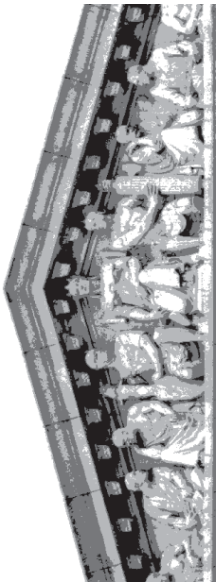

# G-2 Compliance Report

WASHINGTON G-2 REPORTS

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For Hospitals, Laboratories and Physician Practices


## CAP To Implement More Changes To Lab Accreditation, Inspections

The College of American Pathologists (CAP), which accredits more than 6,000 laboratories worldwide, said December 1 that it is implementing additional changes to its Laboratory Accreditation Program (LAP).

The changes include new techniques designed to strengthen the inspection process, new tools to evaluate the lab director's effectiveness, and improved monitoring. These reforms follow CAP's earlier announcement that it will move to unannounced inspections beginning in 2006. The initiatives are largely in response to quality failures uncovered at Maryland General Hospital's laboratory in 2004 (*see related article, pg. 5*).

"The CAP believes these initiatives will enhance the consistency and effectiveness of our inspection process, strengthen monitoring of laboratory quality between inspections, and reaffirm public confidence in the accreditation process," said R. Bruce Williams, M.D., chairman of CAP's Commission on Laboratory Accreditation. "The unfortunate incidents at Maryland General Hospital that came to light in 2004 prompted the college to re-evaluate its accreditation process. We believe the changes we announced today, and those made earlier, will go far toward preventing another case like Maryland General from occurring."

➥ *p. 2*

## OIG Will Review Proficiency Testing, Medicare Pricing Of Lab Services In 2006

The Health and Human Services Office of Inspector General (OIG) will assess laboratory compliance with CLIA requirements to participate in proficiency testing and will look closely at what Medicare pays for lab services, according to the agency's work plan for 2006.

The plan, issued each fall, serves as a blueprint for what the OIG plans to focus on during the following year. Experts advise using the plan as a road map for ongoing internal compliance efforts.

Medicare pays more than $4 billion annually for clinical laboratory services, all of which must meet requirements under CLIA (the Clinical Laboratory Improvement Amendments of 1988).

➥ *p. 8*

### Inside this issue

*Bruce Williams, MD*

**CAP To Implement More Changes,** *from p. 1*

The changes announced by CAP fall into seven areas:

**1. Strengthen the inspection process with new techniques.**

- Supplement traditional documentation review with new techniques that emphasize direct interaction with personnel and observation of testing process. The techniques represent the best practices for evaluating laboratory performance and compliance, according to CAP.

**2. Implement new tools to evaluate the laboratory director's role.**

- CAP has instituted a new checklist to better assess the laboratory director's effectiveness, as well as institutional impediments to the director's authority, performance of core management responsibilities, and execution of the laboratory quality management plan.
- New patient safety inspection checklist questions focus on patient and sample identification at specimen collection, analysis, and reporting; verification and communication of life-threatening or life-altering information (such as malignancies, HIV); coordination of laboratory's patient safety role within healthcare organization; and identification, communication, and correction of errors in a timely manner.

**3. Monitor to ensure sustained compliance.**

- Develop a knowledge management system to integrate quality factors, including proficiency testing results and trend analysis, inspection findings and complaints, for effective accreditation decision making and for a more comprehensive, multi-dimensional assessment of laboratory performance.
- In 2006 and 2007, the College will invest more than $9 million to support development of the knowledge management system of the LAP.

**4. Make consistent through enhanced, required training for inspectors.**

- CAP will require both team leaders and team members to successfully complete training within two years prior to inspections.
- There will be mandatory training for all team leaders beginning in July 2006. A similar subsequent requirement is planned for team members.
- There will be an ongoing requirement to complete training every two years, in addition to update activity.

**5. Reaffirm public confidence in objectivity of accreditation process.**

- CAP validation surveys will start in second half of 2006 to assess effectiveness of program changes and consistency in inspection process.
- Unannounced, routine inspections start in spring 2006 (excluding forensic urine drug testing and reproductive health laboratories).

**6. Coordinate communication among stakeholders.**

- CAP is abiding by a draft communication protocol between it, the Centers for Medicare and Medicaid Services, and other accreditation stakeholders. Protocol promotes information sharing about laboratory quality issues.
- Protocol designed to ensure a coordinated response among all stakeholders when problem laboratories are identified.

**7. Protect laboratory personnel and promote complaint reporting.**

- Accreditation requires prominent display of poster promoting CAP toll-free reporting line. Toll-free line to College provides prompt and confidential routing of complaints and quality concerns.
- CAP policy now protects laboratory workers from employer retaliation related to reporting laboratory quality concerns.

**Resources**

- Carl Graziano, the College of American Pathologists: 202-354-7118
- Bruce Williams, M.D.: 318-621-8820

# *LA Times* Article Highlights Lab Errors
## *CAP Cites Omissions, Distortions*

The discussion about lab quality is far from over. A December 2 article in the *LA Times* that highlights errors at a number of clinical laboratories and calls into question lab oversight and accreditation has once again fanned the flames of this controversial issue.

The article, "Lab Mistakes Threaten Credibility," discusses errors in the labs at Magee-Women's Hospital in Pittsburgh, where a mix-up of biopsy specimens in 1999 resulted in an incorrect cancer diagnosis. The woman wrongly diagnosed had a mastectomy and underwent radiation. Both that woman and the woman who did have cancer have since accepted undisclosed damage settlements in cases sealed by the courts.

> ***"The number of problem labs facing threats that their accreditation could be revoked is growing."***
> ***—LA Times***

Since then, there have been additional allegations of lab errors at Magee, according to the article, which also highlights lab errors at Maryland General Hospital in Baltimore, Yakima Regional Medical and Cardiac Center in Washington, and the Mayo Clinic in Minnesota.

"The number of problem labs facing threats that their accreditation could be revoked is growing," claims the article. "The faulty lab operations have raised alarm among medical experts about federal oversight and inspections of hospital laboratories across the country," it adds.

But the College of American Pathologists (CAP), which accredits more than 6,000 laboratories, says the article "makes significant omissions of fact" and provides a distorted and misleading view of CAP's laboratory accreditation program.

"Many of the story's allegations regarding the quality of laboratory testing have been subject to exhaustive investigation by the college and by state and federal authorities," notes CAP in a response to a the article. "Nevertheless, the article, while repeating the allegations regarding several institutions, ignores many of the official findings of these authorities based on inspections of the institutions."

For example, says CAP, multiple regulatory and private accrediting entities, including the Commonwealth of Pennsylvania and the Centers for Medicare and Medicaid Services (CMS), conducted inspection of the Magee laboratory and investigated the complainants' allegations. All concluded that the claims were unsubstantiated.

CAP also claims the article inaccurately depicts events at the Yakima hospital and the Mayo Clinic. "The CAP inspected the Yakima hospital references by the article in January 2004 and cited a number of deficiencies," says the college. "Accreditation was granted once these deficiencies were corrected to comply with CAP accreditation standards. The reporter, through inference and without factual basis, leaps to the conclusion that the issues identified by emergency room physicians in May 2005 must have been missed or ignored by the CAP when it inspected the lab in 2004, 14 months earlier."

As for the Mayo Clinic, the college consistently cited Mayo's unique specimen processing method as a deficiency over multiple inspections, says CAP. "The college evaluated Mayo's response to the cited deficiencies and never granted it a waiver or an exemption. Mayo provided patient outcome studies that showed their unique method provides an excellent diagnosis for patients. Upon careful consideration in each accreditation cycle, the CAP granted accreditation to Mayo.

"Because this was a recurring issue, the CAP consulted with CMS about the Mayo specimen processing method to determine equivalence with federal standards," CAP continues. "The college understands that CMS is still reviewing the Mayo method and, until the agency renders a final decision, the CAP will not recognize this method as meeting its standards."

**Resources**

- *LA Times* article, "Lab Mistakes Threaten Credibility, Spur Lawsuits": *www.latimes.com*
- College of American Pathologists: 800-323-4040

# OIG Proposes To Exclude Miami Hospital From Federal Healthcare Programs

Miami's South Shore Hospital and Medical Center is facing potential exclusion from Medicare, Medicaid, and all other federal healthcare programs as a result of an alleged breach of the terms of a corporate integrity agreement (CIA) it negotiated with the Health and Human Services Office of Inspector General (OIG) in 2002.

The OIG announced the proposed exclusion December 7 and said that South Shore has 30 days to demonstrate that it is "in compliance with the obligations of the agreement, that it has cured the breach, or that it is timely pursuing cure of the breach with due diligence." If South Shore fails to do so, the OIG may exclude the hospital from participation in the federal health programs. The hospital has the right to request a hearing before an HHS administrative law judge, with a right to further appeal to the HHS Departmental Appeals Board.

"The decision to issue a proposed exclusion letter to South Shore was made after careful consideration of the facts and circumstances regarding the actions of this hospital," said Inspector General Daniel Levinson. "In the majority of cases, provider organizations comply with the terms of the CIA. However, South Shore's repeated and egregious failure in this case to abide by the terms of its CIA requires the OIG, for the first time, to seek exclusion for such a violation."

Specifically, the OIG alleges that South Shore repeatedly failed to submit complete and accurate implementation and annual reports and failed to implement all of the Independent Review Organization requirements of the CIA, which called for particular types of cost reporting reviews and engagement procedures. South Shore also failed to notify the OIG, as required, of its May 2003 sale to new owners, who are also subject to the terms of the CIA.

The OIG says it analyzed the potential impact on beneficiaries if South Shore, which is not currently accredited by the Joint Commission on Accreditation of Healthcare Organizations, was to be excluded. The OIG determined that numerous accredited hospitals existed within a 10-mile radius of South Shore and, therefore, beneficiaries would not be adversely impacted by the exclusion.

In its May 9, 2002, False Claims Act settlement, the hospital agreed to pay the United States $937,000 to settle allegations that it overcharged Medicare by submitting false cost reports for unallowable expenses associated with its Guardianship Health Plan. Although South Shore entered into a comprehensive five-year CIA with the OIG, it has a long history of noncompliance, says the agency, which in November 2003 led to the OIG's imposition of a $50,000 stipulated penalty on the hospital for violating the terms of the CIA.

**Resource**

- Office of Inspector General: 202-619-1343

COMPLIANCE PERSPECTIVES

# Lab Institute 2005: Compliance, Competitive Bidding, & More

*Hope Foster, Esq.*

Clinical laboratories and other healthcare providers should pay close attention to a new approach being taken by the U.S. Attorney's Office for the Eastern District of Pennsylvania in Philadelphia to impose added, detailed compliance obligations over and above those contained in corporate integrity agreements (CIAs), warns Hope Foster, an attorney with Mintz Levin (Washington, D.C.).

Foster, who spoke during Washington G-2 Report's annual Lab Institute, called this unique approach to post-settlement agreements one of the most significant developments in compliance in 2005. The conference was held October 19 to 22 in Arlington, Virginia.

So far, the Philadelphia U.S. Attorney's office is the only one in the country that is imposing additional obligations, said Foster, who noted that this is a new—and significant—strategy to hold providers accountable.

The Philadelphia office has imposed additional obligations in several settlements negotiated in 2005, including one reached with Abington Memorial Hospital in Philadelphia in May. In that case, Abington agreed to pay the federal government $4.2 million to settle allegations that it submitted more than 70,000 false claims for clinical laboratory tests to Medicare over a nine-year period. Terms of the settlement required Abington Memorial to enter into a CIA with the Health and Human Services Office of Inspector General (OIG) and to take certain additional compliance measures for five years (*see box*).

Paul Shapiro, the assistant U.S. Attorney in Philadelphia who negotiated the Abington settlement, says the intent of the additional obligations is to bring about changes in behavior. Shapiro spoke during the same session as Foster.

## Abington's Additional Obligations

Besides entering into a five-year corporate integrity agreement with the HHS Office of Inspector General, Abington Memorial is also required to meet the following additional nonmonetary obligations:

- Implement a restructured compliance function that generally complies with the OIG Compliance Guidance for Hospitals. The restructured plan must be approved by the U.S. Attorney's Office for the Eastern District of Pennsylvania.
- Hire from outside AMH a new compliance group consisting of the following full-time positions: compliance officer, compliance auditor, and staff assistant. This staff will be separate from the existing internal audit staff, and the two staffs shall operate independently of one another.
- The new compliance group will develop and implement an audit program covering hospital billing and coding, physician billing and coding, hospital and physician charge master, hospital and physician billing system integrity, and patient refunds process.
- After each compliance audit, the compliance officer, chief executive officer, and chief financial officer must certify the audit results.
- AMH must implement an education program dealing with corporate integrity and compliance, billing, coding, and collections.
- The hospital must hire an Independent Review Organization to conduct review procedures, must expand its prebill editing capabilities, and must implement a corporate refund policy.

Details of the settlement agreement are found at: *www.usdoj.gov/usao/pae/News/Pr/2005/may/Settlement.Final.pdf.*

### Lab Competitive Bidding

In a separate session at Lab Institute, a key staffer from the Centers for Medicare & Medicaid Services (CMS), said that Medicare is still on track to launch a competitive bidding demonstration for Part B independent lab services (excluding Pap smears and colorectal cancer screening). The demo design is still being finalized, explained Linda Lebovic, MPH, MT(ASCP), director of the project. She also noted some changes to the draft discussed at an August 24 open forum:

- Along with independent lab and hospital outreach services, the demo will include reference services performed by large group practice labs. Most physician office labs would remain exempt, however.
- The two demo sites will be in different states, not a single one, but both sites will be served by a single carrier. CMS plans to announce the sites in the *Federal Register* early in 2006. The project has identified 22 metropolitan statistical areas (MSAs) that meet the demo's criteria. (At a separate session, attorney Jeff Boothe with Holland & Knight in Washington, D.C., said he had identified cities and states that met the criteria, including Austin, Texas; parts of Ohio; and Orlando, Florida. Boothe predicted CMS would choose one site in the Midwest and the other in the South or Southwest. He didn't think California or Illinois would be picked because of their high rate of managed-care penetration.)

In a pre-Institute e-mail survey of participants, Washington G-2 Reports asked which factor in the demo design poses the biggest problem for their lab. Nearly 50% of 117 respondents said: "Winning bidders will be paid for all Medicare tests while losers will get nothing." Nearly 38% said: "It still doesn't adequately reflect how labs do business."

### Cytology PT Testing

In 2005, the first year of cytology proficiency testing (PT) enforcement, 87% of the 4,746 individuals enrolled passed the initial testing event (10 slides in two hours), while 13% failed, according to CLIA data as of Aug. 26, 2005, from the two approved gynecologic cytology PT providers, MIME (the Midwest Institute for Medical Education in Indianapolis) and the State of Maryland program.

Judy Yost, the top CLIA official at CMS, and Rhonda Metzler, MIME's director of PT and continuing medical education, presented the update during Lab Institute.

On the first retesting event (10 slides in two hours), 89% of 404 individuals passed, while 11% failed. On the second retesting event (20 slides in four hours), seven out of 10 passed, and three failed.

Primary physician readers had the highest failure rates. For the initial testing event, it was 41% (64); on the first retesting event, it fell to 33% (17), but on the second retesting event, it was three out of four. The failure rates for the secondary physician reader across all the events stayed steady in the 13% to 14% range.

### Maryland General Revisited

Lab failures at Maryland General Hospital in Baltimore, revealed in 2004, have spurred a number of changes to lab accreditation and inspections, including a move by both the College of American Pathologists and the Joint Commission on Accreditation of Healthcare Organizations to move to unannounced inspections beginning in 2006.

Following an expose by the *Baltimore Sun*, state inspectors discovered that the Maryland General lab reported invalid HIV and hepatitis C test results over a 14-month period ending in August 2003. The lab released hundreds of test results, even though the instrument quality control indicators showed the patient results might not be accurate.

The lab's management and techs who worked with the instrument, a Labotech analyzer, had used unvalidated "work arounds" to try to ensure accurate tests were being sent out. But the work arounds were never documented, and the instrument's quality control values were altered to make them fall within acceptable ranges, so the test results could be reported.

These quality control problems were not detected during previous CAP inspections and went unaddressed until a whistleblower's complaint brought in state inspectors in early 2004.

The new management team at Maryland General's lab described the problems during Lab Institute and explained how they have since reformed lab operations. Sylvia Smith Johnson, senior vice president and chief operating officer at Maryland General, said there were early warning signs of problems at the hospital lab, including a high rate of employee turnover, a lab staff that was 40% part time, and difficulties in recruiting workers due to a pay scale that was 25% below competing labs in the area.

"It was a very cost-driven organization that had lost the balance between cost and quality," she said.

Smith Johnson said the hard costs (excluding lost business) of correcting the situation have totaled $5 million. One of the biggest costs was retesting some 2,500 patients, many of whom were Medicaid recipients. Tracking down these patients was difficult, and Maryland General hired "bounty hunters," who were paid for each patient they located. The cost of consultants—Chi Solutions Inc. was the project manager—also was expensive, she noted.

The "media frenzy" that surrounded Maryland General overshadowed problems at other hospitals in the area, said Smith Johnson, noting that a death at Johns Hopkins Hospital, attributed to a hospital staff error, did not get much press.

Smith Johnson cited three key lessons learned from the Maryland General debacle: 1) don't count on regulators to tell you what's wrong; 2) listen to your staff; and 3) never sacrifice cost for quality.

John Braun, M.D., the new laboratory director at Maryland General, said that retesting showed that the initial results had been 89.5% to 99.8% accurate for HIV and hepatitis testing. One problem at the lab was the lack of day-to-day pathologist involvement in lab quality. "If the whistleblower had not complained, these errors would have been very difficult to find in a focused inspection," he added.

Kathy Murphy, Ph.D., president of Chi Solutions, said the first three months after the problems were discovered at Maryland General were spent responding to the accrediting agencies, which seemed to be playing "a game of one-upmanship in a contest to find deficiencies" they had missed in earlier inspections. In 2004, the Maryland General Lab had 14 different inspections from six different regulatory agencies, she noted.

*Rep. Elijah Cummings*

In response to the Maryland General controversy, Rep. Elijah Cummings (D-MD) introduced legislation (HR 686) that would require the lab inspection agencies to conduct unannounced inspections and force individuals who tipped labs off on the timing of inspections to pay a fine of up to $2,000. Cummings praised the whistleblower, Kristen Turner, and expressed satisfaction that CAP and JCAHO have implemented changes to their inspection and accreditation processes.

Another breakdown in quality controls, such as what occurred at Maryland General, "could result in a fundamental change in the way lab testing is done," said Cummings.

**OIG Will Review Proficiency Testing,** *from p. 1*

Proficiency testing is a statutorily mandated condition of participation in which laboratories are graded for their accuracy in analyzing clinical specimens. It is one of the primary mechanisms for ensuring quality testing, notes the OIG.

The agency also plans to compare Medicare payment rates for certain laboratory tests with the rates of other federal and state health programs and private payers. "This study will build upon prior OIG work in which we found that Medicare paid significantly higher prices than other payers for certain laboratory tests," says the work plan.

Other areas the OIG intends to target in 2006 include:

❖ **Imaging and laboratory services provided in nursing homes.** Medicare pays more than $200 million a year for these services. The OIG intends to determine the extent and nature of any medically unnecessary or excessive billing by examining a sample of services and examining utilization patterns.

❖ **Payment to providers of care for initial preventive physical examination.** The Medicare Modernization Act (MMA) provides for coverage under Part B of an initial preventive physical examination (IPPE), including a screening electrocardiogram (EKG) for new Medicare beneficiaries, effective Jan. 1, 2005. For new Medicare beneficiaries with established relationships, the physician is presented with the opportunity to claim a higher payment for IPPE under a new HCPCS code, G0344, for services that may already have been performed in a past evaluation and management visit. The OIG intends to evaluate the impact of IPPE on Medicare payments and physician billing practices.

❖ **Physician pathology services.** The agency will continue reviewing pathology services performed in physicians' offices to see if they comply with Medicare Part B requirements. Medicare pays more than $1 million annually to physicians for pathology services, says the agency, which also intends to identify and review the relationships between physicians who furnish pathology services in their offices and outside pathology companies.

❖ **Laboratory services rendered during an inpatient stay.** The OIG will continue its review of the extent to which lab services rendered during an inpatient stay are unallowable. According to the agency, preliminary work indicated that $73 million of laboratory services were provided in hospital settings during inpatient stays nationwide in calendar year 2001. This was a considerable increase in cost over similar services rendered in prior period, notes the agency, which wants to determine the percentage of these costs that are unallowable.

❖ **Separately billable lab services under the end-stage renal disease program.** The MMA requires a report on a bundled prospective payment system (PPS) for ESRD services. This bundled PPA would include certain clinical laboratory tests that are currently separately billable. The current facility payment (composite rate) includes payments for certain automated multi-channel chemistry (AMCC) tests provided routinely at specified frequencies. Any AMCC tests performed in excess of specified frequencies or that are not included in the composite rate payment are billed separately if medical necessity is documented. Prior OIG reviews concluded that providers were paid separately for AMCC tests included in the composite rate, according to the work plan. To ensure that the bundled PPS rate is based on valid data, the OIG will review providers' compliance with the current payment policies for AMCC tests furnished to ESRD beneficiaries.

❖ **Medicare Part D administration.** Evaluating various aspects of the new Medicare Part D drug benefit will be the focus of much of the new work the OIG will begin in 2006. In addition to Part D-related evaluations, the OIG will continue to work on Medicare Part B drug pricing

issues, as called for by Congress in the MMA. Among the projects outlined in the work plan is an evaluation of beneficiary awareness of the Part D low-income subsidy program, including ways the federal government sought to educate beneficiaries about the subsidy. In addition, the OIG will evaluate whether marketing materials distributed to beneficiaries by prescription drug plans beginning in October were in compliance with CMS rules and guidelines. The review also will cover the readability of the marketing materials.

❖ **Billing service companies.** The OIG will identify and review the relationships between billing companies and physicians and other providers who use their services.

### Resource

❖ OIG work plan for 2006: *www.oig.hhs.gov/publications/docs/workplan/2006/WorkPlanFY2006.pdf.*

## OIG Warns Drugmakers About Assistance Programs

*"Our office believes that lawful avenues exist for pharmaceutical manufacturers and others to help ensure all Part D beneficiaries can afford medically necessary drugs."*
*— Inspector General Daniel Levinson*

Drugmakers that operate and control patient assistance programs could risk running afoul of fraud and abuse laws—especially the anti-kickback statute—if they subsidize their own products that also are reimbursable by the Part D drug program, the Department of Health and Human Services Office of Inspector General (OIG) said in a recent Special Advisory Bulletin.

The OIG specifically said that pharma-sponsored patient assistance programs (PAPs) that offer assistance in 2006 and beyond to Part D enrollees by subsidizing their Part D cost-sharing obligations would risk violating the anti-kickback statute.

Paying any Medicare cost-sharing obligation on behalf of beneficiaries generally is considered a violation of the anti-kickback statute because it could be construed as a payment to generate or refer business. The OIG emphasized, however, that cash donations to independent, charity PAPs should not be problematic.

"Our office believes that lawful avenues exist for pharmaceutical manufacturers and others to help ensure all Part D beneficiaries can afford medically necessary drugs," Inspector General Daniel Levinson told a conference of pharmaceutical industry professionals the day the bulletin was released. He spoke at the Sixth Annual Pharmaceutical Compliance Congress and Best Practices Forum in Washington, DC.

### Smooth Transition

The OIG said in the bulletin that it recognized the need for a smooth transition from drug company-sponsored PAPs to alternative assistance programs for individuals who choose to enroll in a Part D plan.

For that reason, the OIG said it would exercise "enforcement discretion with respect to the administrative sanctions under the federal anti-kickback statute" and would factor in drug companies' "prompt and meaningful steps" to ensure such transactions.

PAPs were designed to assist low-income individuals who are without insurance but have high drug costs afford pharmaceutical products. PAPs generally provide cash subsidies and free or reduced drugs. While some PAPs are independent charitable organizations, pharmaceutical manufacturers have long sponsored their own PAPs.

The OIG said that because the Part D program would cover most prescription drugs, Part D beneficiaries enrolled in a manufacturer-sponsored PAP no longer would qualify for assistance, in part because of Part D cost-sharing obligations beneficiaries must meet. In addition, many low-income beneficiaries will qualify for federal subsidies, the OIG added.

### No Financial Risk

The advisory bulletin noted that beneficiaries were relieved of any financial risk from accepting assistance from ill-structured PAPs by meeting requirements that such assistance be included in true out-of-pocket calculations.

The OIG said there was no need for drug companies to disenroll all Medicare-eligible PAP participants, only those who choose to enroll in a Part D plan Jan. 1, 2006, or later. Furthermore, the OIG said that "occasional, inadvertent cost-sharing subsidies" were not problematic in cases where the drug company did not and should not know that an individual was enrolled in a Part D plan.

In addition, the advisory bulletin explicitly stated that pharmacies were not prevented from waiving cost-sharing amounts owed by Medicare beneficiaries as long as the waivers were based on good-faith, individualized assessments of patients' financial needs and as long as such waivers were not routine or advertised. However, such waivers could not be funded using cash or in-kind donations by third parties, including PAPs.

The OIG also noted that no law or regulation prevented pharmaceutical companies from providing assistance to uninsured patients, including Medicare beneficiaries not enrolled in the Part D program.

### Resource

❖ OIG special advisory bulletin: *www.oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdv-Final.pdf*

# Compliance Alert: Spotlight Turns To Medicaid Fraud

*This article is an adaptation of Law Watch 05-25, written by Elizabeth S. Elson and Charles B. Oppenheim, attorneys with Foley & Lardner LLP. It is adapted with permission.*

A recent government report and proposed federal legislation clearly indicate that Medicaid fraud and abuse enforcement has become a top priority for the government. Medicaid fraud recoveries are at their highest levels, and increased efforts to combat Medicaid fraud and abuse will likely result in even greater enforcement efforts and recoveries.

On Oct. 27, 2005, the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) released its annual Health Care Fraud and Abuse Control program report that highlights HHS's and the Department of Justice's healthcare savings and recoveries. The report announced that the federal share of Medicaid funds recovered in fiscal year 2004 was $99 million. These funds were recovered as a result of settlements, judgments, and administrative penalties in 2004 and previous years.

According to the report, the OIG conducted or participated in nearly 600 healthcare fraud cases in 2004 and excluded more than 3,200 individuals and entities from participating in federal healthcare programs.

The report emphasizes that the OIG has been recovering substantial sums of money from large and small healthcare providers based on allegations of Medicaid fraud and abuse. One significant case mentioned in the report involved a large pharmaceutical company's settlement of a False Claims Act liability for almost $300 million, for allegedly failing to accurately report to Medicaid programs the company's true best price for one of its drugs. The report also describes funds allocated to CMS in 2004 to combat fraud in Medicaid and in the State Children's Health Insurance Program (SCHIP).

### Congress Proposes Bill To Fight Fraud

The Senate recently filed a budget reconciliation bill that contains specific proposals designed to fight Medicaid fraud and abuse. A significant provision of the reconciliation packages would strengthen the role of state false claims act laws by giving states financial incentives to adopt false claims statutes and pursue cases under those laws.

The legislation would permit states to decrease, by 10%, the federal government's portion of Medicaid recoveries resulting from cases brought under state false claims laws, as long as the state's laws meet certain requirements, such as providing for rewards for whistleblowers and imposing civil penalties at least equal to those under the federal False Claims Act ($5,500 to $11,000 per claim). The bill would give states a direct financial incentive to enact state false claims statutes and to pursue state false claims cases. The reconciliation bill also provides that the state false claims laws do not have to be limited to Medicaid fraud, so states may choose to apply the laws more broadly.

The proposed legislation implicitly mandates compliance programs. It would require every entity that receives at least $1 million in Medicaid payments per year to establish a training program consisting of written policies, procedures, and protocols for all its employees, agents, and contractors. The training program must include a detailed discussion of the federal False Claims Act, federal administrative remedies for false claims and statements, state laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under these laws.

The written training materials must also include the entity's policies and procedures for detecting and preventing fraud, waste, and abuse, and any employee handbook provided by the entity must contain a discussion of these laws and the rights and protections afforded to its employees as whistleblowers.

In addition, the legislation would increase spending for Medicaid fraud and abuse control activities. This includes an additional $25 million each year beginning in 2006 through 2010 for Medicaid activities of the OIG. The bill would also establish a Medicaid Integrity Program, much like the Medicare Integrity Program, allowing HHS to hire companies to:

*1)* review the actions of individuals and entities furnishing items or services reimbursed by Medicaid;

*2)* audit claims for payment for Medicaid items or services furnished or administrative services rendered;

*3)* identify and recover overpayments to individuals and entities receiving federal Medicaid funds, and

*4)* educate providers, managed care entities, and other individuals with respect to payment integrity and benefit quality assurance issues.

Appropriations of $50 million for each fiscal year from 2006 through 2008 and $75 million every year thereafter would fund the Medicaid Integrity Program.

The proposed legislation also includes a provision that expressly prohibits the practice of charging Medicaid twice for the sale of unused drugs that have been returned to pharmacies by hospitals or skilled nursing facilities and directly overrides a recent decision in which an appellate court found this practice lawful.

As GCR went to press, negotiators from the House and Senate were in the process of hammering out differences between budget bills approved by both bodies. The House version does not include these measures to fight Medicaid fraud and abuse, but Senate negotiators are hoping to keep the provisions in a final budget bill.

**Conclusion**

The OIG's recent fraud report and the proposed federal legislation clearly demonstrate both the heightened government efforts to combat Medicaid fraud and the increased resources being directed toward those efforts. Consequently, it is more important than ever that healthcare providers be vigilant in developing and implementing comprehensive compliance programs and in identifying and correcting potential Medicaid compliance problems.

**Cytology PT Bill Pending:** Rep. Nathan Deal (R-GA), chairman of the House Energy and Commerce Subcommittee on Health, has introduced legislation (H.R. 4268) to suspend cytology proficiency testing for one year and not allow it to resume until the Department of Health and Human Services makes changes advocated by the pathology groups. Critics of the program argue that gynecologic cytology has improved greatly since the PT program's creation 13 years ago as part of CLIA, but that the program fails to take these into account.

**NY Hospital Settles Charges:** Beth Israel Medical Center in New York City has agreed to pay $72.9 million to resolve civil charges involving Medicare program reimbursements. The government alleged that, from 1992 through 2001, Beth Israel's cost reports "intentionally and improperly included in reimbursable cost centers" the costs that it spent to support medical services by hospital physicians in their private patient clinical practices. The hospital did not admit any wrongdoing or liability.

**Medicare Payment Errors Decline:** Medicare payment error rates dropped by 50% in 2005, largely the result of improvements in obtaining documentation for claims, says the Centers for Medicare and Medicaid Services (CMS). CMS improperly paid 5.2% of claims in fiscal year 2005, compared to 10.1% of claims in 2004. That represents a $9.5 billion reduction in inappropriately paid claims, bringing the total for improperly paid claims in 2005 to $12.1 billion. Of the total improper payments, nearly $1 billion was in underpayments.

**CMS Can Improve Error Review:** Medicare's outpatient claims errors contractor generally made medical review decisions in accordance with established procedures, but the Centers for Medicare and Medicaid Services (CMS) could do more to ensure consistency and coordination of its error-rate programs, according to a study released November 30 by the Health and Human Services' Office of Inspector General (OIG). The OIG reports found that CMS and its contractor, AdvanceMed, had appropriate controls in place for reviews but did not always follow up. The report is available at *www.oig.hhs.gov/oas/reports/region3/30500006.pdf*.


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