G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. VI, No. 9, October 2004

For Hospitals, Laboratories and Physician Practices

Lab Monitoring Under Increased Scrutiny

Maryland Problems Call System Into Question

The system for monitoring clinical laboratories nationwide is coming under more scrutiny after problems at two Maryland labs are resulting in thousands of people undergoing rescreening for HIV and other diseases.

State inspectors earlier this year disclosed that Maryland General Hospital in Baltimore reported invalid HIV and hepatitis C test results over a 14-month period ending in August 2003. Since the allegations surfaced, the laboratory has been trying to locate more than 2,500 people, some of them homeless, for retesting. The hospital's president/CEO and the lab's medical and administrative directors have resigned, and a consulting firm, Park City Solutions (Midway, UT), has been brought in to manage lab operations.

Officials at a July 7 congressional hearing attributed the problems at Maryland General to failures in the hospital's lab equipment, a serious breakdown in the lab's quality-assurance system, and a lack of communication between the federal, state, and private agencies involved in the oversight of the lab. Whistleblowers ➥ *p. 9*

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Lab Figure Sentenced To 8 Years In Prison

A California judge has sentenced Ron Martin, a principal figure in a $20 million Medi-Cal fraud scheme, to eight years in prison, essentially ending a five-year investigation and prosecution of the fraud, Attorney General Bill Lockyer announced September 3.

Martin was also ordered to pay $2.5 million in restitution to the Med-Cal program and $17,212 to the California Franchise Tax Board. Surinder Singh Panshi, the scheme's mastermind, was sentenced in August 2003 to 16 years in prison. In all, the AG's office has obtained prison sentences of 63 years and four months and restitution of almost $8.3 million for 10 codefendants in the multi-state fraud scheme, Lockyer said.

False Laboratory Billings

The scheme bilked the Medi-Cal program of more than $20 million through a complex arrangement involving 15 clinical laboratories in California, the theft of patient and physician identity information, and the laundering of California warrants through a New Jersey market.

At the heart of the fraud was a plan to take over the operations of legitimate medical laboratories and, through identity theft and fraudulent claims, bill Medi-Cal and Medicare for millions of dollars of work that was never performed, authorities charged.

Panshi, who was twice convicted of Medicaid fraud in New York (in 1987 and 1988), ➥ *p. 2*

Lab Figure Sentenced To 8 Years, *from p. 1*

originated the scheme, using labs that gave the appearance of operating lawfully, sometimes performing some tests on blood samples. That, however, only masked the real enterprise, which involved purchasing blood from homeless people and addicts, paying off clinical employees to draw excess blood from unsuspecting patients, and then selling that blood "out the back door of medical offices," according to papers filed ahead of Panshi's sentencing.

The blood was tested at the labs controlled by Panshi (or one of the other defendants), which then billed Medi-Cal and Medicare. Once the labs obtained patient identification information, that information was entered into a database, and then used at "sister" labs controlled by Panshi to bill the healthcare programs for work never performed, the documents added.

Physicians' identities were also stolen as part of the scheme so that false records could be created that purported that these physicians authorized the labs to perform the tests.

An Orange County grand jury in August 2003 indicted Martin on 41 felony counts related to the scheme. Martin, who was a fugitive for 10 months after authorities broke up Panshi's enterprise in June 2002, was arrested in April 2003 in Arizona and extradited to California in May 2003. He pleaded guilty in November 2003.

No Fines Levied Under HIPAA Privacy Rule

The Department of Health and Human Services (HHS) is receiving nearly 100 complaints per week under the federal healthcare privacy rule, but so far has not levied any civil monetary fines.

Richard Campanelli, director of HHS's Office for Civil Rights (OCR), said September 13 that the agency continues to focus on voluntary compliance. HHS issued the privacy rule under the administrative simplification provisions of the Health Insurance Portability & Accountability Act (HIPAA).

Since the April 2003 compliance date for the privacy rule, OCR has been able to resolve 57% of complaints, Campanelli said during the Ninth National HIPAA Summit, held in Baltimore.

"The most effective way, and the most common way that we would be able to resolve complaints, is typically through voluntary compliance," he said.

Privacy complaints are being lodged against private healthcare practices, general hospitals, pharmacies, outpatient facilities, and group health plans, according to Campanelli. The most frequent allegations involve impermissible use or disclosure of health information, lack of adequate safeguards to protect information, refusal or failure to provide access to health information, disclosure of more information than necessary, and inadequate authorization for disclosure.

Complaints often involve violations that took place prior to the April 14, 2003, enactment of the privacy rule, the OCR director said. In addition, some complaints deal with violations by entities not covered by the rule (the privacy rule applies to providers, payers, and clearinghouses).

Despite the lack of civil money penalties, Alan Goldberg, conference co-chair and a healthcare attorney, urged conference participants not to underestimate OCR's power. Privacy rule infractions could draw unwanted

Levinson Named Acting IG

Daniel Levinson, President Bush's nominee to fill the inspector general (IG) vacancy at the Department of Health and Human Services (HHS), has assumed the duties of the office in an acting capacity pending approval of his nomination.

The White House said in a September 8 personnel notice that Levinson had been designated acting IG for HHS. Levinson reported for work September 14, according to an OIG spokesperson. He now assumes the duties that Dara Corrigan had been performing since she was named principal deputy inspector general in June 2003. Corrigan has recused herself from most healthcare matters and is focusing only on personnel issues and internal investigations, presumably because she is looking for a job outside the agency.

Levinson's nomination is expected to go before the Senate Finance Committee this fall.

publicity, which could attract class action lawsuits, he said.

Compliant Medicare Claims

The majority of claims submitted electronically to Medicare are currently compliant with the HIPAA transactions and code sets (TCS) rule, officials with the Centers for Medicare & Medicaid Services (CMS) said during the conference. So far, 200 complaints have been submitted. CMS enforces the TCS rule.

Most of the 200 complaints involve claim payments that adversely affect cash flow, according to Dianne Faup, advisor to CMS's Office of HIPAA Standards. About 58 of these complaints remain open.

The majority of complaints involve small providers against health plans and clearinghouses, she said. Five corrective action plans have been submitted.

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More information is available at *www.hipaasummit.com*.

OIG: Hospital Can Subsidize Malpractice Premiums

A medical center in a health professional shortage area can pay medical malpractice premiums subsidies for four community-based obstetricians who provide services to a local hospital, the Department of Health and Human Services office of inspector general (OIG) said in an advisory opinion released September 9.

Although the proposal could generate prohibited remuneration to the four doctors, the OIG determined that the premium subsidy program posed little risk for fraud and abuse to federal health programs.

The medical center includes a 142-bed hospital and provides services regardless of patients' ability to pay, according to the opinion. Among those who provide labor and delivery services at the hospital are four community-based obstetricians who hold staff privileges but are not employees or contractors of the medical center.

The obstetricians assist family medical doctors and the nurse midwife – who are employed by the medical center – with high-risk and complicated delivery cases, the OIG said. The obstetricians also assist nurse midwives at a migrant health clinic not affiliated with the medical center but in its service area. The doctors are in full-time practice in the community.

Between 2002 and 2003, the obstetrician's malpractice insurance premiums rose $36,000 per doctor, a price hike that the medical center believes is due in part to the doctors' work at the hospital.

"The medical center asserts that the increased premium expenses derived in part from the special nature of services the obstetricians render to the medical center and the community, in particular their back-up services in high-risk and complicated deliveries," the advisory opinion stated.

The medical center proposed a premium subsidy program that would cover a portion of the obstetrician's malpractice insurance premiums for two years. Specifically, the medical center would pay half of the increase based on the rate hike between 2002 and 2003. The subsidy per physician would be capped at $25,000, would be paid directly to insurers, and would cover all service provided by the obstetricians, not just those rendered at sites affiliated with the medical center, the OIG said.

The doctors would be required to abide by medical center rules and regulations and remain on staff in good standing. In addition, they would be required to continue providing back-up obstetrical services for the medical center and migrant health clinic and notify the medical center of any changes in their scopes of practice that would affect their service to the medical center. The obstetricians also would be required to alert the medical center of any premium reductions so that the subsidy could be recalculated to reflect the change.

Furthermore, the obstetricians would not be required to make referrals to the medical center or generate business for the medical center and could establish staff privileges and

refer patients to any entity of their choosing, according to the opinion. The medical center said it expected that at least 95% of the patients served by the obstetricians would live in a health professional service area (HPSA) or medically underserved area, or be part of a medically underserved population. The proposal also noted that the medical center would obtain certification from the doctors that at least 75% of their patients belonged to one of those three populations.

Safe Harbor

An anti-kickback safe harbor protects some subsidy programs that assist obstetricians working in HPSAs, and the OIG found that the proposal met all but one condition of the safe harbor. Specifically, the safe harbor requires that obstetricians provide services in a primary care HPSA for a subsidy arrangement to be protected. The doctors practice in a low-income, migrant agricultural, homeless population HPSA. Nevertheless, the OIG said in its opinion that, because the four obstetricians provide services in another type of underserved area, rather than a primary care HPSA, there was little risk of fraud and abuse.

"Our conclusion is consistent with the intent of the safe harbor to ensure access to obstetrical care – including expert care for high-risk and complicated deliveries – in places and for populations that do not have sufficient access to care, while at the same time protecting the federal healthcare programs and beneficiaries from fraud and abuse," the OIG said in its opinion.

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Advisory opinion 04-11: *www.oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0411.pdf.*

GAO Recommends Recovery Of Scully Salary

The Department of Health and Human Services (HHS) should recover salary payments to former Medicare program chief Thomas Scully, who barred an agency actuary from telling lawmakers about the projected costs of the 2003 Medicare legislation, the Government Accountability Office (GAO) said in a September 7 letter to Senate Democrats.

The GAO letter, signed by General Counsel Anthony Gamboa, recommended that HHS "seek to recover these payments," referring to department appropriations. The department should recoup the salary payments, GAO said, because of former Centers for Medicare & Medicaid Services Administrator Scully's actions to block CMS Chief Actuary Richard Foster from disclosing estimates of the Medicare legislation's costs. Scully's actions made the HHS appropriation unavailable for payment of his salary, the GAO letter said.

The GAO letter does not specify how much of Scully's salary should be recovered, but the focus in the letter is on fiscal years 2003 and 2004. Scully's annual salary at CMS was $145,600.

Sen. Frank Lautenberg (D-NJ) and other Democrats requested the GAO legal opinion. They have complained that the Bush administration kept high cost estimates of the Medicare drug benefit law under wraps until the legislation was approved in late 2003. Lawmakers working on the bill had estimates from the Congressional Budget Office that the legislation would cost $395 billion over 10 years. Foster's estimates put the price tag of the Medicare drug law at between $500 billion and $600 billion over that period. More recently, the administration has said the bill will cost $534 billion over 10 years.

"The Bush administration went so far as to break the law in order to hide information about their flawed Medicare plan," Lautenberg said in a statement. "President Bush's former Medicare chief needs to pay back his salary, as the Government Accountability Office has ordered."

Scully is now in private practice with the law firm of Alston & Bird.

Resource

GAO letter: *www.gao.gov/decisions/appro/302911.htm.*

COMPLIANCE PERSPECTIVES

The Safe Sharps Race: A Steady Advance To The Finish Line

Dr. Sheila Dunn is president and CEO of Quality America, Inc., a healthcare consulting firm (Asheville, NC) that develops specialized training programs for providers, major medical manufacturers, and distributors.

Needlesticks and other sharps injuries are declining, but will there ever be a day when healthcare workers can collect and handle specimens without risk?

Most hospitals and laboratories have made significant efforts to reduce sharps injuries, either by adopting sharps with built-in safety features or by changing the way procedures are performed to "engineer out" the risk of injuries. The latest sharps injury data shows that despite some nagging problems, for the most part, labs have done a good job.

We've come a long way in the decade since the Occupational Safety and Health Administration (OSHA) began to require that healthcare workers be protected from bloodborne pathogens on the job. Throughout the 1990s, laboratory managers were busy coming into compliance by selecting protective equipment and training employees to use it. In most labs, safety sharps either didn't exist or were an afterthought.

In the late 1990s, the Needlestick Safety and Prevention Act brought sharps safety to the forefront, although OSHA had always intended it to be a part of the Bloodborne Pathogens Standard. Lab managers stood up and took notice, but weren't exactly sure if safety sharps were recommended or required. Finally, three years ago, OSHA added language to the Bloodborne Pathogens Standard to remove any doubt that safety sharps are mandatory in all medical facilities; that is, if a needleless system isn't available.

Despite what OSHA believes is "crystal clear" instruction, several high-profile OSHA citations were recently issued, and several matters are still hotly debated, such as single-use tube holders for phlebotomy.

Data Indicates Progress

It's not possible to quantify the current extent of compliance due to the myriad product types (lancets, butterflies, syringes, scalpels, etc.) and the number of departments in large hospitals. The data that does exist is either old or doesn't apply directly to the lab.

The International Healthcare Worker Safety Center's latest data show an overall 51% decline in percutaneous injuries (PIs) from 1993 to 2001 (*i.e.*, injuries from both conventional and safety devices declined from 19.5 PIs per 100 occupied beds in 1993 to 9.6 PIs per 100 occupied beds in 2001).[1]

Type of Sharp	*PI Decline 1993-2001*
IV catheters	55%
phlebotomy needles	70%
prefilled syringes	62%
winged steel needles	55%
lancets	87%
suture needles	5%

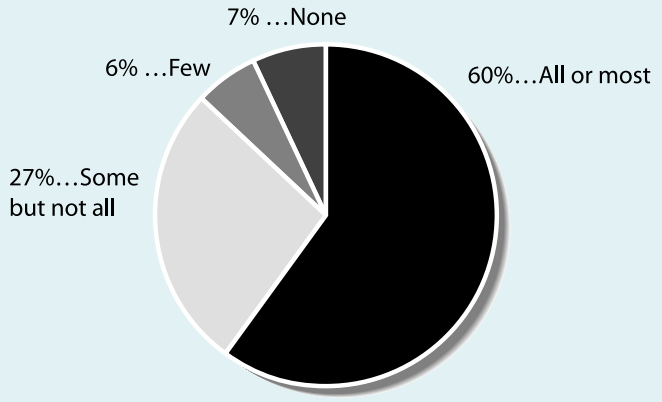
A 2004 survey[2] provides the most current statistics to date, but the data is not specific to laboratories. In this survey, nurses reported that only 68% of the sharps used in the past year had safety features. Forty-six percent of nurses who had sustained sharps injuries admitted that a safety device was NOT in use during the accident.

Safety sharps manufacturers estimate that U.S. hospitals have transitioned more than 80% of their sharps product usage from conventional to safety-engineered designs in IV catheters, needleless IV connectors, blood drawing needles, winged needle sets, and lancets. Estimates for plastic blood tubes are lower at between 55% and 75%. Conversion

[1] *Jagger, J., and Perry, J.: "Comparison of EPINet Data for 1993 and 2001 Show Marked Decline in Needlestick Injury Rates," Advances in Exposure Prevention. 6(3):25–27, 2003.*

[2] *"Needlestick and sharps-safety survey: Getting to the point about preventable injuries." Jane Perry MA, Eileen S. Robinson RN, MSN, Janine Jagger MPH, PhD. Nursing 2004. April 2004. Volume 34 Number 4 Pages 43 – 47.*

Institutions Providing Safety Sharps



Source: Nursing 2004: "Needlestick and Sharps-Safety Survey"

is also lower for syringes and needles, surgical blades, scalpels, and other categories of devices used for specialty medical procedures.

Frank Meilinger, an OSHA spokesperson, says that despite more inspections in 2003, citations for not using safety sharps were down from 28 in 2002 to 21 in 2003. Most OSHA inspections are complaint driven, and Dionne Williams, an industrial hygienist at OSHA's national office, says that she is fielding more calls this year about the use of unsafe sharps during surgery, as well as similar calls from dentists' and physicians' offices.

As expected, across all product categories, the overall level of transition to safety products remains lower in clinics and physicians' offices than in hospitals.[3] Becton Dickinson & Co. (BD-Franklin Lakes, NJ) estimates that 42% of the combined physician office and long-term care markets have made the switch and believes that the long-term care market contributes disproportionately to this percentage. Physician offices either aren't aware of the OSHA regulations or believe that they're below OSHA's radar screen on this issue.

Complain and OSHA Will Come Knocking

Some workplaces underestimate OSHA's resolve when it comes to mandating safety products for *all* employees and have chosen to stock safety and conventional versions of sharps devices side by side. Leaving it up to workers to decide which to use is a blatant OSHA violation unless facilities can provide written justification for having to use conventional devices.

Melody Sands, M.S., director of OSHA's Office of Health Enforcement, announced that healthcare facilities that were inspected and cited for failure to use safety sharps declined from 50% in 2002 to 20% in 2003. Despite these encouraging trends, two recent high profile OSHA citations show the agency's willingness to impose huge fines if safety devices aren't implemented facilitywide.[4]

The Beaver Valley Nursing and Rehabilitation Home in Beaver Falls, Pennsylvania, was slapped with over $92,000 in bloodborne pathogens penalties. Of that amount, $22,500 was assessed for "serious" violations such as not including frontline workers in the safety evaluation process. The maximum penalty possible, $70,000, was charged for a "willful" violation for not using safety devices when injecting medications and working with catheters. A willful violation is one committed with an intentional disregard of, or plain indifference to, OSHA requirements.

Montefiore Medical Center in Bronx, New York, is typical of most large teaching hospitals in that it has implemented safety in many, but not all, areas. After several resident physicians complained to OSHA, Montefiore was fined several thousand dollars in late 2003 for failing to use safety products in 26 different instances. Moreover, sharps injuries had actually increased by 2% in 2001 and 7.3% in 2002.

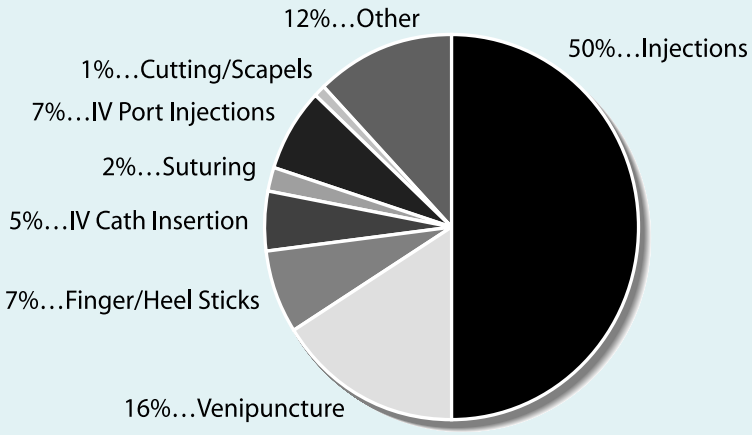
Three Issues Remain Unsolved For Laboratories

Three areas continue to confuse and confound laboratories: the blood tube holder single-use issue, the mandate to use plastic blood collection tubes, and the annual re-evaluation of safety sharps.

1. Blood Tube Holders. Reuse of standard phlebotomy tube holders has been a common practice and hotly debated over the past year as a practice that poses a potential risk of injury. OSHA maintains that removing a needle from a phlebotomy tube holder to reuse the holder poses a risk of injury from the "back end" needle. Other experts disagree, such as Gina Pugliese, RN, MS, vice president of Premier Safety Institute, who believes the risk

[3] *Infection Control Today. Kelly M. Pyrek. March 2003.*
[4] *Advances in Exposure Prevention Vol 6, No. 6, 2003. "Ground Breaking Citations issued by OSHA for Failure to use Safety Devices."*

Where Sharps Injuries Occur



Source: Nursing 2004: "Needlestick and Sharps-Safety Survey"

of injury in this case is miniscule compared to the environmental impact and the enormous cost to throw away every tube holder.

Despite the controversy, OSHA maintains its position prohibiting the removal of contaminated needles attached to phlebotomy tube holders and requires the immediate disposal of the entire unit after each blood draw.[5] Experts estimate that 70% to 90% of labs have complied and discard tube holders after each phlebotomy with the safety needle attached.[6]

LabCorp and Quest Diagnostics, however, have defied OSHA's mandate. Both have been inspected and cited by OSHA, but continue to contest their citations. LabCorp even wrote a letter to clients explaining that tube holders for phlebotomy can legally be reused. When asked about the status of Quest's dispute with OSHA, Gary D. Samuels, vice president, external communications, replied, "This is an open case, and as we continue to discuss it with OSHA, we don't feel it is appropriate to comment publicly on the matter at this time." Brad Hayes, LabCorp senior vice president for investor relations and corporate communications, says, "We continue to believe that we are correct in our interpretation of this issue, and we will continue to work with OSHA as they contact us regarding these matters."

Earlier this year, when interviewed for Quality America's OSHA Watch Newsletter, OSHA's Dionne Williams said, "It's unfortunate that LabCorp is sending this memo out to people who can be influenced by it, because it is erroneous. What is LabCorp hoping to gain by this?" She went on to say that the one-use requirement for blood tube holders is an OSHA regulation and that "LabCorp does not set policy for the nation." Currently, OSHA won't comment on the status of either LabCorp's or Quest's citation.

Dennis J. Ernst, MT (ASCP), director, Center for Phlebotomy Education, Inc., is well aware of the issue. "There's no question OSHA was subjected to some serious arm-twisting, but the bulletin issued last year tells me everyone else is expected to comply," he says. "I'd say 90% of hospitals do. The rest continue to place their bets that an employee won't turn them in."

Physician offices and others who send specimens to LabCorp and Quest continue to use whatever blood collection supplies are provided by the referral lab, and you can bet those are reusable tube holders and glass tubes. In fact, LabCorp's specimen collection instructions say to: "Use the appropriate release device on the safety holder to discard the safety needle in the sharps container."

2. Glass vs. Plastic Tubes. The second issue of confusion for most laboratories is the conversion from glass tubes to safer, less breakable plastic tubes. OSHA says to substitute plastic blood tubes for glass whenever possible, stressing that glass equipment that contacts body fluids or tissue specimens should also be converted to plastic. You won't find this exact verbiage in the Bloodborne Pathogens Standard, though, so like the safety needle issue, OSHA may need to issue a bulletin to clarify its stance.

Plastic blood-collection tubes have been on the market for at least eight years, but there are still some barriers to their use. First, labs need to perform parallel tests before switching to plastic to ensure that patient test results are comparable. Second, many labs believe that plastic tubes are much more expensive. Not so, according to Dennis Ernst, director, Center for Phlebotomy Education. Plastic is only marginally more expensive, and when

[5] Safety and Health Information Bulletin issued on Oct. 15, 2003: http://www.osha.gov/dts/shib/shib101503.html
[6] Chris Bickel, global product manager for blood tube holders at BD, and Dennis Ernst Director, Center for Phlebotomy Education.

Where to Buy Plastic Tubes

Complete Line: Greiner Vacuette (Monroe, NC) and Sarstedt (Newton, NC)
Complete Line except coagulation tubes: BD (Franklin Lakes, NJ)
Plastic gel separator tube: Kendall (Mansfield, MA)
Blood culture tubes: BioMerieux (Durham, NC)

you look at plastic tubes' lighter weight and the fact that they can be more efficiently incinerated, plastic tubes cost significantly less to use overall. However, critical tests in coagulation and blood banking may prove a challenge for some manufacturers of plastic tubes.

Despite the paucity of literature about plastic tube conversions in laboratories, Ernst speculates that most labs have converted for all tubes except coagulation, and that less than half have made the switch to them for coagulation.

Some Things In Life Are Free

Besides switching to safety sharps, there are other ways to decrease injuries, including changing worker behavior and looking for ways to consolidate and eliminate unnecessary punctures.

Premier's Gina Pugliese suggests that the best way to ensure that healthcare workers are protected is to "engineer out" the problem by changing the way a procedure is performed so that no decision needs to be made by a worker. Examples from other industries where "forcing functions" have been used are ATM cards that only work when swiped a certain way and gas tanks that will only fit certain type nozzles.

Louise G. Grant, Senior Marketing Manager for Microbiology at bioMerieux, says that their BacT/ALERT blood culture system has been 100% glass free for over a year now. Grant says that bioMerieux invested in plastic tubes to help customers comply with the law. Other companies with automated blood culture systems, such as Trek Diagnostics and Becton Dickinson, haven't yet made the switch to plastic bottles.

3. The Annual Re-evaluation of Safety Sharps. The requirements for continual (annual) evaluation of new safety devices continue to confuse and confound lab managers, and for good reason. If the injury rate has been reduced and there are no reports of employee dissatisfaction, what is a lab's obligation to consider or evaluate a different device?

OSHA's Dionne Williams confirms that annual re-evaluation is a problem for many. "A lot of what we're seeing for citations this year is the failure to review new devices on an annual basis." Although OSHA does not say exactly what needs to be included in an annual review, its intent is to make sure that the devices being used remain appropriate, control the hazard, and reduce risks to workers.

So, common sense prevails. Consider that you wouldn't choose a device and keep using it year after year despite employee complaints and documented ongoing problems with the device. You also wouldn't evaluate every new device on the market each year.

Instead, conduct an annual review of your *program* that includes a review of the devices in use. What this review entails will differ among labs, but factors such as what data will be reviewed and by whom and what devices are evaluated, if necessary, must be outlined in your Exposure Control Plan. Keep abreast of new technology, and document this on an annual basis so that the staff can consider additional options if the current product selected has been improved or if some newer technology has been shown to offer better protection. In small labs, the annual review could be as simple as documenting both the review of sharps injury data and staff feedback about how well the current devices are working.

The Bottom Line

Almost four years after OSHA's challenge to eliminate occupational needlesticks among healthcare personnel, we've dramatically cut worker injuries, but the process is not yet complete. About one in 10 healthcare facilities aren't using safety devices at all. Most large institutions are approaching total compliance by using available safety devices (or no needles at all, in some instances) or by adopting safer work practices to prevent sharps injuries.

Removing alternative (unsafe) products would seem an easy solution, but products such as syringes are often used for tasks that don't transmit bloodborne pathogens and, as such, can't be totally phased out. Abbott Laboratories has stopped selling needle-based infusion therapy products, and BD is phasing out many conventional sharps devices, including IV catheters, winged needle sets, and lancets.

Needlesticks and other sharps injuries are declining, but will there ever be a day when healthcare workers can collect and handle specimens without danger of acquiring a bloodborne disease? Don't bet on it. A risk-free laboratory will only emerge when noninvasive ways to test patients become the norm. And, that's not likely to happen in this lifetime.

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Ronald Lepoff, MD

Nelson Sabatini

Clinical Lab Monitoring, *from p. 1*

Teresa Williams and Kristin Turner, both employees of Maryland General's lab at the time the invalid results were released, testified during the hearing that there were a number of problems in the lab that led to the bogus results.

In a second case, Maryland health officials in August ordered the closure of Reference Pathology Services of Maryland, located in Baltimore, after concluding that the lab poses "an immediate jeopardy to the health of its patients and that of the general public." Officials alleged that the lab failed to report sexually transmitted diseases to the Baltimore County Health Department, failed to report cervical cancer cases to the Maryland Cancer Registry, failed to conduct required controlled testing on lab equipment and materials, and reused filters in cervical cancer test kits that should have been discarded.

The problems at Reference Pathology Services first came to light in April when a whistleblower reported them to Maryland health officials and the College of American Pathologists (CAP). CAP reinspected the lab on May 19 and revoked its accreditation May 28. After the lab failed to correct deficiencies, the state suspended its license and ordered it to shut its doors on September 5. However, the lab is offering free retesting to 3,000 patients for chlamydia, gonorrhea, and human papillomavirus (HPV).

Monitoring & Accreditation Questioned

These cases have raised concerns about the process by which clinical labs are accredited and monitored. Both Maryland General's lab and Reference Pathology Services were accredited by CAP. At the July congressional hearing, critics accused CAP of operating an accrediting process that is too collegial. CAP officials dispute those charges, saying the organization carefully inspects every lab it accredits but that it is impossible for inspectors to turn up every possible deficiency, particularly in instances when laboratories are dishonest.

Ronald Lepoff, MD, FCAP, chair of the CAP Commission on Laboratory Accreditation, tells *GCR* that the system worked exactly as it should have in the case of Reference Pathology Services. When CAP learned of problems at the lab, it moved quickly to reinspect the facility and revoke accreditation. In the case of Maryland General, the laboratory actually falsified records. No accreditation system can ensure that people will be honest, he says.

At the same time, CAP's accreditation system can always be improved, Dr. Lepoff acknowledges. "There are problems with any system," he says. "But there isn't any system that can possibly have a regulator in every laboratory 24 hours a day, 365 days a year, to uncover malfeasance."

Maryland's Secretary of Health Nelson Sabatini believes that the problems are "merely a symptom of a system failure" and calls into the question the legitimacy and adequacy of the entire regulatory process. In particular, he said during the congressional hearing, the Centers for Medicare & Medicaid Services (CMS) should not assume that labs accredited by organizations such as CAP or the Joint Commission on Accreditation of Healthcare Organizations meet or exceed CLIA standards and, therefore, do not require separate CMS surveys.

"Patient safety is ultimately a government responsibility, but we have subcontracted it out," he said.

Problems at Maryland General persisted because the regulatory and accrediting bodies did not share information about the testing deficiencies, Sabatini argued. "Even if there were good communications between all the agencies, there are too many of them," he said, calling for legislative correction at both the federal and state level.

Changes Planned

Sean Tunis, chief clinical officer and director of CMS's Office of Clinical Standards and Quality, told lawmakers that CMS is developing a plan with tighter communication protocols to coordinate activities among states with licensure programs, the state agencies surveying on behalf of CMS, the CMS regional offices, and the accrediting organizations. The agency also is addressing its processes for handling complaint surveys as well as the validation surveys it conducts of samples of labs accredited by outside bodies.

In addition, CMS plans to beef up the regulatory coordination processes through training, reapproval of accrediting bodies, and changes to the State Operations Manual for CLIA lab surveys, Tunis said. "This improved communication will ensure that entities performing CLIA surveys, state licensure, and private accreditation organizations are aware of complaints and deficiencies that each has found within a time frame to prevent further exacerbation of identified problems." The agency also is considering adding performance measures for approved accrediting bodies.

"Patient safety is ultimately a government responsibility, but we have subcontracted it out."
—Nelson Sabatini

Judy Yost, director of CMS's Division of Laboratory Services, tells *GCR* that the agency is responding to requests by Maryland lawmakers to convene a meeting between CAP, hospitals, state health agencies, and lab workers.

"We will have a meeting later this year, during surveyor training, to talk about best practices and how we can improve them and how we can be more consistent and do a better job during the surveyor process," she explains. The meeting is scheduled for November 15.

Yost does not believe that legislative changes to lab accreditation and monitoring are needed. "Absolutely not," she says. "We can accomplish what needs to be done administratively, through the authority of the CLIA program."

CAP also is making changes to its accreditation process to encourage workers to bring problems to light as soon as possible, notes Dr. Lepoff. For example, CAP has:

- Required labs it certifies to post signs by October 1 encouraging whistleblowers to call a confidential hotline when they suspect problems (866-232-7212);
- Established a policy that harassment of whistleblowers is grounds for immediate revocation of a lab's certification; and
- Begun tracking specimens throughout a lab's workflow, rather than relying so much on reviewing records.

Resources

- Judy Yost: 410-786-3407
- CAP: 847-832-7574
- July 7 congressional hearing testimony: *http://reform.house.gov/CJDPHR/HearingsEventSingle.aspx?EventID=1201*

Feds Intervene In Case Against Mississippi Health System

The federal government has intervened in a whistleblower case charging a Mississippi health system, four doctors, and two physician practice groups with conspiring in a broad kickback scheme that involved illegal referrals of Medicare patients, the U.S. attorney for the Southern District of Mississippi said in a complaint filed September 7.

Mississippi Baptist Health Systems (Jackson, MS) was charged with violating the False Claims Act and anti-kickback statute by paying kickbacks and other illegal remuneration to doctors and physician groups between 1994 and 2001 to induce the referral of more than $38 million in Medicare business to its hospital, Mississippi Baptist Health Center.

Drs. William Causey, Samuel Peeples, Fred McDonnell, and John Long—all employed by one of two physician practice groups also named in the complaint—were charged with violating the anti-kickback statute and physician self-referral law (known as the Stark law) by soliciting and accepting kickbacks from Baptist, according to the complaint. Federal prosecutors are investigating whether false claims also were submitted to Medicaid and TRICare (a military health program) as a result of the kickbacks and other illegal remuneration, the complaint stated.

Baptist denied the government's claims. "Baptist Health Systems believes the allegations in the so-called 'whistleblower' lawsuit are without merit and is disappointed that the federal government is joining some portions of that lawsuit. It is important to know that absolutely none of the allegations involve quality of patient care," Baptist spokesman Robby Channell said in a September 8 written statement.

Ambulance Company Settles False Claims Charges

A Connecticut ambulance company and an affiliated firm have agreed to pay a $1.6 million fine and enter into a five-year corporate integrity agreement to settle charges related to improper billing for transportation services, the Health and Human Services Office of the Inspector General (OIG) said September 16.

Under the terms of a September 10 settlement with the federal government, American Ambulance Service and Professional Ambulance Service of Norwich, Connecticut, will pay $1,598,000 to settle charges that it filed false claims with federally funded health programs.

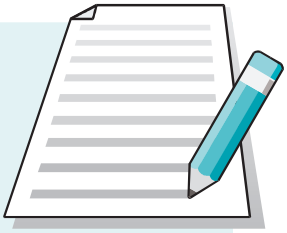
The settlement centers on the filing of claims between 1997 and 2001 with Medicare, Medicaid, and TRICare by the ambulance company for transportation of kidney dialysis patients. The claims were deemed not to be medically necessary or reasonable. The settlement figure represents double damages, as allowed under the federal False Claims Act.

Professional Ambulance Service said in a statement that "several billing inconsistencies were unintentional and a result of confusing and often contradictory federal rules." The company stressed that it has cooperated fully with the government in its investigation into the former billing practices.

In addition, the firm said the documentation and billing for state and federal agencies had been upgraded as of November 1999, and that an approved compliance plan is in place. The company also noted that it believed it was easier to settle the case than engage in years of litigation and pay the major legal fees associated with an extended period of litigation.

For the Record

Helpful Tips In Complying With HIPAA Security Rule



In just about seven months, covered entities will be required to meet security requirements mandated by the Health Insurance Portability & Accountability Act (HIPAA). As healthcare providers and others affected by the security rule prepare for its April 21, 2005, implementation, the Centers for Medicare & Medicare Services (CMS) is offering helpful advice in the form of frequently asked questions (FAQs).

Here are samples of tips you'll find on CMS's Web site at *www.cms.hhs.gov/hipaa/hipaa2/default.asp*:

Q: Does the HIPAA Security Rule allow for sending electronic protected health information (PHI) in an email or over the Internet? If so, what protections must be applied?

A: The HIPAA security rule does not expressly prohibit the use of email for sending electronic PHI. However, the standards for access control, integrity, and transmission security require covered entities to implement policies and procedures to restrict access to, protect the integrity of, and guard against the unauthorized access to electronic PHI. The standard for transmission security also includes addressable specifications for integrity controls and encryption. This means that the covered entity must assess its use of open networks, identify the available and appropriate means to protect electronic PHI as it is transmitted, select a solution, and document the decision. The security rule allows for electronic PHI to be sent over an electronic open network as long as it is adequately protected.

Q: Do the HIPAA security rule requirements for access control, such as automatic logoff, apply to employees who telecommute or have home-based offices if the employee accesses electronic PHI?

A: Yes. Covered entities that allow employees to telecommute or work out of home-based offices and have access to electronic protected health information must implement appropriate safeguards to protect the organization's data. The automatic logoff implementation specification is addressable and must therefore be implemented if, after an assessment, the entity has determined that the specification is a reasonable and appropriate safeguard in its environment.

If the entity decides that the logoff implementation specification is not reasonable and appropriate, it must document that determination and implement an equivalent alternative measure, presuming that the alternative is reasonable and appropriate.

Medical Device Manufacturer Fined: A federal court in Minneapolis September 8 ordered Augustine Medical Inc. and four of its former executive officers to pay millions of dollars in fines for knowingly and willfully withholding material facts used to determine Medicare benefits. U.S. District Judge Ann Montgomery ordered the company, based in Eden Prairie, Minnesota, to pay a fine of more than $5.2 million and placed it on probation for five years. The four former executives were fined a total of $2.3 million, and each was placed on probation for three years. Augustine Medical and its officers were charged with Medicare fraud in 2003 for allegedly representing that one of their products, Warm-Up Active Wound Therapy, was reimbursable under Medicare.

Medtronic Hit With Second Case: A second whistleblower lawsuit has been filed against medical technology company Medtronic Inc., alleging illegal kickbacks to doctors, the company said September 2 in a regular quarterly filing to the Securities & Exchange Commission. The whistleblower charges that Medtronic subsidiary Medtronic Sofamor Danek Inc. (MSD) improperly paid inducements to physicians who used the company's products and services for treatment of spinal injuries and disorders. Medtronic says it believes the allegations in the most recent case are similar to those brought in September 2003. Both cases remain under seal in the U.S. District Court for the Western District of Tennessee.

Ophthalmologist Charged: A federal grand jury in Vermont charged an ophthalmologist with cheating Medicare, Medicaid, and private health insurance companies of more than $1 million for unnecessary cataract surgeries, state and federal government officials announced September 16. David Chase of Burlington, Vermont, was indicted on 80 counts of healthcare fraud and making false statements in connection with a healthcare benefit program. Chase allegedly devised and executed a scheme to defraud Medicare, Medicaid, and private insurers by offering, recommending, and performing unnecessary cataract surgeries. The indictment also contended that Chase conducted a scheme to maintain false and misleading medical records to support his fraudulent diagnoses of cataracts. If convicted of fraud, Chase could face a maximum sentence of 10 years imprisonment and a fine of up to $250,000 on each count. He also faces a maximum five years in prison and a fine of up to $250,000 on each count of making false statements.

G-2 Compliance Report (ISSN 1524-0304). © 2004 Washington G-2 Reports, 1111 14th St, NW, Suite 500, Washington DC 20005-5663.
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