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House Panel Grills Regulators Over Maryland Lab Errors

Critics say the case shows that governmental and private oversight bodies need to be more proactive in ferreting out lab quality problems and need a faster track to share their inspection findings and initiate solutions

In the wake of media reports over flawed HIV and hepatitis C testing as well as other quality lapses at the Maryland General Hospital laboratory in Baltimore, a subcommittee of the House Government Reform Committee is investigating how the problems could have persisted for over a year and why it took so long for CLIA oversight bodies to enforce corrective action.

The panel, chaired by Rep. Mark Souder (R-IN), held a hearing on the issues on May 18 and plans another on June 10 to examine regulatory gaps that need to be addressed. The hospital is in the district of the panel's ranking Democrat, Rep. Elijah Cummings.

The subcommittee has heard from officials of the College of American Pathologists, the Maryland Department of Health & Mental Hygiene and the Centers for Medicare & Medicaid Services. All cited the need for improved protocols on sharing each other's inspection findings. But the hearing also raised questions about the vigilance of private nonprofit CLIA-accrediting bodies and CMS' diligence in monitoring their performance. See the *Focus*, pp. 4-6 in this issue.

INSIDE *NIR*

More Tissue Donor Testing Required

The Food & Drug Administration has expanded testing and screening requirements for donated human cells, tissues, and cellular and tissue-based products to help stop the spread of communicable disease when these products are transplanted. The changes were published in a final rule in the May 25 *Federal Register* and take effect May 25, 2005.

The FDA has required screening and testing of donors of musculoskeletal, skin and eye tissues for HIV, hepatitis B and C since 1993. The new rule expands the types of covered tissues to include reproductive and hematopoietic stem cell tissues, as well as cellular therapies and other innovative products. It also requires testing for additional diseases, including human transmissible spongiform encephalopathies (TSEs) and syphilis. For donors of viable cells and tissue rich in leukocytes, such as semen and stem cells, testing is required for human T-lymphotropic virus (HTLV). For reproductive tissues, the rule requires testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. The agency said it would issue further guidance ➥ *p. 2*

Donor Testing & Screening

The final rule lists eight "relevant communicable disease agents or diseases:"

- ❑ HIV-1 and 2
- ❑ Hepatitis B virus
- ❑ Hepatitis C virus
- ❑ TSE, including Creutzfelt-Jakob disease and vCJD
- ❑ Syphilis
- ❑ HTLV, types I and II
- ❑ Chlamydia
- ❑ Gonorrhea

The draft guidance lists diseases FDA believes also meet the criteria:

- ❑ West Nile virus
- ❑ Sepsis
- ❑ Plague
- ❑ SARS

Source: FDA draft guidance accompanying the final rule

More Tissue Donor Testing, *from p. 1*

when it decides to add more diseases. It has flexibility to add requirements to screen and test for emerging disease threats such as West Nile virus, severe acute respiratory syndrome (SARS) and sepsis.

Autologous donations and reproductive cells or tissues from sexual partners are exempt from the donor testing and screening requirements. Other cells and tissues which are subject to the rule, but may be used with appropriate communication, labeling and documentation of the relevant results even if the donor is determined to be ineligible include reproductive cells or tissues from a directed donor; those for use in first or second-degree blood relatives; and those that meet a documented urgent medical need.

In other provisions, the rule:

- ❑ Allows specimen collection for donor tissue testing up to seven days before or after tissue recovery, a substantial increase from the 48 hours that the FDA previously proposed. However, for peripheral blood stem progenitor cells, testing is allowed up to 30 days prior, so it can precede the decision to prepare the patient for treatment with chemotherapy and irradiation.
- ❑ Requires, for donors who are one-month old or younger, testing of the mother only, due to the possibility of transmission of agents such as hepatitis B during birth, which would leave the infant infected, but without the telltale antibodies.
- ❑ Relaxes the testing requirement for anonymous, repeat sperm donors from whom a specimen has already been collected and tested, as long as donated semen is quarantined pending re-testing at least six months after donation.
- ❑ Requires testing of sperm and stem-cell donors for cytomegalovirus. For CMV-reactive donors, who either have an active infection or still carry antibodies from a previous infection, the rule leaves open the possibility of procedures allowing donation to CMV-reactive recipients.
- ❑ In terms of CLIA compliance, allows testing by labs as long as they meet equivalent requirements, as determined by the Centers for Medicare & Medicaid Services, such as veterans' hospital labs, labs in states exempt from CLIA and labs accredited for CLIA by private nonprofit organizations.
- ❑ Allows any qualified pathologist to perform the full brain autopsy, including gross and histological examination, to see whether dura mater donors have TSE. The agency had proposed to let only neuropathologists do the autopsy. FDA would consider dropping this requirement if a sufficiently sensitive TSE test were approved.
- ❑ Specifies that donors are ineligible under the rule if their plasma was diluted prior to testing. FDA sets specific requirements for determining whether plasma was diluted by transfusions or infusions.
- ❑ Requires retention of donation and transplantation records for 10 years, due to the long latency period of TSEs such as vCJD, which is of particular concern with dura mater and corneas, but can be an issue with other tissue types as well.

The FDA rule is the second of three proposed rules finalized under the agency's plan to regulate tissues and related products with a comprehensive, risk-based approach

The final rule is posted online at: *http://www.fda.gov/OHRMS/DOCKETS/98fr/97N-484S-nfr0001.pdf*. Draft guidance related to the rule is posted at *http://www.fda.gov/cber/gdlns/tissdonor.pdf*.

Senate Passes BioShield Legislation

The House passed counterpart legislation (H.R. 2122) last July by a vote of 421-2. Rep. Christopher Cox (R-CA), who chairs the Select Committee on Homeland Security, said he doesn't expect a formal House-Senate conference will be needed to forward BioShield legislation to the President

The Senate, by a vote of 99-0, approved on May 19 a BioShield bill (S. 15) that would speed approval and production of medical countermeasures against bioterrorism. These may include drugs, biologics or medical devices such as diagnostic tests that the Secretary of Health & Human Services determines to be a priority to "treat, identify or prevent harm from any biological, chemical, radiological or nuclear agent that may cause a public health emergency affecting national security."

The measure, introduced Mar. 11 by Sen. Judd Gregg (R-NH), chairman of the HELP Committee, aims to assure pharmaceutical companies of governmental support if they invest in research and development of products to thwart agents such as smallpox and anthrax before they are ever needed.

The Senate-passed bill authorizes $5.6 billion over 10 years to procure bioterror counteragents (the money has already been appropriated under the 2004 Homeland Security spending legislation, Public Law 108-90). The BioShield bill would authorize procurement spending only if:

- The Department of Homeland Security determines that a particular agent is a "material threat" against the U.S. population sufficient to affect national security;
- HHS determines a countermeasure is in order; and
- The countermeasure is FDA-approved or the HHS Secretary decides it is reasonably likely to win FDA approval within eight years.

The Secretary may limit competition through sole-source procurement in the event of "certain emergency conditions," said a GOP Senate aide. The bill also allows expedited peer review of anti-bioterror research and development and gives the National Institute of Allergy & Infectious Diseases at the National Institutes of Health authority and flexibility to award grants and contracts for such R&D.

States Get More Money For Bioterror Preparedness

In the three years since the 9/11 attacks and the subsequent anthrax mailings, HHS has awarded $3.7 billion to states to prepare for bioterror and other disasters

The HHS Health Resources & Services Administration has awarded $498 million of fiscal 2004 funds to states, territories and four major metropolitan areas to enhance the readiness of hospitals and other healthcare facilities for bioterror attacks, infectious diseases and natural disasters.

Recipients will use the money in part to increase coordination between hospital-based laboratories and public health laboratories in reporting on disease outbreaks, including those that could result from bioterror attacks. Very likely, the first indication of such an attack would be an influx of unusual emergency room visits. A vigilant early-warning system would help the public health system and homeland defense authorities respond quicker and more effectively.

The Department of Health & Human Services also said the Centers for Disease Control & Prevention will soon announce an estimated $844 million of public health preparedness grants. Meanwhile, HHS is being criticized for slow disbursement of bioterror funding. The National Governors Association and the Association of State & Territorial Health Officials say that states have obligated some 90% of the money, but HHS has been holding up final approval of their spending plans. But HHS says that states have spent only half of the money they have already received.

focus on: CLIA Lab Oversight

Who Fumbled The Ball In Maryland Hospital Lab Case?

"Patient safety is ultimately a government regulatory responsibility, but we have subcontracted it out"—Maryland Secretary of Health Nelson Sabatini, criticizing how CMS and private accrediting bodies exercise their CLIA oversight duties

Clinical laboratory regulators at both federal and state levels, along with officials of CLIA accrediting organizations, are taking political heat following recent disclosures that on their watch the laboratory at Maryland General Hospital in Baltimore reported invalid HIV and hepatitis C test results over a 14-month period ending in August 2003.

Critics have faulted both internal management and the analyzer used for the testing, but congressional overseers want to know why governmental and private-sector bodies responsible for assuring compliance with CLIA (the Clinical Laboratory Improvement Amendments) failed to address the problems early on and what steps they'll take to improve their oversight role.

Since the allegations surfaced in March of this year, the laboratory has been trying to locate more than 2,500 people, some of them homeless, for re-testing (which has been outsourced to ensure credibility). So far, there have been few positive re-tests, and no way to tell whether those tested became infected before or after the invalid testing. The hospital's president/CEO and the lab's medical and administrative directors all have resigned. A consulting firm, Park City Solutions (Midway, UT), has been brought in to manage lab operations.

CAP Accredited The Lab, Unaware Of Complaints

In testimony before a House Government Reform subcommittee on May 18, Ron Lepoff, MD, chairman of the College of American Pathologists' Commission on Accreditation, acknowledged that CAP granted the hospital lab "accreditation with distinction" in April 2003 after a 13-member CAP inspection team conducted a biennial inspection. The team found nine deficiencies, but endorsed the accreditation after the lab showed it had corrected them.

Unknown to CAP, lab employee Theresa Williams had filed a complaint in 2002 with the state of Maryland, alleging that the laboratory failed to monitor quality control and instrumentation, falsified proficiency testing results, failed to follow manufacturer's instrumentation protocols, and reported patient results on testing runs for which quality control checks failed.

Had the state shared this complaint with CAP, Lepoff said, the College would have checked it out, and "if the allegations had been substantiated, it almost certainly would have led to revocation of the laboratory's accreditation and, possibly, additional penalties by the Centers for Medicare & Medicaid Services."

The state, he noted, also failed to share with CAP a second complaint, filed by Williams' coworker, Kristen Turner, in December 2003, which included the allegations about the HIV and hepatitis testing. Turner has since sued the hospital, claim-

A Crowd Of Overseers

Who's involved in one way or another in overseeing the performance of the laboratory at Maryland General Hospital?

- ❑ CAP, which agreed, at the lab's option, to serve as its accrediting body
- ❑ JCAHO, which deemed CAP's lab accreditation as equivalent to the Commission's lab-related requirements for hospital accreditation
- ❑ CMS, which deemed CAP accreditation as equivalent to CLIA standards
- ❑ The state of Maryland, which enforces state lab licensing requirements
- ❑ CMS and the state of Maryland, which enforce Medicare/Medicaid Conditions of Participation for hospitals

ing that the Labotech analyzer it had been using for such testing spilled blood on her, infecting her with both viruses.

Maryland's Department of Health & Mental Hygiene, under the state's lab licensure requirements, inspected the laboratory on Jan. 23, 2004, in response to Turner's complaint. It found that lab personnel had been altering quality control values on reports produced by the instrument that were outside an acceptable range. This, Lepoff said, "would have concealed the quality control problems from the CAP inspectors."

Role Of Accrediting Bodies Questioned

Maryland's Secretary of Health Nelson Sabatini told the House panel that "the Maryland General experience is merely a symptom of a system failure, and I believe it calls into question the legitimacy and adequacy of the entire regulatory process." In particular, he said, 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 regulatory responsibility, but we have subcontracted it out."

Problems at Maryland General persisted because the regulatory and accrediting bodies involved did not share information about the testing deficiencies, he argued. "Even if there were good communication between all the agencies, there are too many of them." He said the oversight problems "will require legislative corrections at both the federal and the state level."

JCAHO Calls For Better Coordination

JCAHO, which accredits Maryland General Hospital, reacted strongly to Sabatini's comments. "I think he's severely missed the boat," vice president of external relations Margaret Van Amringe told the *National Intelligence Report*. "If the [complaints] had come to us, we would have done something about it—and there would have been a report to the state. If the state found something and didn't tell the accrediting body, that's outrageous."

JCAHO includes an appraisal of lab operations as part of its hospital accreditation process. In the case of Maryland General, JCAHO deemed CAP accreditation sufficient for this purpose. However, when CAP suspended the lab's accreditation in the wake of the problems identified, JCAHO assumed direct oversight of the lab for hospital accreditation purposes. The Commission then surveyed the lab, found some deficiencies, required an immediate plan of correction and downgraded the hospital's overall accreditation.

JCAHO and CAP are discussing how to improve communications and better coordinate their processes in the event of another 30-day suspension of accreditation. "We'll go over this in July at our next annual meeting on our recognition agreement with CAP," Van Amringe said. "We should take this as a learning experience and not throw darts at each other."

CMS To Require More Information Sharing

Sean Tunis, chief clinical officer and director of CMS' Office of Clinical Standards & Quality, told the House panel that in a series of inspections by various agencies dating back to November 2002, "similar issues were identified concerning the management and quality assessment processes of the laboratory … Each oversight entity addressed these issues, but did not inform all of the remaining involved parties of their findings. Therefore, each oversight entity did not have the benefit of the findings of the others."

Based on the state's investigation of the HIV and hepatitis testing complaint, CMS and the state of Maryland jointly investigated the lab on Mar. 16-24. On Apr. 6, CMS decided to no longer deem the lab CLIA-accredited under CAP's program and ordered the lab to report directly to the state until the condition-level deficiencies were corrected. On Apr. 26, CAP suspended accreditation of the lab's chemistry and point-of-care areas for 30 days after a follow-up inspection confirmed findings of the joint CMS/state survey.

More Perspectives On The Case

In comments to *NIR*, the top CLIA official at the Centers for Medicare & Medicaid Services, Judy Yost, confirmed that when an accrediting body suspends a laboratory's CLIA accreditation—as CAP did with the lab at Maryland General Hospital—the oversight function defaults to CMS, and CMS in turn carries out this function through state survey agencies, in conjunction with the respective CMS Regional Office.

CMS has ultimate authority under CLIA, she said, and can send the state in at any time, even when a lab is CLIA-accredited.

Is corrective legislation needed as Maryland's health secretary has argued? "I don't believe that's the case at all," Yost said. "I think that communications can be improved and that's what we're working on at this point."

In her view, the fundamental problem at Maryland General lies with the hospital, not the oversight agencies, and the incident is an aberration. Asked if the cause was a device problem or a personnel problem, she attributed it to management infrastructure issues. "The instrument didn't help," but management should be able to deal with instrument problems, she said.

Tunis assured lawmakers that CMS is responding to the regulatory complexity that delayed response to the Maryland General incident by "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.

CMS plans to beef-up the regulatory coordination processes through training, re-approval 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 timeframe to prevent further exacerbation of identified problems." The agency also is considering adding performance measures for approved accrediting bodies.

Meantime, the laboratory at Maryland General remains under state agency monitoring. Its plan of correction is under review by the state of Maryland and the CMS Regional Office in Philadelphia. If the plan is not acceptable, the Regional Office may impose civil money penalties, suspend the lab's CLIA certification and/or deem it ineligible for Medicare/Medicaid payments. Maryland, under its licensing authority, could fine the lab, but for now is relying on the lab to carry out its plan of correction. The state plans a follow-up survey to verify that the plan is being implemented; CAP plans a follow-up visit as well.

Democrats Press For Disclosure Of Medicare Cost Estimates

Congressional Democrats continue to pursue the Bush Administration for its handling of the dispute over how much the Medicare reform law would cost. At the time the legislation was being debated, lawmakers approved a $400-billion ceiling over 10 years. The Congressional Budget Office projected the cost would be $395 billion over 10 years. But lawmakers were allegedly kept in the dark about a much higher estimate from the Medicare chief actuary, Richard Foster. He pegged the price at $534 billion over 10 years. Allegedly, his boss, Thomas Scully, then head of the Centers for Medicare & Medicaid Services, forbade him from disclosing his estimate to Congress. The alleged reason? Fear that the disclosure might help derail the legislation, though technically it's the CBO estimate that matters.

Responding to a request from Rep. Charles Rangel (NY), the Ways & Means Committee's ranking Democrat, a lawyer with the Congressional Research Service opined Apr. 26 that such a gag order is prohibited under the 1912 Lloyd-LaFollette Act, and more recently by legislation banning payment of salary to any federal official who resorts to threats to prevent employees from communicating with Congress. Further, CRS legislative attorney Jack Maskell noted, the Medicare chief actuary may be removed from office "only for cause."

HHS officials continue to withhold most details of Foster's cost estimates. Scully's acting successor, Dennis Smith, in April rebuffed a request for the estimates made by the 19 Democratic members of the House Committee on Government Reform, citing an obscure statutory provision. On May 17, the members filed suit to compel Health & Human Services Secretary Tommy Thompson to release Foster's estimates.

♦ QUESTION *of the* M·O·N·T·H

Under a "grandfather" provision in the Medicare reform law, independent clinical laboratories may continue to bill Medicare directly for the technical component (TC) of physician pathology services furnished to hospital inpatients and outpatients. This protection applies to hospital-lab arrangements in place as of July 22, 1999.

Will a hospital lose its protection if it gets new owners?

Medicare official Jim Menas said new ownership would make it a new hospital, and new hospitals cannot take advantage of the grandfather provision. Section 732 of the Medicare Modernization Act of 2003 extended the protection through 2006 (*NIR, 25, 4/Nov. 25, '03, p. 2*). Draft legislative language that would have protected hospitals where there was a change of ownership never made it into the final legislation.

It is possible, however, that technically there has been no change in ownership even though the hospital has new owners, said attorney Tom Coons with Ober/Kaler in Baltimore, MD. Ownership does not change, for example, when there has been merely a transfer of corporate stock or for a hospital that acquires another, as per 42 C.F.R. Section 489.18.

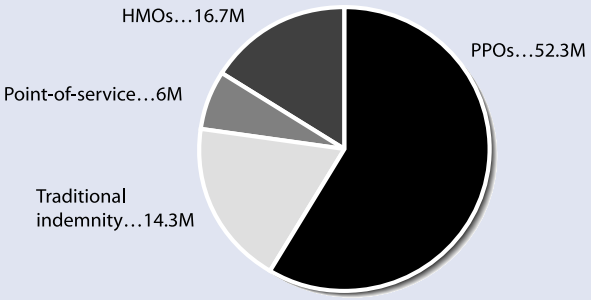
Does the grandfather provision protect all pathology services or just anatomic services?

The Centers for Medicare & Medicaid Services has defined the TC of physician pathology services to include the TC of cytopathology and surgical pathology. See the second paragraph of Transmittal AB-01-47, *cms.hhs.gov/manuals/pm_trans/AB0147.pdf*.

Growth Of The Blues Continues For 9th Straight Year

Enrollment in 41 independent Blue Plans across the country increased for the 9th year in a row, reaching a total of 88.8 million in 2003, reports the Chicago-based Blue Cross and Blue Shield Association. The prior year the total was 85.3 million. If the new Medicare managed care program, Medicare Advantage, gets off to a start in 2006 as scheduled, the Blue Plans are expected to offer a range of coverage options tailored to new members, but also designed to retain baby-boomers after they become Medicare-eligible.

Blues Members By Type Of Plan



Source: BCBS Assn.

According to the BCBS Association, the independent plans grew and improved financially in many ways last year:

- ❑ Total system-wide revenue reached $182.7 billion, up from $162.8 billion in 2002, thanks to rate and enrollment increases.
- ❑ Claims paid totaled $156.9 billion, up from $141 billion in 2002.
- ❑ Claims accounted for 85.9% of premiums, down from 86.6% in 2002.
- ❑ Administrative expenses declined to 10.9% from 11.1% the prior year.

Aggregate statutory capital reserves at the end of 2003 were $31.9 billion, up from $24.5 billion at the end of 2002. Growth in capital reserves reflects the need for plans to hold increased contingency funds as enrollment rates and healthcare costs continue to rise dramatically nationwide.

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