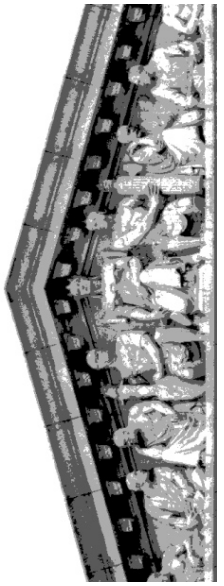

G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. IX, No. 3, March 2007

For Hospitals, Laboratories and Physician Practices

Lab Groups Blast FDA's IVDMIA Strategy

Groups representing clinical laboratories and diagnostic manufacturers have largely denounced the Food and Drug Administration's (FDA) draft guidance on in vitro diagnostic multivariate index assays (IVDMIAs).

More than 30 groups commented on the draft guidance during a public meeting held in February. Some argued that the document does not clearly define what the FDA considers IVDMIAs and does not explain how the guidance would dovetail with the Clinical Laboratory Improvement Amendments (CLIA).

The draft guidance, issued by the FDA last fall, defines a narrow niche of devices—whether commercially distributed or laboratory developed—that is subject to FDA regulation rather than enforcement discretion (*GCR*, Oct. 2006, p. 1). *Continued on p. 2*

President's FY 2008 Budget Request Boosts Fraud Fighting By $200 Million

President Bush's budget request for fiscal 2008, released on February 5, proposes to boost fraud fighting and program integrity efforts in the Medicare and Medicaid programs by $200 million.

The increase would include a new $183 million discretionary funding stream from the Health Care Fraud and Abuse Control Fund (HCFAC), which has been the primary source of mandatory funding for the Department of Health and Human Services Office of Inspector General's (OIG) Medicare and Medicaid fraud, waste, and abuse work.

The HCFAC program and account were created by Congress under the Health Insurance Portability and Accountability Act of 1996 and also have provided mandatory funding streams for the Medicare Integrity Program, as well as the healthcare fraud activities in the Department of Justice and the Federal Bureau of Investigation. *Continued on p. 9*

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Washington G-2 Reports

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Inside this issue

FDA's IVDMIA Strategy, *from page 1*

According to Elizabeth Mansfield, Ph.D., a senior policy advisor with the FDA, a device must meet a three-prong test to be considered an IVDMIA. It must:

- ❖ Use clinical data to empirically identify an algorithm;
- ❖ Employ the algorithm to calculate a patient-specific result (e.g., a classification, score, or index); and
- ❖ The result cannot be interpreted by a well-trained healthcare provider without help from the test developer.

The FDA has extended the comment period on the IVDMIA draft guidance to March 5. Comments may be submitted to *www.fda.gov/dockets/ecomments*.

Speaking at Washington G2 Report's Molecular Diagnostic Conference, held February 7 to 9 in Tampa, Dr. Mansfield explained that IVDMIAs are a growing category of tests that include elements that are not standard ingredients of in-house tests and that raise safety and effectiveness concerns. The number of IVDMIAs currently available is fairly small, she estimated—between 10 and 20.

Formal Rule-Making Urged

Among the presenters at the FDA meeting was Sharon Terry, CEO of Genetic Alliance, who testified that the "existing industrialized manufacturing regulatory model of the 19th century will not lay over well in the new era of personalized medicine. We want authorities to be looking forward to this new age.

"We stand at the tipping point of dramatic and powerful advances and understanding and potential management of these disease pathways, and the regulatory pathway can either promote or stymie innovation, access, affordability, and transparency," she said. "So, we feel that this guidance fails to adequately deal with this dynamic reality, and in our community, a great deal is at stake. We feel we really need to get this right now."

Terry urged that the guidance be withdrawn and that a formal rule-making process be initiated. Alan Mertz, president of the American Clinical Laboratory Association (ACLA), concurred, saying the FDA should issue a proposed rule to address the matter.

"The procedural recommendation in favor of notice and comment rule making is important for several reasons," he testified. "Since the draft guidance announces that laboratory-developed tests deemed IVDMIAs are Class II or Class III devices requiring FDA premarket clearance or approval, it represents a significant change from the agency's historical practice regarding laboratory-developed tests and has a present, binding effect.

Rather than merely stating the agency's current thinking on the topics without creating or conferring any rights or binding FDA or the public, the draft guidance operates as a substantive rule; as such, its subject matter should be vetted through the formal, on-the-record, notice and comment rule-making procedures of the Administrative Procedure Act," he says.

Narrow & Clarify Definition

Mertz also recommended that the FDA consider proposals to narrow and clarify its definition of IVDMIAs to avoid confusion and unintended consequences. He said that while the FDA has noted that IVDMIAs are intended to describe a narrow niche of "devices," the draft guidance defines IVDMIAs so broadly, and so vaguely, that the scope of the draft guidance's application could easily be interpreted to extend far beyond its intended reach.

"As written, the draft guidance could be interpreted to apply to many well-established tests that are part of the standard of care," said Mertz. "Upon citing examples of such tests to FDA, ACLA was informed by FDA officials that it was not their intent to include such well-established tests within the scope of the draft guidance." In fact, the FDA requested ACLA's as-


Alan Mertz

sistance in clarifying and narrowing the definition of IVDMIAs to conform to its intended application.

ACLA believes the FDA should consider the following linked factors in formulating a definition of IVDMIAs:

- A new, single-source test system;
- Uses patient and/or clinical data derived from one or more in vitro diagnostic assays together with a proprietary, nonpublished algorithm;
- Generates a patient-specific, binary result that is intended definitively to diagnose a condition or to direct behavior for the cure, mitigation, treatment, or prevention of disease.

> ***"As written, the draft guidance could be interpreted to apply to many well-established tests that are part of the standard of care.Upon citing examples of such tests to FDA, ACLA was informed by FDA officials that it was not their intent to include such well-established tests within the scope of the draft guidance."***
> **—Alan Mertz**

Finally, Mertz urges FDA to consider working with the Centers for Medicare & Medicaid Services (CMS) and through the Department of Health and Human Services to enhance the CLIA regulations and provide means for their systematic and rigorous enforcement.

Resource

- IVDMIA draft guidance: *www.fda.gov/cdrh/oivd/guidance/1610.html*
- ACLA comments: *www.clinical-labs.org.*

White House Repeats Call For Lab Competitive Bidding

President Bush's budget request for fiscal 2008 repeats his call for nationwide competitive bidding for Medicare lab services, even though a congressionally required lab bidding demonstration project has yet to be launched.

The president first called for nationwide competitive bidding in his budget proposal for FY 2007, submitted to Congress in February 2006. The current proposal estimates that lab competitive bidding would save Medicare $110 million in FY 2008 and $2.38 billion between FY 2008 and 2012.

But lab industry critics note that the Centers for Medicare & Medicaid Services (CMS) has yet to launch the lab bidding demonstration required by the Medicare Modernization Act of 2003. At press time, the demo project was awaiting clearance from the Office of Management and Budget, and there was no official word on the proposed demo sites. CMS has said it would launch the demo in at least one site by April 1. However, the timeline is expected to be modified, given the delay in getting the go-ahead.

The American Clinical Laboratory Association (ACLA) has registered its opposition to the nationwide bidding plan, saying the whole notion of competitive bidding is unworkable in the lab arena since it treats testing as a commodity rather than a complex medical service. ACLA is also lobbying key congressional health committees to get the demo project repealed and has met with "positive reaction," says ACLA President Alan Mertz.

"I believe we'll get a bill introduced to repeal it, and we'll gather support around it," he tells *GCR*. "Most likely it would have to be attached to another piece of healthcare legislation. We're doing everything we can to build a grassroots effort. That ultimately will decide whether this gets repealed or not—whether there's a groundswell of opposition."

Federal Officials End Payment Probe Of DaVita

The U.S. attorney's office for the Eastern District of Pennsylvania has closed its five-year investigation of DaVita Inc., the California-based renal care provider said in a January 30 news release.

DaVita said it was informed by federal prosecutors that they have completed their civil investigation of the company, which first received notice of the probe in February 2001 and was issued a formal subpoena in May 2002.

"We are pleased that the government, after a lengthy and thorough review, has decided to close this broad investigation into our business practices," DaVita Chairman Kent Thiry said in a statement. "We are proud of our culture of regulatory compliance at DaVita."

DaVita provides dialysis services in 42 states and the District of Columbia for people with chronic kidney failure.

In March 2005, the company announced it had received a subpoena from federal prosecutors in Missouri who were investigating DaVita's compensation arrangements with physicians, joint-venture agreements, and pharmaceutical services provided to patients.

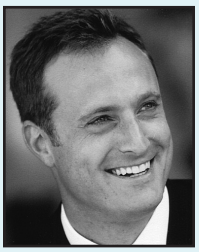
DaVita said at the time that the subpoena, which sought documents from DaVita facilities around the country and covered the period from December 1996 to March 2005, overlapped substantially with a February 2001 information request from Meehan.

In a separate case, DaVita said February 22 that it had received a subpoena from the federal government related to records for claims submitted for the Amgen Inc. anemia drug Epogen.

DaVita is one of several companies targeted in a string of federal investigations of practices at dialysis centers and firms that provide dialysis services and products. A number of companies have received subpoenas from U.S. Attorney for the Eastern District of New York Roslynn Mauskopf, in what appears to be a broad-ranging probe into parathyroid hormone testing and vitamin D therapies at kidney dialysis centers.

COMPLIANCE PERSPECTIVES

The McNulty Memorandum: Revising DOJ Policy For Gauging Cooperation & Bringing Charges Against Corporations



Adam Kamenstein is a partner in the law firm of McDermott Will & Emery LLP, based in the firm's Los Angeles office. A member of the Trial Department, Kamenstein is a six-year veteran of the United States Attorney's Office in Los Angeles with extensive trial and investigative experience.

On Dec. 12, 2006, after a growing chorus of criticism from the bar, the bench, and the business community, and under the threat of legislative intervention, the U.S. Department of Justice (DOJ) revised its guidelines for measuring cooperation from corporations during an investigation and for deciding whether to bring charges against them. While some welcome the revisions as much needed sea change in DOJ policy, others view it as only a slight shift of the sands. One thing is clear: The revisions have practical implications for corporations and their counsel who find themselves in the crosshairs of a government investigation.

Background

The issue of corporate cooperation has been one of the key issues in white-collar criminal defense and internal investigations over the past two decades. One of the hardest decisions general counsel must make in advising clients is how to assess the costs and benefits of such cooperation. The recent policy shift by the DOJ underscores the need for very careful assessment of these issues.

In 1999, then-U.S. Deputy Attorney General Eric Holder Jr. issued a memorandum (the Holder Memorandum) to all federal prosecutors suggesting numerous factors to consider in deciding whether to bring charges against a corporation. The underlying purpose of the memorandum was to incentivize corporate cooperation with the government during an investigation and to provide prosecutors with a yardstick by which to measure the extent of cooperation in deciding whether to bring charges.

In 2003, in the midst of Enron and other high-profile corporate prosecutions, the Department of Justice took a decidedly more assertive stance, when then-U.S. Deputy Attorney General Larry D. Thompson issued a memorandum (the Thompson Memorandum) that mandated, rather than permitted, prosecutors to consider the factors initially set forth in the Holder Memorandum when they decide how to proceed against a corporation.

Two of the factors the Thompson Memorandum required prosecutors to consider were whether the corporation under investigation assisted the government's investigation by waiving attorney-client privilege/work product protections and whether the corporation advanced the attorneys' fees of culpable employees. It was these two factors that prompted the harshest criticism from all corners of the legal and business communities.

Additional events further highlighted the tension between the Department of Justice and the interested public. In 2006, a federal district court in Manhattan sharply rebuked the government for unduly aggressive tactics in seeking to prevent KPMG International, under investigation for allegedly structuring illegal tax shelters, from advancing attorneys' fees to witnesses the government deemed uncooperative. Also in 2006, Sen. Arlen Specter (R-PA), then-outgoing chairman of the Senate Judiciary Committee, introduced

legislation to prohibit federal prosecutors from considering whether a corporation waived attorney-client privilege and advanced legal fees to employees. The American Bar Association also had been actively expressing its disagreement with DOJ policy.

The McNulty Memorandum

Against this backdrop of widespread disapproval and legislative intervention, on Dec. 12, 2006, Deputy Attorney General Paul McNulty issued a new memorandum (the McNulty Memorandum) curtailing and softening the inflammatory guidance set forth in the prior two memorandums.

In terms of its philosophy, the McNulty Memorandum ostensibly seeks to reassure the public that DOJ appreciates the fundamental role of attorney-client privilege in the United States' legal tradition and its importance for the candid and confidential exchange of communications between corporations and their counsel. It acknowledges that prior DOJ policies may have had the unintended effect of discouraging that practice.

Specifically addressing attorney-client privilege and work-product doctrine, the memorandum reiterates that it is "one of the oldest and most sacrosanct privileges under U.S. law . . . [the purpose of which] is to encourage full and frank communications between attorneys and their clients . . ."

In terms of its philosophy, the McNulty Memorandum ostensibly seeks to reassure the public that DOJ appreciates the fundamental role of attorney-client privilege in the United States' legal tradition and its importance for the candid and confidential exchange of communications.

Accordingly, the McNulty Memorandum states that waiver of attorney-client privilege is not a prerequisite to finding that a company has cooperated in a government investigation. Nevertheless, the memorandum does make clear its preference for waiver by positing that it helps expedite a government investigation and provides a mechanism to verify the "completeness and accuracy" of a corporation's voluntary disclosures.

In terms of its new procedural requirements, the McNulty Memorandum mandates that "prosecutors may only request a waiver of attorney-client privilege or work-product protections when there is a legitimate need for privileged information to fulfill their law enforcement obligations. A legitimate need for the information is not established by concluding it is merely desirable or convenient." Whether there is a legitimate need depends on the following factors:

- The likelihood and degree to which the privileged information will benefit the government's investigation;
- Whether the information sought can be obtained in a timely and complete fashion by using alternative means that do not require waiver;
- The completeness of the voluntary disclosure already provided; and
- The collateral consequences of a waiver to a corporation.

The McNulty Memorandum then divides attorney-client privileged material into two categories, which it labels "Category I" and "Category II." Category I material is purely factual and includes "copies of key documents, witness statements, or purely factual interview memorandums regarding the underlying misconduct, organization charts created by company counsel, factual chronologies, factual summaries, or reports (or portions thereof) containing investigative facts documented by counsel." Also included in this category, which may be of particular interest to general counsel, is legal advice contemporaneous to the underlying misconduct when the corporation was relying upon it.

For a prosecutor to request that the corporation waive privilege as to Category I material, the prosecutor first "must obtain written authorization from the United States Attorney, who must provide a copy of the request to, and consult with, the Assistant Attorney General for the Criminal Division before granting or denying the request." Importantly, if the request is authorized, the corporation's response to the request may be considered in determining whether a corporation has cooperated in the government's investigation.

If corporations are consistently quick to voluntarily waive privileges and withhold attorneys' fees in an effort to distinguish themselves from their peers, such behavior may produce a paradox where ultimately the only corporations that do distinguish themselves do so negatively by maintaining privilege and advancing attorneys' fees.

Category II material includes attorney-client communications and nonfactual work product, including legal advice given to the corporation before, during, and after the misconduct occurred. This category of material may include "the production of attorney notes, memorandums, or reports (or portions thereof) containing counsel's mental impressions and conclusions, legal determinations reached as a result of an internal investigation, or legal advice given to the corporation."

The standards for requesting Category II materials are much higher: It can be requested only if the production of Category I material "provides an incomplete basis to conduct a thorough investigation," "only in rare circumstances," and only after the U.S. Attorney has obtained written authorization from the Deputy Attorney General, the second highest-ranking official within DOJ.

Significantly, if a corporation declines to provide Category II material, a prosecutor must not consider that declination in making a charging decision. However, a prosecutor may favorably consider a corporation's acquiescence to the government's request.

New Guidelines On Advancing Attorneys' Fees Of Employees

Whether a corporation is shielding its culpable employees in a way that impedes the government's investigation remains as relevant and available a consideration for prosecutors today as ever. However, under the McNulty Memorandum, merely advancing attorneys' fees of culpable employees will not be construed as such a shield. Now, prosecutors are advised that they "generally should not take into account" whether a corporation is advancing attorneys' fees.

Accordingly, whereas corporate general counsel and outside counsel previously were often concerned with whether the law of the state of incorporation, the law of the jurisdiction in which the corporation operated, or the company's bylaws and employment contracts justified (or required) the advancement of attorneys' fees, this is generally no longer necessary.

In extremely rare cases, prosecutors still may consider advancement of attorneys' fees, but only when the totality of the corporation's conduct otherwise indicates an attempt to impede the government's investigation. Prosecutors may still inquire about attorneys' fee arrangements to assess other relevant legal issues, such as conflict-of-interest.

Moving Forward Under The McNulty Memorandum

The long-term effect of the McNulty Memorandum will depend on both the Department of Justice's subsequent interpretation and implementation of the memorandum, as well as the behavior of corporations and their counsel under

investigation. On the DOJ side of the equation, it remains an open question how the department will determine when a prosecutor has set forth a legitimate need for a privilege waiver. It will depend also on the readiness of U.S. Attorneys to spend political capital at the department, asking for approval.

On the other side of the equation, how corporations and their counsel act in the aggregate may also shape the impact of the memorandum. For instance, if corporations are consistently quick to voluntarily waive privileges and withhold attorneys' fees in an effort to distinguish themselves from their peers, such behavior may produce a paradox where ultimately the only corporations that do distinguish themselves do so negatively by maintaining privilege and advancing attorneys' fees. Accordingly, one of the most important things that attorneys and their clients can do is to pay attention to the emerging trends. The bar and business communities should continue to encourage the exchange of information and report on trends in these areas.

In the short term, corporations should anticipate continuing government requests for privilege waivers, though perhaps to a lesser degree, and be mindful that acquiescence to such requests will continue to be viewed favorably. However, at least with respect to Category II material, the corporation can take a slightly less risk-adverse view of its cost-benefit analysis when determining whether to acquiesce to a government request for waiver because the government may not negatively view the corporation's refusal to do so.

Further, corporations conducting internal investigations should also be mindful of the department's new multi-tiered view of privileged material—Category I and Category II—and should be tactical in carrying out their investigations. A corporation's cooperation by producing one category of material while still maintaining privilege over the other category may prove significant. The manner in which the internal investigation is conducted may enable counsel to make a more persuasive and defendable case to the prosecutor about what category of material is implicated by a request for waiver, thus giving the corporation more flexibility and control over its waiver.

The least ambiguous shift from the old memorandum to the McNulty Memorandum is with respect to advancement of attorneys' fees to employees. Here, it is evident that in most cases, corporations may advance attorneys' fees to their employees without fear of retribution (although joint defense agreements with culpable employees and other obstructive behavior remain problematic). Only in extremely rare circumstances will the mere advancement of attorneys' fees pose a risk to the corporation.

Summary

While the rules appear to have changed, the overall game remains the same. The McNulty Memorandum is not a retreat from DOJ's desire to obtain full and valuable cooperation from corporations under investigation. This remains a primary objective of DOJ in these matters, and it will continue to use the revised factors discussed here, as well as the numerous factors not affected by the new memorandum, in making its charging decisions.

Successfully guiding a corporation through a government investigation remains a delicate and complex undertaking. Intelligent advice from informed counsel and clients' awareness of the implications of their decisions will continue to minimize the threat from a government investigation and allow a corporation to get back to the business of its business.

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FDA's IVDMIA Strategy, *from page 1*

Discretionary Funding

The OIG and DOJ (including the FBI) would each get $17.5 million in additional discretionary funding. The Medicaid and State Children's Health Insurance Program would receive an additional $10.1 million, and the Medicare Integrity Program would get an additional $137.8 million.

The president's budget proposal states that the discretionary funds would be used toward safeguarding the Part D program and Medicare advantage plans against fraud and abuse, as well as improving financial management oversight in the Medicaid program.

Each of the programs also was slated for an increase in mandatory funding over 2007. The OIG would receive a $3 million increase, bringing mandatory HCFAC funding to $169 million in 2008. The OIG also would continue to receive $25 million in 2008 for Medicaid integrity program work called for in the Deficit Reduction Act of 2005.

The president's 2008 budget further called for a $5 million increase in OIG discretionary funding used for non-Medicare and nonMedicaid work, such as public health, children and families, and aging.

Cost Cutting

The president's budget included details on three legislative proposals aimed at improving program integrity and slashing $7.8 billion in Medicare and Medicaid spending over five years. The proposals were estimated to save $230 million in 2008.

The largest of the three proposals would eliminate bad-debt reimbursements for unpaid beneficiary costs for all providers. Medicare pays 70% of unpaid beneficiary copayments and deductibles to hospitals and skilled nursing facilities, and the White House estimates ending those payments would cut nearly $7.2 billion from Medicare spending by 2012.

The president also proposed a requirement that group-health plans and other third-party payers report Medicare as secondary payer data and create a federal clearinghouse for data sharing with other federal health insurance programs, including the Federal Employees Health Benefits Program, TRICARE, and the Department of Veteran Affairs to determine when Medicare is not the primary payer for beneficiary services. Such an effort is expected to cut $640 million in Medicare spending.

A third measure would limit mandamus jurisdiction as a basis for obtaining judicial review in the Medicare program. The proposal further calls for clarifying the HHS secretary's authority to resolve appeals of Medicare determinations. The proposal is expected to save $80 million by 2012.

Medicaid Program Integrity

The president's budget also proposed Medicaid program integrity reforms projected to save the federal government $75 million in 2008 and $725 million over five years.

The biggest of that savings ($640 million over five years) would come from extending to HHS programs a Social Security Administration (SSA) pilot program that uses electronic financial records to verify applicant's assets, according to the budget plan.

The proposal would require state Medicaid agencies to establish pilots in conjunction with existing SSA pilots that are testing asset verifications through electronic records.

An additional $85 million in Medicaid savings over five years could come from enhancing laws that allow states to avoid costs for prenatal and preventive pediatric claims that should be paid by a third party.

Furthermore, the White House called for collecting medical child support in

cases where health insurance "is derived from non-custodial parent's obligation to provide coverage," and by recovering Medicaid expenditures from beneficiary liability settlements.

Resource

- Bush administration proposed fiscal 2008 budget for HHS: *www.hhs.gov/budget.08budget.2008BudgetinBrief.pdf*.

Increase In Quality-of-Care Data Helps Feds Target Provider Failure, Says Sheehan

Enforcement actions targeting institutions' failure to provide adequate care, whether civil or criminal, increasingly are being built on the growing amount of quality-of-care data and information culled from a growing array of sources, according to a February 6 presentation to a gathering of healthcare attorneys.

James G. Sheehan, associate U.S. attorney for the Eastern District of Pennsylvania, said his office is continuing its focus on ensuring that healthcare providers receiving federal healthcare dollars give patients high-quality care, as they adjust to the "Medicare revolution" that is changing the federal reimbursement system from one based on payment for procedures performed to one based on outcomes.

As this revolution moves ahead, he said, new enforcement cases targeting lapses in delivery of quality care will be developed from data-mining activities conducted by a range of regulatory and oversight entities, as well as from information from regulators, whistleblowers, media, and others. Discrepancies in the information from multiple sources on one provider or facility may serve as the "red flag" that gets prosecutors' attention, he said.

"We are reviewing assorted sources of quality information on your facility to see what it says and if it is consistent. You should be doing the same," he said. The fact that the data may be flawed or missing will not itself give rise to a claim of fraud or false statement, he added, but it does bring attention to and raises concerns about the facility.

"We are certainly going to look further at institutions where the data just doesn't make sense," Sheehan said, speaking before the American Health Lawyers Association Hospitals and Health Systems Law Institute.

Egregious Cases

Sheehan, who said he was not speaking in an official capacity, said his office will continue to focus criminal investigations only on the most egregious failure of care cases and that the general approach is to give voluntary compliance efforts a chance to work.

Administration Proposes Medicare Cuts
Physicians, Other Providers Targeted

As part of his plan to balance the federal budget by 2012, President George W. Bush is calling for whopping spending cuts in Medicare totaling nearly $76 billion over the next five years, with most of the savings achieved by reducing provider payment updates and raising premiums for higher-income beneficiaries.

The budget seeks net Medicare savings of $65.6 billion over the next five years from legislative changes and $10.2 billion from administrative changes. This would slow the program's annual rate of spending growth from 6.5% to 5.6%, according to HHS budget documents.

Specifically, the budget proposes to: reduce the update for inpatient hospitals, outpatient hospitals, hospices, and ambulance services by 0.65% annually starting in fiscal 2008; freeze the update for skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities in 2008 and reduce it by 0.65% annually thereafter; and reduce the annual update for ambulatory surgical centers by 0.65%, starting in 2010.

The budget also assumes a projected 8% cut in Medicare physician spending will go forward in 2008, as scheduled under current law, which would be bad news for pathologists. The budget does not address reforms to the statutory Sustainable Growth Rate (SGR) formula used to calculate annual Part B physician fee updates.

He noted that his office has received complaints from some whistleblowers who were asked whether they had attempted to avail themselves of internal remedies. That should be done first, he said, but if voluntary compliance and corrective action efforts do not solve the problem, his office is prepared to act.

> ***"It is not a question of if, but when, quality-of-care issues will arise in an enforcement context."***
> **—Cheryl Wagonhurst**

Sheehan said his office would continue to ask the same underlying questions to determine whether prosecution is appropriate:

- Was there a systemic failure by the institution's management and the board to address quality issues?
- Did the institution make false reports about quality or fail to file mandated reports?
- Has the institution profited from ignoring poor quality or ignoring providers of poor quality?
- Have patients been harmed by poor-quality care or been given false information about it?

Sheehan said some of the sources of data that will be "mined" and considered in initiating or pursuing such an investigation include information from the reporting hospital quality data for annual payment update (RHQDAPU), information from the Joint Commission on Accreditation of Healthcare Organizations, state reporting, mandated reporting of errors and near misses, mandated apologies required under some state laws, quality improvement organizations, pay-for-performance contracts in the private sector, and whistleblowers.

With respect to this last group, Sheehan noted provisions of the Patient Safety and Quality Improvement Act of 2005 that gave quality-of-care whistleblowers most of the same protections afforded whistleblowers under the False Claims Act. "I expect an increase in the number of mixed cases in which whistleblowers allege both quality lapses and false claims in one action," he said.

Compliance Programs

The wider threat of enforcement actions against providers makes the development of programs designed to assess and maintain compliance in the quality-of-care arena paramount, Sheehan said. Cheryl Wagonhurst, who made the presentation with Sheehan, agreed.

Wagonhurst, a former compliance counsel with Tenet Healthcare and now an attorney with Foley and Lardner in Los Angeles, emphasized the need for a commitment to quality care and outcomes to become completely integrated into an institution's compliance program.

"It is not a question of if, but when, quality-of-care issues will arise in an enforcement context," she said. "If not [Sheehan], then it will be CMS, based on the increasing amount of data at their disposal, that will be knocking at your door."

Wagonhurst stressed the need to create a mechanism to audit the existing compliance regime to assess quality assurance, utilization review, peer review, and training of the medical staff and the institution's board members. It is this process that leads to discovery of breakdowns in the system that can cause quality-of-care problems, she said.

She said the compliance program built on this assessment must ensure that all data, reports, hotline calls, and other feedback is integrated and assessed by the compliance team with the support of senior management and the board, and Wagonhurst concluded that "[m]edical staffs and boards need to know this stuff."

News-At-A-Glance

Part D Transparency: Price transparency in the Medicare Part D prescription drug benefit is key to curbing fraud and abuse in the program and could result in lower drug prices for the federal government and beneficiaries, pharmaceutical industry experts and government officials said February 9 in a House Oversight and Government Reform Committee hearing. University of Minnesota College of Pharmacy Professor Steven Schondelmeyer said markets work best when prices are transparent. He said he was especially troubled that rebates—which he defined at "institutional kickbacks"—paid to Part D plans could not be verified, meaning there was no incentive for plans to pass rebate savings on to beneficiaries.

Fraud Indictments: An Atlanta orthopedic surgeon and four chiropractors were charged in two separate federal indictments in U.S. District Court for the Northern District of Georgia February 20 with allegedly fraudulently billing about $6 million for a back pain procedure known as Vertebral Axial Decompression. The orthopedic surgeon, Howard Berkowitz, was charged with five counts of healthcare fraud, as were two of the chiropractors, Arthur Hargraves (Douglasville, GA) and Daniel Puffenberger (Kissimmee, FL). According to the indictment, the three were the owners of Associated Spinal Care Network, based in Douglasville, and allegedly billed Blue Cross and Blue Shield of Georgia $3 million for the VAX-D procedure from 2001 through 2005. In a second indictment, two additional Atlanta-area chiropractors were charged with healthcare fraud for also billing Blue Cross $1.8 million in 2003 and 2004 for the VAX-D procedure. Indicted were William Stearns (Marietta, GA) and Steven Levine (Roswell, GA), who own Comprehensive Care Medical Group.

Survey On E-Health: The Department of Health and Human Services (HHS) has proposed a national survey of physicians and group practices to measure the adoption of electronic health records, according to a February 9 *Federal Register* notice. The survey will allow the HHS Office of the Secretary to evaluate barriers and ways to facilitate the adoption of electronic recordkeeping in medical practices, according to the notice. The results will allow HHS to identify policy choices that would encourage the use of electronic health records.

G-2 Compliance Report (ISSN 1524-0304) is published by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Tel: 212-244-0360. Fax: 212-564-0465. Order line: 212-629-3679. Web site: www.g2reports.com.

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