WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 27th Year of Publication

Vol. 27, No. 18, July 17, 2006

GAO Report Calls For Tougher CLIA Program Oversight

Join in our special July 27 audio conference, Putting CLIA Inspections In The Spotlight, *to discover how the GAO's conclusions will affect CMS policy for your lab. For registration and other information, see p. 5.*

A new report on the quality of clinical laboratory testing, recently issued by the Government Accountability Office, urges the Centers for Medicare & Medicaid Services to do a better job in its oversight role to ensure that labs meet requirements under CLIA (the Clinical Laboratory Improvement Amendments of 1988).

The GAO, which serves as the investigative arm of Congress, identified a series of problem areas in lab inspection, complaint, and enforcement procedures and recommended steps to beef up CLIA oversight by CMS and survey organizations. The corrective measures include standardizing how deficiencies found during inspections are reported so that meaningful comparisons can be made across survey organizations and ensuring that emphasis on an educational approach during lab inspections doesn't preclude tough sanctions on labs with repeat deficiencies.

The GAO's study was requested by lawmakers in the aftermath of widely publicized lab quality failures at Maryland General Hospital in 2004 that went undetected by federal, state, and private accrediting inspectors and came to light only in a whistle-blower suit. For more on the GAO's findings, see the *Focus*, pp. 3-6.

INSIDE *NIR*

Senate Bill Protects Pathology TC Billings

A bill has been introduced in the Senate to continue the "grandfather" protection that allows independent clinical laboratories to bill and be paid by Medicare for the technical component (TC) of pathology services for hospital inpatients and outpatients. The "grandfather" provision expires at the end of this year, but the bill, S. 3609, would make it permanent, beginning January 1, 2007.

The bipartisan measure—the *Physician Pathology Services Continuity Act of 2006*—was introduced June 29 by Sen. Blanche Lincoln (D-AK), with three co-sponsors: Sens. Craig Thomas (R-WY), Jim Bunning (R-KY), and Kent Conrad (D-ND).

The College of American Pathologist strongly backs it. CAP president Thomas M. Sodeman, MD, FCAP, said in a statement, "Without this legislation, independent labs will have to seek payment from already cash-strapped hospitals that would receive no new funds ➥ *p. 2*

Under current policy, the "grandfather" protection applies to the hospital, not the lab. So, hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. Medicare also has defined the TC of pathology services to include not only anatomic services, but also cytopathology and surgical pathology (CMS Transmittal AB-01-47).

Pathology TC Billings, *from p. 1*

from Medicare to pay for these medical services. The burden will fall especially hard on small and rural hospitals, which typically cannot afford in-house pathology services and rely heavily on independent labs."

The "grandfather" protection applies to hospital/lab arrangements in effect as of July 22, 1999, the date when the Centers for Medicare & Medicaid Services proposed to end separate payment under Part B for the pathology TC services and require labs to seek reimbursement from the hospital instead, contending that the TC is included in the hospital's Part A payments (*NIR, 25, 4/Nov. 25 '03, p. 2*). Congress has stepped in repeatedly since—most recently in the 2003 Medicare reform law—to stop CMS from implementing this policy change.

S. 3609 also would stipulate that a change in ownership on or after July 22, 1999, would not affect a hospital's "covered" status under the protection. Currently, a hospital loses the protection when it gets new owners, because it is considered a "new" hospital and thus cannot be "grandfathered" (*NIR, 25, 16/Jun 7 '04, p. 7*).

When Congress extended the "grandfather" provision through 2006, it did so despite a Government Accountability Office report that favored eliminating direct TC pathology payments to independent labs. That report triggered a sharp rebuke from key provider groups, including the American Hospital Association, CAP, and the Rural Health Association. They attacked the "duplicate payment" argument, noting that Medicare has required hospitals to exclude pathology services from base-period costs and charges since 1983, when inpatient prospective payment was introduced (*NIR, 24, 21/Sep 12 '03, p. 1*).

The GAO found that in 2001, 4,773 PPS hospitals and critical access hospitals, or approximately 95% of all such facilities, outsourced some TC pathology services to labs that received direct payment for those services. In 2001, out of approximately 1.4 million outsourced TC pathology services, the median number of these services per hospital was 81. Urban hospitals outsourced almost twice as many services as rural hospitals. In addition, 64% of these services were for outpatient beneficiaries. By eliminating direct payment, Medicare would have saved $42 million in 2001, the GAO estimated, while beneficiary cost-sharing for inpatient and outpatient services would have been cut by $2 million.

CMS To Phase-In 'Medically Unbelievable' Edits

The "medically unbelievable" edits (MUEs), set to be implemented in January 2007, will be limited to anatomical edits (*e.g.*, billing for more than one appendectomy per patient) and will include many of the 2,800 suggested edits in the first round of comments on the MUE proposal, a top official at the Centers for Medicare & Medicaid Services told the Clinical Laboratory Coalition during a June 29 meeting.

The first round of proposed Phase 1 edits, which closed June 19, is not expected to provoke more controversy, said Lisa Zone, deputy director of the CMS Program Integrity Group, which is spearheading the MUE initiative. Moreover, CMS will hold an additional round of comments in mid-July, she told Coalition representatives. ➥ *p. 7*

focus on: CLIA Lab Oversight

CMS In The 'Hot Seat' Over Ensuring Quality Testing

Clinical labs performing tests of moderate or high complexity, along with the state and private survey organizations that inspect them, face tougher scrutiny following a recent report to Congress on the quality of lab testing under CLIA and CMS's response to recommended changes.

Government oversight is not sufficient to ensure that clinical laboratories are complying with requirements of CLIA (the Clinical Laboratory Improvement Amendments of 1988), concludes a report by the Government Accountability Office that was released at a June 27 House subcommittee hearing into the quality of lab testing nationwide.

The report urges the Centers for Medicare & Medicaid Services to bolster its oversight of on-site lab inspections, reporting of deficiencies, and confidentiality safeguards for lab workers filing complaints. It also calls on CMS to impose tougher sanctions on labs that repeatedly fail to correct identified deficiencies. Weaknesses in these areas hide real and potential quality problems, said GAO's healthcare director Leslie G. Aronovitz in her briefing to the House Government Reform Subcommittee on Criminal Justice, Drug Policy & Human Services.

Subcommittee chairman Mark Souder (R-IN) and the ranking Democrat, Elijah E. Cummings (MD), along with Senate Finance Committee chairman Charles Grassley (R-IA), requested the GAO study in the wake of revelations in 2004 of serious lab quality lapses at Baltimore's Maryland General Hospital, which is located in Cummings' district, as well as a separate incident that led to the closure of Reference Pathology Services, also in Baltimore (*NIR, 25, 16/Jun 7 '04, pp. 4-6; 25, 21/Sep 13 '04, p. 1*).

In remarks at the hearing, Cummings praised whistle-blower Kirstin Turner, a young lab technician at Maryland General Hospital, for disclosing problems with HIV and hepatitis testing quality that went undetected by federal, state, and private inspectors. "Only because of her," he said, did "state officials discover that over a 14-month period, more than 2,000 patients were issued unvalidated positive HIV and HCV test results." She also became infected with these viruses when a machine she was using malfunctioned and splattered her with blood, he noted.

The GAO study was conducted from January 2005 through May 2006 and resulted in 13 recommendations for change. CMS said it will implement 11 of them, but it disagreed with the GAO over proficiency testing intervals and the extent of simultaneous validation reviews by accrediting bodies. With regard to PT, the GAO noted that the CLIA statute calls for conducting this quality check on a quarterly ba-

The CLIA Lab Survey Universe

- As of December 2005, there were approximately 193,000 CLIA-certified labs, ranging from very small physician office labs performing fewer than 2,000 tests annually to hospital labs that perform millions of tests each year.
- About 81% (157,000) don't undergo routine biennial inspections because they perform only waived or physician microscopic procedures.
- About 19% (36,000) that perform moderate- or high-complexity testing are required to undergo an on-site inspection every two years. They also must participate in proficiency testing.
- Of these labs, 55% (19,700) are inspected by state survey agencies under contract with CMS, and 42% (15,200) are inspected by private accrediting organizations. Of the latter, COLA inspects 17%, CAP 15%, JCAHO 9%, and AOA, ASHI, and AABB 1% each.

sis, but CMS requires it for almost all lab tests only three times a year. CMS replied that it had consulted with the Centers for Disease Control & Prevention and both agreed that "on technical and scientific grounds, PT three times a year is appropriate."

Thomas E. Hamilton, director of the CMS survey & certification group where the CLIA program is housed, told the House panel that the agency "has either taken steps to address the GAO's recommendations or is responding in a positive manner." But he did balk at several of the GAO's criticisms of how CMS manages its staffing resources. Highlights of the GAO findings and CMS's replies are as follows:

'Standardize Data Reporting'

The CLIA program outsources its lab inspection duties to state survey agencies, exempt-state programs (Washington and New York State), and six private accrediting organizations. State programs use the federal CLIA rules, while the others inspect according to their own standards, which must be CMS-approved as at least CLIA-equivalent and may even be more stringent. So, it is vital, the GAO says, to standardize how deficiencies and other survey findings are reported to allow meaningful analysis across the varying survey entities, including trends in condition-level deficiencies (the most serious deficiency category).

CMS "endorses this concept," Hamilton said, but cautioned that a straightforward crosswalk from differing state and private standards to federal CLIA condition-level deficiencies is limited. But recognizing the importance of data comparison, Hamilton said CMS is concentrating on outcomes in its oversight of how the CLIA accrediting bodies are performing. "If a program has the highest standards but does not enforce them appropriately, these standards have little value in ensuring lab quality."

To improve data collection and meaningful comparisons of the data, CMS's Partners in Lab Oversight workgroup is looking into data-driven performance indicators, similar to those used to monitor how well state survey agencies satisfy their CLIA responsibilities, Hamilton said. The Partners in Lab Oversight initiative got underway soon after the Maryland General Hospital incident to facilitate information sharing among survey organizations and make sure there was coordinated follow-up to resolve quality problems.

'Hire More Staff'

The GAO said the CLIA program should "fully use revenues it has generated to hire sufficient staff to fulfill its statutory responsibilities," including meeting deadlines for required reviews of the inspection require-

Leading Accrediting Bodies Respond To The GAO's Report

Top officials of the three major private nonprofit CLIA accrediting bodies—COLA, the College of American Pathologists, and JCAHO—testified at the House subcommittee hearing on lab testing quality.

All stated that they believed quality has definitely improved in accord with the CLIA rules. They agreed for the most part with the bulk of what the GAO recommended and noted they are already carrying out some of the suggested reforms, such as featuring prominent information on how lab workers can file anonymous complaints and beefing up the training of lab inspectors.

The groups also noted that they have gone beyond what CMS requires and what the GAO recommended by switching from announced to unannounced inspections. CAP and JCAHO did so this year. So too has COLA for the facilities it accredits under its cooperative agreement with JCAHO.

CMS continues to use announced inspections (with roughly two weeks' advance notice) for the state agency surveys it oversees. However, the GAO urged the agency to reduce the lead time for surveys of physician office labs (the current longest advance notice is up to 12 weeks) and bring it in line with CMS policy for state agency surveys. CMS said it will do so and will work with state agencies and accrediting bodies to promote unannounced surveys in larger labs.

The GAO report raised potential conflict-of-interest concerns about CAP's use of volunteer teams from other CAP-inspected labs to conduct surveys. In reply, CAP said it has revised its related policy to instruct all parties to be cautious to retain objectivity in fact-finding during inspections. CAP also said it now will require mandatory training of both team leaders and team members within two years prior to inspections.

ments of survey and accrediting organizations to ensure that these requirements are at least CLIA-equivalent. GAO investigators said CMS officials told them that deadlines were missed because there were too few staffers. Moreover, because CLIA program staffers are part of the CMS Center for Medicaid & State Operations, they are subject to its personnel limits, regardless of whether the CLIA program has enough money to hire more staff.

The CLIA program has approximately 21 FTEs vs. a peak of 29 several years ago. It also had a $70 million surplus as of September 30, 2005, the GAO noted. The surplus is "far more than required to hire an additional six to seven staff members," GAO observed.

Hamilton's reply was terse: "CMS is fulfilling its statutory responsibilities" and "will continue to consider staffing adjustments" as needed. And while agreeing that CLIA-equivalency evaluations should be completed before their deemed status expires as well as whenever state or private accrediting bodies change their requirements, he pointedly noted, "We reserve the right to manage the work within available resources and priorities." The agency will address this issue through its Partners in Lab Oversight workgroup, he added.

'Balance The Educational & Regulatory Approach'

The GAO faulted CMS and survey organizations for sometimes being too lenient in emphasizing inspections as a forum for educating lab personnel on testing requirements at the expense of penalizing serious problems, especially repeat deficiencies. "The balance struck between educational and regulatory goals is sometimes inappropriately skewed toward education," the GAO said. "For example, even though initial test failure rates were high, CMS instructed state survey agencies not to cite deficiencies during the first two years of required Pap smear proficiency testing, to allow labs to become familiar with the program."

The regulatory approach should be the primary goal of survey organizations, the GAO recommended, but added that education to improve quality does not preclude identifying and reporting deficiencies that affect testing quality.

CMS agrees, Hamilton said, and will develop protocols to guide surveyors in balancing enforcement and educational functions of the survey process, including training on which deficiencies must be cited without any variation. Emphasis on the educational approach is limited to situations involving major new requirements and only for limited periods, he said. This applies to only two areas at present: quality control rules that took effect in 2003 and affect moderate complexity testing, and cytology proficiency testing rules that were implemented nationwide in 2005.

'Don't Be Too Lenient When It Comes To Sanctions'

The GAO questioned the effectiveness of CMS's enforcement of sanctions, noting that few labs were sanctioned by the agency from 1998 through 2004, despite repeat deficiencies in consecutive surveys, and urged CMS to crack down on repeat offenders. During the above period, more than 9,000 labs had sanctions proposed, but only 501 were actually sanctioned.

The GAO report, Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened *(GAO-06-416), can be accessed at www.gao.gov.*

Hamilton defended CMS's policy of progressive enforcement of sanctions, beginning with corrective action plans and increasing in severity for continuing failures. He said the agency will monitor citations of repeat deficiencies as part of the overall redesign of the CMS information system (converting from the Online Survey & Certification Reporting System [OSCAR] database to the ASPEN information system).

'Publicize Ways To File Confidential Complaints'

The GAO urged CMS to require all survey organizations to develop, and require labs to prominently display, posters instructing lab workers on how to file anonymous complaints *(see also box, p. 4)*. GAO investigators found less than one complaint per lab per year for 2002 through 2004—a significantly small number relative to the number of labs, they concluded. The GAO noted that the College of American Pathologists saw a significant increase in the number of complaints it received since October 2004 when it began requiring CAP-inspected labs to display posters on how to file complaints. From October through December 2004, CAP received an average of 22 complaints per month vs. an average of 11 complaints per month in the nine months prior to the poster requirement.

In reply, CMS said that information on filing complaints has been included in the updated surveyor interpretive guidelines, and most states have a hotline to receive complaints. CMS will augment its complaint tracking system, Hamilton said, so that accrediting organizations can send in their complaint data, thereby enabling CMS to create a national complaint repository. This would help ensure that complaints received are acted upon in a timely manner, he noted.

'Ensure An Independent Assessment Of Survey Organizations'

Validation reviews are a means by which CMS can evaluate lab inspections conducted by both state survey agencies and private accrediting bodies. But the GAO found that CMS does not validate state survey agency work consistently in each state. Also, many validation reviews are performed at the same time that a survey organization conducts a lab inspection, thus preventing an independent evaluation. Seventy-five percent of the validations of state lab surveys were conducted simultaneously from fiscal years 1999 through 2003, the GAO said. With regard to accrediting bodies, CMS officials were unable to tell the GAO investigators how many of some 275 validation reviews conducted each year in the above same period were simultaneous, but JCAHO estimated that 33% of its validation reviews were done simultaneously.

Hamilton replied that while there is no statutory requirement for the number of validation reviews in each state to assess a lab inspector's competency, this oversight is important and the agency will ensure that at least one comparative survey is conducted for each surveyor each year. He defended the use of simultaneous validation work as a way for surveyors to share "best practices" and promote understanding of each other's programs. The vast majority of validation surveys now undertaken are independent assessments of performance, Hamilton asserted, and CMS will continue to make sure that this remains the norm.

'Establish An Enforcement Database'

The GAO recommended this step to monitor actions taken by state survey agencies and regional offices on labs that lose their accreditation. Hamilton said that CMS is already working on setting up such a database to track such cases that may require federal enforcement actions.

'Medically Unbelievable' Edits, *from p. 2*

Phase 2 of the MUEs will start in April 2007 and will concentrate on "typographical edits," Zone said. When these proposed edits are released for comment this October, CMS will provide more detail on the rationale and methodology behind them, she noted. The "typo" edits could include lab and pathology services, noted Alan Mertz, president of the American Clinical Laboratory Association, who attended the meeting. Meantime, CMS has told the lab coalition that the Phase 2 edits would be done in consultation with lab interests, he told *NIR*.

The MUEs—renamed by CMS as "medically unlikely" edits at the request of Medicare's Practicing Physicians Advisory Council—are limits on the units of service that a healthcare provider can bill a particular CPT/HCPCS code per Medicare beneficiary per day. The edits have been highly controversial among pathology, laboratory, and other medical groups since CMS proposed them (*NIR, 27, 26/Jun 12 '06, p. 3*). The original list encompassed nearly all CPT/HCPCS codes but gave no explanation of the why and wherefore used to determine the units-of-service limits.

Lab Bidding Demo Not Seen As Threat To Quest, LabCorp

CMS has issued a report on a draft lab bidding demo design and a proposed lab application form, but at press time, had yet to make known its proposed two areas within single states where the demo would operate.

Medicare's planned competitive bidding demonstration for Part B independent lab services (excluding Pap smears and colorectal cancer screening) will not have much impact on market leaders Quest Diagnostics and LabCorp, concludes a July 10 report by the equity research unit at Wachovia Capital Markets, LLC.

"Both companies already are the low-cost provider for most clinical lab tests in most regions throughout the country and thus would be well-positioned to win such competitive bids," the report said. Both also have thousands of patient service centers "and thus would have a huge advantage in providing convenient access to Medicare patients."

The report is uncertain "if competitive bidding would require either company to raise or lower their current pricing structures." Both companies derive less than 20% of their revenue from Medicare, so "regardless of competitive bidding, the impact on overall pricing would be less significant," the report concludes.

"The Office of Management & Budget must also sign off on the demo design before CMS can begin implementation," Wachovia cautions. "We do not know how long this approval process will take, but as the project is in the President's budget, we would expect a sign off within the next six months."

Medicare Interest Rate Rises

Effective July 19, the interest rate for Medicare overpayments and underpayments will rise to 12.625%, up from 12.125% set April 24 and 11.875% in effect on January 25, 2006. The rate increase was announced by the Centers for Medicare & Medicaid Services in a July 12 transmittal (Change Request 4076). The interest rate hit a high in this decade of 14.125% in early 2001 and has since fluctuated in the range of 10.75 % to 12% since early 2002. Under Medicare regulations, interest may be assessed at the higher of the current value of funds rate (2% for calendar 2006) or the private consumer rate fixed by the Treasury Department.

Medicare Part B Lab Spending Up 10%, Says CMS

All of the increase is driven by greater volume and intensity of lab services, CMS noted, since Medicare lab fees have been frozen since 2004.

Medicare spending for Part B clinical laboratory services increased an estimated 10% in fiscal 2005, said Mark McClellan, MD, PhD, head of the Centers for Medicare & Medicaid Services, in a conference call on the HHS mid-session budget review for fiscal 2007 (which begins this coming October 1).

Overall, Part B spending rose by 11% in 2005, according to the budget review, fueled mainly by rising expenditures for physician services and hospital outpatient care. The rapid growth in services furnished in the physician office setting, CMS said, is driven by more intensive services, including lab tests, imaging, physician-administered drugs, physical therapy, and dermatology.

In calendar 2004, according to official estimates, Medicare spent a total of $304.4 billion. As a percentage of this spending, all Part B lab services (including hospital outpatient and outreach testing) accounted for only 2% or $6.018 billion, up 9.4% from $5.5 billion the year before. From 1998 to 2004, total Part B lab spending has risen from $3.6 billion to the $6B mark, an average annual increase of 8.8%.

washington WATCH

Price Transparency, Quality To Get Top HHS Priority

HHS Secretary Michael Leavitt said his Department will flex its market clout to encourage healthcare providers to fully disclose to the public the prices they charge for their services and the performance measures they use to assure quality. And expect this emphasis throughout the duration of the Bush administration, he stressed.

"Very few people know what they pay for healthcare … We intend to use the paying power of the federal government to foster transparency," Leavitt said June 26 at the American Health Lawyers Association annual meeting.

The Bush administration is pushing for price transparency and quality data to enable individuals to become "smart shoppers," stimulating competition among providers and lowering costs. In line with that strategy, Medicare on June 1 began posting information on the Internet on how much it pays for 30 elective inpatient hospital procedures, as well as other information on hospital admissions (*NIR, 27, 16/Jun 12 '06, p. 2*).

 NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Telephone: (212) 244-0360. Fax: (212) 564-0465. Web site: www.g2reports.com. Order Line: (212) 629-3679.

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