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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lessons In Lab Testing From Ireland

IN REAL TIME, PATHOLOGISTS ACROSS THE GLOBE CAN WATCH the meltdown of the Irish Health Service Executive's ambitious effort to revamp cervical cancer screening services in the country. It reorganized these screening services in order to achieve its declared goal of reducing death rates in Ireland from cervical cancer to rates at or below the average of the European Union.

So far, the new cervical cancer screening program, called CervicalCheck, has found few supporters within the Irish healthcare profession. In 2008, it alienated pathologists and laboratory scientists by outsourcing all the nation's Pap testing to **Quest Diagnostics Incorporated** in the United States. That act also set an international precedent, as it marked the first time that a government health program in a developed country chose to send all its specimens for an important diagnostic test to an overseas laboratory.

Since the fall of 2009, the CervicalCheck program has alienated general practitioners (GP) in Ireland. That happened when the government unilaterally changed both the way GPs are paid for providing cervical cancer screening services and by requiring GPs to deny free screening services to women who show up in their medical clinic, but who are unregistered with CervicalCheck.

Ireland has the same challenge as every developed nation in the world. Demand for healthcare services increases year-by-year at a rate which exceeds the ability of the government health program to adequately pay providers for this care. Thus, how elected officials and health department bureaucrats set policies for coverage guidelines and reimbursement in such situations gives us a hint of how politicians in other nations may respond to this same situation.

There is additional irony to the Irish Pap test situation. Irish health bureaucrats justified the Pap test outsourcing and the creation of CervicalCheck by stating that the average Pap result turnaround time of six months was intolerable. Its chosen lab vendor, Quest Diagnostics, would have to meet a 10-day turnaround time for Pap results. However, now CervicalCheck requires women to register—then wait as long as six months—for the "invitation" which allows them to then make an appointment to see their doctor for their screen. Thus, newly-registered women are now forced to wait as long as six months for their invitation! Plus, women who are unregistered, but show up in the doctor's office, will be denied the free cervical cancer screening service. I don't think this was supposed to be the way any nation's promise of universal healthcare was to be kept. TDR

In South Carolina, TC/PC May Be "Misconduct"

South Carolina Board of Medical Examiners sends advisory memo to all doctors in the state

CEO SUMMARY: Last month, the South Carolina Board of Medical Examiners advised all physicians in the state that certain arrangements for technical component/professional component (TC/PC) services between referring physicians and pathologists may be in violation of state law. These actions came in response to a letter from the South Carolina Society of Pathologists. The letter explained the TC/PC arrangements and asked whether they violate state law, constitute illegal fee splitting, compromise patient care, and are unethical.

ACROSS THE NATION, the proliferation of TC/PC arrangements in anatomic pathology as a competitive market strategy has been viewed unfavorably by many pathologists.

Now comes news that the **South Carolina Board of Medical Examiners** has looked into TC/PC arrangements and believes that this business arrangement "raises serious legal and ethical concerns for its licensees." To alert physicians to its findings, on June 24 the Board of Medical Examiners sent a memo to all permanently-licensed physicians in South Carolina, writing that "…the arrangements in question may constitute misconduct under the state's medical practices act."

This is a rare instance of a regulatory body recognizing the potential of some TC/PC business arrangements to be in violation of the law. Events yet to unfold in South Carolina may provide pathologists in other states with useful strategies on how to rein in the most abusive forms of TC/PC business arrangements that occur within their own state.

TC/PC describes a specimen referral arrangement where the TC (technical component) and the PC (professional component) for each case are split apart and billed separately by the laboratory and the referring physician or medical group.

Over the past six years, certain national laboratory companies have used PC/TC arrangements as a way to win new business. The pathology company will perform the TC and bill for that service. The pathology lab company then sends

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the finished slides back to the referring physician group.

These physicians may have engaged a pathologist to read the cases at a discounted rate. This allows the physicians to directly bill the insurer for the professional component. They profit from the difference in the amount paid by the health insurer that exceeds the discounted fee the medical group paid the pathologist for reading the case. These TC/PC arrangements have become quite common, particularly among urology and gastroenterology groups.

Many in the pathology profession contend that most TC/PC arrangements are a way for national pathology companies to allow physicians to generate a profit from referring their patients' specimens. Existing laws at the federal and state level do not provide clear and objective guidance as to how various forms of TC/PC arrangements may violate anti-kickback laws or prohibitions against physician inducement.

However, that is not the case in South Carolina. In 2005, the South Carolina legislature enacted House Bill 3891, which added Section 44 132 10 to Section 44 132-50 of the South Carolina Code. This new language defines which providers can direct bill for anatomic pathology services. This legislation generally prohibits a physician from directly billing for a professional pathology service for which that referring physician did not personally render nor supervise. *(See sidebar on page 5.)*

Advice And Warning

The South Carolina Board of Medical Examiners issued its advice and warning about TC/PC arrangements in response to a letter it received that was written on behalf of the **South Carolina Society of Pathologists**.

This letter, dated May 13, 2010, was written by attorneys Jane Pine Wood and Steven M. Harris of **McDonald Hopkins**, the law firm based in Cleveland, Ohio. Because pathologists in South Carolina were being asked to participate in TC/PC arrangements, this letter requested guidance from the Medical Board of Examiners as to whether the participation of pathologists in these arrangements would be permissible.

The South Carolina Medical Board of Examiners provided a rather fast answer. In a letter dated June 9, Sheridan H. Spoon, the board's Assistant General Counsel, wrote that "Based upon the facts outlined in your letter and the supplemental information presented to the Board at its meeting on May 19, 2010, it is the position of the Board of Medical Examiners that the [TC/PC] arrangement described raises serious legal and ethical concerns for its licensees."

Memo Sent To All Physicians

The Medical Board of Examiners then sent the following memo to all licensees on June 24:

S.C. Medical Board considers anatomic pathology services arrangements.

At its May 2010 meeting, the SC Board of Medical Examiners considered the legal and ethical issues related to certain anatomic pathology services arrangements. The board concluded that the arrangements in question may constitute misconduct under the medical practice act. While it has not received a complaint and has not investigated any specific arrangement, based on the facts outlined in the presentation made at the May meeting, these relationships raise serious legal and ethical concerns. Accordingly, the board cannot advise that they are permissible under the medical practice act at this time.

The Medical Board of Examiners was precise in how it stated its findings. But it did seem to open the door for further investigation on the legality of certain TC/PC business arrangements. In its June 9 letter to Wood and Harris, Spoon wrote that "The Board cannot advise that the practice arrangement described is permis-

South Carolina Has a State Law that Defines How Physicians May Bill for Pathology Services

PATHOLOGISTS IN SOUTH CAROLINA showed foresight when, in 2005, they encouraged the passage of revisions to state statutes. These revisions provided objective definitions for specific situations when a referring physician might be permitted to directly bill for an anatomic pathology professional service.

In their May 13 letter to the South Carolina Board of Medical Examiners on behalf of the South Carolina Society of Pathologists, attorneys Jane Pine Wood and Steven M. Harris described the relevant sections of the South Carolina legal code that would apply in TC/PC arrangements. The points were presented as follows:

Legal Analysis of Arrangements

The South Carolina legislature enacted House Bill 3891 in 2005, which added Section 44-132-l0 to Section 44-132-50 to the South Carolina Code. Section 44-132-10 et. seq. establishes procedures and requirements for the direct submission of claims for anatomic pathology services by the pathology providers performing these services. Section 44-123-10 of the South Carolina Code provides that: "Except as provided for in Section 44-132-20, no person licensed to practice in this state as a physician, surgeon, or osteopath, a dentist or dental surgeon, a nurse practitioner, or a physician assistant shall charge, bill, or otherwise solicit payment for outpatient anatomic pathology services unless the services were rendered personally by the licensed practitioner or under the licensed practitioner's supervision."

Section 44-132-20 explains that: "A person who is licensed to practice medicine in this state or the professional legal entity of which the person is a shareholder, partner, employee, or owner, may submit a bill for outpatient anatomic pathology services only to: (1) the patient directly; (2) the responsible insurer or other third party payer; (3) the hospital, public health clinic, or non-profit health clinic; or (4) the referring laboratory or the primary laboratory."

As explained above, the referring practices in the TC/PC arrangements submit the bills for professional pathology services which the referring physicians neither personally render nor supervise. Such arrangements would be in violation of these provisions of the South Carolina Code.

This conclusion appears consistent with the analysis set forth in a September 26, 2006, letter from Assistant Deputy Attorney General Robert D. Cook to Representative Hagood, which explains that "Section 44-132-10 clearly prohibits a licensed practitioner who does not personally perform or supervise the performance of anatomic pathology services from billing a patient for those services. We [the Office of the Attorney General] do not believe the licensed practitioner who does not perform or supervise the performance of anatomic pathology services may bill a patient for the performance of such services by a laboratory."

Furthermore, Section 44-132-20 explains that: "A person who is licensed to practice medicine in this state or the professional legal entity of which the person is a shareholder, partner, employee, or owner, may submit a bill for outpatient anatomic pathology services..." *If the pathologist is hired as an independent contractor of the referring practices, rather than an employee, then the submission of any claim for the pathologist's services clearly violates Section 44-132-20."*

sible under the South Carolina Medical Practice Act, or other state and federal laws. Accordingly, the Board would caution its licensees that such arrangements may constitute misconduct; while acknowledging that to date, the Board has not received or investigated a complaint concerning the arrangement described and would conduct an independent investigation based upon the specific facts presented by such a complaint. To start said process would require that an initial complaint be submitted to the Board administrator, Mr. Bruce Duke."

The second issue centered around fee-splitting arrangements in which the referring physicians get 70% of the professional component and the pathologist gets 30%.

Given the fact that pathologists in South Carolina have been pro-active on the issue of how anatomic pathology services are to be billed, there is a high probability that some individual or entity might file such a complaint to the Medical Board of Examiners in coming months. That would give it the opportunity to investigate a specific example of a TC/PC business arrangement in the state.

In making a presentation to the Board of Medical Examiners on May 19, attorneys Wood and Harris addressed three specific issues. First is the legality of TC/PC arrangements, particularly if the pathologist is an independent contractor and not an employee of the referring physician.

The second issue centered around fee-splitting arrangements in which the referring physicians, for example, get 70% of the professional component and the pathologist gets 30%. The third involved patient care issues related to whether the pathologists in these TC/PC arrangements have been credentialed—as is true of pathologists who practice in South Carolina's hospitals.

Events are unfolding quickly in the Palmetto State. From receipt of the South Carolina Pathology Society letter requesting a review of TC/PC business arrangements dated May 13, it took just four weeks for the Board of Medical Examiners to conduct a public meeting on the topic, then issue a memo of advice to all licensees in the state. It remains to be seen whether the Board of Medical Examiners would move just as expeditiously to review any future complaints of specific TC/PC business arrangements that might be filed.

One immediate consequence of the Board's advisory memo could be to discourage physician groups currently considering such a TC/PC business arrangement to delay or cancel it. That would be a favorable outcome for pathologists in South Carolina.

For the wider pathology profession, these developments in South Carolina offer a useful lesson. The most effective way to curtail abusive laboratory marketing practices—both in anatomic pathology and clinical laboratory testing—is likely to be at the state level. The language in South Carolina's statutes is much more precise on the TC/PC issue than any federal legislation or regulatory guidance.

Anti-Kickback Laws

There is a widely-held opinion across the pathology profession that many common marketing practices, including TC/PC , violate federal anti-kickback laws. But the absence of effective regulatory enforcement at the federal level has created a situation where laboratories and pathology groups with conservative compliance policies find themselves continuously losing business to labs willing to aggressively push compliance.

That is what makes the recent events in South Carolina significant. The rare combination of a well-written law with teeth, and regulators willing to diligently enforce compliance with the law, might just curb the more abusive aspects of some TC/PC arrangements. TDR

SC Pathologists Question Legality of TC/PC in State

South Carolina Society of Pathologists asks for review of the legality and ethics of TC/PC

CEO SUMMARY: Recently the South Carolina Society of Pathologists (SCSP) requested that the state's Board of Medical Examiners review the legality, under state law, of certain technical component/professional component (TC/PC) arrangements between referring physicians and pathologists. SCSP asked that the Board assess how TC/PC arrangements might violate state law, constitute illegal fee splitting, compromise patient care, and be unethical. State law in South Carolina has specific language that applies to some forms of TC/PC.

In South Carolina, anatomic pathology TC/PC business arrangements were recently the subject of a review by the state's **Board of Medical Examiners**. The information provided to the board offers a look at the different ways that some TC/PC arrangements might run afoul of legal and ethical requirements.

The review had been requested by the **South Carolina Society of Pathologists** (SCSP). In a letter it submitted to the Board of Medical Examiners, attorneys Jane Pine Wood and Steven M. Harris of the law firm **McDonald Hopkins** described one type of TC/PC business arrangement often used by pathology companies.

Questions About TC/PC

In the letter, the board was asked to assess how TC/PC business arrangement involving pathology services might be problematic in four areas: 1) does it violate South Carolina law; 2) does it constitute fee-splitting under applicable rules and regulations; 3) does it present a substantial risk to patient safety; and, 4) does it violate ethical practices?

The letter from Wood and Harris explains in detail that the intent of current federal and state laws is for Medicare and other payers to reimburse pathologists and laboratories for the technical and professional components of services involved in reviewing human tissue samples. "Unfortunately, a loophole in the federal Stark regulation (which the Office of Inspector General and the Centers for Medicare & Medicaid Services are working to limit) allows other medical specialists who generate the referrals for these pathology services to collect large portions of the pathologists' fees for professional services which are not rendered by these other medical specialists," wrote Wood and Harris.

"The South Carolina Society of Pathologists is aware of several arrangements, commonly referred to as 'TC/PC' arrangements, whereby referring physicians practices (both urology and gastroenterology practices) contract with a pathologist on a part-time basis for the provision of the professional pathology interpretation services," the letter said. The lawyers were uncertain about whether

the pathologists in these arrangements were employees or independent contractors, a factor that is important to the patient care issues raised later in the letter to the South Carolina Board of Medical Examiners.

Marking Up Path Services

"In this arrangement, the professional pathology interpretations are billed by the referring physician practice, which in turn pays the pathologist a markedly reduced fee for his or her professional services," the letter said, adding that "...The pathologist's laboratory either bills patients/payers directly for the technical component services or sells the technical component services to the referring physician practices which re-bill the purchased services to patients/payers with a mark-up in price."

Inappropriate utilization was a concern. Wood and Harris pointed out that "...The SCSP has information indicating that the pathologist provides a [financial] pro forma to the referring practice which includes an excessive number of special stains, even on normal tissue, which would generate significant additional charges to the patient for both the technical and professional components of the special stains, and would substantially increase the profits realized by the referring practice from the fee splitting arrangement for these excessive services.

Training in Pathology

"It is important to distinguish the TC/PC arrangement from a legitimate multi-specialty practice in which pathologists and other medical specialties jointly provide services in a single, integrated medical practice," the letter continued. "Such legitimate multi-specialty practices are not uncommon among pathologists and dermatologists, for example, especially in light of the dermatopathology training received by most dermatologists. The TC/PC arrangement at issue involves primarily urology and gastroenterology practices, whose physicians have no training in pathology, and who view the [TC/PC] arrangement solely, if not primarily, as a lucrative source of additional revenue.

"In these arrangements, the contracted pathologist may not have the same level of experience, skills, training, and expertise as a pathologist based in a hospital or in an independent lab, and may not hold medical staff privileges at a hospital," explained Wood and Harris. "If not, the pathologist would avoid the stringent credentialing processes of hospital medical staffs, as well as those third party payers who rely upon medical staff credentialing of pathologists."

AMA Stance on Fee Splitting

The potential for TC/PC arrangements to violate ethics was discussed. "The **American Medical Association** (AMA) has clearly stated that fee splitting as described in the letter is prohibited," noted the two attorneys. "AMA Ethical Opinion 6.02 states unequivocally that 'Payment by or to a physician solely for the referral of a patient is fee splitting and is unethical." In addition, AMA Ethical Opinion 6.10 provides that: "'No physician should bill or be paid for a service that is not performed; mere referral does not constitute a professional service for which a professional charge should be made or for which a fee may be ethically paid or received.'"

The letter also said "Similarly AMA Ethical Opinion 6.03 explains that: "Clinics, laboratories, hospitals, or other health care facilities that compensate physicians for referral of patients are engaged in fee splitting, which is unethical."

These statements from the May 13 letter submitted by the South Carolina Society of Pathologists (SCSP) to the state Board of Medical Examiners provide insight as to how SCSP views the legal and ethical issues that may be relevant when evaluating TC/PC business arrangements between pathology laboratories and referring physicians, including specialist physicians such as urologists and gastroenterologists. TDR

New Criticisms in Ireland About Cervical Screening

Physicians report how CervicalCheck's restrictions reduce women's access to Pap testing

CEO SUMMARY: Pathologists worldwide are witnessing how a government health service can erode its nation's pathology capabilities in cytology. Ireland's experiment in off-shoring all its Pap testing even as it requires women to register in a national database in order to get free cervical cancer screening is not turning out well. A growing number of credible critics is turning up the heat on government health officials in the Emerald Isle.

IN IRELAND, CRITICS ARE HAVING A FIELD DAY after news reports indicated that the Irish Health Service Executive's national program to expand coverage of cervical cancer screening—called CervicalCheck—has actually reduced the number of women getting access to screening services and Pap testing less than one year after its full implementation.

Ireland's CervicalCheck is a free national cervical cancer screening program that began to roll out in 2008. It is the latest example and reminder of how a government's helping hand often has unintended consequences for the very people it was designed to help.

Ireland's problem is that its mortality rate for cervical cancer, at 4.2 deaths per 100,000, is nearly twice the average of the European Union (EU), where the average is 2.7 deaths from cervical cancer per 100,000. Ireland is the last EU nation to implement a universal Pap smear program. CervicalCheck was an effort to improve this situation.

Part one of the government's plan to reform cervical cancer screening sent all the nation's Pap testing overseas to **Quest Diagnostics Incorporated**. That contract became effective on July 1, 2008, and took literally 100% of the nation's Pap tests away from Irish laboratories. *(See TDR, August 31, 2009.)*

Phase two was the deployment of CervicalCheck, which was introduced on September 1, 2008, and took full effect on September 1, 2009. The CervicalCheck program limits free Pap testing to women between the ages of 25 and 60. A woman is required to register with CervicalCheck to qualify for free cervical cancer screening services as part of Ireland's health insurance.

After registration, CervicalCheck sends out an invitation for cervical cancer screening. A woman must have the invitation and make an appointment with her physician in order to get the free cervical screening service. Critics point out that newly-registered women must wait up to six months for CervicalCheck to send them the invitation that allows them to schedule an appointment to have the test.

Published statistics provide evidence that CervicalCheck is failing in its goal to

increase the number of women getting annual cervical cancer screens.

First, once on the list, the CervicalCheck call/re-call system automatically sends women an annual invitation. But more than 53,000 invitations or reminders mailed to women between September 2009 and May 2010 were returned unopened. Further, if a woman is not on the CervicalCheck registration list or has not had a screening in more than three years, she must call a national helpline or go on-line to register with the program in order to receive an invitation.

Fewer Women Get Screens

Second, Irish physicians are speaking up about the remarkable drop-off in the number of women undergoing cervical cancer screening this year—under CervicalCheck—compared to previous years before the program's introduction.

The **Dublin Well Woman Centre** reported in June that, since last September 2009, its three clinics have experienced a dramatic drop in Pap tests performed, from an average of 830 to just 340 per month. That's 59% fewer women.

Alison Begas, the centre's chief executive, blamed the decline on changes "from a free and accessible model to a much more restrictive one." She noted that last year, the centre experienced a 15% increase in Pap screenings overall, due in part to the "Jade Goody factor."

More Woman Wanted Tests

The 27-year-old British reality TV star and mother of two, died in August 2008 of cervical cancer. She had allowed filming of her own battle with cervical cancer, which raised public awareness of the screening program across the British Isles. Begas also noted that, in the wake of publicity over Goody's death, the center experienced a record number of abnormal results, with more than 650 women referred for colposcopies.

Ronan Boland, M.D., a general practitioner who heads the **Irish Medical Organisation** (IMO) has declared that, since the policy change became effective in September 2009, cervical screening at his own practice has "effectively ground to a halt."

Critics charge that these policies—put in place as part of the CervicalCheck program—are putting the lives of Irish women at risk. James Reilly, M.D., health spokesperson for the nation's largest opposition political party **Fine Gael** (United Ireland Party), described the policy as "a cynical attempt to limit the demand for the smear test."

Pamela Morton, former president of the **European Cervical Cancer Association** and founder of the **Irish Women Against Cervical Cancer Association**, called these policy changes unacceptable. "It is worrying because there are a lot of women out there not in the system and so do not know they are entitled to a free smear."

Turning Away Patients

Primary care physicians complain that when unregistered patients show up in their office for an annual Pap smear, they now must turn them away.

Following announcement of the new registry policy, Marian O'Reilly, M.D., head of the CervicalCheck program, sent a letter to GPs to inform them that CervicalCheck would no longer pay them for performing this service! The program, however, would continue to facilitate testing by paying for clinical materials and test processing at the designated laboratory.

This action came as a surprise to Boland. In a story published by the *Irish Medical Times*, he said that, regrettably, what was supposed to be a free national program is "being rapidly dismantled." Boland pointed out that by not paying GPs for performing cervical screening services, the National Cancer Screening Service (NCSS) "effectively reintroduced charging to vulnerable groups."

He also criticized O'Reilly for the unprofessional handling of notification of

physicians about policy changes. Boland pointed out that letters were sent directly to physicians without the courtesy of prior notification of the IMO, which has become the sounding board for physician anger over government policy changes.

Boland noted that CervicalCheck's change to a call/re-call policy was not part of the extensive negotiations with the Irish Medical Organization last year, and physicians are very unhappy with this sudden and unexpected change. "I have had a lot of contact from people who are not normally in contact with the IMO, who are not militant in any way, who do not usually complain," said Boland.

The medical community also continues to be critical of Health Minister Mary Harney's decision to outsource all Pap test processing to overseas laboratories. During the BioMedica 2010 conference in Dublin this May, keynote speaker Marie Culliton, President of the Irish **Academy of Medical Laboratory Science** (AMLS), who is an outspoken critic of NCSS' decision to offshore laboratory jobs, pointed out that it was "short-sightedness" that led the outsourcing of all cervical cytology to America. She suggested that as a result of new CervicalCheck policies, the waiting has not been shortened, but rather the "bottleneck" had simply moved from waiting for a Pap test result to waiting for a smear to be taken.

Dismantling Lab Capabilities

"In addition, the competence to provide the service has been decimated within this country," she charged. "The intellectual capital that took 40 years to build up in this country was written off at the stroke of a pen. This decision has led to the exporting of high worth, skilled jobs. This is not smart for a knowledge economy," Culliton said, noting that 70% of all clinical decisions are based on results of a diagnostic test, which accounts for less than 5% of healthcare budgets.

These developments in Ireland presage the types of decisions about how to restrict use of pathology and clinical laboratory tests that other government health programs will make when faced with inadequate budgets. Outsourcing Irish Pap testing to an overseas laboratory evidently cut the Irish health service's cost by as much as one third. Not paying GPs for cervical cancer screening services is another blunt cost-cutting tactic.

Unfortunately, it is Irish women who will pay the true price. To date, the CervicalCheck program has not demonstrated that it will improve access to cervical cancer screening services. TDR

Irish Doc Calls CervicalCheck a "Dog's Breakfast" Disaster

SOME IRISH PHYSICIANS ARE BLUNT in their criticism of CervicalCheck. In a letter to the editor of the *Irish Medical Times*, John O'Keeffe, M.D., a practitioner at **Morehampton Clinic** in Donnybrook, Dublin, summed up physician frustration, calling CervicalCheck "a monstrosity of a breakfast that any respectable dog would refuse."

He blasted the program for both ignoring sexually-active women under 25 and the bureaucratic registry requirement. "Since September first [2009], any woman who plucks up the courage to have a smear and goes to her doctor to request this is now turned away because she has not registered with CervicalCheck. Of course, she has not registered; she has never heard of CervicalCheck.

"A conspiracy theory is probably too far-fetched, but if the HSE (Health Service Executive) wanted to find another way to save money by cutting down the number of smears being performed by GPs (general practitioners) then they, for once, have succeeded beyond their dreams," he sarcastically wrote. "I cannot think of any possible objection to this, except that whatever 'experts' set up this ridiculous scheme do not want women to have smears. It's as simple as that, and that is what my colleagues also feel."

Patient Privacy Laws Create Legal Risk for Labs

➤Laboratories must comply with a patchwork of federal and state requirements for patient privacy

➤➤CEO SUMMARY: Before the nation's healthcare system can achieve the integrated universal EHR, it must fix the crazy contradictions in state and federal laws governing patient privacy. There is discordance between federal law and state law that defines the role and responsibility of the clinical laboratory which performs a laboratory test and reports those results to the referring physician. The federal Centers for Medicare and Medicaid Services (CMS) did publish revised language this March, but more needs to be done.

FOR THE CLINICAL LAB INDUSTRY, the road to the universal health record (EHR) is loaded with plenty of patient privacy potholes and detours. Blame it on the patchwork of federal and state laws enacted when lab test reports were generally printed on paper and delivered to doctors by courier or by fax.

Clinical laboratories and pathology groups are all too familiar with the consequences of breaching patient privacy. Laboratory test results often represent highly sensitive information about the patient's health. For that reason, laboratories are diligent in their compliance with patient privacy mandates.

However, increasingly, laboratories find themselves in a Catch 22 situation when they are asked to support electronic medical record (EMR) systems and health information exchanges (HIEs). When it comes to reporting a patient's laboratory test results to the referring physicians, clinical laboratories generally have clear, well-defined protocols.

However, existing federal and state laws create thorny problems for clinical labs when they are asked to pass patient lab test data to EMRs and HIEs. Existing laws create situations where laboratories may have legal liability should a patient privacy violation occur within these EMRs and HIEs, even though the labs no longer have control over who views this laboratory data.

Within the laboratory testing profession, efforts are under way to fix the legal jeopardy created by the existing patchwork of federal and state patient privacy laws. For example, **the American Clinical Laboratory Association** (ACLA) is actively lobbying for reforms in two areas.

➤Two Proposed Amendments

Both proposed reforms would change existing language in the Clinical Laboratory Improvement Act (CLIA). One amendment would allow more consistent and reasonable rules about the release of laboratory test results. The second amendment would limit the laboratory's responsibility in how lab test data is displayed by end users.

The first proposed amendment deals with the ability of clinical laboratories to release historical lab test data to health information networks for treatment pur-

poses or for peer-to-peer release for secondary uses.

These secondary uses of laboratory test data include: 1) transmission to health plans for quality improvement efforts; 2) case management; 3) patient safety; and/or, 4) pay-for-performance initiatives. Currently, some state laws allow these uses of laboratory test data, even as other states make it illegal without individual patient or provider permission.

This state-by-state variation is due to CLIA. While access to most individual health information is governed by federal regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, release of data from clinical laboratories falls under the purview of CLIA. And because CLIA—which predates HIPAA—defers to state law in defining who has access to laboratory test data, privacy rules often change according to the geography of the clinical laboratory and the providers that it serves.

"This CMS guidance now allows the provider who orders the laboratory test to designate on the requisition other persons who are authorized to receive the lab test results."

This problem becomes immense when it involves HIEs, for example. In testimony before the HIT Policy Committee Information Exchange Workgroup in October of last year, Don Horton, Vice President of Public Policy and Advocacy for **Laboratory Corporation of America** observed that "While obtaining authorization may not be difficult with respect to a single lab test result to be sent, for example, to a non-ordering treating provider, it is far more difficult in the context of making millions of historical test results available for health information networks."

"It's important to recognize that laws governing labs at the state level were not promulgated to protect patient privacy," stated Joy Pritts, J.D., who is Chief Privacy Officer for the **Office of the National Coordinator for Health Information Technology** (ONC). ONC is part of the Department of Health and Human Services (HHS).

Now At The ONC

Prior to joining ONC, Pritts was on the faculty at **Georgetown University** where she held a joint appointment as a Senior Scholar with the **O'Neill Institute for National and Global Health Law** and as a research associate professor with the **Health Policy Institute**. Her work has focused on the privacy of health information and patient access to medical records at both the federal and state levels.

"State laws focus on patient safety and ensure that providers work within their scope of practice," noted Pritts, who gave the example of how, in some states, laws governing licensure of chiropractors might prohibit them from receiving laboratory test results.

Differences In State Laws

CLIA allows release of laboratory test results only to an "authorized person" (a term which CLIA allows individual states to define) or to a "person responsible for using the results" (a term that CLIA does not define). Thus, state-by-state, there are varying interpretations of who can receive a patient's laboratory test data.

"In response to the testimony given in the October hearing, CMS issued new guidance in March of this year as to whom lab data could be released," explained Pritts. "This CMS guidance now allows the provider who orders the laboratory test to designate on the requisition other persons who are authorized to receive the lab test results.

"There was another helpful change," she added. "CMS guidance also clarified that the laboratory may release test results to the patient—as long as state law does not expressly forbid it. Under this guidance, the patient is defined as a person who is responsible for using the test results. Also, CMS guidance did not change current references in state laws."

CMS's new guidance did not address the issue of how clinical laboratories release laboratory test data to health information networks. Experts say that existing laws and requirements will continue to be a major barrier to sharing of laboratory test data and the creation of a universal electronic health record.

When asked if HHS was considering any action on this aspect of sharing of laboratory test data, Pritts chose her words very carefully, saying, "Clinical laboratories continue to raise this issue with HHS, and HHS continues to listen to labs and other parties and is taking their concerns under consideration."

Final Report Destination

The second area about which ACLA and other laboratory groups seek action from HHS has to do with the responsibility of clinical laboratories for accurate and timely test reporting to "the final report destination." Currently, data transmitted by laboratories to electronic health record (EHR) interfaces can be reformatted however the EHR vendor chooses.

However, under current CLIA regulations, the lab retains responsibility for the end product—how the report of the patient's laboratory test results is presented within the provider's EHR system. This legal situation exists despite the fact that the clinical laboratory has no way of knowing how the EHR vendor manipulates the data or even the location of the final report destination.

LabCorp's Horton addressed this dilemma in his testimony last October before the HIT Policy Committee Information Exchange Workgroup. "In the current electronic health information exchange environment, 'the final report destination' has become a virtually meaningless term," he stated.

Existing Requirements

ACLA's proposed reform centers around changing existing requirements so that the clinical laboratory's responsibility ends "once the result is provided to the ordering provider's EHR, or to the system of another permitted intended recipient, or to an intermediary contractually obligated to send the result to the intended destination," explained Horton.

It is important for pathologists and clinical laboratory administrators to be aware of how state and federal laws governing patient privacy and lab test reporting are in conflict with federal efforts to bring about a universal electronic health record. It is a situation where the different federal and state patient privacy requirements involving the reporting of laboratory test results create added legal risks for clinical laboratories and anatomic pathology groups.

This confusing mix of conflicting reporting standards and patient privacy requirements shows how rapid and ongoing advances in information technology are outrunning the ability of health policy experts and elected officials to keep pace.

Need To Enact Reforms

There is a clear need for federal and state health officials and elected representatives to enact needed reforms to the existing patchwork of requirements for patient privacy and lab test results reporting. Until such reforms are put into place, all clinical laboratories and pathology groups will need to be diligent in their efforts to comply with existing state and federal patient privacy mandates. TDR

—K. Branz

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Better Blood Utilization Reduces Costs by 29%

Hospital slashes annual blood costs through physician engagement and donor recruitment

CEO SUMMARY: Use of an innovative two-pronged approach helped University of Alabama at Birmingham Hospital rein in runaway cost increases in blood products. Not only did it achieve annual savings of $3.5 million in three years—a 29% reduction—but it increased blood donations from 200 units per year to more than 6,000 units per year. Education and physician engagement were two cornerstones of this hospital-wide effort to improve utilization of blood products in ways that improved patient safety and outcomes.

IN THE WORLD OF TRANSFUSION SERVICES and blood banking, the dramatic rise in the price of blood products over the past decade has become the number one budget-buster for most hospital laboratories.

However, there is often an equally-serious problem that gets less attention. It is the gap between blood use and blood collections in a community or region. Any hospital or health system laboratory attempting to bring the surging cost of blood products under control needs to address both of these issues.

That's what makes the outcomes at **University of Alabama at Birmingham Hospital** (UAB) notable for pathologists and laboratory administrators looking for solutions to control the sky-rocketing costs of blood products costs in their own institution. Since 2006, UAB's focused effort on better blood products utilization has produced annual savings of $3.5 million. That's a 29% reduction in spending in three to four years.

On the supply side, during the 2007-2008 period, UAB increased its blood collections from less than 200 units per year to more than 6,000 units per year. Collectively, these twin initiatives provide a useful road map for other hospital laboratories that would like to break their upward spending curve for transfusion services and blood products.

Pathologist Marisa B. Marques, M.D., who is Medical Director, Transfusion Service, at the **University of Alabama at Birmingham Hospital** (UAB), said that, in recent years, hospital laboratories in Alabama found themselves at a special disadvantage in purchasing blood products. In 2006, there was a 35,000-unit gap between blood use and blood collections in the state.

Gap In Supply And Demand

Moreover, 908-bed UAB, the flagship hospital of the University's health system, was a significant contributor to this gap. The hospital used 37,000 blood units more than it collected! That gap meant rising costs, as well as justified concerns about shortages in essential blood products.

"From 1997 to 2006, blood use at UAB increased 60%," commented Marques. "That rate of increase was clearly not sustainable, particularly given the critical shortage of blood. It motivated us to take decisive action."

In 2006, UAB hospital administration teamed with laboratory management to address this situation. An organization-wide, intensive campaign was initiated to achieve two goals. One goal was to improve how physicians utilized blood products. The second goal was to increase donations, thus adding to the supply of available blood.

"Our first step was to get recognition of the need for change from UAB physicians, along with their buy-in," noted Marques. "We didn't want to start until we had everyone on board. We also recognized the importance of having the physician champions at UAB involved in the process. Physicians want to hear from their peers—from those whom they respect."

Improving Blood Usage

Because most physicians at UAB were willing to acknowledge shortages in the supply of blood, that made it easier for Marques and the change team to gain their agreement to explore and support strategies that would lead to reduced use of blood products.

Marquez' group also studied how other hospitals had succeeded in improving blood utilization and controlling the cost of transfusion services. Impressed with the outcomes at 747-bed **St. Vincent Indianapolis Hospital** in Indianapolis, Indiana, the team sought advice from anesthesiologist Timothy Hannon, M.D., MBA, Medical Director of the Blood Management Program at St. Vincent. He is also President and CEO of **Strategic Healthcare Group LLC**, a blood-management consulting firm.

Hannon recommended a strategy of physician education and feedback, anchored in data. To gather that data, UAB had Hannon's firm survey blood use by UAB physicians. Each physician received an individual report of their performance, benchmarked against high performers in their specialties.

"Pathologists and laboratory scientists know the power of good data," stated Marques. "Providing credible data to the individual physicians was the right first step. We all know that physicians are competitive people. They want to be the best and provide the best care for their patients.

"Some of our surgeons had never compared their blood utilization with blood utilization rates at other hospitals," she continued, "and when they saw their data, they were ready to make changes to improve their performance."

The next step in the UAB lab's program to improve blood utilization was physician education. Hannon's firm organized a series of CME (continuing medical education) lectures on blood management. These lectures were organized around the landmark study published in 1999, "Transfusion Requirements in Critical Care."

"It's incredible that 'Transfusion Requirements in Critical Care' was published more than 10 years ago, but many physicians still don't know about it," observed Marques. "It's powerful information and we made that study an essential part of our blood management program."

This study was published in the medical journal *Transfusion* in 1999. The study's researchers determined that critically ill patients did better when treated with a restrictive transfusion approach.

Unaware Of Risks

"Physicians at UAB were unaware of these risks associated with utilization of blood products," noted Marques. "The CME lectures we instituted also included information on the wide variations in blood use among physicians in the same specialty, as well as variation among hospitals and across national boundaries.

"We involved enough physicians in the CME to be sure that all the UAB physicians felt they were hearing from someone in their field whom they respected," added Marques.

"Another element to the change compaign was the employment of a nurse to be a transfusion safety officer," she noted. "This individual works with nursing and laboratory staff on blood management, and also educates them on blood administration, patient monitoring, as well as transfusion reactions and other issues.

"One element of this was to have her work with staff to help minimize anemia, including reducing the amount of blood collected for laboratory testing," continued Marquez. "We succeeded in cutting blood loss from about 70 MLs per day per ICU patient to about 39 MLs per day. This reduces iatrogenic anemia and eventually the need for transfusion."

UAB's Blood Utilization Committee was renamed the Blood Utilization and Management Committee. It was empowered to work with physicians on reduction strategies. Marques, who had been the committee's sole chair, recruited a co-chair, Donna E. Salzman, M.D., who is a bone marrow transplant specialist. "This physician could stand up and say 'My patients, who don't have a functioning bone marrow, don't need as much blood as we've been using.' In turn, this made an impact on other physicians."

Clinical Practice Change

Many UAB physicians had been trained to order two units of packed red blood cells at a time, explained Marques. They were encouraged to change that practice and order only one unit—unless the physician was certain that more would be needed. This is now standard practice with most UAB physicians.

The cardiovascular OR team instituted blood-saving protocols to reduce blood loss and to capture and reuse the patients' blood during surgery. "These new protocols have produced good results," noted Marques. "In the two years since the initiative began, blood use in patients undergoing cardiac valve procedures dropped from an average of 9.5 units per patient to less than three units per patient."

The team also created a laminated Transfusion Guidelines pocket card and distributed these cards widely throughout the medical and nursing staff. Even the hospitals' electronic medical record (EMR) system plays a role in managing the utilization of blood products. Marques and Salzman use the EMR to review patient records for transfusion justification.

"If the patient record does not show evidence that justifies the transfusion, the physician is sent an email message asking for an explanation about why the transfusion was ordered," stated Marques. "It's critical to have a non-punitive review process and create a way for physicians to feel comfortable discussing blood use."

Improved Utilization

Positive feedback is regularly offered to physicians and has contributed to sustaining the progress made in improved utilization of blood products at UAB. "Everyone wants to be thanked for their work; to hear someone say, 'Your blood use is improving. Thank you for your efforts'," said Marques.

This ongoing campaign has produced impressive accomplishments. "In the decade prior to the program's launch in 2007, our hospital had doubled its use of red blood cells," declared Marques. "From 2007 to 2009, these efforts succeeded in reducing use of packed red blood cell units by 29%, from .925 units per discharge to .65 units per discharge."

These achievements were anchored in two fundamental practice changes at UAB. Not only were fewer patients being transfused, but the amount of blood per patient was greatly reduced. Notably, utilization of blood products at UAB had declined so much that it was below the national averages for every patient type that was studied.

"Financial results have also been positive," explained Marques. "The annual cost of blood product acquisition has declined by $3.5 million, which is a 29% decline compared with 2006, the last year before implementation of the blood management program. There were also significant savings produced by improved administration and the reduction in risk of complications.

Supply Of Blood Products

"Of course, improving utilization of blood products was only one side of our two-pronged strategy," she added. "Even as these steps were underway, we worked with the local American Red Cross, one of our main suppliers, on the supply side of the blood products equation.

"UAB administrators negotiated a contract with the American Red Cross which reduced the price UAB paid for blood if it met collection targets," continued Marques. "From the beginning of 2007 to the end of 2008, the hospital increased collections from less than 200 units per year to more than 6,000 units per year. This went a long way in helping close the gap between resources used and resources gathered.

"To jump start this collection program, we developed a reward-points strategy," she stated. "This rewarded our employees for giving blood. It also encouraged those in the community to donate blood. Another source of donors was the **University of Alabama** student body, which prior to their efforts had not participated fully in blood collection drives.

Blood Drive Champion

"Within the hospital, we recruited blood drive champions for each department. The departments engaged in friendly competition for quarterly celebrations in honor of the highest scoring team," recalled Marques. "Another helpful secret is to convince managers to agree to let their workers give blood during their shifts, rather than using personal time. For the future, we plan to arrange a light lunch for donors who come during their noon breaks."

The UAB team now ties these blood drives into local events, such as the local Susan G. Komen Race for the Cure. They also created holiday-themed blood drives, such as an appeal to staff patriotism on July 4th, to keep staff enthusiasm high.

UAB's contract with the American Red Cross called for lowering the price of each unit of packed red blood cells supplied if the hospital met annual collection goals. So far, the hospital has met and exceeded their goals, further reducing their costs.

"This process of reducing blood use and increasing collections required the efforts of all hospital staff," stated Marques. "There was a critical need for success and that translated into widespread support. Hospital management was a driving force for change throughout the process.

Education Was Key

"If I had to sum up our success in one word which had the biggest impact, I'd say it was education," concluded Marques. "Education, when combined with good data, allowed all staff involved in blood transfusions to understand how patient safety and improved patient outcomes were associated with better utilization of blood products."

As the UAB experience shows, pathologists and lab managers do not have to accept the spiraling cost of blood products and transfusion administration. A concerted reduction campaign anchored in evidence-based practice, combined with effective blood donation marketing, can save money, relieve blood shortages and improve patient safety. TDR

—K. Branz

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Point-of-care testing (POCT) continues to gather momentum and grow at much faster rates than routine clinical laboratory testing. That's the finding of analysts at **Frost & Sullivan**. In the United States, POCT product sales totaled $2.1 billion in 2009. Frost & Sullivan predicts that POCT sales will top $3.9 billion by 2016. It says the annual compounded growth rate of POCT products between 2006 and 2016 will be 9.2%. This compares with growth rates in the low single digits for routine tests, such as chemistry and hematology.

MORE ON: *POCT*

What are the hottest areas in point-of-care testing? According to Frost & Sullivan, in 2009, the big winners were POC influenza testing because of the 2009 H1N1 pandemic and POC coagulation patient self-monitoring, due to the 2008 Medicare reimbursement policy for patients with chronic atrial fibrillation and deep vein thrombosis. Going forward, Frost & Sullivan predicts that big market drivers will be POCT products for cardiac biomarkers, blood gas, and electrolytes.

FTC IS REVIEWING SALE OF WESTCLIFF TO LABCORP

Laboratory Corporation of America disclosed that its acquisition of **Westcliff Medical Laboratories, Inc.**, is undergoing review by the **Federal Trade Commission** (FTC). The FTC is considering the anti-trust consequences of the acquisition. LabCorp says that it has entered into an agreement with the FTC to hold the WestCliff business unit as an independent laboratory called **LabWest**, during the FTC review. No date for the completion of the FTC review was announced. LabCorp paid $57.5 million to purchase California-based Westcliff Medical Laboratories, which had filed for Chapter 11 bankruptcy reorganization on May19. *(See TDR, June 1, 2010.)*

MAX PLANCK INSTITUTE BUILDING LAB IN FLORIDA

On June 23, ground was broken in Jacksonville, Florida, for a new research laboratory to serve the **Max Planck Florida Institute**. The new 100,000 square foot facility will be part of the John D. MacArthur campus of **Florida Atlantic University**. The Max Planck Florida Institute will conduct research in the areas of neuroscience and integrative biology.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 2, 2010.