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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Read "Waiver of Charges" for What It Is: FREE!

TODAY I AM AN OLD CURMUDGEON WHO IS IN HIGH DUDGEON. What's got my dander up is the disturbing revelation in this issue of THE DARK REPORT about the willingness by some of our industry's biggest companies to use "free testing" as a way to protect and build market share. *(See pages 2-8.)*

This is an important story. I believe it might signal the earliest stages of a competitive market strategy which could end up being as self-destructive to the laboratory industry as did below-cost bidding of capitated HMO contracts in the 1990s. I also believe it is a harbringer of how the two blood brothers will use their national oligopoly to enlarge their regional monopolies.

You will learn how both the two blood brothers have established corporate policies that allow their sales reps to approach physicians with a proposition that boils down to this: "Since we are not a contract provider to this HMO, we will 'waive charges' for lab testing done on behalf of these patients while continuing to do all your other lab testing work." This is offered selectively in situations which meet OIG anti-kickback guidance.

My first observation is this: "waiving charges" is the same as "free testing." I believe that the two blood brothers are taking the entire lab industry down a slippery slope should they expand their use of this heretofore unpublicized market ploy. How will private payers and Medicare respond if they see a national lab willing to do work for free? This certainly does not bolster the arguments of the lab industry, including the two blood brothers, that reimbursement for many critical lab test procedures is inadequate.

My second observation is this: The OIG Fraud Alert which supports this practice of "free testing" has been around since 1994. Yet the two blood brothers have not used this tactic extensively in past years. Why not? I would bet that, in the days when there was a **SmithKline Beecham Clinical Labs**, a **Dynacare**, an **AML**, competition at both the national and regional level made "free testing" a poor strategy. But now, with much less competion, the oligopoly/monopoly power of the two blood brothers makes this a more inviting market ploy—at least in the short term.

My final observation is simple. Once again, actions of the two blood brothers demonstrate that they emphasize their self interest regardless of their public pronouncements and the long-term interests of the entire lab industry. After all, how do public statements of "lab test pricing discipline" square with private offers of "free lab testing?" TDR

Two Blood Brothers Use "Free Testing" Strategy

Nation's two biggest labs implement strategy to counter hospital lab outreach competition

CEO SUMMARY: It's a business strategy that Quest Diagnostics Incorporated and Laboratory Corporation of America use in selected areas where they have lost exclusive managed care contracts to regional lab competitors. In order to retain access to a physician's fee-for-service testing business, each lab company is willing to waive HMO testing fees in specific situations that conform to an OIG fraud alert.

HERE'S A STORY WITH FUTURE implications for the ongoing profitability of clinical laboratory testing services delivered to physicians' offices.

THE DARK REPORT has learned that the two blood brothers have quietly implemented a corporate-wide policy with wide-ranging implications for the entire laboratory industry.

In situations where a national lab loses an exclusive managed care contract, it will selectively approach a physician with an offer to waive testing fees for that HMO's patients as a way to encourage the physician to continue sending his/her non-contract lab testing their way.

In effect, they are using "free testing" as a market tool to compete against smaller regional labs which may have won the exclusive HMO contract in an open bidding process.

"This is precisely the situation we see in Detroit," stated Jack Shaw, Executive Director of **Joint Venture Hospital Laboratories** (JVHL), a regional laboratory network owned by nine of the region's integrated health systems. "In open, competitive bidding, JVHL won the exclusive lab testing contract offered by **Health Alliance Plan** (HAP), an HMO with 125,000 members. *(See TDR, March 11, 2002.)*

"That contract had formerly been held by Quest Diagnostics," he continued. "Since May 1, when the new contract took effect, sales reps from Quest have approached certain physicians and offered to waive lab testing fees on

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their HAP patients if the physicians will continue to send all their other lab testing work to Quest.

"Having one of the national labs offer free testing is a new competitive dynamic in Southeast Michigan," said Shaw. "Over ten years, JVHL has worked hard to compete in traditional ways on value and service at a competitive price. HAP selected JVHL over Quest for exactly those reasons. Quest's decision to compete by offering free testing is an unexpected twist and circumvents the business objectives established by the lab testing contract between HAP and JVHL."

Why HAP Selected JVHL

In particular, one important reason why HAP selected JVHL is because the regional laboratory network could provide more complete sets of lab test data on HAP patients than either of the two blood brothers. HAP would thus have more complete utilization data, as well as higher HEDIS scores. Both are important benefits to a health insurer.

"This contract was negotiated on features other than price," explained Shaw. "Since HAP was interested in the fuller sets of patient lab test data that JVHL could provide, Quest's efforts to divert HAP specimens directly erode that benefit.

"Moreover, as director of a regional laboratory network, I am concerned that a national lab like Quest is using its economic power to offer free testing to doctors in our city, subsidizing this 'free testing' with profits from other segments of its national business. How do the regional labs of JVHL, which generally offer a higher level of service than out-of-town lab companies, get the economic capability to match such 'free testing' marketing ploys?"

From the payer perspective, the "free testing" offer creates its own problems. THE DARK REPORT spoke to a Detroit-based payer familiar with aspects of the HAP-Quest situation.

This insurance company executive noted two specific concerns which a "waiver of charges" scheme would trigger at his insurance plan. "First, we would be concerned that physicians, who are often unfamiliar with *all* the clauses of their multiple managed care contracts, may sign one of these disclosure agreements without realizing that they may actually be in violation of the OIG fraud advisory," he said. "I think neither the physicians nor the laboratory sales reps probably understand all the legal implications of what the physician is being asked to do.

"Second, we negotiate a detailed contract with our chosen laboratory provider for specific business reasons," he continued. "Thus, to have a non-contract laboratory try to convince our providers to not use the contracted laboratory is a situation which would raise some serious business, legal, and ethical issues for us."

"Below-Market" Pricing

Hospital administrators and pathologists involved in laboratory outreach programs should be alert to the use of this "free testing" sales ploy by the two blood brothers. It is a marketing tactic which uses the economic clout of the national lab companies to subsidize a "below-market" pricing scheme to selected physicians.

In the sidebar at left, THE DARK REPORT provides information about the OIG fraud alert upon which the "waiver of charges to managed care patients" tactic is based, along with a basic analysis of at least five legal concerns which could come into play whenever a laboratory company offers this type of arrangement to an interested physician. **TDR**

Contact Jack Shaw at 313-271-3692; and Jane Pine Wood at 508-385-5227.

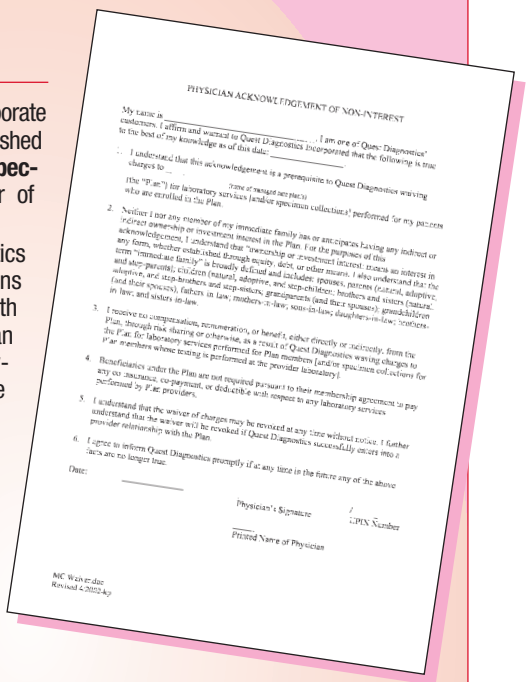
"Free Testing" Meets Anti-Kickback Statutes If It Complies With a 1994 OIG Fraud Alert

Quest Diagnostics Uses A Special Form With Docs

BOTH NATIONAL LABORATORIES developed corporate policies to comply with the fraud alert published on December 19, 1994 by the **Office of Inspector General** (OIG) that addresses "Waiver of Charges to Managed Care Patients."

In Detroit, sales reps at Quest Diagnostics have circulated the form at right to physicians serving beneficiaries covered by the Health Alliance Plan (HAP) HMO. Titled "Physician Acknowledgement of Non-Interest," it covers the specific points mentioned in the OIG's fraud alert.

Quest Diagnostics will use this form in situations where it is not a contract provider with a specific HMO. It will selectively approach physicians with an offer to waive charges for lab tests done on that HMO's patients in exchange for continuing to receive all that physician's other lab testing work.



PHYSICIAN ACKNOWLEDGEMENT OF NON-INTEREST

My name is _____. I am one of Quest Diagnostics' customers. I affirm and warrant to Quest Diagnostics Incorporated that the following is true to the best of my knowledge as of this date: _____

1. I understand that this acknowledgement is a prerequisite to Quest Diagnostics waiving charges to _____ (name of managed care plan(s))

(the "Plan") for laboratory services (and/or specimen collection) performed for my patients who are enrolled in the Plan.

2. Neither I nor any member of my immediate family has or anticipates having any indirect or indirect ownership or investment interest in the Plan. For the purposes of this acknowledgement, I understand that "ownership or investment interest" means an interest in any form, whether established through equity, debt or other means. I also understand that the term "immediate family" is broadly defined and includes spouses, parents (natural, adoptive, and step-parents), children (natural, adoptive, and step-children), brothers and sisters (natural, adoptive, and step-brothers and step-sisters), grandparents (and their spouses), grandchildren (and their spouses), fathers in law, mothers-in-law, sons-in-law, daughters-in-law, brothers-in-law and sisters in-law.

3. I receive no compensation, remuneration, or benefit, either directly or indirectly, from the Plan, through risk sharing or otherwise, as a result of Quest Diagnostics waiving charges to Plan members where testing is performed at the provider laboratory.

4. Beneficiaries under the Plan are not required pursuant to their membership agreement to pay any co-insurance, co-payment, or deductible with respect to any laboratory services performed by Plan providers.

5. I understand that the waiver of charges may be revoked at any time without notice. I further understand that the waiver will be revoked if Quest Diagnostics successfully enters into a provider relationship with the Plan.

6. I agree to inform Quest Diagnostics promptly if at any time in the future any of the above facts are no longer true.

Date: _____

_____ Physician's Signature

_____ UPIN Number

_____ Printed Name of Physician

MC Waiver.doc
Revised 6/2002-kp

"Free-Testing" Practice May Raise Other Legal Issues

BASED ON HER EXTENSIVE EXPERIENCE WITH laboratories and pathology group practices, attorney Jane Pine Wood has not seen much use of the "free testing" offer Quest Diagnostics is now making to selected physicians in Detroit.

"I've seen forms similar to Quest's 'Physician Acknowledgement of Self-Interest'," she said. "But only a handful of times in the last few years and most of those involved other services besides lab testing.

"The form used by Quest Diagnostics is carefully tailored to remove the issues that the OIG says could be a problem in triggering anti-kickback statutes," observed Wood, who practices at **McDonald, Hopkins, Burke & Haber** of Cleveland, Ohio. "From that perspective, it appears this practice is compliant with Medicare/Medicaid anti-kickback statutes."

However, Wood could identify at least four other legal concerns that could be triggered if a laboratory offered to waive testing fees for HMO patients treated by a client physician. "One issue is the lab's usual and customary charge versus what it charges Medicare," explained Wood. "Is the lab providing free testing to a large enough number of patients to make this issue a legitimate concern?

"Another legal consideration involves antitrust statutes," she continued. "A lab offering to perform testing at no charge may, in consideration of market share and other factors, might be viewed as engaging in anti-competitive behavior.

"I can see two other legal issues triggered by 'free testing' that involve a lab's contractual relationship with health insurers in that same regional market," continued Wood. "Such a business practice could violate contract anti-discrimination language with other insurers. It might also trigger a violation of any most-favored nation clauses."

Will "Free Testing" Ploy Financially Affect Labs?

Wider use of marketing strategy could lead lab industry into unwelcome financial turmoil

CEO SUMMARY: It's a marketing scheme which public lab companies have quietly used for years. Now there is evidence that the use of "Waiver of Charges to Managed Care Patients" (free testing) seems to be on the increase, raising new questions about how and why competitive practices are changing. Will the two blood brothers use their increasing clout to bring more intense competitive pressures against regional labs?

By Robert Michel

REMEMBER THE TAG LINE FROM THE movie *Jaws*? It said "Just when you thought it was safe to go into the water..."

That describes the lab industry and the revelation in this issue of THE DARK REPORT that several public lab companies have come up with another wacky and destructive pricing scheme; one that has many financially disruptive elements similar to the "below-cost" capitated lab test prices of the 1990s. Sales reps of the two blood brothers call this new scheme "Waiver of Charges to Managed Care Patients." In reality, however, it boils down to an arrangement where they will perform lab tests on certain patients "for free."

Antikickback Guidelines

In selected situations which meet the requirements set out by an OIG Fraud Alert issued December 19, 1994, any provider, including laboratories, can "waive charges" for services provided to managed care patients for which it is not a contract provider as a way to continue providing services to the physicians' patients which are covered by other health plans. This can be only be done in situations where "free testing" generates no benefit to either the physician or his patients. *(See pages 2-4 in this issue.)*

This sales tactic should get the full attention of all lab executives and pathologists who compete against the two blood brothers. To date, it has not been used very often. But that situation may be changing. A growing number of local laboratories report that the national labs have introduced "free testing" as a competitive marketing tool in situations where they do not hold the managed care contract.

If this is true, and if the biggest lab companies are willing to more aggressively promote "waiver of charges" arrangements in regional markets, why is this happening now?

More importantly, is the laboratory industry seeing the earliest stages of a market cycle where the public lab companies, under intense pressure to

boost specimen volume and net profits, believe this is an effective tool for protecting existing business and building market share?

These are serious questions about a serious issue. Let me frame the issue this way: In our industry, the leading lab companies are going to physician-clients with this proposition: "To make it more convenient for you to use our laboratory, we will take non-contract managed care work and perform those tests for free. All your other work can continue to come to us and we will be your 'sole source' for laboratory testing."

Uncannily Similar Argument

Does this sound familiar? It's deja vu. It is uncannily similar to the argument used by public lab companies starting in 1988, when the first capitated, full-risk lab services contracts were signed with managed care plans.

Clever laboratory executives at that time had this logic: "We'll bid the managed care contract at a price below our cost to do the testing. Our sales reps will then convince physicians that, since our lab holds the managed care contract, they should give us both their contract specimens as well as their fee-for-service specimens. That non-managed care business will provide the profits needed to offset the losses incurred on the managed care testing we do."

"Free Testing" Not Smart

I'd like to point out a simple truth: offering to do testing free or at below cost is never a long term strategy for success. The below-cost managed care prices established by public lab companies ten years ago continue to drag down overall reimbursement for lab testing services even today.

So the lab industry has lived through one cycle of public labs bidding below costs to protect and expand

How Below-Cost Cap Rates Created Big Revenue Gap

PUBLIC LAB COMPANIES were willing to lose substantial amounts of money in the early 1990s to capture capitated, full-risk managed care contracts.

Two examples illustrate how big the gap became between the cost of providing this testing and the reimbursement paid by managed care companies for lab testing services. During the 1996-97 period, a CFO of a public lab company in California discussed the financial consequences of offering to do lab testing for less than the cost of the work.

He calculated that, on a fully-expensed basis, it cost his lab about $2.50 per member per month (PMPM) to provide lab testing services to a commercial population. However, the typical managed care contract at this time was paying between 50¢ and 70¢ PMPM. His lab was subsidizing the cost of testing by more than $20 per year per member!

MetPath (now Quest Diagnostics) provides another example of the gap between cost and revenue. At the time MetPath purchased **Nichols Institute** in 1994, executives from Teterboro told the Nichols executive team that the future growth of managed care testing was the company's biggest financial challenge. At that time, MetPath's national revenue per requisition averaged $25. Its cost per requestion averaged $20. For managed care requisitions, the revenue averaged about $10.

MetPath had a strategic dilemma, said these execs. In 1994, managed care contracts represented only 10% of the company's total revenue. But projections indicated it would grow to 40% within two to three years. Thus, what could MetPath do to close the gap between its $20 per req average cost and the $10 per req average revenue from managed care contracts?

market share. The result was a string of bankruptcies and near-death financial struggles for those public lab companies which operate today.

Are the nation's larger commercial labs embarking on a new cycle of offering "below cost" pricing? Will use of the "waiver of charges" marketing scheme expand? As it does, will independent commercial labs and hospital outreach programs feel the need to respond in kind to protect their business?

Formal Policies In Place

The Fraud Alert of December 19, 1994 is known to all the major lab players. Each of these companies has a formal policy, protocols, and the forms necessary to document compliance. *(See page 4.)* THE DARK REPORT has called **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** to verify their policies governing "waiver of charges." As of press time, neither company had provided a spokesperson knowledgeable on this topic.

As noted on pages 2-5 of this issue, Quest Diagnostics is using the "free testing" tactic in Detroit as a response to losing the **Health Alliance Plan** (HAP) contract to **Joint Venture Hospital Laboratories** (JVHL). In Greensboro, North Carolina, **Spectrum Laboratory Network** is actively using the "free testing" scheme in its regional market. Its CEO, a veteran of the capitated pricing wars of California in the 1990s, is introducing this marketing ploy in its region.

Because the use of this "free testing" scheme is still in its infancy, there is still time to influence how it is used and ameliorate the potentially negative impact it can have on the entire lab industry. In that spirit, I'd like to pose some thoughtful questions to you.

First, is it any surprise that public lab companies are willing to give away free lab testing as a way to maximize their short-term market benefit? They did it in the early 1990s with money-losing cap rates. The "waiver of charges" scheme is consistent with this past precedent.

Second, it must be acknowledged that the nation's biggest labs are launching what is really a "price war" to retain access to specimens where they are not the managed care company's contract laboratory. Price wars only benefit financially strong companies. Thus, is this an example of anticompetitive behavior? Are national labs demonstrating their willingness to subsidize free testing financed by the profits from their national lab system to squeeze regional providers? Certainly once the local labs are put out of the game, the national labs will cease offering free testing and try to raise rates.

Third, how will payers respond when they see a (non-contract) national lab willing to perform testing for free to gain access to the physician's other lab testing specimens? My conversations to date with insurers in Detroit indicate that this will only create downstream pricing problems for labs serving that region.

Will Medicare Notice?

Fourth, and not the least, what will be the reaction of Medicare officials should the "waiver of charges" scheme be used more frequently by clinical laboratories. Doesn't the concept of offering free testing on patients covered by a specific managed care plan in order to gain access to other lab specimens, including Medicare patients, run counter-intuitive to the thinking and expectations of Congress and Medicare regulators?

These are tough questions. I believe that if the use of "waiver of charges" marketing schemes widen, it will have negative and long-lasting impact on the lab industry over the long run. TDR

Lab Informatics Update

Newly-Issued HIPAA Regs Generate Lots of Controversy

HIPAA IS A SUBJECT that is little understood and generates lots of concern among clinical laboratories and every type of healthcare provider that generates clinical data.

On August 14, final privacy regulations were published in the *Federal Register*. The implementation deadline for most healthcare entities is April 14, 2003, just a short eight months away.

Although the privacy aspects of HIPAA stimulate much public debate, other parts of the legislation mandate common formats for submitting claims and transferring clinical data. With much justification, providers of all types expect to spend lots of time and money on compliance.

Labs To Be Affected

Because information is the stock in trade of all laboratories and pathology group practices, the long-term impact of HIPAA will be profound. That's because laboratory test data makes up a substantial part of every patient's permanent health record.

One aspect of HIPAA which makes it more treacherous than other types of legislation is the penalties for breaching a patient's privacy. HIPAA makes it possible for employees within an organization to face legal consequences for violations of the law. This is a primary reason why HIPAA is getting the full attention of so many hospital administrators.

What has grabbed headlines, however, is the battle between certain consumer groups and the healthcare industry. As originally drafted during the Clinton Administration, HIPAA privacy regulations would have placed a heavy burden on providers to get every patient's written acknowledgement to access or release information, even for purposes of treatment.

Requirements Relaxed

As issued by the **Department of Health and Human Services** (HHS) on August 14, the final regulations relax many of these requirements. In opposition to this change are groups like the **American Civil Liberties Union** and the **Health Privacy Project** at Georgetown University.

The final rule does not require hospitals and providers to obtain written consent from patients to access their medical records for treatment and claims. They must, however, provide some notice of privacy practices and make a good-faith effort to have the patient acknowledge that notice was given.

For hospital inpatients and outpatients, laboratories will be covered by documentation presented at time of admission or registration. Testing done for physicians' offices will present different challenges. THE DARK REPORT expects that very practical and relatively simple procedures will be quickly developed and become an accepted industry standard.

One unknown factor is how the plaintiff's bar will use HIPAA to attack providers, including labs, for alleged violation of a patient's privacy. At this point in time, that is certainly one of the biggest wild cards that come with HIPAA. TDR

Moving Physicians to Web-Based Lab Reporting

Lab Competitors Pool Lab Data For Clinicians In British Columbia

CEO SUMMARY: In British Columbia, two commercial laboratory competitors have found common ground. BC Biomedical Laboratories and MDS Metro Laboratories are using LOINC to link their laboratory test databases. Physicians use a single system to access their patient's test results, regardless of which lab performed the test. Coming enhancements to the system include wireless access to patient test data in emergency rooms, enriched reporting, two-way order entry, and treatment ordering algorithms. The first of several hospital laboratories is now participating in this system.

EDITOR'S NOTE: This is the second of a two-part feature on how pioneering laboratory organizations are using LOINC (Logical Observation Identifier Names and Codes) to standardize laboratory test data on a major scale.

BY JUNE SMART, PH.D.

WITHIN GEOGRAPHICAL REGIONS, integrated clinical healthcare requires easy and quick access to laboratory test results, regardless of how many laboratories may have done testing for a particular patient.

Yet the ideal of a uniform capability for pooling laboratory test data across multiple lab organizations for the benefit of attending physicians is still just a dream and a wish for most laboratorians. That's because technological and organizational barriers continue to make it an extraordinarily difficult feat.

Lab Data "Tower of Babel"

In two regions, pioneering laboratories are tackling the lab data "Tower of Babel" problem with the goal of creating a standardized laboratory test result repository. Clinicians can retrieve and view standardized lab test data on their patients, regardless of whether different laboratories originally performed the laboratory tests.

Earlier this summer, THE DARK REPORT provided updated information about efforts within the United States Armed Forces health system to create a common lab test data repository that uses LOINC (Logical Observation Identifier Names and Codes) to eventually link laboratory test data generated by Army, Air Force, Navy, and Veterans' Administration laboratories throughout the world. *(See TDR, June 24, 2002.)*

An equally ambitious LOINC-based project is unfolding in the Canadian Province of British Columbia. Two competing commercial laboratory companies have joined forces to create a "one-stop" method of pooling all the lab test data generated by the province's independent laboratories and hospitals.

Douglas Buchanan, Managing Director and CEO of **BC Biomedical Laboratories**, Surrey, British Columbia and John Rayson, MD, CEO and Vice Chairman of **MDS Metro Laboratory Services**, Vancouver, British Columbia (owned by **MDS Inc.**) formed a joint venture called PathNET to provide seamless transfer of information from their lab facilities to physicians' offices throughout British Columbia.

Together, these two labs perform 70% of the laboratory tests ordered by physicians' offices in the province. As politicians discussed reforms to British Columbia's single-payer health system in the mid-1990s, the two labs recognized that it was an auspicious time to collaborate and demonstrate that the private sector could innovate in ways that improved patient care in a cost-effective manner. "Both lab companies had a common vision: to deliver laboratory results to all BC physicians in a seamless manner, regardless of which lab or hospital the patient visited," explained Buchanan and Rayson.

Uniform Lab Data Standards

"In 1998, BC's Ministry of Health formed the HealthNet/BC Project to improve the way healthcare data was collected, stored, and accessed," noted Buchanan. "The Lab Test Standard Task Group was part of this project. It included representatives from HealthNet/BC working groups, the BC Health Information Standards Council, and private and public sector labs.

"It was that task group that originally brought our two laboratories together," recalled Buchanan. "Because our two labs provide more than half of the laboratory work in the province, we could each see that, if we collaborated successfully, we could improve clinician's access to lab test data in a meaningful way, on a province-wide basis."

Efforts in U.S. to Develop Health Info Standards

BRITISH COLUMBIA and other Canadian provinces are not alone in their work to develop common healthcare information technology standards.

Similar efforts are under way in the United States. The **National Alliance for Health Information Technology** (NAHIT) has 30 participating organizations. It's first goal is for voluntary bar code standards on all medication and biological packaging, then all medical surgical supply packaging.

Other priorities include standards for connectivity and network communications, computerized order entry and medication administration, electronic medical records, universal identifiers, and nomenclature. This is the second effort to achieve consensus on health care information technology standards.

Another related initiative has been funded with $2 million from the **Markle Foundation**, based in New York City. Called "Connecting for Health," it will convene meetings of various healthcare interests during the next nine months to identify and develop standards for healthcare information which also meet privacy requirements. The consortium intends to build upon existing standards, such as HL-7 and LOINC.

BC Biomedical and MDS Metro decided to create a stand-alone joint venture to develop and provide this service. Called PathNET, it is a 50/50 partnership between the two lab companies and was organized to develop patient-centered diagnostic reporting.

"The province's Lab Test Standard (LTS) defines the business and technical requirements for the electronic exchange of lab test data in BC, including a unique patient identifier," said Buchanan. "The LTS includes all information exchanges from the time an order is issued until the time when a final result is achieved. Effectively, LTS allows our labs to develop PathNET with the confidence that all providers in the province will have the common capability to access and view the lab test data in our repositories."

This province-wide capability may lead PathNET to some further opportunities. As PathNET is built to BC's lab test standards, it is positioned to participate with other agencies working to develop a pan-Canadian electronic health record.

Province-Wide Standards

In tackling a province-wide lab test data repository, the two laboratory competitors were helped by the fact that the province developed and defined the key components of the health information management plan. Included were 1) an integrated record of health services received by an individual over time (regardless of the source of the service); 2) a common information repository to enable health planning, evaluation and research activity; 3) a common data format and processes to ensure consistency of similar health activities across BC (e.g., consistent demographic, eligibility and enrollment information); 4) a common information-sharing network to ensure the ability to exchange health information; and 5) standards, policies, and practices necessary to ensure privacy and confidentiality concerns.

"PathNET became feasible because the province was supporting this common vision of healthcare informatics," commented Buchanan. "Strategically, each of our labs had certain information technologies already in place. Our challenge was to develop the software necessary to pull lab test data from each of our laboratory systems and allow clinicians to communicate with our lab test data repository."

Trust was an issue as the two lab competitors developed the business strategy for PathNET. "Shared vision is the key to our relationship," declared Rayson. "This is an unusual joint venture between rivals. One partner, BC Biomedical, is wholly owned by 41 pathologists. The other, MDS Metro, is a publicly-held company.

Advantage By Partnering

"Given the evolution of healthcare in British Columbia, there was competitive advantage in partnering," he added. "PathNET's leadership group used our shared vision to create a viable business plan. To foster trust, the board consists of three people from each lab and meets on a monthly basis to make sure we remain on the right track."

In tackling a province-wide lab test data repository, the two laboratory competitors faced some interesting challenges. Not the least was money. "Development costs were almost C$2 million," commented Buchanan and Rayson. "Both our labs consider this an ongoing investment. It requires a total of about C$500,000 per year to sustain PathNET. As other laboratories join the PathNET venture, they will share in the costs."

"However, PathNET is not a business play, it is part of our strategic plan; to put the patient information in the right place at the right time," emphasized Buchanan.

Low-Bandwidth Solution

PathNET is built on a virtual private network (VPN) platform using Web technology funneled through the Internet. By intention, the system is simple. "Nicholas Szirth (CIO at BC Biomedical) and Stephan Meuller (system architect) lead our development team. They recognized that most physicians are not computer-savvy. Their computer systems still use dial-up modems and often run on Windows 95," said Buchanan. "Szirth and Mueller built a low bandwidth solution. It provides clinicians with a 2-second response time at 56K to view or print patient results.

"Both labs contributed labor to the PathNET venture," Rayson stated. "We had a mixed group of staff from each lab working together over a period of four years. As many as 35-40 people at different times worked on getting PathNET up and running. In addition, senior staff contributed considerable time to the project."

One lesson learned is the importance of having medical technologists involved in the LOINC coding. "In our lab, Judi Morgan was central to the system for compliance of coding. Our project managers all have lab backgrounds," noted Buchanan.

Must Work Immediately

Rayson and Buchanan also knew that they had to make PathNET work the first time it was offered to clinicians. "In the laboratory business it is difficult to make a comeback if the initial rollout fails," observed Buchanan. "Physicians are critical thinkers. They have low tolerance for any product or service that fails to deliver as promised."

PathNET has ambitious launch plans. By April of this year, it had introduced PathNET to 2,000 physicians. This number will increase to 3,000 physicians by the end of August 2002. "Our next goal is 4,000 physicians by August 2003," added Buchanan. "At that time, almost 80% of physicians in BC will have access to lab test results through PathNET.

"To accomplish this goal, PathNET appointed Lindsay Allan as its first General Manager in June 2001," continued Buchanan. "This gave Lindsay just nine months to prepare an aggressive rollout of PathNET to 2,000 physicians."

In using LOINC to link lab test data across multiple laboratory sites, PathNET shared a common challenge with the U.S. Armed Forces' laboratory LOINC project. "Assigning LOINC codes to routine chemistry and hematology tests is much less difficult than assigning microbiology and anatomic pathology (AP) codes," declared Buchanan. "Coding micro and AP is significantly more complex.

"In particular, anatomic pathology is highly textural and varies widely. Each pathologist has individual preferences in the formatting and style of reports. We are working on a mixture of LOINC and SNOMED for AP. To tell us whether we are on the right track, we are doing a pilot project with **Surrey Memorial Hospital**. Working with the public sector takes a long time, as it is difficult for them to find funding and technology."

Marketing PathNET

Marketing PathNET to physicians was another challenge. "Our strategy was to have the product sell itself," Buchanan said. "It must add value to physicians. It is also easy for both technical and non-technical staff to use.

"Currently we offer test reporting, cumulative charting based on the historical data and an HL7 interface to the **Clinicare** and **Wolf Medical** patient management systems," he added. "PathNet also supports an interface with **McKeever**, for MacIntosh PCs."

"By the end of September we plan to provide service in five emergency rooms, two of which are on a wireless basis," noted Buchanan. "Using a flat panel monitor, physicians will tap in the patient's unique identifier to obtain any data in the PathNET system. This is a practical example where a life-saving use of data intersects with privacy concerns, but we are resolving that barrier in consultation with the province's Privacy Commissioner."

Prior to PathNET, both MDS Metro and BC BioMedical used **Medinet** for the electronic reporting of lab test results to physician clients. But Medinet was not Internet-capable. "When PathNET was ready to launch, we notified clients that Medinet was to be retired in favor of a significantly better service," explained Buchanan. "This is one reason why some clients converted so rapidly.

Docs Saw Immediate Value

"At BC Biomedical Laboratories, we loaded six months of historical lab data in the PathNET system," he explained. "Right away physicians could see added value.

"In the next phase of PathNET's market roll-out, we are developing graphics, two-way order entry, and results forwarding with note attachment for consultations," observed Buchanan. "We are also excited about two added value features: treatment ordering logarithms and logic links to artificial intelligence. These could assist the physician in ordering the appropriate test based on the patient's symptoms.

"To add functionality to PathNET, we are experimenting with an 80211b wireless system and flat panels to transmit AP or slide confirmations to physicians. This equipment configuration provides better resolution and system access throughout a facility. All these features are under development."

PathNET's Shared Costs

PathNET's laboratory owners bear the cost of the service. "Our two labs currently split the cost of PathNET, which currently has 14 FTEs," said Buchanan. "The cost of each patient encounter is C42¢, regardless of the number of tests, number of locations that the result is sent to, or number of times the encounter is accessed.

"We consider this a bargain, since our laboratories no longer have to pay

Competing Labs Learn Interesting Lessons From LOINC Mapping

SEVERAL RELEVANT MANAGEMENT LESSONS emerged from the experience of BC Biomedical Laboratories and MDS Metro Laboratory Services in mapping their labs' test catalogs to LOINC.

IT Vendor Support

"One critical component for PathNET is the Internet service provider (ISP). **Telus** is the major ISP for BC and they helped us make this possible. On the other hand, PathNET's use of new technology has stretched the ability of our LIS technology business partners to support it." —*Buchanan*

Physician Use of PathNet

"Physicians use a two-button system: they view results and print a copy. PathNET acts as their storage vault. At any time, physicians can access cumulative reporting and historical patterns of their patients' health. Most only use the 2-button approach and do little else with the system." —*Rayson*

Standardization

"It's essential that participating labs agree to use a standard approach. It is ideal to work with the payers in development of the standards, as there is instant credibility with the end result." —*Buchanan*

Functionality

"Technology must be robust, 'thin client,' and provide true functionality—not lots of bells and whistles. Physicians still want hard copy and do not want their workflow changed. Your solution must fit with their work patterns and allow them to evolve technically." —*Rayson*

Government Issues

"There are always concerns about privacy and how clinical data is shared. The public and private sector lab relationship is slow to develop, but there is now some recognition of the value of the product, cost and efficiency." —*Buchanan*

for printing reports, then sorting, faxing, and delivering them," he added. "We see net savings in shifting to this type of lab test reporting system.

"To further drive down costs, we are enlisting more labs to become part of PathNET," declared Buchanan. "We are also negotiating with several hospitals to have them join us and make their lab test results available through the PathNET repository."

St. Mary's Hospital, New Westminster, is the first hospital to join PathNET. "St. Mary's now uses PathNET to deliver lab test results," said Rayson. "It performs numerous outpatient surgeries throughout the province. We anticipate that more than 1,000 doctors will benefit from access to PathNet. The contract is priced for 80 to 100 patients a day. There is great potential for improved patient care and much better utilization management."

Marketing Team Beefed Up

To sustain momentum in launching PathNET to physicians, Buchanan and Rayson decided to beef up the marketing effort. "We provided opportunities for couriers, phlebotomists and MTs to become part of the marketing team," noted Buchanan. "Some have a natural sales ability, others are technical and good with installing software and taking care of clients' needs.

"They work in teams of two: one with the technical competence on the computer side and the other with technical competence in laboratory medicine," he explained. "In opening these jobs to all laboratory staff we saw

many people blossom in their new role. This is a great morale-booster for each lab and the PathNET staff."

One unexpected consequence of the PathNET joint venture between two lab competitors is their mutual interest in going to higher levels of collaboration. Rayson and Buchanan are both enthusiastic about the future. "We see the opportunity to become the early adopter and provider of digital information in BC," stated Rayson.

PathNet Is improving patient care even as it reduces lab costs associated with reporting test results to physicians.

Data mining is a potential and obvious opportunity with PathNET, but Buchanan notes that several privacy issues in Canada remain unresolved. "The government is likely to err on the cautious side and look closely at invasion of privacy," he predicted "From the public health point of view, CDC would like to access to this type of data. But the data will be made anonymous and so be limited to research purposes."

Demand For New Services

PathNET is a reminder that the changing healthcare marketplace wants new services and solutions from clinical laboratories and pathology group practices. Both Canada and the United States underwent widespread consolidation of clinical services during the 1990s. One basic goal of consolidation was to integrate clinical care in ways that would improve the quality of care while eliminating or reducing redundant and unnecessary costs.

PathNET is a direct consequence of this healthcare consolidation trend. It represents two laboratory competitors working together to provide integrated access to lab test data by physicians throughout British Columbia. In the process, PathNET is improving patient care even as it reduces lab costs associated with reporting test results to physicians.

Benefits From PathNET

From this perspective, PathNET is a double win. It's good for physicians and it's good for the two lab competitors who invested considerable time and money in PathNET.

THE DARK REPORT sees LOINC as a step in the evolutionary process of laboratory standardization, which is likely to become mandatory in Canada during the next five to ten years and may encourage a similar directive from the Medicare and Medicaid programs here in the United States.

Because laboratory test data is an important part of the digital health record for individual patients, any effort to create regional repositories of healthcare data will require a response from laboratories serving that region. The early efforts and successes of PathNET in British Columbia and the U.S. Military's Global Laboratory Interoperability Project (G-LIT), built upon using LOINC to map results across multiple lab sites, provide early evidence that it is possible to pool laboratory test data in ways that are useful to clinicians.

LOINC can also be viewed as part of the healthcare quality movement gathering momentum in the United States. Effective use of LOINC across different laboratories doing tests on the same patient can help doctors reduce errors attributable to interpreting test results. It can also lead to lower costs through improved utilization of lab tests. TDR

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Lab Industry Briefs

QUEST DOES DEAL WITH CVS DRUGSTORES FOR LAB TESTING

PATHOLOGISTS CONCERNED about pharmacists moving into the lab testing arena should closely watch the newly-announced relationship between **Quest Diagnostics Incorporated** and **CVS Corporation**.

Starting this month, CVS pharmacies in Columbus, Ohio and Tampa/St. Petersburg, Florida now sell lab tests. Participating pharmacies have a card display for 12 different types of laboratory tests. The customer purchases the card, then goes to one of Quest's patient service centers to have blood drawn.

Quest Diagnostics will perform the test at one of its regional laboratories. Results can either be accessed on-line within 48 hours, or mailed directly to the patient within a week. This program involves 80 CVS pharmacies in two states which permit direct patient access to ordering and receiving laboratory test results.

It should be no surprise that CVS, which operates 4,191 pharmacies in 33 states, wants to evaluate consumer demand for laboratory testing offered through its stores. Many pharmacists are keenly interested in exploring how diagnostic testing can be incorporated into a retail pharmacy operation.

Pharmacists understand that the rapidly-evolving field of pharmacogenomics will soon deliver an ever-growing number of prescription drugs that require a diagnostic test before the prescription can be filled. The lab test will determine if the patient will respond favorably to the therapy and whether an individual patient may have negative side effects to that particular drug.

An early example of this pharmacogenomics model is breast cancer. Before a patient gets Herceptin therapy, she undergoes a test for the her2neu mutation. It is this concept of the diagnostic test married to a prescription drug that has caught the attention of forward-looking pharmacists.

Pharmacogenomics is one reason why bills that would allow drug stores to perform laboratory tests have been introduced into a number of state legislatures in recent years. The pharmacy industry wants to position itself to benefit from the coming need for lab tests to be done before a prescription is filled.

Plenty will be written in the laboratory press about the Quest/CVS deal. But it is important for pathologists to recognize that pharmacy involvement in laboratory testing represents both a threat and an opportunity. It will require active leadership by the pathology profession to insure that it is the opportunity side which prevails.

CONGRESS PRESSURES TWO MAJOR GPOS TO MAKE MAJOR CHANGES

TWO OF THE NATION'S BIGGEST group purchasing organizations (GPOs) are bending under pressure from the Senate Judiciary Committee's antitrust subcommittee.

Earlier this month, **Premier, Inc.** and **Novation**, facing serious criticisms of their business practices, individually agreed to change the way they operate. Lab directors and pathologists can expect to see several key differences in how these two GPOs negotiate contracts with diagnostics manufacturing companies.

Among the nation's largest GPOs, Premier and Novation were singled out

for the most criticism by a tag team consisting of the *New York Times* and the Senate's antitrust subcommittee.

This winter, the *New York Times* wrote several in-depth articles about how the business practices of the GPO industry held back innovation, favored large medical device manufacturers at the expense of smaller companies, and didn't always deliver the lowest prices to their hospital members.

During hearings in the Senate this spring, Senator Herb Kohl (D-Wisconsin) identified three areas of concern. Conflicts of interest was the first concern, as both Premier and Novant tie some contracts to participation in arrangements where executives of the GPOs hold a financial stake.

Second is the concern that contracting practices of GPOs stifle competition and impede innovation. Sole source contracts and high commitment levels restrict the physician's ability to choose the best products for his patient.

Third, GPOs "don't always get the best deal." Many laboratorians would concur, since their hospital laboratory frequently negotiates a lower price on its purchase than that offered under the GPO's national contract.

Premier's agreement specifies that "contracts for physician preference items will be made on a multi-source, unbundled, no commitment-level basis;" vendor payments to the GPO will be capped at 3% per year; products from different vendors will not be bundled; and contract terms will be limited to three years to the maximum extent possible.

Days later, Novation agreed to a similar range of reforms. Among other things, it "will not award sole source contracts for clinical preference items when alternative products exist that offer patient care or safety benefits; a commitment to reduce administrative fees that exceed 3% to the 3% level; no bundling of clinical preference items with commodities or other unrelated clinical preference items; no commitment requirements to be a member of the GPO or gain a base level discount; and, contract terms will be limited to three years.

There may be more to this story. The HHS Inspector General has subpoenaed Premier in a probe on executive compensation. The Federal Trade Commission (FTC) and the General Accounting Office (GAO) are also investigating Premier and Novation to determine whether the business practices of these GPOs have limited competition in the hospital supply industry.

LUMINEX AND CARESIDE FIND TOUGH GOING IN THE MARKETPLACE

HERE'S AN UPDATE on two companies which have promising technology, but are definitely ahead of the market.

Luminex Corporation, based in Austin, Texas, announced the resignation of Mark B. Chandler, Ph.D., company founder, Chairman, and CEO. Thomas W. Erickson will be interim CEO. Luminex offers a multiplex bioassay technology which is capable of performing 100 tests on a single specimen. Revenues are lagging because its licensees have not developed applications as fast as projected.

Meanwhile, **Careside, Inc.** of Culver City, California still has its CEO, but recently underwent a major downsizing. It laid off a sizeable number of its employees and outsourced the manufacture of its instruments, designed to do routine chemistry and hematology at the point-of-care (POC).

Careside's strategy was to sell its POC system to physicians' offices. One observer speculates that Careside's sales are slow because lab test reimbursement is so low in California, physicians can't make much money performing routine lab tests in their office. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's a fact of significance. *Economy.com* reports that, in 2001, revenues from fixed-line telephone service declined for the first time in decades. Analysts say that consumers and businesses are shifting spending to wireless telephones. It is confirmation that our economy continues to move toward a wireless, Internet-based information society. Labs and pathology groups should be preparing their organization to connect with providers, payers, and patients through these new electronic gateways.

UNILAB REPORTS ON SECOND QUARTER

While **Unilab Corporation** waits for the results of the **Federal Trade Commission's** (FTC) antitrust review of its acquisition by **Quest Diagnostics Incorporated**, it continues to push in the California marketplace. Second quarter revenues were up 10.4% over the same quarter last year. Specimen volume accounted for 5.9% of this increase, while revenue per requisition grew by 4.2%.

WILL LAB RATS YIELD TO ZEBRA FISH FOR GENETIC STUDIES?

Researchers looking to speed up genetics research are discovering the benefits of zebra fish. They breed with ease. They are easy to maintain. The embryos grow outside the body, giving researchers ready access. Best of all, zebra fish embryos are transparent, allowing scientists to watch them develop. In recent years, the **National Institute of Health** (NIH) has supported a variety of projects to map the zebra fish genome and develop appropriate strains for research. Go to *www.zfin.org* for more info. Maybe that beloved and long-standing epithet—lab rat—will give way to a new one: lab fish!

ADD TO: Zebra Fish

Zebra fish are not the only finny denizen of the deep yielding genetic secrets. Scientists have sequenced the genome of the pufferfish, called Fugu in Japan. It is believed to have the smallest genome of all vertebrates. Pufferfish have about 30,000 genes, similar to the number in humans. But it has only one-eighth the DNA as humans. Gene-mappers at the **Joint Genome Institute** in Walnut Creek, California compared the pufferfish genome, which lacks the DNA "junk" of other animals, with the human genome. They identified 1,000 genes in the fish that appear to be nearly identical with previously unidentified human genes.

One of **American Medical Laboratories'** (AML) executive team members is heading to a new company. John R. Hadden, who was the Senior V.P., National Business Development Group at AML, is heading to Clearwater, Florida. He's accepted the position of CEO at **VitalLabs, Inc.**, a newly-organized public lab company. *(See TDR, July 15, 2002.)*

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 16, 2002.

THE DARK REPORT

UPCOMING...

- ***Genetic-Based Wellness Testing: Great Smokies Lab Tackles A New Market Niche.***
- ***East Coast Hospital Hits Lab Outreach Home Run.***
- ***Pathology Moves to Molecular Testing: A Look At Early-Adopter Path Group Practices***

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