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For Hospitals, Laboratories and Physician Practices

Stimulus to Benefit Independent Pathologists
Privacy Remains a Concern

The $787 billion economic stimulus bill passed by Congress February 13 appears to be a mixed bag for laboratories and pathologists. While the measure includes incentives for physicians to adopt electronic health records, it also makes changes to certain privacy provisions that could put additional burdens on laboratories and other health care providers.

The American Recovery and Reinvestment Act of 2009 (ARRA) will provide $19 billion, including $2 billion in discretionary funds and $17 billion for investments and incentives through Medicare and Medicaid, to ensure widespread adoption and use of interoperable health information technology (IT).

Specifically, the measure includes incentives for physicians to incorporate electronic health records into their practices. However, for pathologists, qualifying for the incentive program will depend on your practice, notes the College of American Pathologists (CAP).

Independent pathologists will be eligible for a $15,000 incentive payment for adopting electronic health records starting 2011, with a declining incentive scale each subsequent year until 2015, according to CAP.

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CMS Modifies RAC Program to Minimize Burden

The Centers for Medicare & Medicaid Services (CMS) has made several changes to the recovery audit contractor (RAC) program to minimize the burden on health care providers and ensure accuracy, an agency official told the American Health Lawyers Association (AHLA) Hospital Law Institute February 10.

Now that a challenge to the award of RAC contracts has been settled, the program will go into effect this year nationwide, but with some key improvements based on feedback from an earlier demonstration project, CMS's Marie Casey told AHLA. CMS announced in early February that the stop work order had been lifted and that the permanent RAC program would be implemented. RACs set up in four regions will review Medicare claims on a post-payment basis and be paid a contingency fee based on the errors they find, she said.

To minimize the provider burden, Casey said *Cont., page 9*

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Stimulus Bill, *from page 1*

Hospital-based pathologists are ineligible for this particular incentive payment due to concerns over double payment. Legislators have allocated health information technology (HIT) incentive payments directly to hospitals and have assumed it would negate the need to provide HIT incentives directly to hospital-based pathologists. Additional HIT grants may also be made available for physicians through low-interest loans provided by the federal government to the states.

The Congressional Budget Office estimates that approximately 90 percent of doctors and 70 percent of hospitals will be using electronic health records within the next decade as a result of ARRA of 2009. CAP says it anticipates tremendous advantages from the adoption of the electronic health record system and will continue to advocate for incorporation of health information technology provisions in the health care agenda.

Privacy Concerns

The compromise bill also makes a number of changes to privacy provisions under the Health Insurance Portability and Accountability Act (HIPAA). The American Clinical Laboratory Association (ACLA) has expressed concerns about several of the provisions, noting that they will require laboratories and other providers to develop additional procedures and processes, at a considerable expense, to address the new requirements.

Among the provisions that are of concern:

- **Notification in the case of a breach:** Requires that a covered entity or business associate notify each individual whose unsecured protected health information (PHI) has been accessed, acquired, or disclosed as a result of a breach. ACLA believes that the requirement for notification should take effect only if some level of harm results from the breach. Otherwise, covered entities and business associates would be required to notify individuals each time PHI is inadvertently misdirected although no harm results, which would be unnecessarily burdensome and costly for providers.
- **Breaches treated as discovered:** A breach is treated as discovered by a covered entity or by a business associate as of the first day on which the breach is known. ACLA believes the time line for making such notification should be based upon confirmation of the breach by the covered entity or business associate, as opposed to "the first day" on which the breach is known to the covered entity or business associate. This would allow the covered entity or business associate to validate that a breach has, in fact, occurred and determine whether it is necessary to notify the individual involved.

Enforcement

ACLA is also concerned about a couple of enforcement provisions contained in the stimulus packages.

- **Tiered increase in the amount of civil monetary penalties:** Establishes a tiered approach for applying civil monetary penalties to violations under HIPAA of $100 to $50,000 for each violation, not to exceed $25,000 to $1,500,000 for the same violations within a calendar year, respectively. ACLA notes that these civil monetary penalties are "exorbitantly" higher than the penalties under existing law and fail to appropriately reflect the nature of the violation.
- **Enforcement through State Attorneys:** Permits the Attorney General of a state to bring a civil action on behalf of residents of the state for violations under HIPAA. ACLA argues that this provision enables an unprecedented private right of action for violations under HIPAA, which will create unnecessary lawsuits and further overload the judicial system and increase costs to taxpayers.

Court Refuses to Certify Class in Claims Against Quest
Plaintiffs Allege Improper Billing

A group of individuals who allege they were improperly billed for diagnostic testing services may not pursue claims under the Racketeer Influenced and Corrupt Organizations Act (RICO) or other laws as a class action, a federal court ruled February 11 (*Agostino v. Quest Diagnostics Inc.*).

The U.S. District Court for the District of New Jersey said the allegations brought against Quest Diagnostics Inc. and assorted collection agencies involved too many different laws, benefit plans, payers, payer contracts, and damage claims and could not, therefore, properly be certified for resolution on a classwide basis.

Although the plaintiffs, including Denise Agostino, alleged that there were common legal questions stemming from the hold harmless provisions in the provider agreements Quest entered into with private and government payers, the legal questions actually varied significantly depending on the terms of specific agreements, benefit plan terms, and the nature of the applicable state laws involved, the court said.

These variations on the nature of the claims asserted, and the proof required to pursue them, led the court to conclude that the class plaintiffs were unlikely to be able to prove the liability of Quest or the collections firms as a class. "Various individual issues of fact and law destroy any modicum of cohesiveness among members of the class," the court concluded.

Underlying Allegations

According to the court, the proposed class action was brought against Quest, the nation's leading provider of diagnostic and clinical testing, and the outside debt collection agencies with which it works.

The complaint alleged Quest improperly billed consumers at full list price at times when it has unanswered questions concerning consumers' insurance information or when insurance providers do not respond in a timely way to a claim or respond without adjudicating a claim due to incorrect patient information. It also alleged similar actions with respect to Medicare Part B beneficiaries, the court added.

The plaintiffs specifically alleged that the defendants improperly billed for laboratory testing and engaged in deceptive, misleading, abusive, and fraudulent debt collection practices.

These actions, according to the complaint, violated RICO, the Employee Retirement Income Security Act, and the Fair Debt Collection Practices Act. The defendants also violated state law requirements including the New Jersey Consumer Fraud Act and similar consumer protection and fraud laws of other states, the complaint alleged.

The plaintiffs specifically alleged that the defendants improperly billed for laboratory testing and engaged in deceptive, misleading, abusive, and fraudulent debt collection practices. They alleged improper balance billing, double billing, overbilling, and fraudulent billing, the court added.

For their part, the collection agencies collected or attempted to collect debts that they knew or should have known were not owed, the complaint alleged. In addition, all of the defendants acted jointly and severally in a common enterprise controlled by Quest to carry out an unlawful scheme under RICO, it added.

ACLA Calls for Crackdown on Certain FISH Testing

The American Clinical Laboratory Association (ACLA) is calling for a crackdown on certain types of arrangements that permit referring physicians to profit from their referrals of FISH (fluorescent *in situ* hybridization) testing.

In a discussion paper posted online February 13, ACLA notes that recently there have been a variety of new types of abusive arrangements that permit referring physicians to profit from their referrals in violation of Medicare fraud and abuse and billing laws. According to ACLA, certain laboratories are providing services involving FISH analysis to urologists and other clinicians in a way that raises legal concerns. Under these arrangements, clinical laboratories offer to provide the technical component (TC) of FISH analysis and then perform additional services that appear to go well beyond the TC.

The manner in which these services are being marketed to referring physicians only underscores its concerns, says ACLA, which is calling on the appropriate agencies to examine these arrangements and take action against laboratories that are marketing the tests and the physicians who are billing for them inappropriately.

In the case of FISH testing, some laboratories, under the guise of performing the TC, not only prepare the slides for examination but also employ personnel (including qualified cytotechnologists) who examine the specimen cells fixed on slides under a fluorescent microscope, select those individual cells that appear suspicious for malignancy, identify the number and color of signals for each cell, distinguish overlapping cells, and classify abnormal cells. Neither the referring physician nor any member of his group practice is involved in, or supervises, these functions at the laboratory, notes ACLA.

These clinical laboratories then provide the information derived from the analysis to the physician who ordered the test, along with a picture of a representative cell. This information is basically what would constitute the professional component (PC) of the service. In this way, says ACLA, the laboratories basically provide the referring clinician with a "cheat sheet" that gives the results of the PC analysis, an exercise that allows the clinician to bill for the professional component as if he had done the analysis himself.

In some situations, the laboratories may use a slight variation on the arrangement described above, which is still subject to significant abuse, according to ACLA. In these instances, the referring physician may contract with a pathologist on a part-time basis to review the reports received from the laboratory.

In these cases, the pathologist may come in one day a week, for example, and review the reports of the TC prepared by the clinical laboratory. The pathologist may then review and sign off on the reports, for which he is paid a fairly nominal amount. The referring physician is then permitted to bill Medicare at the full Medicare fee schedule amount for the PC of that service, thereby earning a significant profit.

The manner in which these tests are marketed and performed raises serious legal questions, says ACLA. First, because TC FISH is considered a high complexity laboratory test, any entity performing the PC must meet the strict regulatory requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which are particularly rigorous for cytogenetics testing like TC FISH. However, it appears that most doctors billing for this testing do not meet these requirements.

Second, the arrangements involving these tests raise significant questions under the anti-kickback law because it appears that the billing physician is being provided with the PC of the test surreptitiously and at no charge.

COMPLIANCE PERSPECTIVES

New Directions in Antitrust Enforcement: Obama Appoints Christine Varney to Head DOJ Antitrust Division

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During the presidential campaign, now-President Obama vowed to "reinvigorate antitrust enforcement."[1] He sharply criticized the Bush administration as having the "weakest record of antitrust enforcement of any administration in the last half century."[2]

In particular, Obama faulted the Bush administration's record in merger challenges. He cited statistics showing that between 2001 and 2006, the antitrust agencies challenged mergers at less than half the rate of challenges during the prior four years under the Clinton administration.[3] Obama thus promised to "step up review of merger activity and take effective action to stop or restructure those mergers that are likely to harm consumer welfare."[4] Moreover, Obama criticized the Bush Department of Justice (DOJ) for not bringing a single monopolization case in seven years.[5]

Shortly after being sworn in, President Obama took the first step in fulfilling his vow—he appointed a Clinton administration antitrust veteran, Christine Varney, to head the DOJ Antitrust Division. From 1994 to 1997, Varney served as a Commissioner at the Federal Trade Commission (FTC). If her record as an enforcer is any indication, Varney, if confirmed by the Senate, will likely bring change in both merger and nonmerger antitrust enforcement. Specifically, companies may expect the DOJ to take a more aggressive stance in 1) mergers in innovation-focused industries, 2) mergers involving vertical integration, and 3) mergers involving privacy issues. In addition, the DOJ may take a harder look at nonmerger cases involving vertical restraints.

Merger Enforcement

Mergers in Innovative Industries

Varney's appointment may mean closer scrutiny of mergers in high-tech and other innovation-focused industries. Specifically, her appointment may signal a resurgence of a doctrine developed in the Clinton administration but largely abandoned during the Bush administration—innovation market analysis.

During her tenure at the FTC, Varney was on the leading edge of the development of this type of merger analysis. In 1995, the FTC and the DOJ issued guidelines that formally recognized the concept of innovation markets—markets consisting of the research and development directed toward particular goods or services.[6] The agencies thereby defined a means to evaluate the competitive effects of merg-

[1] *Statement of Senator Barack Obama for the American Antitrust Institute, available at http://www.antitrustinstitute.org/archives/files/aai- Presidential campaign - Obama 9-07_092720071759.pdf.*
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] *U.S. Department of Justice & Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (1995).*

ing competing research and development efforts, even if the product of the research and development may be years off. The idea is that preserving competing research and development efforts can spur innovation. Prior merger enforcement focused only on existing products or products that were likely to enter the market in a short time frame.

Should Varney be confirmed to head the DOJ, innovation market analysis may well be used more often. Parties seeking mergers in high-tech and other innovation-focused industries should be prepared to address the implications of this analysis in matters before the DOJ.

Varney defended this new development as necessary for the antitrust agencies to "understand all of the dimensions of competition among firms" and to thereby protect innovation, which is vital to "advancing consumer welfare."[7] She also joined in several decisions applying innovation market analysis to require that merging parties make divestitures to protect innovation.

In 1994, for instance, the commission used innovation market analysis in reviewing the acquisition of American Cyanamid by American Home Products, which were two of three companies conducting research to develop a rotavirus vaccine. The commission required the parties to license Cyanamid's rotavirus vaccine research to ensure that the merger did not reduce innovation.[8]

Similarly, Varney joined the majority in using innovation market analysis to impose compulsory licensing in *Ciba-Geigy/Sandoz*.[9] The majority brushed aside objections that the licensing scheme was based on the much-maligned "essential facilities" doctrine and would put the commission in the role of price regulator.[10]

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Vertical Mergers

Mergers in high-tech industries may also face closer scrutiny if they involve vertical integration. An increasingly aggressive focus on vertical merger issues marked Clinton administration antitrust enforcement, but the Bush administration soon broke with that trend.[11]

Varney's appointment may signal a return to a more aggressive stance on vertical mergers. While at the FTC, she repeatedly defended the commission's vertical merger enforcement efforts, emphasizing that vertical mergers may create entry barriers, raise rivals' costs, and facilitate collusion.[12] Although she

[6] *U.S. Department of Justice & Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (1995).*

[7] *Christine Varney, Innovation Markets in Merger Review Analysis, 9 Antitrust 16, 16 (1995).*

[8] *Am. Home Products, 59 Fed. Reg. 60,807 (Nov. 25, 1994).*

[9] *Separate Statement of Chairman Robert Pitofsky, and Commissioners Janet D. Steiger, Roscoe B. Starek, III, and Christine Varney in Ciba-Geigy, Ltd., C-3725, available at http://www.ftc.gov/os/1997/04/others.htm.*

[10] *Id.*

[11] *See, e.g., Deborah A. Garza, A Comparative Analysis of the Clinton Antitrust Program and Suggestion Of Changes To Come, 15 Antitrust 64, 67 (2001)*

[12] *See Christine Varney, Vertical Merger Enforcement Challenges at the FTC, remarks before the PLI 36th Annual Antitrust Institute, July 17, 1995 ("Vertical Merger Enforcement"), available at http://www.ftc.gov/speeches/varney/varta.shtm; see also Christine Varney, The Dangers of Health Industry Consolidation and Corporatization and the Effect on Quality, Cost and Access, remarks before the Citizens Fund Conference, May 10, 1995, available at http://www.ftc.gov/speeches/varney/citi.shtm ("I am concerned about the overall competitive impact of vertical integration by drug companies into the pharmacy benefits management market."); Christine Varney, Efficiency Justifications in Hospital Mergers and Vertical Integration Concerns, Remarks before the Health Care Antitrust Forum, May 2, 1995, available at http://www.ftc.gov/speeches/varney/varht.shtm.*

recognized that there is "a great deal of theoretical controversy about the effects of vertical mergers," Varney argued that antitrust enforcers have "the tools" to separate those vertical mergers that are likely to cause anticompetitive effects from those that are not.[13]

Varney's commitment to vertical merger enforcement was manifest in her decisions involving high-tech industry transactions. For example, in the Silicon Graphics case, Varney joined a 3-2 Commission decision that relied on a vertical foreclosure theory to impose conditions on a vertical integration.[14] The majority was concerned that the merger would raise barriers to entry in the entertainment graphics workstation and software markets. It therefore required the merging parties to maintain an open architecture and publish their applications programming interfaces.

Varney's appointment may signal a return to a more aggressive stance on vertical mergers.

Similarly, in Cadence Design Systems, Varney joined the majority in applying vertical merger theory to an acquisition in the market for software for the design of integrated circuits.[15] The majority found that Cadence's acquisition of the only firm that developed the most advanced version of a particular software tool to be used with Cadence's dominant layout software could raise entry barriers. The commission therefore required Cadence to allow other tool developers continued access to interface protocols for its layout software. Varney also joined the majority in the commission's challenge to Time Warner's acquisition of Turner and TCI, which highlighted vertical merger analysis.[16]

The American Bar Association has urged the incoming administration to provide greater guidance regarding vertical merger analysis.[17] Under Varney's leadership, the DOJ may be happy to do so.

Mergers Involving Privacy Issues

Varney's expertise in privacy and Internet issues may also mean that the DOJ will consider privacy concerns in future mergers. In reviewing the recent *Google/DoubleClick* merger, the FTC struggled with integrating privacy issues in merger analysis. Two commissioners thought that privacy concerns should have played a part in the analysis of that merger, but the majority believed that privacy concerns remain a consumer protection, not an antitrust, issue.[18] Given her background, Varney will be well attuned to the debate over the role that privacy issues should play in merger analysis.

Nonmerger Enforcement

Vertical Restraints

Bush administration antitrust enforcers also broke with their predecessors when it came to challenging vertical

[13] *See Vertical Merger Enforcement, supra note 12.*

[14] *See Press Release, Fed. Trade Comm'n, FTC Settlement Would Preserve Competition on Price and Innovation for Entertainment Graphics Software and Hardware (June 9, 1995), available at http://www.ftc.gov/opa/1995/06/sgi.shtm.*

[15] *See Statement of Chairman Robert Pitofsky and Commissioners Janet D. Steiger and Christine A. Varney in the Matter of Cadence Design Systems, Inc./Cooper & Chyan Technology, Inc., File No. 971-0033, available at http://www.ftc.gov/os/1997/05/state01.htm.*

[16] *See Separate Statement of Chairman Pitofsky and Commissioners Steiger and Varney, In the Matter of Time Warner Inc., File No. 961-0004, available at http://www.ftc.gov/os/1996/09/twother.htm.*

[17] *See American Bar Association Section of Antitrust Law, 2008 Transition Report, Recommendation 41.*

[18] *See Dissenting Statement of Pamela Jones Harbour, In the Matter of Google/DoubleClick, File No. 071-0170, available at http://www.ftc.gov/os/caselist/0710170/071220harbour.pdf; Concurring Statement of Commissioner Jon Leibowitz, In the Matter of Google/DoubleClick, File No. 071-0170.*

restraints. The Clinton administration brought a number of actions challenging such restraints, while challenges to such restraints have been few and far between in the last eight years. Varney may change that.

During her tenure at the FTC, Varney pushed enforcement against vertical restraints. In a speech before the ABA in early 1995, she explained her thoughts on resale price maintenance (RPM) cases: "[O]ur enforcement agenda today is that resale price maintenance agreements are unlawful *per se* and the commission will enforce the law in this area."[19] This was a clear change from Reagan administration antitrust enforcement, which did not bring a single pure vertical restraint challenge.

True to her word, Varney joined in several important RPM challenges, including cases that expanded the scope of the *per se* rule in RPM cases.

In a case against American Cyanamid, Varney joined the majority in inferring the existence of a *per se* illegal RPM agreement despite the fact that the defendants had never announced resale prices nor sought a commitment from distributors to sell at or above a certain price level.[20] In a case against Reebok, Varney joined the commission in condemning an RPM policy, enjoining Reebok from using "structured terminations" to effect RPM even though such terminations "fall into the 'gray' area of RPM jurisprudence."[21] Varney also joined in a number of other cases challenging vertical price fixing agreements.[22]

The Bush administration, however, did not bring a single challenge against an RPM policy. Instead, the Bush administration urged the Supreme Court to overturn the per se rule against RPM, which it did in *Leegin Creative Products v. PSKS, Inc.*[23]

Since that time, there has been much speculation regarding when, under a rule of reason analysis, RPM is unlawful. Given her prior positions in this area, Varney's Antitrust Division may be the one to lead the charge in testing the boundaries set in *Leegin* by bringing challenges to vertical price restraints.

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[19] *Christine Varney, Vertical Restraints Enforcement at the FTC, Remarks before the ALI-ABA Eleventh Annual Advanced Course on "Product Distribution and Marketing," January 16, 1996 ("Vertical Restraints"), available at http://www.ftc.gov/speeches/varney/varnmg.shtm.*

[20] *American Cynamid Company, 123 F.T.C. 1257 (1997)*

[21] *Vertical Restraints, supra note 19.*

[22] *See, e.g., In the Matter of New Balance Athletic Shoe, Inc., Dkt. No. C-3683, available at http://www.ftc.gov/os/1996/09/c3683.do.htm.*

[23] *127 S. Ct. 2705 (2007).*

RAC Program, *from page 1*

CMS has limited the RAC "look-back period" to three years, with a maximum look-back date of Oct. 7, 2007. That responds to concerns raised about indefinite retrospective review of past claims, she said.

To prepare for the RAC audits, Casey said providers should look to see what improper payments have already been found by RACs during the demonstration project, on the CMS Web site at www.cms.hhs.gov/rac.

Second, to reduce the paperwork burden, RACs will accept imaged medical records from providers on CD/DVDs. CMS will outline the format requirements soon, she said.

Third, CMS is limiting the number of medical record requests that RACs can make, Casey said. For inpatient hospital claims, the limit will be 10 percent of average monthly Medicare claims per 45 days, up to a maximum of 200. Limits for physician claims will vary by the size of the practice, with larger groups exceeding 16 individuals having to submit a maximum 50 medical records per 45 days.

To ensure accuracy, each RAC will be required to employ a physician medical director and certified coders, Casey said. CMS also has created a New Issue Review Board to offer greater oversight of RAC audit subjects. Also, if a provider contests a RAC audit and the RAC loses at any level of appeal, it must return its contingency fee, Casey said.

To maximize transparency of RAC procedures, new issues targeted by audits must be posted to the RAC's Web site. And when CMS finds patterns of "vulnerabilities," these will be posted to the CMS Web site, Casey said. RACs also must provide a detailed review results letter following all complex reviews.

To prepare for the RAC audits, Casey said providers should look to see what improper payments have already been found by RACs during the demonstration project, on the CMS Web site at *www.cms.hhs.gov/rac*.

Permanent RAC findings will be listed on each RAC's Web site. Providers also can look online (*www.cms.hhs.gov/CERT/*) to see what improper payments have been found in audits conducted by the Office of Inspector General and the Comprehensive Error Rate Testing Program (CERT), she said.

Casey advised that health care providers conduct their own internal assessments to determine if they are compliant with Medicare rules and identify corrective actions that may be necessary.

Once the RAC audits begin, providers should keep track of denied claims, look for patterns, and implement corrective actions to avoid improper payments, Casey said. She advised providers to "appeal when necessary," noting that although there is a "RAC discussion period" to give RACs further information on rejected claims, providers must nevertheless file a formal appeal within 120 days of receiving a demand for payment letter.

Information on the RAC program is available on the Web at *www.cms.hhs.gov/RAC/01_Overview.asp#TopOfPage*.

Recovery Audit Contractors

The final RACS and their jurisdictions are as follows:

- **Diversified Collection Services Inc. of Livermore, Calif.**—Region A (Rhode Island, New Hampshire, Vermont, Massachusetts, Delaware, Connecticut, New York, Pennsylvania, New Jersey, and Maine).
- **CGI Technologies and Solutions Inc. of Fairfax, Va.**—Region B (Minnesota, Michigan, Wisconsin, Indiana, Illinois, Kentucky, and Ohio).
- **Connolly Consulting Associates Inc. of Wilton, Conn.**—Region C (South Carolina, North Carolina, Florida, Colorado, New Mexico, Texas, Oklahoma, Alabama, Tennessee, Georgia, Mississippi, West Virginia, Virginia, Louisiana, and Arkansas).
- **HealthDataInsights Inc. of Las Vegas, Nev.**—Region D (Montana, Wyoming, North Dakota, South Dakota, Utah, Arizona, Washington, California, Oregon, Idaho, Nevada, Nebraska, Kansas, Iowa, Missouri, Hawaii, and Alaska).

New York Proposes Compliance Programs for Medicaid Providers

The New York State Office of Medicaid Inspector General (OMIG) on January 14 published proposed regulations in the *New York State Register* that would establish requirements for mandatory compliance programs Medicaid providers must develop to reduce fraud and abuse.

The regulations, which are subject to a 45-day public comment period, would implement a 2006 law that created OMIG and required providers to develop the compliance programs.

The proposed regulations would apply to hospitals, nursing homes, home care providers, medical equipment service agencies, and mental health facilities. They also apply to providers for which the Medicaid program comprises "a substantial portion of their business operations."

Under the proposed regulations, providers would have to develop plans to routinely identify compliance risk areas and undertake internal and external audits to evaluate risks. The compliance programs also would include plans for responding to compliance issues, investigating potential fraud and abuse, and correcting problems.

Could Be Model

The regulations were applauded by Richard P. Kusserow, chief executive officer of Strategic Management Systems, Alexandria, Va., and the former inspector general of the Department of Health and Human Services. Kusserow said that many other states are looking at New York's requirements as a possible model.

"I'm sorry the State of New York is getting ahead of the federal government by mandating it, rather than making it voluntary," Kusserow said. "If New York thinks that these programs should be mandated [for Medicaid], why doesn't the federal government think they should be mandated for Medicare?"

The mandatory compliance programs will be an effective tool against fraud "because it puts the onus on the providers to police themselves," Kusserow said. "The first line of defense is for you [providers] to ensure that the claims you are submitting are correct and appropriate."

Francis J. Serbaroli, an attorney with Greenberg Traurig in New York, believes the requirements are "long overdue," considering the size of New York's Medicaid program. Serbaroli said most large providers should already have a compliance program in place and will probably only need to "fine tune it" to suit the New York regulations. The actual effect of the regulations, therefore, will probably be limited to small and midsize providers.

"The big hospitals already have them," Serbaroli said. "What this is aimed at, though, would be nursing homes. There are a lot of small and medium size nursing homes that probably don't have compliance programs in place. I think this is a wakeup call for them to get on the compliance bandwagon."

Reporting Compliance

In addition, plans would have to include a system for reporting compliance issues to OMIG or the state Department of Health, according to the regulations.

"Medicaid providers may be able to detect and correct payment and billing mistakes and fraud, if required to develop and implement compliance programs," the OMIG said in a question-and-answer sheet on the compliance programs.

"It is the purpose of such programs to organize provider resources to resolve payment discrepancies and detect inaccurate billings, among other things, as quickly and efficiently as possible and to impose systemic checks and balances to prevent future recurrences," the OMIG said.

The proposed regulations would apply to hospitals, nursing homes, home care

providers, medical equipment service agencies, and mental health facilities. They also apply to providers for which the Medicaid program comprises "a substantial portion of their business."

Under the regulations, compliance programs must include:

- a code of ethics or code of conduct for employees;
- a designated employee with day-to-day responsibility for overseeing the compliance program;
- training and education for employees;
- disciplinary policies to encourage good-faith participation in the program by employees.

Providers, under the regulations, would be required to certify to the state upon enrollment in Medicaid, and each year thereafter, that they have a compliance program that meets state requirements. Failure to develop a satisfactory program could result in revocation of a provider's rights to participate in Medicaid.

The costs for complying with the new regulations will vary, depending on whether a provider already has a compliance program and what type of program, according to a regulatory impact statement released with the proposed regulations. Providers can expect to offset some of the costs with savings resulting from compliance programs.

For providers with an operating compliance program, potentially little or no costs may be incurred to establish a program that satisfies the proposed regulations, while those providers that do not have a program that meets the new requirements will incur some costs.

"The extent of those costs will depend on the level of effort that is necessary for the provider to establish a compliance program that satisfies each of the eight mandatory elements," it said.

The regulations are available at *www.dos.state.ny.us/info/register/2009/jan14/pdfs/rules.pdf*.

CVS Agrees to Settlement in Privacy Case

Behemoth pharmacy chain CVS Caremark Corp. agreed to settle Federal Trade Commission (FTC) charges that it failed to take reasonable and appropriate security measures to safeguard its consumers' and employees' financial and medical information, FTC announced February 18 (*In re CVS Caremark Corp.*).

In addition, the retail pharmacy subsidiary, CVS, has entered into a separate but related agreement with the Department of Health and Human Services (HHS) under which it will pay HHS $2.25 million to settle claims its actions violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule.

Specifically, both FTC's and HHS's charges stem from allegations that CVS Caremark pharmacies nationwide were disposing into open dumpsters a multitude of sensitive personal health and financial information, including pill bottles containing patient names, addresses, prescribing physicians' names, medication, and doses; medication instruction sheets containing personal information; computer order information from the pharmacies that contained consumers' personal information; employment applications including Social Security numbers; payroll information; and credit card and insurance card information.

"This is a case that will restore appropriate privacy protections to tens of millions of people across the country," FTC Chairman William E. Kovacic said in a February 18 press release. "It also sends a strong message to other organizations that possess consumers' protected personal information. They are required to secure consumers' private information."

News-At-A-Glance

Eli Lilly Agrees to Settlement: Eli Lilly and Co. agreed to pay more than $1.4 billion to resolve allegations that it promoted its antipsychotic drug Zyprexa for off-label uses, the Department of Justice said January 15. That amount, DOJ added, included a criminal fine of $515 million, the largest criminal fine for an individual corporation imposed in a U.S. criminal prosecution of any kind. Eli Lilly also agreed in a civil settlement agreement to pay $800 million to the federal government and various states to resolve four False Claims Act *qui tam* lawsuits filed by former company sales representatives and related state claims.

OIG Reports on ROI: The Department of Health and Human Services Office of Inspector General said in its *Annual Performance Report* for fiscal year 2008 that the return on investment for expenditures related to the Medicare and Medicaid programs—which account for most of OIG's spending—was $17 for every dollar spent over the three-year period from FY 2006 through FY 2008. The report said that, the OIG recovered $14.70 for every dollar spent by the office on audits and investigations over the same three-year period. According to the report, $2.3 billion was returned to the federal government in 2008 as a result of OIG investigations. OIG audit work returned an additional $1.3 billion to the federal government. The report is available at *www.oig.hhs.gov/publications/docs/budget/FY2008_APR.pdf*.

Court Dismisses FCA Case: A federal trial court in Texas January 22 dismissed a False Claims Act *qui tam* action alleging Christus Spohn Health System Corp. exchanged below-market rents for physician referrals, finding the allegations lacked the specificity required for fraud claims (*United States ex rel. Smart v. Christus Health*). Although it dismissed the case, the U.S. District Court for the Southern District of Texas rejected the defense argument that the suit was barred because its allegations had already been publicly disclosed in a state action. In one of the first such rulings in the Fifth Circuit, the court adopted the majority rule on *qui tam* provisions of the FCA, which holds that the jurisdictional bar did not apply because the whistleblower suit was not "based upon" the allegations in the state suit.

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