unethical for a specialty practice physician to do TC/PC where the PC portion of the billing from a pathologist is marked up. Does anyone know of a physician who was booted out of the AMA for this ethics infraction?

Probably not. Unless the AMA actively enforces its own Code of Ethics, or federal or state legislation is enacted, TC/PC will continue to exist. Of course, pathologists at the local level could refuse to be a party to TC/PC, but that is highly unlikely. There are too many dollars at stake to do that in these days of falling reimbursement and shrinkage of pathologists' incomes.

Thanks for your interest in keeping this topic in the forefront of the industry.

Truly yours,

Name Withheld by Request

Editor's Response

For the pathology profession, a major sore point about the emergence of TC/PC business agreements is that physician groups, seeking a pathologist to do only the professional component, are shopping for the lowest price.

With the concept of "client billing" long established and legal in many states, it is not surprising that specialty physicians, like urologists and gastroenterologists, would want to mark up the pathology professional service, just as they always have done with clinical laboratory testing—often provided in earlier years by the local clinical labs owned by the same pathology groups now being asked to discount their professional fees.

Further, the economic incentives behind TC/PC arrangements encourage physicians to treat pathology services like a commodity and base buying decisions mostly on lowest price. This is certainly a most unwelcome development for the pathology profession. **—Editor**

Contact the editor at labletter@aol.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last Friday afternoon, it was announced that **Siemens AG** would acquire the diagnostics division of **Bayer Healthcare**. Siemens will pay $5.4 billion and the deal is expected to close in early 2007, subject to regulatory approval. Sales at Bayer Diagnostics totaled $1.8 billion in 2005. **Bayer AG**, the parent corporation, is currently in a battle with **Merck & Co.** to acquire control of **Schering AG**.

RAISING THE BAR FOR LAB TESTING SERVICES

Does your lab get these kinds of compliments from its patients? This was received today from a longtime fan of THE DARK REPORT, who lives and works in Portland, Oregon. "Yesterday, I had a huge number of lab tests at the **Kaiser Permanente** facility, an HMO I sometimes love to hate. However, you can't beat the efficiency of their labs! Shortly after I arrived home after negotiating heavy traffic, almost all the results were online under my personal mailbox with Kaiser. The lab reports not only provide the actual test results but also explain each test in detail. Talk about efficient! Score one for Kaiser!" Note how impressed this patient was with: 1) fast test TAT; 2) results posted in her Kaiser email box; and, 3) a consumer-friendly explanation of each test result. This is the type of customer service that builds patient loyalty. Our compliments to the laboratory at Kaiser Northwest!

LAST CHROMOSOME IN HUMAN GENOME IS SEQUENCED

It's another milestone in the advance of genetic medicine. A team of American and British scientists has sequenced the last chromosome in the human genome. Chromosome 1 turned out to be packed with 3,141 genes and holds 8% of the human genetic code. The sequence will be published on the Web site of the journal *Nature*. Researchers also identified 4,500 new SNPs (single nucleotide polymorphisms) as part of this project. More than 350 diseases, including cancer, Parkinson's, Alzheimer's, high cholesterol and porphyria, have been linked to this chromosome, as well as a gene identified with a common form of cleft lip and palate.

ADD TO: Chromosome 1

"This achievement effectively closes the book on an important volume of the Human Genome Project," declared Simon G. Gregory, Ph.D., who led this project team. He is Assistant Research Professor in the Section of Medical Genetics, Department of Medicine at **Duke University Medical School** in Durham, North Carolina. According to Gregory, researchers identified approximately 1,000 new genes on Chromosome 1 and work will now be directed at identifying what these genes do and how they interact.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 24, 2006.

UPCOMING...

- ***More IVD Industry Consolidation: Siemens Buys Bayer Diagnostics.***
- ***Overlooked Compliance Issues Likely to Trip Up PC/TC Arrangements.***
- ***Major Health System Makeover: Why Laboratory Services Plays a Key Role.***

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