Volume XII, Number 9 Monday, June 20, 2005

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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

Judicial Earthquake Shakes Canada's Health System

IT'S BEEN CALLED A "BOMBSHELL SUPREME COURT RULING" by no less than the *Wall Street Journal*. On June 9, 2005, the Supreme Court of Canada ruled that the province of Quebec cannot prevent individuals from purchasing private health insurance policies for healthcare procedures covered under the Canadian health plan, called medicare.

The case started in 1997 when Quebec resident George Zeliotis learned he would have to wait a full year for a hip replacement, despite his painful arthritic condition. His anger increased when he next learned that it was against the law for him to privately pay for his hip replacement. In collaboration with his physician, Jaques Chaoulli, the two filed a lawsuit. They had lost in two provincial courts before prevailing in the Supreme Court review of their case.

It is expected that this Canadian Supreme Court Ruling will open the door for private health insurance to be sold as an adjunct to the government health system. One consumer advocate noted that wait times are much shorter in many European countries where a private health system is allowed to operate alongside the government health system.

In an editorial, the *Wall Street Journal* observed that:

> The larger lesson here is that healthcare is not immune from the laws of economics. Politicians can't wave a wand and provide equal coverage for all merely by declaring medical care to be a 'right,' in the word that is currently popular on the American Left.
>
> There are only two ways to allocate any good or service: through prices, as is done in a market economy, or lines dictated by government, as in Canada's system. *The socialist claim is that a single-payer system is more equal than one based on prices* [our italics], but last week's court decision reveals that as an illusion. Or, to put it another way, Canadian healthcare is equal only in its shared scarcity.

Thoughtful lab executives and pathologists should consider these words as they watch political forces battle in Washington over both the design and funding of federal healthcare programs. Most health professionals I know recognize that the manner in which elected officials and bureaucrats handle the Medicare and Medicaid programs has done much to erode the quality of healthcare services in the United States during the past two decades. More market discipline in the U.S. healthcare system would be quite beneficial to physicians and patients alike. TDR

DOJ Sends Subpoenas To Quest & LabCorp

Unexpected development raises questions as to what lab business practice is of interest

CEO SUMMARY: In Newark, New Jersey, the Office of the U.S. Attorney served subpoenas to each of the two blood brothers, seeking information on "capitation and risk-sharing arrangements with government and private payers for the years 1993 through 1999." At this point, little is known or understood about the interest and motives of federal prosecutors in researching this aspect of laboratory business practices.

JUST A DAY APART, SUBPOENAS were issued to **Quest Diagnostics Incorporated** (on June 6) and **Laboratory Corporation of America** (on June 7) by the U.S. Attorney's office for the District of New Jersey.

Both subpoenas were for the same information. Each lab company issued a press release revealing that it had been asked to produce "business and financial records regarding capitation and risk sharing arrangements with government and private payers for the years 1993 through 1999." The words used to describe the subject of the U.S. Attorney's subpoena were identical in each lab firm's press release.

News that the two blood brothers had received subpoenas from the **Department of Justice** (DOJ) rippled throughout the laboratory industry. Lab executives and pathologists who lived through the federal "Lab Scam" prosecutions of the 1990s consider these subpoenas to be an ominous portent.

That's because these subpoenas have an uncanny resemblance to the prosecutorial patterns of "Lab Scam." In 1993, the Department of Justice sent subpoenas, almost simultaneously, to at least five of the nation's largest public laboratory companies. By that act, the DOJ sent a message that it was looking for industry-wide practices it suspected to be in violation of Medicare statutes.

And, just as these new subpoenas request the production of documents dating between six and 12 years ago, the 1993 wave of subpoenas requested

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

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documents that reached back five to six years earlier, into the late 1980s.

It will be some time before the exact motives of the U.S. Attorney in New Jersey become known. Federal officials cannot comment publicly about ongoing investigations. Meanwhile, officials at both Quest Diagnostics and LabCorp each said that the Department of Justice had stated that their company was not the target of an investigation.

No One's Talking...Yet

In the absence of specific facts, informed speculation can be useful. First, by the language used in the federal subpoena, it is clear that federal investigators want to look at the capitated pricing contracts that Quest Diagnostics and LabCorp have offered to both private payers and government health programs. It is probably a safe assumption that laboratories which have never engaged in capitated pricing arrangements would not be targets of this federal inquiry, if it were to expand beyond the two blood brothers.

Second, the interest in capitated contracts dating between 1993 and 1999 is interesting. Although this may be considered "ancient history" by those of us managing in 2005, these are the years when the use of capitation in laboratory testing contracts exploded. By looking at this six-year period, federal investigators will be able to see how this trend evolved.

Medicare HMO Enrollment

Third, THE DARK REPORT observes that 1993 to 1999 coincides with peak enrollment in Medicare managed care programs offered by private payers. If federal investigators are exploring a "usual and customary price" violation, then it would be logical for them to identify the capitated lab test pricing granted by these two lab companies to commercial HMOs and Medicare HMOs. It is even possible that lab test pricing for these Medicare HMO contracts, whether capitated or highly-discounted fee-for-service, might be compared to what these companies billed Medicare for lab tests done on behalf of Medicare beneficiaries under Part B fee-for-service during the same years.

The lab industry has never seen an enforcement action that involved violations of the Medicare "usual and customary" price statutes. However, during the course of the 1990s, Medicare's fee schedule became one of the "most generous" of all major payers. That means many providers are giving the nation's largest insurers a significantly lower price than they give Medicare. Because of this market evolution in pricing, federal healthcare investigators might have a new motive to review this situation. New guidelines on how to calculate "usual and customary" charges, coupled with enforcement action, could yield significant savings to the Medicare and Medicaid programs.

Warning Shot For Labs

At a minimum, these new subpoenas by a U.S. Attorney must be seen as a warning shot to the entire laboratory industry. Since federal investigators have limited resources, they tend to devote their time to issues which promise: 1) that the federal government will prevail if the case comes to court; and/or, 2) will generate a substantial economic benefit (return) for the effort expended on the investigation and subsequent prosecution of the case.

Of course, because these cases take many years to reach a conclusion, it is likely that we may have to wait another three to five years to learn if the fresh subpoenas served to Quest Diagnostics and LabCorp two weeks ago are a significant event for both companies and the entire laboratory industry. **TDR**

Contact Robert Michel at 512-264-7103.

Crime In the Lab Industry: A Poor Track Record

Since 1990, almost 20% of public lab firms had a CEO indicted or convicted of federal crimes

***CEO SUMMARY:** In a remarkable finding, THE DARK REPORT demonstrates how 17.5% of the public laboratory companies in operation since 1990 have had an existing or former CEO indicted for federal crimes! This is a powerful statement about business practices in the laboratory industry and the allure of "skirting" the full intent and meaning of federal laws governing the Medicare and Medicaid programs.*

By Robert L. Michel

IF NEW FEDERAL SUBPOENAS recently served to the two blood brothers eventually lead to a wave of significant civil settlements or even criminal indictments across the laboratory industry, no long-time laboratorian will be surprised.

But what will surprise and shock most lab managers and executives is a startling fact: Compared to most industries of the American economy, public laboratory companies have what may be possibly the highest rate of CEOs who have been indicted for federal crimes!

Since 1990, THE DARK REPORT can identify at least four CEOs of publicly-traded laboratory companies who have been indicted and/or convicted of federal crimes. What makes this statistic even more powerful is another fact: There have been only 23 public laboratory companies doing business since 1990. And just 16 of these could be considered "national/multi-regional," with the other seven classified as either regional or specialized, focused on drugs of abuse, for example.

Doing the math, it means that 25% of the public lab companies doing business nationally saw their CEO indicted for federal crimes! If the focus includes those public lab firms that were regional or specialty testing companies, the ratio is 17.5%.

There may be no other industry in America which has as poor a track record. By any standard, this is an appalling track record of corporate ethics. If the lab industry has a bad reputation with Congress and the Medicare program, it is not without cause.

Public Lab "Hall Of Shame"

The public laboratory industry hall of shame includes these indictments and convictions under Medicare Fraud and Abuse statutes:

• Robert E. Draper, former CEO of **National Health Laboratories, Inc.**, pled guilty to two felony counts and served prison time.

• Joseph Isola, former CEO of **Damon Clinical Laboratories, Inc.** pled *nolo contendere* and received a sentence of five years probation. (A former

Damon Vice President, Robert Thurston, was convicted of similar crimes and served prison time.)

Currently under federal indictment and awaiting trial are:

• William Hagstrom, former CEO of **UroCor, Inc.**, facing charges of violating Medicare anti-kickback and SEC statutes. (Also indicted are former UroCor Vice Presidents Mark Dimitroff and Michael MacDonald). *(See TDR, July 19, 2004.)*

• Anu Saad, Ph.D., former CEO of **IMPATH, Inc.**, facing multiple criminal counts under securities and fraud statutes. (Also indicted are former IMPATH President and COO Richard Adelson and four other former employees.) *(See TDR, April 18, 2005.)*

Attracting Federal Scrutiny

The number of public laboratory CEOs indicted for federal crimes jumped out at me as I fielded comments and responses from clients and subscribers following THE DARK REPORT's publication of a story titled "Why Is There Crime in the Lab Industry?" in its May 9, 2005 issue. Most respondents work in not-for-profit laboratory organizations and wanted to state their displeasure that such a large number of public laboratory companies seemed willing to push Medicare compliance far enough across the line to attract the attention of federal healthcare prosecutors.

Our story about the cumulative number of crimes in the public laboratory sector of the industry was in response to the mass indictments of former IMPATH executives, which the U.S. Attorney in New York City made public on March 30, 2005. Thus, the coincidence of new federal subpoenas issued to **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** on June 7 and 8 was eerie. Many veteran laboratory executives and pathologists have concerns that these subpoenas might represent the first steps in a new federal campaign to prosecute long-standing laboratory marketing and contracting practices.

Waiting For Direction

However, based on past experience with federal investigations and prosecutions, it may be two to five more years before any federal investigation reaches the stage where civil actions are commenced or criminal indictments are filed. Until then, laboratories will not fully understand if certain existing business practices may now be considered in violation of federal laws.

It also relevant to note that federal prosecutors have a track record of convictions in their criminal indictments of ex-public lab CEOs. In the two cases resolved, Draper pled guilty and Isola pled *nolo contendere*. At this point, Hagstrom and Saad have entered "not guilty" pleas and are preparing to go to trial. That means federal prosecutors still have the potential to gain convictions on 100% of the cases involving ex-public lab company CEOs.

Time To Improve Ethics?

For my part, the insight that the public company sector of our industry has a federal indictment rate as high as 25% for CEO-level leadership is both unexpected and confounding. It changes the perspective on laboratory compliance and the "unlevel playing field" about which lab managers in both public and not-for-profit laboratories constantly complain. Maybe this insight can trigger a debate within the laboratory industry which leads to a higher standard of ethics and fewer abuses of federal and state laws. TDR

Contact Robert Michel at labletter@aol.com.

NOTE: reader responses on this topic are welcome for publication.

Pondering Why Public Lab CEOs Are Often Hit With Federal Indictments

HERE IS A SUMMARY of publicly-traded laboratory companies which have operated since 1990, along with a list of ex-public lab company CEOs either indicted or convicted of federal crimes during the past 15 years.

The four CEOs who have been indicted represent 17.5% of all public laboratory companies since 1990. If the category is further refined to include those public laboratory companies which served a national or multi-regional market, then the four indicted CEOs represent 25% of that total.

More CEOs might have been indicted. In February 1997, when **SmithKline Beecham Clinical Labs** (SBCL) agreed to pay $325 million to settle allegations of Medicare Fraud and Abuse, THE DARK REPORT heard consistent, and never confirmed, rumors that one reason the SBCL settlement was so large was that it included a clause that no SBCL executive would face criminal charges in this case.

THE DARK REPORT believes this is the first time the laboratory industry has seen this type of analysis—comparing the number of former public laboratory CEOs indicted for federal crimes against the total number of publicly-traded laboratory companies that were in business at some point during the years 1990 through 2005.

Publicly-traded Laboratory Companies Since 1990

(Lab Firms considered national or multi-regional)

1. Quest Diagnostics Incorporated (formerly MetPath)
2. Laboratory Corp. of America (formerly Roche Biomedical Labs)
3. Lab*One*
4. Bio-Reference Laboratories
5. AmeriPath
6. Specialty Laboratories
7. Enzo Biochem
8. IMPATH (acquired by Genzyme)
9. Dynacare (acquired by LabCorp)
10. DIANON Systems (acquired by LabCorp)
11. UroCor (acquired by DIANON)
12. SmithKline Beecham Clinical Labs (acquired by Quest)
13. National Health Laboratories (acquired by LabCorp)
14. Nichols Institute (acquired by Quest)
14. Damon Clinical Laboratories (acquired by Quest
16. Allied Clinical Laboratories (acquired by LabCorp)

(Lab firms considered regional or specialty/niche testing)

17. MedTox (Drugs of Abuse)
18. Unilab (acquired by Quest)
19. Meris Labs (acquired by Unilab)
20. Universal Standard Med Labs (acquired by LabCorp)
21. Pharmchem (Drugs of Abuse–bankrupt)
22. Lab Specialists of America (Drugs of Abuse–acquired by Kroll O'Gara)

CEOs of Publicly-traded Lab Companies Indicted and/or Convicted Under Federal Statutes Since 1990

CEOs Indicted and Convicted Under Medicare Fraud & Abuse laws:

- Robert E. Draper, former CEO of **National Health Laboratories, Inc.**, pled guilty to two felony counts and served prison time.
- Joseph Isola, former CEO of **Damon Clinical Laboratories, Inc.,** pled *nolo contendere* and received a sentence of five years probation.

CEOs Currently Under Federal Indictment and Awaiting Trial:

- William Hagstrom, former CEO of **UroCor, Inc.**, charged with violations of Medicare anti-kickback and SEC statutes.
- Anu Saad, Ph.D., former CEO of **IMPATH, Inc.**, charged with violations of securities and fraud statutes.

Compliance Update

National HIPAA Conference Overlooks Patient ID Theft

IN APRIL, SEVERAL THOUSAND PRIVACY OFFICERS and HIPAA compliance officers gathered in New Orleans for the **Health Care Compliance Association's** (HCCA) "2005 Compliance Institute."

THE DARK REPORT was in attendance to learn about new issues and concerns for provider compliance with HIPAA (Health Insurance and Accountability Act). There was one notable observation.

Collectively, the healthcare compliance establishment has yet to recognize patient identity theft as the growing threat that it is to labs, hospitals, physician group practices, and other types of healthcare providers. Over the three days of the event, there were no presentations specifically about patient ID theft, but a few speakers included comments about patient ID theft in their speeches.

Conference speaker, attorney Paul Litwak, an expert on information risk management and HIPAA compliance, observed that, "Providers must get out of the HIPAA box. While HIPAA compliance is important, the greater risk to patient and provider interests—and greater legal exposure thus far—has come from the improper accessing and use of personal patient information, such as social security numbers.

To date, there have been no civil penalties for HIPAA violations. But there are a growing number of liability claims based upon organizational failure to safeguard confidential information. "Providers must think risk management and avoid the trap of thinking that security is an IT problem," cautioned Litwak. "It is important to understand that information security is not a product that can be purchased. It is an ongoing risk management process. While security depends on IT, it is not an IT problem. In fact, the greatest single risk to providers comes from employees and contractors who have access to confidential information! For example, the **University of West Virginia** was ordered to pay $2.3 million after an employee disclosed confidential psychiatric records."

Risk From Employee Actions

Litwak's message was unmistakable. He is telling providers, including laboratories and pathology group practices, that their greatest vulnerability comes from failure to train and supervise employees who have access to confidential information.

This will require a different mindset by laboratory compliance officers. Work flow and access to information in labs and hospitals has been generally developed based on an assumption of employee trust that may no longer be valid. This is particularly true where sensitive patient data is handled, like patient service centers, couriers, data entry, billing/collections, and client services.

THE DARK REPORT has been first in the laboratory industry to identify the still-new threat of patient identity theft. Such early warning allows laboratories and pathology group practices to develop effective protections to prevent such crimes from occurring. TDR

—by Pamela Scherer McLeod

Patient ABNs Can Save On Expensive Send-outs

Detroit hospital lab develops a way to minimize budget-busting test costs

CEO SUMMARY: Throughout the United States, the growing number of high-priced, patent-protected specialty tests is eating into the laboratory budgets of many hospitals. At Hospital Consolidated Laboratories in Southfield, Michigan, this budget-busting threat triggered an innovative response. Now the lab uses ABNs to alert patients that they will be personally responsible to pay for such tests.

HIGH-PRICED, SPECIALTY ESOTERIC TESTS, marketed directly to physicians by niche laboratories, have become a significant problem for many hospital laboratory outreach programs.

"Such esoteric specialty tests and test panels are often expensive, with prices ranging from several hundred dollars to several thousand dollars," observed Gary Assarian, D.O., FCAP, Medical Director of Laboratories at **Hospital Consolidated Laboratories** (HCL) in Southfield, Michigan. "Not only are such tests quite expensive, but a significant portion of payers do not recognize these esoteric assays for reimbursement. For those payers that do, reimbursement is often pennies on the dollar.

"Consequently, when physicians order these tests, it puts hospital-based laboratories like ours in a financial black hole," he noted. "We can't get adequate reimbursement from the payers, even as the specialty laboratory presents a bill to us for the full amount of their 'retail' price for the test.

"What adds to the aggravation is that, because these specialty testing companies often by-pass our pathologists and our laboratory in marketing these tests to physicians in our community, we've not had the opportunity to determine what diagnostic technology supports these assays and assess the clinical utility such tests actually offer the referring physician," he said.

Budget-Busting Lab Tests

"Like other hospital laboratories across the country, we must then deal with the consequences of this marketing approach," added Assarian. "Physicians detailed in their office about these tests begin to order them, without prior notice or discussion with our pathologists."

At Hospital Consolidated Laboratories, these specialty test companies were disrupting the laboratory budget—both in the HCL lab outreach program and with inpatient testing. Assarian explained the details. "HCL's outreach program is part of **Joint Venture Hospital Laboratories** (JVHL), the regional lab network here in Michigan. JVHL

text continues on page 11

Using ABNs to Control the High Costs of Expensive Proprietary Specialty Tests

HOSPITAL CONSOLIDATED LABORATORIES
23775 Northwestern Hwy.
Southfield, MI 48075

PROMETHEUS® ADVANCE BENEFICIARY NOTICE (ABN) CONSENT FORM

- I understand that my physician and I deem it necessary to my medical treatment to have this testing performed and the results of this testing will be sent directly to my physician
- **I understand that my insurance may cover all, part or none of the cost of this testing**
- I understand that the cost of the test(s), circled below, and I will be responsible for payment if my insurance does not cover

Circle Applicable Test(s):	
Test Description:	*Cost:*
IBD First Step Generation II	140.00
IBD Diagnostic System Generation II	445.00
Comprehensive Celiac Disease System	730.00
Celiac Disease Serology	290.00
PRO-Genologix Celiac Genetics (HLA DQ2/DQ8)	440.00
FIBROSpect Liver Fibrosis Test	350.00
PRO-GenoLogix Lactose Intolerance	296.00
RA Diagnostics Panel	484.00
PRO-Predict TPMT Genetics Assessment	395.00
PRO-Predict EnzAct	220.00
PRO-Predict Metablolites	270.00
PRO-Predict Serum Infliximab/HACA Measurement	225.00

Billing inquiries should be directed to Prometheus Laboratories at (888) 423-5227. By signing below I acknowledge that I assume responsibility for the payment of this/these test(s).

Print Patient Name: _____ SSN: ___-___-____

Patient Signature: _____ Date: _____

Phone Number: (___)_____

HCL Employee Signature: _____

For Laboratory Use Only:
- *Provide duplicate copy of the signed ABN form as a patient receipt*
- *Attach this ABN form to the original Prometheus Laboratories request form*

WHAT ARE THE IMPORTANT STEPS?

- Identify which tests are appropriate for an "ABN arrangement."
- Negotiate an arrangement with the test provider that allows your laboratory to be paid a fee for specimen collection, for prepping, and sending the specimen to the lab company.
- Prepare an appropriate ABN to cover the tests involved in this arrangement.
- Visit client-physicians and provide in-office education to explain the new agreement and how to use the ABNs with patients.
- Train all phlebotomists and in-house service staff on the new arrangement and how to work with patients, physicians, and the staff in physicians' offices.

HOSPITAL CONSOLIDATED LABORATORIES
23775 Northwestern Hwy.
Southfield, MI 48075

NMR LIPOPROFILE® ADVANCE BENEFICIARY NOTICE (ABN) CONSENT FORM

- I understand that my physician and I deem it necessary to my medical treatment to have this testing performed and the results of this testing will be sent directly to my physician
- **I understand that my insurance may cover all, part or none of the cost of this testing**
- I understand that the cost of this test is $150 and I will be responsible for payment if my insurance does not cover
- All insurance billing procedures will be handled directly by:
  LipoScience
  2500 Summer Blvd.
  Raleigh, NC 27616

For patient assistance and questions, please call LipoScience toll free at 866-547-0245 from 8:30am-5:30pm Eastern Standard Time.

- Results of this testing will be sent directly to my doctor from LipoScience

By signing below I acknowledge that I assume responsibility for the payment of this test.

Print Patient Name: _____ SSN: ___-___-____

Patient Signature: _____ Date: _____

Phone Number: (___)_____

HCL Employee Signature: _____

For Laboratory Use Only:
- *Provide duplicate copy of the signed ABN form as a patient receipt*
- *Attach this ABN form to the original NMR request form*

Here Are Actual ABNs Used by Health Consolidated Laboratories

MOST LABORATORIES ARE FAMILIAR WITH "ADVANCED BENEFICIARY NOTICES" (ABNs) used when the physician orders a test that is not covered by Medicare. Patients sign this form to acknowledge that Medicare does not reimburse for such tests and that they will be personally responsible to pay for the tests.

In recent years, Health Consolitated Laboratories (HCL) of Southfield, Michigan found itself stuck with the bill for a growing number of patient-protected or proprietary specialty tests either not covered by private payers or inadequately reimbursed. Medical Director Gary Assarian, D.O., F.C.A.P. recognized that a custom-tailored ABN could be a solution to the problem. By having the patient sign the ABN in advance, the fully-informed patient would become responsible for paying the specialty lab company for the test.

To assure a good working relationship with each specialty lab company offering such tests, HCL negotiated an arrangement that allows it be to paid for specimen collection, accessioning, and shipment.

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holds contracts with most of the major insurance plans in our region. Many of these plans reimburse under capitated arrangements, and those agreements don't carve out laboratory tests offered by specialty/niche test companies," noted Assarian.

The $2,000 Test Panel

"Obviously, when an outreach physician-client orders one of those $2,000 test panels from such a specialty/niche lab company, the added expense greatly exceeds our cap rate budget," he said. "Simply put, our laboratory loses a big chunk of money.

"For inpatient testing, the financial effect is just as devastating. The physician admits a patient, then orders a test panel costing several thousand dollars. It is likely that most payers won't reimburse at all for these types of tests," added Assarian. "If they do, the reimbursement is just a fraction of the niche test company's charges. So our lab's budget is blown apart when such inpatient test orders hit the laboratory.

Outreach And Inpatient

"In both the outreach and inpatient segments of our business, these specialty/niche test companies represent a threat to the fiscal solvency of our laboratory," he declared. "This is independent of whether or not the tests in question provide useful clinical value. There are ongoing debates within the laboratory profession about the clinical utility versus high cost of these patent-protected or proprietary tests and test panels.

"Moreover, the number of these types of companies—and the tests they offer—only increases each year," he observed. "As sales reps for new companies make the rounds in our community, we begin to see our physician-clients ordering these tests.

"In our laboratory, we believe the phenomenon of the patent-protected or proprietary specialty test is now firmly established in the laboratory services marketplace. This business model is working for those specialty/niche lab test companies. Because it will not go away, we decided to develop strategies to cope with the situation," stated Assarian.

"The solution we came up with was to remove HCL from the physician–patient–specialty/niche laboratory loop," he said. "It is a simple strategy. HCL's physician-clients, whenever they want to order one of these tests, have the patient sign an advance beneficiary notice (ABN) tailored specifically to the tests being ordered.

"In our laboratory, we believe the phenomenon of the patent-protected or proprietary specialty test is now firmly established in the laboratory services marketplace."

"This makes the patient financially responsible for payment, not our laboratory," noted Assarian. "Next, our laboratory simply acts as a collection and transportation service to the specialty/niche test company. We deliver the specimen to that company, which has full responsibility to perform the test, report the results, bill for the service, and collect from the payer and/or patient."

Both the physician and the specialty/niche test company understand that HCL has no other role to play. HCL is paid by the specialty/niche test company for collection and transportation services. "This has made a big difference. Prior to implementing this strategy about 24 months ago, we had monthly bills for these types of tests, which reached as high as $1,000. That has been whittled way down. We are now at zero billings for this book of business for the last fiscal year. Savings from this source are

compounded even more because that burden was increasing rapidly. I have heard these types of billings total as much as $4,000 per month at other labs," stated Assarian.

HCL did need to do some upfront work to implement this new business strategy. "We contacted each of these companies and met with them. We told them that the existing situation was unacceptable," explained Assarian. "We made our business case. The company would need to cooperate with the ABN procedure, pay us for collection, logistics, and handling expenses, and take responsibility for the laboratory test order. If not, HCL would naturally protect its financial interests and discourage physicians in the community from ordering such tests.

"Many of these specialty/niche testing companies immediately understood our proposal," continued Assarian. "They cooperated in briefing physicians about the new billing and service arrangements with HCL. They also helped us establish these new protocols.

"As I mentioned, the effect of this strategy was to greatly reduce our lab's financial exposure to the unreimburseable high costs of such tests. Physicians and patients, once the reasons for this arrangement were explained, have generally been supportive." he stated.

A Win-Win Arrangement

"I would not be out of order to say that this policy is proving to be win-win for all the involved parties," he added. "We have a working relationship with the specialty/niche test company and physicians and patients can make their own decisions about the clinical value of the tests, relative to what it will cost the patient."

THE DARK REPORT believes that Assarian and Hospital Consolidated Laboratories have developed a clever and effective way to convert a threat into a collaborative opportunity. HCL's unorthodox use of Advance Beneficiary Notices is a deft solution to a financial threat which is growing in laboratories across the nation.

It is noteworthy that, in the time since HCL implemented this policy with several specialty testing lab companies, it has not experienced a significant number of complaints by either patients or physicians. From the physicians' perspective, it helps forestall complaints by their patients that their insurance did not cover nor adequately reimburse for the test. Further, these are specialty tests which the physician does want to order. The introduction of an ABN into the physician/patient relationship doesn't seem to be a problem.

Paying More for Healthcare

Looking at the patient acceptance of this arrangement, it may be an early sign that consumers are resigned to the fact that they will be paying more out-of-pocket for their healthcare. As informed customers, they want the benefits of the specialty lab test and are thus amenable to paying for such tests.

It is also worth adding that these same consumers will pay, without question, several hundred or several thousand dollars to the veterinarian when their dog or cat needs treatment. HCL's use of lab testing ABNs for high-priced tests may be an early market sign that the expectations of consumers are changing. They are accepting the fact that the days when their health insurance benefits plan pays literally everything for every ailment are ending.

For the laboratory industry, HCL's use of ABNs to address the laboratory's unlimited financial exposure to growing utilization of high-priced specialty tests is a reminder that there are solutions to such new market developments. It is a noteworthy example of creative management thinking. TDR

Contact Gary Assarian, D.O, FCAP at 248-358-4510.

Coding Update

Problems with ICD-9 Codes Contribute to Coder Shortage

Slow progress toward U.S. adoption of ICD-10, More providers are outsourcing coding

ALTHOUGH ICD-9 IS CONSIDERED inadequate to effectively meet the needs of today's healthcare system, a number of hurdles prevent implementation of the proposed ICD-10 codes.

Of equal significance is another problem intertwined with the inadequate ICD-9 coding system: a nationwide shortage of coders. A 2001 survey by the **American Hospital Association** revealed an 18% vacancy rate for coder positions, compared to an 11% vacancy rate for nursing.

"The task of keeping up with rapid—and often illogical—changes to ICD-9CM while navigating often-inconsistent reporting rules has become so onerous, and the scrutiny on coded data so intense, that many qualifed coders have left the field," observed Rita Scichilone, Director of Coding Products and Services at the **American Health Information Management Association** (AHIMA) in Chicago, Illinois.

Tracking The ICD-10 Story

Some pathologists and laboratory directors have been tracking efforts to convert to ICD-10. But overall, this story has received little mention in the lab industry trade press, despite the implications of final conversion to the ICD-10 system.

The replacement system to ICD-9-CM is ICD-10-CM and a related procedure classification, ICD-10-PCS. In 1994, the **World Health Organization** adopted ICD-10 and this system is now in use in Europe. Unlike ICD-9, which is built on a five-digit numeric code structure, ICD-10 has a seven-character code length. This expanded structure is designed to accommodate new procedures and new technologies for many years into the future.

The United States is probably two years away from launching implementation of ICD-10. Meanwhile, to cope with the shortage of qualified coders, a growing number of providers are turning to outsourcing as a solution. Within this country, providers are establishing off-site coding centers. However, the more interesting development is the increased use of off-shore contractors to handle coding.

As well, a number of information technology companies are developing automated coding products. There is even research into ways to map codes to standardized medical nomenclature, such as SNOMED-CT.

Lab managers and pathologists should begin to track progress on the implementation of ICD-10 codes within the United States. The time is approaching when all healthcare providers, including laboratories, will need to devote management time and resources to the issue of ICD-10 and decide how to best introduce it into their own organizations. TDR

Unique Solution to Control Reagents, Other Supplies

Innovative use of pharmacy automation to store and manage laboratory reagents

CEO SUMMARY: *This San Francisco hospital laboratory hit a home run with its clever use of automated materials management units, originally used in pharmacies. Reagents, phlebotomy supplies, and other laboratory consumables are stored in an access-controlled environment. Benefits have been significant reduction in reagent and other lab supply costs, fewer stock-outs, and reduced loss from unused lab supplies with expired dates.*

MANAGING THE STORAGE and timely use of expensive reagents is an ongoing problem at many laboratories across the country. But the laboratory at **California Pacific Medical Center** (CPMC) in San Francisco has a unique answer to this longstanding problem.

"We now use **Pyxis®** automated materials management units [sold by **Cardinal Health**] to manage our reagents," revealed Jennifer Schiffgens, Director of Laboratory and Pathology Services at CPMC. "It's a solution that's made our staff happier and is generating significant cost savings within the lab."

The story of how Schiffgens cleverly recognized that an automated pharmacy storage system could also be used to store and control reagents is a great example of innovative laboratory management. "It started when I participated in a hospital-wide project using Pyxis to control office supplies. I was surprised at some unexpected benefits of the program," observed Schiffgens.

"Besides direct savings in better utilization of office supplies, use of the automated Pyxis system created a sense of accountability. I noticed that the staff automatically became much more aware of supply usage, waste and inventory control in general—things that weren't necessarily on their mental radar before.

"When I saw how effective the Pyxis was in improving management and usage of office supplies," continued Schiffgens, "I realized this could be a highly effective solution for reagent storage and management.

Managing Reagent Supply

"Like most labs, we faced the usual problem of maintaining optimum inventories. We also had a problem with disappearing reagents for rotorvirus, rapid microbiology testing, hCG qualitative kits, and vacutainer tubes. We had been searching for an effective mechanism to monitor usage," she observed. "Manual management of the supply chain tends to be inefficient. It's time-consuming and just too difficult to keep up with where things are."

What makes this story of even greater interest for other lab administrators and pathologists is how the hospital's purchasing department funded, from its budget, the purchase of the Pyxis systems used to store and manage reagents in Schiffgens' lab. This is especially notable, since it may be the first known use within the United States of an automated pharmacy system to store and manage laboratory reagents and supplies.

"My vice president knew I was very cost-conscious. And the timing was right," recalled Schiffgens. "A JCAHO (**Joint Commission on Accreditation of Healthcare Organizations**) inspection was soon to occur and the laboratory had some important issues it needed to resolve before the inspection.

Schiffgens sold her idea to use Pyxis systems by demonstrating that, not only would the automated storage program control supplies, it would also slash inventory costs by a significant amount.

"In particular, at this time we were having a consistent problem with expired tubes," Schiffgens explained. "We had outrageous costs associated with phlebotomy tubes that were expired or missing. We were motivated to find a solution. We had to make supplies accessible, but at the same time we needed a reliable way to account for them, even when managers were not there to directly supervise pulling inventory from stock."

Schiffgens sold her idea to use Pyxis systems by demonstrating that, not only would the automated storage program control supplies, it would also slash inventory costs by a significant amount. "More surprising was the discovery that use of Pyxis systems in the laboratory would cut purchasing department costs," commented Schiffgens. "In fact, we were able to identify enough cost savings within the purchasing department alone that purchasing volunteered to provide, from its budget, the capital required to acquire the Pyxis systems.

"It's an innovation which has been win-win for all stakeholders in the hospital and the laboratory," noted Schiffgens. "As we roll out, we're connected to the purchasing department through our **Lawson** system. Orders for resupply of laboratory products are now automatic."

The laboratory at CPMC is implementing the reagent/lab supply storage solution in phases. "In phase one, all our phlebotomy supplies, needles, etc. are now stored in Pyxis systems," she explained. "We will roll out phase two for dry reagents by the end of June. Phase three will entail monitoring systems for our refrigerated reagents.

Total of Eight Pyxis Units

"Currently we have three Pyxis units up and running, one each in hematology, microbiology, and chemistry," added Schiffgens. "Eventually, our laboratory will have a total of eight systems distributed across our three hospital campuses, Pacific, California and Davies.

"When we get to the phase three refrigerated units, we'll buy the Pyxis SupplyCenter™ monitoring system, rather than the refrigeration unit itself," she added. "The monitoring system has sensors that go on our existing refrigeration units and are accessed by using a security code."

Because of heightened concerns within healthcare about security and the need to control access to certain products, CPMC's use of supply management automation adds extra protection,

Managing Lab Supplies and Reagents With Automated Inventory Systems

WHEN THE LABORATORY at California Pacific Medical Center (CPMC) in San Francisco, California decided to use automated materials management systems to control reagents, phlebotomy supplies, and other laboratory consumables, there were plenty of benefits—both expected and unexpected.

- **Eliminated date-expired phlebotomy supplies from reaching ward floors.**
- **Dramatically reduced loss of supplies because of expired dates.**
- **Eliminated hoarding of reagents in various sectors of the laboratory.**
- **Reduced the quantity of inventory because of better management and more accurate resupply.**
- **Generated significant savings in hospital purchasing department, due to automated ordering.**
- **Increased staff morale, because supplies are always available when needed.**

Pyxis SupplyStation®
Automated materials management unit

without impeding normal work processes. "All our lab staff have access," stated Schiffgens, "but they have to enter their security code to get into the Pyxis. We know who accessed the unit and when."

According to Schiffgens, it is up to the individual accessing Pyxis to key in the specific quantity of inventory that was removed. "Technically, someone could try to fake out the system by not entering the correct amount of supplies taken," Shiffgens added. "But this is unlikely, because we can easily audit who accessed the system."

As most lab managers and pathologists know, med techs don't always embrace changes in long-established work processes. Therefore, the fact that the new Pyxis system met with no resistance from the staff at CPMC was an unexpected and welcome outcome. "Everyone loved the system because it is open and easy to see the contents inside," Shiffgens noted. "Now they can look in and quickly see if we're running low on something.

"Our units are stocked by a clerk from the purchasing department," added Schiffigens. "This assures 'first in–first out' for our inventory of supplies and reagents. That is one reason why we have significantly reduced the laboratory supplies which must be discarded because their expiration dates have passed. Savings from this improvement are worthwhile.

"As to shortages, we've seen some stock-outs for certain items, but it is no

longer a big problem for us. We have the **Sutter West Bay** supply distribution center as a backup" she declared. "We can get supplies within four hours. We keep about a week's supply of inventory on hand."

In addition to the benefits and improvements to work processes in the laboratory, the implementation of the Pyxsis automation materials management systems has produced impressive financial benefits, both in the laboratory and in the hospital purchasing department. "We saw a tremendous reduction in our laboratory's supply costs—around 8% in a year," Shiffgens observed.

"The equipment paid for itself within the first six months, just from the savings realized by not having tubes walk off the shelf."

"The units we use, the Pyxis SupplyStation, run about $15,000 each and are sold by Cardinal Health. The savings in purchasing costs alone justified that department's picking up the tab for the capital outlay for the equipment—so it didn't even come out of the lab's budget," she continued. "The equipment paid for itself within the first six months, just from the savings realized by not having tubes walk off the shelf.

"There is no question that this Pyxis program exceeded our expectations," Schiffgens stated. "We gained efficiencies and cost savings. In eliminated the expired tube problem, we corrected a potential JCAHO issue—no more compliance and regulatory issues, and no hoarding! This JCAHO outcome was an unforeseen benefit, since it got expired tubes off the floor."

Having harvested the benefits from phase one, Schiffgens is eager to implement the next two phases. "Like all laboratories, we need to take every advantage of any opportunity to improve our operational efficiencies and reduce our supply expenditures," she said. "As we go forward with this project, we are seeing a number of unexpected benefits, which shows that an improvement in one area can unlock unanticipated gains in other areas of laboratory operations.

"I can offer an unqualified recommendation that any hospital or reference laboratory will find it worthwhile to automate their inventory management in a similar fashion," advised Schiffgens. "As to advice for anyone looking to implement an inventory automation system, I would recommend having accurate par volumes so they can better estimate ordering intervals. That way you never have to worry about running out of reagents."

THE DARK REPORT considers this innovation at the CPMC laboratory to be a great example of why laboratory managers and pathologists should think "out-of-the-box." Across business and commerce, management solutions abound which can be adapted and imported into clinical laboratory operations.

Purchasing Provides Capital

In the case of CPMC's laboratory, it spotted an opportunity to take automated supply management systems, first developed in pharmacy settings, and apply it to the control of inventories in the laboratory. This allowed CPMC's lab to resolve a gnawing compliance problem and to save significant dollars while maintaining buy-in from lab personnel. Further, it even triggered savings in the hospital purchasing department, which offered to provide the capital to realize these benefits from its own budget. TDR

Contact Jennifer Schiffgens at 415-600-3730.

By Pamela Scherer McLeod

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Meet Engel von der Killer Tal Schanze! She's the newest member of THE DARK REPORT Team and came to us all the way from Germany. Engel (which means Angel in English) is just 12 weeks old and is latest in a long line of Deutsche Schaeferhunds (German Shepards) raised for serious Schutzhund duties. In fact, her sire was a Shutzhund and worked for the U.S. **Department of Defense** in Germany. Accordingly, she already displays high intelligence and a motivation for disciplined work.

ADD TO: Engel

Following the tenth annual *Executive War College* on May 5-6, Robert Michel and Debbie Lucas traveled to Germany for a family reunion and vacation. Engel was a surprise for Debbie. A young and eager Engel is now on daily security duty in the offices of THE DARK REPORT. Clients and members can feel welcome, especially with Engel on the alert and watching out for the bad guys!

HMO RATE INCREASES EASE FOR 2006, STILL IN DOUBLE DIGITS

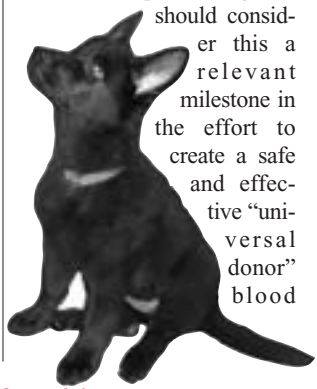
HMO premium rate increases for 2006 show early signs of easing, according to **Hewitt Associates**, a global HR consulting firm. HMO rates will still rise in 2006—but at 12.7% it's the lowest level in more than five years and is down 1.3% from the 13.7% increase of one year ago. Hewitt also noted that employers who managed their health costs aggressively saw an average HMO rate increase of 9.0% in 2005. This was attributed to plan design adjustments and aggressive negotiations. In particular, the number of companies requiring $20 office co-payments increased from 16% in 2004 to 25% this year while the number of employers offering $10 office co-payments is down from 29% in 2005 to 22% this year.

MORE ON: HMO Rates

"The positive impact of employee cost-sharing on utilization rates, stabilization in the frequency of hospital visits, and the increased focus of companies on health management programs are playing a major role in ongoing cost moderation," stated Paul Harris, Senior Health Care Strategist at Hewitt Associates. "While this is good news, it's important to remember that growth in health care costs continues to well outpace inflation."

HUMAN STEM CELLS CREATE BLOOD CELLS

Researchers at **Monash University** in Melbourne, Australia recently announced a technical milestone. They developed a method to turn human embryonic stem cells into red and white blood cells. The team's system was able to stimulate the stem cells specifically into becoming red or white cells. Although clinical applications are believed to be years away, lab managers and pathologists should consider this a relevant milestone in the effort to create a safe and effective "universal donor" blood



That's all the insider intelligence for this report. Look for the next briefing on Monday, July 11, 2005.

THE DARK REPORT

UPCOMING...

- *Local West Coast Pathology Group Gets Savvy with Professional Sales & Marketing.*
- *Update on Anatomic Pathology Laboratory Condos: The Dark Report's Journalism Award.*
- *"Best of Breed": What the Nation's Most Successful Hospital Lab Outreach Programs Have in Common.*

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