G-2 Compliance Report

WASHINGTON G-2 REPORTS

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For Hospitals, Laboratories and Physician Practices

Quest Admits to Problems With Vitamin D Testing

A recent acknowledgement by Quest Diagnostics (Madison, N.J.) that it provided possibly erroneous Vitamin D test results to thousands of people has raised new questions about such testing.

The company said in December that it had sent letters to thousand of doctors offering to provide free retests for patients who may have received questionable results. Incorrect results could lead to patients either not getting Vitamin D supplements that they need or getting supplements that they don't need, which in rare instances can lead to a toxic overdose.

According to Wendy Bost, a spokesperson for Quest, the company implemented the retesting program in fall of 2008 after determining that some of its laboratories, at times, produced questionable Vitamin D test results.

Continued on page 8

CMS Proposes Changes to Cytology Proficiency Testing

The Centers for Medicare and Medicaid Services (CMS) has proposed a number of changes to its cytology proficiency testing (PT) requirements that it believes will improve the effectiveness of the program while reducing the regulatory burden on clinical laboratories.

Specifically, CMS is proposing to increase the number of slides in the first test and first retest from 10 to 20 and increase the time for each test from two to four hours. The score required to pass would remain at 90 percent, but by doubling the number of challenges, each error would have only half as much impact on the total score. Missing two high-grade lesions or cancers would result in automatic failure.

The proposed rule would also require proficiency testing biennially (every two years) rather than annually as under the current rules. The proposal also provides for the approval of media other than glass slides for cytology PT to accommodate the use of future PT technologies. Cytology challenge material may include glass slides, digital images, or other CMS-approved testing media.

In addition, the proposed rule would also affect the providers of cytology PT by requiring them to explain their appeals process prior to the administration of a test and imposing more stringent obligations on PT programs to maintain high-quality testing sets. CMS is also requesting additional information from cytology PT providers and others to analyze trends in PT failures over time. *Continued on page 2*

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Cytology Proficiency Testing, *from page 1*

Controversial Program

The cytology PT program has been highly controversial since CMS began enforcing it nationwide in January 2005, triggering opposition from a broad coalition of pathology and lab groups. CMS said it had no choice, since the law stated that labs are to be subject to cytology PT when commercially available.

One organization, the Midwest Institute for Medical Education (MIME), stepped forward and in late 2004 was approved as the first national cytology PT provider. The MIME program was later purchased by the American Society for Clinical Pathology (ASCP).

There are currently two CMS-approved cytology PT programs that operate nationwide—the one offered by ASCP and one offered by the College of American Pathologists (CAP). A third program, run by the state of Maryland, was approved to begin testing in 1995 but is limited to laboratories offering Pap test screening to residents of Maryland.

A number of the changes included in the proposed rule reflect recommendations from the Clinical Laboratory Improvement Advisory Committee (CLIAC).

Comparison of Key Provisions

Current Regulation	*Proposed Regulation*
10 slides/test	20 slides/test
2 hours/test	4 hours/test
Annual Test	Biennial Testing
Test Composition:	***Test Composition:***
1 unsatisfactory challenge	1 unsatisfactory challenge
1 normal challenge	1 normal challenge
1 low-grade (LSIL) challenge	1 low-grade (LSIL) challenge
1 high-grade (HSIL) or cancer (CA) challenge	2 high-grade (HSIL) or cancer (CA) challenge
1 missed HSIL/CA=automatic failure	2 missed HSIL/CA-automatic failure
Glass slide test	Glass slide test and opportunity for new technologies
Field validation of slides not required	Continuous field validation of slides required
Appeals process not required	Appeals process required
Different scoring grids for pathologists and cytotechnologists	Different scoring grids for pathologists and cytotechnologists

New Controversy Erupts Over FDA Regulation of Lab-Developed Tests

The biopharmaceutical company Genentech, a developer of cancer drugs, has reignited concerns within the clinical laboratory industry over how much additional control the Food and Drug Administration (FDA) should have over laboratory-developed tests (LDTs), including many commonly used genetic tests that currently are not subject to premarket review.

The company wants LDTs, developed by labs for in-house testing, to be subject to the same scientific and regulatory standards, including premarket review and post-market surveillance, that the FDA applied to *in vitro* diagnostic tests developed and sold by device makers as test kits.

Genentech, based in South San Francisco, California, has filed a 32-page citizen petition with the FDA, asking it to "initiate rulemaking to exercise regulatory juris-

diction over all LDTs and use its current risk-based classification system to determine the level of regulatory oversight and review that is necessary and appropriate for these tests."

Further, Genentech wants the FDA to simultaneously initiate enforcement action against "any clinical laboratory or any other company that is selling an LDT or making claims about its potential indication for use, effectiveness or value, or that otherwise impacts patient safety without having sufficient analytical and clinical evidence to support such claims."

ACLA and the College of American Pathologists oppose further expansion of the FDA's authority over LDTs, saying CLIA standards assure the analytical and clinical validity of these tests.

The American Clinical Laboratory Association, which represents national and regional labs as well as test manufacturers, assailed Genentech's move as posing a "chilling effect on innovation in patient care while stifling the promise of personalized medicine," which tailors a particular treatment and therapy to an individual's genetic profile.

LDTs include commonly used tests for breast and colon cancer, AIDS, and other diseases that have a history of being safe and effective, ACLA said. "All health care-related lab tests are already either cleared by the FDA or are performed in a lab regulated by the Centers for Medicare and Medicaid Services under CLIA, or both. Also, labs that perform genetic tests must meet the most stringent level of CLIA complexity oversight, often are also regulated by states, and most have further oversight via lab accrediting bodies."

More FDA regulation would threaten rare and low-volume tests for genetic diseases, such as spinal muscular atrophy, Gaucher disease, Tay Sachs disease, and Canavan disease, among others, ACLA warned. "Because of small populations for clinical trials, [these tests] would not be able to meet FDA requirements and, with limited markets, could disappear."

The FDA currently regulates analyte-specific reagents used in LDTs and a category of LDTs known as IVDMIAs (*in vitro* diagnostic multivariate index assays) that use a proprietary algorithm to produce patient-specific results. Legislation to require premarket review of all LDTs (S. 736) was introduced in the previous Congress by Sen. Edward Kennedy (D-Mass.). Hearings were held but no action was taken.

CAP Has Change of Heart on State Licensure of Lab Personnel

The College of American Pathologists (CAP) will no longer oppose state legislation for the licensure of medical technologists and technicians as long as the legislative language meets model criteria that addresses specific concerns of CAP members.

In announcing the change, CAP President-elect Stephen Bauer, M.D., F.C.A.P., said that it "reaffirms the college's support for its clinical laboratory partners who desire to raise the standards of their profession through state licensure."

To pass muster with CAP, state licensure legislation would have to:

- Define the scope of work for medical technologists and technicians to avoid conflict between physicians and nonphysicians;
- Support creation of limited specialty licenses for personnel who perform specialty services in the lab;
- Establish minimum education standards for each licensure category;

- Specifically ensure that the lab director has control over all personnel in the lab;
- Incorporate a definition of medically independent judgment that makes clear that in the lab, pathologists alone make independent medical judgments in the diagnosis and treatment related to clinical lab tests;
- Provide for greater on-the-job training; and
- Restrict the authority of state licensing boards to modify and expand licensing requirements provided by state statute.

While CAP will not oppose any bill consistent with its model approach, "it will not impede any state pathology society from seeking other modifications it deems appropriate," Bauer noted.

CAP's stance is designed to accommodate its concerns that overly stringent licensure rules would exacerbate the shortage of qualified lab personnel and the concerns of licensure proponents that labs will fail to attract qualified personnel if work requirements are not stringent enough. The college supports "qualification requirements that can be met either through college-level course completion and testing or through on-the-job training. Ultimately, licensure may have little to do with the personnel shortage issue, so we should not let it distract us from working together to find a solution."

ASCP Welcomes Shift

The American Society for Clinical Pathology (ASCP) applauded CAP's revised position, set forth in a letter to society President Barbara McKenna, M.D., from CAP President Jared Schwartz, M.D. In response, McKenna told Schwartz, "Going forward, we look forward to working with you in developing and maintaining high standards for laboratory professionals who are working to ensure patient safety and health."

According to ASCP's *ePolicy News*, the society has supported licensure initiatives since 2005 to ensure that lab professionals possess appropriate academic and clinical training, pass competency-based exams conducted by an approved national certifying organization, and participate in continuing education programs. The ASCP Board of Registry certification is the only certification that has approval in all 13 states that require licensure for laboratory personnel, including most recently New York and California.

COMPLIANCE PERSPECTIVES

Compliance Officers See Greater Risk of Ethics Failures

The current economic environment increases the risk of compliance and ethics failures, believe the vast majority of compliance professionals responding to a recent survey conducted by the Health Care Compliance Association and the Society of Corporate Compliance and Ethics.

The survey, completed by more than 600 compliance and business ethics professionals, showed that 85 percent of respondents feel that the current economy greatly or somewhat increases the risk of failures. Only 1 percent said they felt the legal and ethics risk might decline in this period, and not one person felt the risk would be greatly reduced.

The fear of risk was greatest among those outside of the health care industry, where 48 percent felt the risks were increasing greatly, compared to 30 percent for health care professionals. This is likely due to the health care industry being somewhat less cyclical than the economy as a whole, say authors of the survey report.

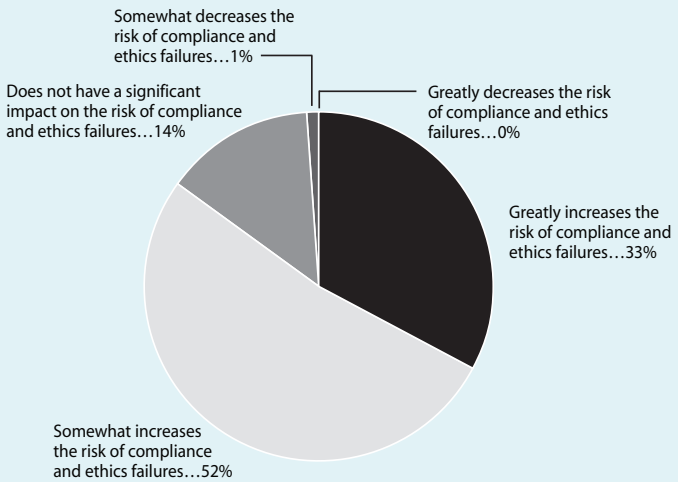
"In what may be a warning sign of future corporate scandals, despite the increase in perceived risk, survey respondents were far more likely to believe that their budgets and staffing would decline rather than increase," they wrote, noting that 49 percent felt their budget would stay about the same, and 36 percent felt their budgets were likely to decline. In terms of staffing, 69 percent felt there would be no change, while 20 percent anticipate some reductions.

When asked about their own job security, just 22 percent felt that their job was somewhat or much more at risk than the jobs of their peers in their organization, and 44 percent were "not at all" concerned about losing their job as a result of the current economy.

"Taken as a whole, the data show that companies are increasingly seeing compliance and ethics as an integral part of their business and not a luxury to be discarded during an economic downturn," write the authors. "But, at the same time, the stagnant budgets or potential declines in resources at a time of increased risk for failures creates a gap between the level of risk and the ability to manage them. After the latest series of high-profile scandals, it is clear that a gap of any kind is dangerous even in the best of times."

Figure 1

Do you think the current economy:



Risk Factors

In what should be troubling for anyone in business, the survey reveals a dramatically increased perceived risk of compliance and ethics failures, with 33 percent of respondents saying they feel the cur-

rent economy has greatly increased risk of failure. Another 52 percent of respondents believe the current environment somewhat increases the risk of compliance and ethics failures, which means that 85 percent are concerned that the current times pose significantly higher risks for companies.

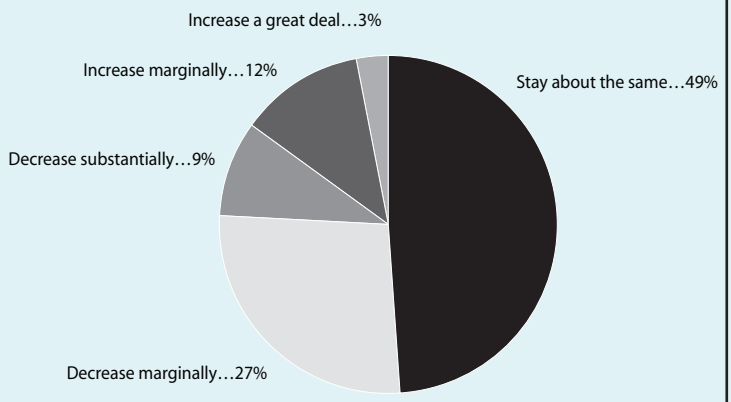
2009 Budget Expectations

As might be expected in a down economy, 36 percent of compliance and ethics professionals surveyed expect their budgets to decline in 2009, although most of them anticipate the decrease to be marginal. Those outside of health care were more likely to take this view than those inside it—42 percent vs. 35 percent.

About half of respondents expect their budgets to remain stagnant. Perhaps surprisingly, 15 percent expect their budgets to increase in the coming year.

Figure 2

What do you anticipate will happen to your organization's compliance and ethics program in 2009?

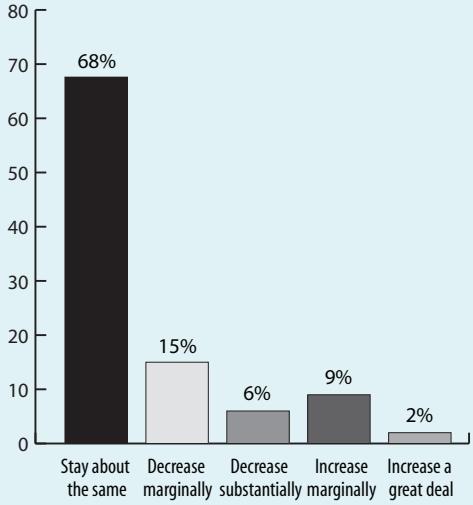


Staffing Expectations

Mirroring the budget picture, many compliance and ethics professionals expect to see a downturn in staffing, although the numbers are softer, according to the survey. While 27 percent expected a marginal decrease in budgets, the comparable number for staffing is just 15 percent. In addition, the vast majority—79 percent—expect staffing levels to stay about the same or actually increase.

Figure 3

What is the likely impact on staffing of your compliance and ethics program in 2009?

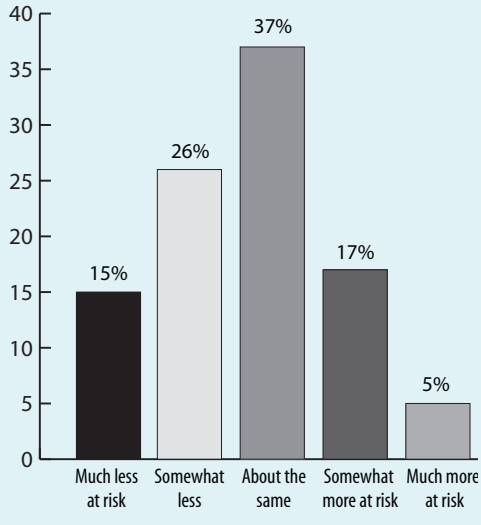


Fear for Own Job

For the most part, compliance and ethics professionals feel that their jobs are relatively safe. Fully 41 percent feel that their jobs are somewhat or much less at risk than those of others in the organization. A bit more than a third, 37 percent, feel that their risk was comparable.

Figure 4

Do you feel that your position is more at risk than others in your organization?



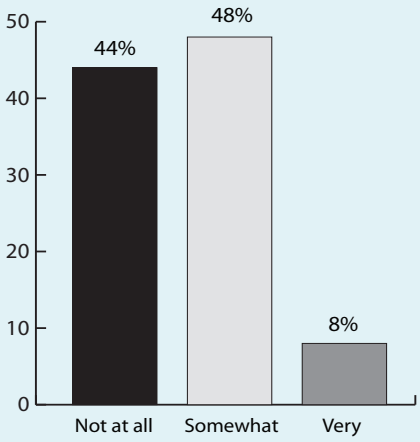
Only about 8 percent said they are very concerned about losing their jobs, while 48 percent say they are somewhat at risk, and 44 percent are not at all concerned.

Management Perceptions

Anxiety about job loss was kept at bay, perhaps, by a feeling that senior management is far more likely to see compliance and ethics as an asset during the current economic conditions. According to the survey, 50 percent feel that senior management sees compliance and ethics as either a somewhat or very positive asset for these times, and just 13 percent feel that management sees it as somewhat of or a great hindrance.

Figure 5

How concerned are you about losing your job as a result of the current economy?



"The latter number is disturbing," note the authors, "given the ethics and compliance-related failures that helped contribute to the current economic situation."

Implications

The data reveal several points of concern, say the report's authors. First is the perceived increase in the level of risk of legal and ethics failures. "Given the current fragility of the economy, a scandal could be devastating both to the company involved and to the economy as a whole," they write. "There is little capacity for the market to absorb bad news."

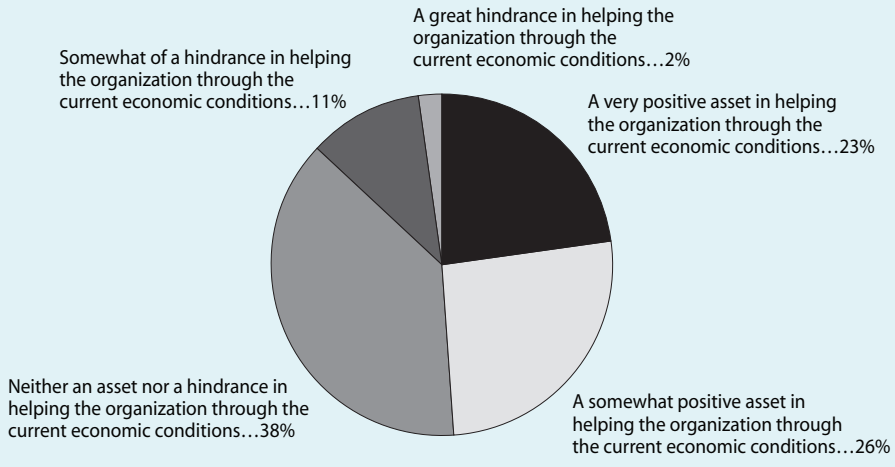
Second, while budgets are tight everywhere, the authors note that it is dismaying to see that budgetary pressures are being applied in this area at this time. As a recent settlement by Siemens AG demonstrates, that risk can be great, and the costs in the long term could far outstrip any near-term savings.

In the Siemens case, the company acknowledged paying millions of dollars in bribes to secure business in Venezuela and Argentina. U.S. prosecutors said in their sentencing document that some payments were cut with or paid into U.S. accounts and that investigators found "a strong nexus to the U.S." in some of the payments.

Under terms of the settlement, announced in December, Siemens and its subsidiaries will pay about $450 million to the U.S. Justice Department to settle charges of making bribes and trying to falsify corporate books from 2001 to 2007. It will pay an additional $350 million to settle charges from the U.S. Securities and Exchange Commission. Siemens will also pay 395 million euros ($533.6 million) in fines to European authorities.

Figure 6

In your opinion, does senior management see compliance and ethics as:



The implications for compliance programs are significant, note the report's authors. "When scandals do occur during these challenging economic times, it would be a mistake to lay the blame on the failure of compliance and ethics programs," they write. "The failure may, in fact, be due to a declines in resources for these programs."

Vitamin D Testing, *from page 1*

"In an abundance of caution, we defined as questionable any result that had the potential for error in a run of tests if there was any question about the overall run," said Bost in response to questions posed by Washington G-2 Reports. "After completing our exhaustive review, we concluded that the vast majority of our historical Vitamin D test results have been reliable. We are confident that the test is producing reliable results."

The problems with testing were related to reagent preparation and, in some cases, with "less than strict adherence to our rigorous operating procedure for the test," said Bost, who emphasized that the issues were limited to specific time periods and only affected some of its labs.

According to a January 8 report in the *New York Times*, Quest's problems with the vitamin D test began after it shifted to a new test of its own design, replacing an older test approved by the Food and Drug Administration (FDA).

Dr. Wael Salameh, the medical director of endocrinology at Quest's lab in San Juan Capistrano, California, told the Times that some materials used to calibrate test results had been faulty. According to Dr. Salameh, four of the seven Quest labs running the Vitamin D tests did not always follow proper procedures.

While Bost would not say how many patients are estimated to have received inaccurate test results, the *Times* said that thousands of doctors were sent letters in October. Each doctor could have had multiple patients affected.

Even so, Dr. Salameh told the *Times* that the inaccurate test results represented less than 10 percent of all vitamin D tests done by Quest from early 2007 to mid-2008.

According to Bost, Quest uses LC-MS/MS (liquid chromatography tandem mass spectrometry, or tandem mass spect) as its new method of reference for many hormones and vitamins, including Vitamin D. LC-MS/MS has certain advantages over older testing methods, said Bost, including the ability to specifically and precisely quantify specific forms of Vitamin D, including D2 and D3.

"This is an important advantage as Vitamin D2 therapy is the predominant form of therapy in the U.S. for treating Vitamin D deficiency," she said. "Physicians may not be able to accurately assess a patient's Vitamin D2 levels using other techniques."

According to the *Times* article, the incident raises questions about Vitamin D testing, which has increased in recent years. Quest and other laboratories have experienced strong double-digit growth for the test in recent years, which many believe is due to increased awareness of the role Vitamin D plays in health. Medicare pays about $40 for a Vitamin D test.

Experts have complained that there is no standardization in Vitamin D testing, so results vary among labs, notes the *Times*. While the FDA approves test kits used by labs, hospitals, and doctors offices, the Quest Vitamin D test is a lab-developed test and is not subject to FDA approval.

Revised Report Reveals More Appeals for RAC Demo

An updated report from the Centers for Medicare and Medicaid Services (CMS) shows that providers appealed more improper payment decisions made by recovery audit contractors (RACs) between 2005 and 2008 than the Medicare agency first reported in July 2008.

CMS said in the newly revised report on the RAC demonstration program, dated January 2009, that of the more than 525,000 overpayment determinations made by audit contractors, providers appealed more than 118,000, or 22.5 percent.

Of the decisions that were appealed, CMS said, 34 percent were overturned in the providers' favor, resulting in a total of 7.6 percent of all RAC determinations ultimately appealed in favor of providers.

In its initial report in July 2008, CMS said that providers had appealed only 14 percent of all determinations and that just 4.6 percent of all RAC determinations had been overturned as a result of those appeals.

CMS said in the newly revised report on the RAC demonstration program, dated January 2009, that of the more than 525,000 overpayment determinations made by audit contractors, providers appealed more than 118,000, or 22.5 percent.

Medicare providers and hospital groups in the demonstration states had sharply criticized the July 2008 report, saying it did not accurately reflect the total number or final outcome of RAC-related appeals because many cases were waiting to be heard by administrative law judges at the first stage of the process or had moved to higher levels of appeal.

Periodic Appeals Announced

In the updated report, CMS said that the revised numbers reflected appeals data as of Aug. 31, 2008, and that the report would be updated periodically until all appeals had worked through the system. CMS noted that most first-level appeals of RAC decisions should have been filed by July 1, 2008.

The demonstration was widely criticized because of the contingency fees paid to contractors to identify improper payments and because of the nature of audits and numbers of claim denials generated by the contractors. CMS has made changes to the structure of the permanent program, which include recouping the contingency fees in cases of overturned RAC decisions and limiting the scope of RAC reviews.

CMS said it could not attribute the appeals to specific RACs because of the way the data are tracked by a separate contractor. It said, though, that it was implementing changes for the permanent RAC program—set to begin in 2009—so that it could better track appeals on a contractor-by-contractor basis.

While CMS has updated the appeals numbers for the RAC demonstration, it has not revised the total value of improper payments corrected by RACs during the demonstration.

Improper Payments Corrected

CMS continued to report that as of March 27, 2008, the RAC audits had corrected $1.03 billion in improper payments, including $37.8 million in underpayments to Medicare providers. RACs in the demonstration program are credited with returning nearly $700 million to the Medicare program.

Congress authorized the RAC demonstration in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as a way to identify improper payments in the Medicare program. The program was made permanent in the Tax Relief and Health Care Act of 2006.

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CMS has made changes to the structure of the permanent program, which include recouping the contingency fees in cases of overturned RAC decisions and limiting the scope of RAC reviews.

The report is available at *www.cms.hhs.gov/RAC/Downloads/AppealUpdatethrough83108ofRACEvalReport.pdf.*

HHS Delays Transition to ICD-10 Until 2013

Responding to widespread industry concerns, the Department of Health and Human Services (HHS) issued a final regulation January 15 that will give health care plans and providers two additional years—until October 2013—to adopt a new health care coding system.

Because a large majority of public comments stated that more time would be needed for effective industry implementation of the new coding system, HHS said it has agreed to accommodate these concerns by delaying the compliance deadline.

Under a proposed rule issued last August, health care providers would have been required to adopt the new health care coding system, the *International Classification of Diseases*, Tenth Revision (ICD-10), by October 2011. This system greatly expands on the ICD-9-CM codes sets, which were developed nearly 30 years ago. However, many leading health care provider groups warned that this would not provide enough time to transition to the new system.

Along with the ICD-10 rule, HHS issued a related final rule updating standards for electronic health care transactions under the Health Insurance Portability and Accountability Act (HIPAA). The final rules were published in the January 16 *Federal Register*.

Two Final Rules

According to a fact sheet issued by the Centers for Medicare & Medicaid Services (CMS), the rules will facilitate the nation's transition to an electronic health care environment.

Under the first regulation setting forth adoption of the ICD-10 system, CMS is adopting the new medical code sets as standards under HIPAA for use in reporting diagnoses and inpatient hospital procedures in health care transactions. By setting an Oct. 1, 2013, compliance date, HHS said, the industry will have nearly five years from the date ICD-10 was first published to implement the new code sets.

The second final rule adopts updated versions of the standards for certain electronic health care transactions, under the authority of HIPAA. This rule is necessary because the current version of the X12 (version 4010/4010A1) standard cannot accommodate the use of greatly expanded ICD-10 code sets, CMS explained. HIPAA "covered entities," such as health plans, health care clearinghouses, and certain health providers, must begin using the updated standard on Jan. 1, 2012, although small health plans have an additional year and must comply on Jan. 1, 2013.

"These regulations will move the nation toward a more efficient, quality-focused health care system by helping accelerate the widespread adoption of health information technology," HHS Secretary Michael Leavitt said. "The greatly expanded ICD-10 code sets will fully support quality reporting, pay-for-performance, biosurveillance, and other critical activities. The updated X12 transaction standards, Version 5010, provide the framework needed to support the ICD-10 codes."

According to HHS, adoption of the ICD-10 code sets is expected to support Medicare's value-based purchasing initiative and antifraud and abuse activities by accurately defining services and providing specific diagnosis and treatment information. In addition, HHS said, the expanded code sets will:

- support comprehensive reporting of quality data;
- ensure more accurate payments for new procedures, fewer rejected claims, improved disease management, and harmonization of disease monitoring and reporting worldwide; and
- allow the United States to compare its data with international data to track the incidence and spread of disease and treatment outcomes.

3,000 Comments

Kerry Weems, acting CMS administrator, said HHS received more than 3,000 comments on the ICD-10 proposed rule. While noting that support for the transition "is strong throughout the health care industry," Weems said many commenters asked for a delay in the compliance dates for both ICD-10 and Version 5010, citing implementation costs, as well as the need to train health care personnel and provide ample time for testing between trading partners.

In response, HHS delayed the implementation dates between the proposed and final rules by 21 months for the 5010 standards, and by 24 months for the ICD-10 codes, he said.

"We look forward to working with all parties to ensure a smooth conversion to the updated transaction standards and ICD-10 code set," Weems said.

UnitedHealth to Pay $350 Million in Settlement With Physicians

UnitedHealth Group has agreed to pay $350 million to resolve a class action lawsuit by physicians challenging the health insurer's system for reimbursing out-of-network claims, the parties announced January 15 (*American Medical Ass'n v. United Healthcare Corp.*).

The agreement marks the largest monetary settlement of a class-action lawsuit against a single U.S. health insurer, according to the American Medical Association (AMA), which brought the lawsuit with the Medical Society of the State of New York and others in 2000. The settlement agreement was signed January 14 and must be reviewed in U.S. District Court for the Southern District of New York.

It followed the January 13 announcement by New York Attorney General Andrew M. Cuomo (D) that United will shut down its Ingenix health billing information subsidiary and pay $50 million toward establishing an independent body to set rates for reasonable and customary charges. That agreement resulted from an investigation into charges that Ingenix, in a conflict of interest, skewed the rates to favor insurers.

Also on January 15, Cuomo announced that Aetna will pay $20 million to help fund the new rate-setting body, to be administered by a nonprofit group.

AMA Hails 'Victory'

AMA President Nancy H. Nielson, in announcing the class action settlement, said that United would be held accountable for "shortchanging" patients and physicians. "By agreeing to the settlement," she said, "UnitedHealth Group has recognized the importance of restoring its relationship with patients and physicians by ending use of a rigged database. The AMA has long fought to increase the transparency of the health insurance industry's payment system, and this settlement is a giant step toward achieving that goal."

Stanley M. Grossman, an attorney with the New York law firm Pomerantz Haudek Block Grossman & Gross, who led the class action litigation, called the settlement "truly historic."

"It not only establishes the largest settlement fund ever achieved in a private health care litigation, but, working through the attorney general, it provides for resolving the entire Ingenix problem with the creation of a properly independent database," he continued.

Other plaintiffs included the Missouri State Medical Association and various individual subscribers and providers. The settlement also covers separate actions filed in New York and New Jersey federal district courts (*Oborski v. United Healthcare*).

News-At-A-Glance

Eli Lilly Settlement: American pharmaceutical giant Eli Lilly and Co. has agreed to plead guilty and pay $1.415 billion for promoting its drug Zyprexa for uses not approved by the Food and Drug Administration (FDA), the Department of Justice announced January 15. This resolution includes a criminal fine of $515 million, the largest ever in a health care case and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind. Eli Lilly will also pay up to $800 million in a civil settlement with the federal government and the states. The government alleged that from September 1999 through at least November 2003, Eli Lilly created marketing materials promoting Zyprexa for off-label uses, trained its sales force to disregard the law, and directed its sales personnel to promote Zyprexa for off-label uses.

Direct Billing Legislation: Ohio Governor Ted Strickland on January 6 signed into law direct-billing legislation that will prohibit markups on certain anatomic pathology services by an ordering physician who does not perform or supervise the service. The measure requires billing to be sent directly from the laboratory or physician performing or supervising anatomic pathology services to the patient or insurer. After negotiations with legislators and other medical groups, an exemption was included in the legislation allowing a physician to bill for anatomic pathology services performed on a dermatology specimen if the billing physician discloses the name of the laboratory used and the amount charged for the service by that laboratory.

OIG Clears Group Practice Arrangement: Physician owners of a group practice will not be subject to administrative sanctions for kickback violations because of their investment arrangement involving the group medical practice, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion released January 7. The OIG said the arrangement closely complied with all the requirements of the anti-kickback statute safe harbor for group practices, except that one of the physician stakeholders does not practice in the group. The opinion is available online at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-24.pdf.*

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