# G2 Compliance Report

For Hospitals, Laboratories and Physician Practices

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## HHS Proposal Provides Details on ACOs, Shared Savings Program

A much anticipated proposed rule governing creation and implementation of accountable care organizations (ACOs) should help clarify how these entities will operate and share cost savings.

The Department of Health and Human Services (HHS) released the proposed rule March 31. The proposal, which will be published in the April 7 *Federal Register*, is designed to help doctors, hospitals, and other health care providers better coordinate care for Medicare patients through ACOs.

The Medicare Shared Savings Program will reward ACOs that lower health care costs while meeting performance standards on quality of care and putting patients first. Patient and provider participation in an ACO is purely voluntary.

According to HHS, more than half of Medicare beneficiaries have five or more chronic conditions such as diabetes, arthritis, hypertension, and kidney disease. These patients often receive care from multiple physicians. A failure to coordinate care can often lead to patients not getting the care they need, receiving duplicative care, and being at increased risk of suffering medical errors.

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## New Enforcement Tools Will Aid Efforts To Combat Health Care Fraud, Officials Say

Enhanced enforcement tools contained in the health reform law can provide significant aid to federal efforts to combat an estimated $70 billion in improper Medicaid and Medicare payments over the past year, officials from the Department of Justice (DOJ) and Department of Health and Human Services (HHS) told lawmakers March 9.

But these new tools will reduce health care fraud only if they are effectively implemented, according to the director of the Government Accountability Office's health care section, who pointed out that the Centers for Medicare and Medicaid Services at HHS has failed to implement previous GAO recommendations on ways to reduce fraud.

Under the Patient Protection and Affordable Care Act, HHS will have authority to impose tougher screening procedures for providers and suppliers as well as increased funding for fraud prosecution efforts by the

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## HHS Proposal Provides Details on ACOs, *from page 1*

On average, each year one in seven Medicare patients admitted to a hospital has been subjected to a harmful medical mistake in the course of their care, says HHS. And nearly one in five Medicare patients discharged from the hospital is readmitted within 30 days—a readmission many patients could have avoided if their care outside of the hospital had been more aggressive and better coordinated. According to an analysis of the proposed regulation for ACOs, Medicare could potentially save as much as $960 million over three years.

Under the proposed rule, an ACO refers to a group of providers and suppliers of services that will work together to coordinate care for the patients they serve. The Patient Protection and Affordable Care Act specifies that an ACO may include the following types of groups of providers and suppliers of Medicare-covered services:

- ACO professionals (i.e., physicians and hospitals meeting the statutory definition) in group practice arrangements;
- Network of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals; and
- Other Medicare providers and suppliers as determined by the secretary of HHS.

The law requires that each ACO include health care providers, suppliers, and Medicare beneficiaries on its governing board. The ACO must take responsibility for at least 5,000 beneficiaries for a period of three years.

Though the Medicare Shared Savings Program does not actually take effect until Jan. 1, 2012, many hospital and provider networks have already begun forming ACOs. According to G2 Intelligence, there were at least 123 ACOs being implemented in the United States as of February 2011. We estimate that there will be a total of about 375 ACOs in early 2012, with an additional 75, or 450 total, by 2013.

### Sharing Savings

Under the proposed rule, Medicare would continue to pay individual health care providers and suppliers for specific items and services as it currently does under the original Medicare payment systems. CMS would also develop a benchmark for each ACO against which ACO performance is measured to assess whether it qualifies to receive shared savings or to be held accountable for losses. CMS also is proposing to establish a minimum sharing rate that would account for normal variations on health care spending so that the ACO would be entitled to shared savings only when savings exceeded the minimum sharing rate. The amount of shared savings depends on whether an ACO meets or exceeds quality performance standards.

CMS is proposing to implement both a one-sided risk model (sharing of savings only for the first two years and sharing savings and losses in the third year) and a two-sided risk model (sharing savings and losses for all three years), allowing the ACO to opt for one or the other model. This will help organizations with less experience with risk models to gain experience with population management before transitioning to a risk-based model, said CMS Administrator Donald Berwick.

ACOs that participate in the two-side model would be able to obtain greater savings. However, the rule also proposes to establish a minimum sharing rate. ACOs in the one-sided risk program that have smaller populations (and have more variation in expenditures) would have a larger sharing rate, and ACOs with larger populations

  

(and have less variation in expenditures) have a smaller rate. Under the two-sided approach, CMS proposed a flat 2 percent minimum sharing rate.

### Measuring Quality Improvement

CMS said the proposed rule would establish quality performance measures and a methodology for linking quality and financial performance "that will set a high bar on delivering coordinated and patient-centered care by ACOs, and emphasize continuous improvement around the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures."

The proposed rule would require the ACO to have in place procedures and processes to promote evidence-based medicine and beneficiary engagement in their care. The proposed rule would also require ACOs to report quality measures to CMS and give timely feedback to providers. The rule proposed 65 quality measures across five key areas: patient/caregiver care experiences, care coordination, patient safety, preventive health, and at-risk population/frail elderly health.

Under the proposed rule, an ACO that meets the program's quality performance standards would be eligible to receive a share of the savings it generates below a specific expenditure benchmark that would be set by CMS for each ACO. The proposed rule would also hold ACOs accountable for downside risk by requiring ACOs to repay Medicare for a portion of losses (expenditures above its benchmark). The benchmark would take into account beneficiary characteristics and other factors

### Lab-Related PQRI Measures

- Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus
- Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus
- Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients
- Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade
- Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade
- Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment
- Hepatitis C: HCV Genotype Testing Prior to Treatment
- Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment
- Hepatitis C: Testing for Chronic Hepatitis C – Confirmation of Hepatitis C Viremia
- Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
- Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry
- Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy
- Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow
- Appropriate Testing for Children with Pharyngitis
- HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis
- HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea
- Ischemic Vascular Disease (IVD): Complete Lipid Profile
- Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL-C) Control
- Coronary Artery Bypass Graft (CABG): Lipid Management and Counseling
- HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy
- HIV/AIDS: CD4+ Cell Count or CD4+ Percentage

*Source: G2 Intelligence*

  

that may affect the need for health care services. This benchmark would be updated for each performance year within the three-year performance period.

The quality measures are aligned with the measures in other CMS programs such as for electronic health records (EHR) and the Physician Quality Reporting Initiative (PQRI). An ACO that successfully reports the quality measures required under the shared savings program would be deemed eligible for a PQRI bonus. However, the rule specifies that ACOs may not participate in any other shared savings program or demonstration under the Center for Medicare and Medicaid Innovation or Independence At Home Medical Practice pilot program to ensure that savings are not counted twice.

Among the physician quality reporting initiative measures used to assess performance, at least 21, or 12 percent, can be identified as relating to laboratory testing (*see chart, p. 3*).

The proposed rule is available at *www.ofr.gov.*

## ACOs, Labs, and Fraud and Abuse

Clinical laboratories and pathologists can participate in ACOs in a number of ways—as ACO suppliers, as ACO owners and partners, and as integrated components of ACOs. But as Carrie Valiant, a health care attorney with EpsteinBeckerGreen (Washington, D.C.), noted in the March issue of *G2 Compliance Report*, such participation could potentially implicate the anti-kickback statute and Stark law.

CMS Administrator Donald Berwick says the agency has worked closely with other federal agencies, including the HHS Office of Inspector General (OIG), the Department of Justice (DOJ), the Federal Trade Commission (FTC), and the Internal Revenue Service (IRS) to ensure that providers and suppliers have the guidance they need to form ACOs without running afoul of the fraud and abuse, antitrust, and tax laws.

Concurrently with the publication of the HHS proposed rule, the following documents have been issued: a joint CMS and OIG notice and solicitation of public comments on potential waivers of certain fraud and abuse laws in connection with the Medicare Shared Savings Program; a joint FTC and DOJ proposed antitrust policy statement; and an IRS notice requesting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the shared savings program.

In its notice, the OIG sets forth proposals for waivers of fraud and abuse laws that it believes will be necessary to carry out the Medicare Shared Savings Program. The agency says it is soliciting comment on these proposals and expects to issue waivers applicable to ACOs participating in the savings program concurrently with CMS's publication of final regulations for the program.

Essentially, the OIG is proposing to waive application of the physician self-referral law (known as the Stark statute) and the anti-kickback law to distributions of shared savings received by an ACO from CMS under the shared savings program to or among ACO participants, providers, or suppliers during the year in which the savings were earned or for activities necessary for and directly related to the ACO's participation in and operations under the program.

The intent, says the OIG, is to protect financial relationships created by the distribution of shared savings within the ACO. It is not to protect distributions of shared savings dollars to referring physicians outside the ACO, unless those referring physicians are being compensated (using shared savings) for activities necessary for and directly related to the ACO's participation in and operations under the shared savings program.

The OIG also proposes to waive the prohibition on hospital payments to physicians to induce reduction or limitation of services (gainsharing) but only in certain circumstances.

Comments on the proposal are due 60 days after publication in the *Federal Register*. The joint CMS-OIG notice is available online at *www.ofr.gov*. The proposed antitrust policy statement is available at *www.ftc.gov/opp/aco*. The IRS guidance is available at *www.irs.gov/pub/irs-drop/n-11-20.pdf.*

  

G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

# Fraud and Abuse Enforcers Turn Their Attention to Individuals

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The Department of Health and Human Services Office of Inspector General (OIG) and the Food and Drug Administration (FDA) are in the midst of a sea change in fraud and abuse enforcement in the health care industry. Recent guidance documents, statements from high-level agency officials, and criminal prosecutions clearly indicate that the OIG and FDA intend to pursue individual prosecutions against the *corporate officials* who are responsible for alleged fraud and abuse by health care entities. In the past 20 months, executives at InterMune Inc., Purdue Frederick Co., Synthes Inc., and WellCare Health Plans Inc. have been either indicted or convicted for various health care crimes. As a result, owners, officers, and managing employees at health care entities now face an unprecedented level of exposure for corporate fraud and abuse.

### OIG Statements

Inspector General Daniel Levinson testified before Congress on March 9, 2011, about new tools for curbing waste, fraud, and abuse in Medicare and Medicaid.[1] Levinson asserted that the authority to exclude health care providers from participation in Medicare and Medicaid is one of the OIG's most powerful tools for combating fraud and abuse. Once the OIG determines that an individual or entity has engaged in fraud or abuse or provided substandard care, it can exclude that provider from participating in Medicare, Medicaid, and all other federal health care programs. Exclusion has the practical effect of a death sentence for health care entities. The exclusion of an individual has the practical effect of making that person unemployable in the health care industry.

Levinson opined that although the risk of exclusion from Medicare and Medicaid creates a strong incentive to comply with program rules and requirements, some hospital systems, pharmaceutical manufacturers, and other providers may believe that they are too integral to the health care delivery system to be subject to program exclusion because it could compromise the welfare of Medicare and Medicaid beneficiaries. Levinson cited the fact that some pharmaceutical manufacturers have paid hundreds of millions of dollars in False Claims Act (FCA) settlements as evidence that large providers may consider engaging in fraudulent schemes and paying civil penalties and criminal fines "as a cost of doing business." He concluded that abusive corporate behavior is likely to continue as long as the profit from the fraud exceeds those costs.

Levinson suggested that one way to address corporate fraud and abuse is "to alter the cost-benefit calculus of the corporate executives who run these companies." Specifically, Levinson asserted that the OIG can influence corporate behavior without endangering patient access to care by "excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in the fraud." Under Section 1128(b)(15) of the Social Security Act, the OIG has the discretionary authority to exclude the

[1] Testimony before the U.S. Senate Committee on Homeland Security and Governmental Affairs, March 9, 2011, "New Tools for Curbing Waste and Fraud in Medicare and Medicaid."

owners, officers, and managing employees of a health care entity that is excluded, convicted of, or pleads to certain health care offenses, even if the executive has not been convicted of a crime. In a significant statement about where OIG enforcement efforts are headed, Levinson stated that "moving forward, [the OIG intends] to use this essential fraud-fighting tool in a broader range of circumstances."

***The trend toward an increasing focus on individual liability for corporate fraud and abuse is reflected in recent congressional activity.***

In light of the OIG's intention to increasingly use its exclusion authority to target and pursue individual corporate officers, it is instructive to consider the nonbinding criteria that the OIG has enumerated to guide the use of its permissive exclusion authority.[2] Two separate bases for exclusion from Medicare, Medicaid, and all other federal health care programs are relevant to the discussion. First, individuals who have an ownership or control interest in a sanctioned entity may be excluded if they knew, or should have known, of the conduct that led to the sanction. If the evidence supports a finding that the owner knew, or should have known, of the conduct, the OIG will operate with a presumption in favor of exclusion, which may be overcome only if "significant factors weigh against exclusion."

Second, officers and managing employees[3] may be excluded based solely on their position within the sanctioned entity. There is no knowledge element, and the OIG can exclude every officer and managing employee of the sanctioned entity. While the OIG is unlikely to exclude all officers and managing employees, it will operate with a presumption in favor of exclusion if there is evidence that the individual knew, or should have known, about the conduct. Absent such evidence, the OIG will consider the following factors: (1) the circumstances of the misconduct and the seriousness of the offense, (2) the individual's role in the sanctioned entity, (3) the individual's actions in response to the misconduct, and (4) information about the entity. Notably, the OIG has interpreted "misconduct" to include not just the factual basis for the entity's sanction, but also "any other conduct OIG considers relevant." OIG guidance specifically identifies allegations in criminal, civil, and administrative matters involving the convicted or excluded entity or any related entity to be relevant in its consideration.

The trend toward an increasing focus on individual liability for corporate fraud and abuse is reflected in recent congressional activity. On Feb. 11, 2011, Rep. Wally Herger introduced H.R. 675, the Strengthening Medicare Anti-Fraud Measures Act of 2011. The proposed legislation would amend Title XI of the Social Security Act to expand the OIG's permissive exclusion authority to individuals and entities that are affiliated with a sanctioned entity. The bill would authorize the OIG to impose a permissive exclusion even if the individual or entity is no longer *affiliated* with the sanctioned entity but was at the time of the conduct at issue. At present, the legislation is being considered by several House committees.

### FDA Activity

The FDA also has signaled an intention to increase its pursuit of individual prosecutions. On March 4, 2010, FDA Commissioner Margaret Hamburg announced in a letter to U.S. Sen. Charles Grassley that the FDA's Office of Criminal Investigations (OCI) intends to "increase the appropriate use of misdemeanor prosecutions . . . to

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[2] See "Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act," available at *http://www.oig.hhs.gov/fraud/exclusions.asp.*

[3] A "managing employee" is defined as an individual (including a general manager, business manager, administrator, or director) who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity.

  

hold responsible corporate officers accountable." Under the *Park* doctrine, sometimes referred to as the responsible corporate officer doctrine, the government can seek a misdemeanor conviction against a corporate officer for alleged violations of the Food, Drug, and Cosmetics Act (FDCA)—even if the officer was neither involved in nor aware of the violation. To do so, the government must prove that the corporate officer was in a position to prevent or correct the violation of the FDCA but failed to do so.[4] Although neither criminal intent nor actual knowledge of the underlying offense is required, the jury may not "find guilt solely on the basis of the [officer's] position in the corporation."[5] Instead, the jury must find that the officer "had a responsible relation to the situation and by virtue of his position had authority and responsibility to deal with [it]."[6] The only defense to liability under the *Park* doctrine is a showing by the corporate officer that he or she was powerless to prevent the wrongdoing.[7]

***The OIG and FDA's increased emphasis on pursuing individual liability for fraud and abuse perpetrated by health care entities, along with the severe consequences of exclusion from federal health care programs, create an unprecedented level of exposure for health care industry owners, officers, and managing employees.***

In 2007, OCI and Department of Justice (DOJ) revived the *Park* doctrine to prosecute three executives at the Purdue Frederick Company—the chief executive officer, the executive vice president, and the chief legal officer—for misdemeanor drug misbranding violations of the FDCA. The prosecutions stemmed from a governmental investigation and settlement with Purdue for misbranding the drug Oxycontin with the intent to defraud or mislead. Supervisors and employees at Purdue allegedly marketed the drug as being less addictive, less subject to abuse, and less likely to cause dependency than other painkillers. The executives accepted an agreement to plead guilty to the charges in order to avoid jail time. The agreed statement of facts stipulated that none of the executives had personal knowledge of the misbranding but that all were responsible corporate officers during the relevant period and thus had the responsibility and authority to either prevent or correct the wrongdoing.

After the criminal case against the Purdue executives concluded, the OIG used its Section 1128(b)(15) authority to exclude the executives from participation in Medicare, Medicaid, and all other federal health care programs for a period of 12 years. The OIG determined that the misdemeanor misbranding convictions were sufficient to trigger its permissive exclusion authority, notwithstanding the fact that the executives disclaimed any knowledge of or participation in the misbranding. The U.S. District Court for the District of Columbia recently affirmed the OIG's decision to exclude the former executives for a period of 12 years.[8] Given that the exclusion imposed was substantially longer than the typical three-year exclusion period, the prosecution and settlement with the Purdue executives illustrates the government's enhanced focus on individual liability for fraud and abuse perpetrated by health care entities.

The FDA recently issued guidelines to help agency officials determine whether to recommend a misdemeanor prosecution against a corporate official under the *Park* doctrine.[9] The FDA stated that the key factors to consider are the individual's position in the company and relationship to the violation, and whether the official

[4] *United States v. Park*, 421 U.S. 658, 673-74 (1975).
[5] *Id. at 674.*
[6] *Id.* (internal quotation marks omitted).
[7] *Id. at 672-73.*
[8] *Friedman et. al v. Sebelius*, 1:09-cv-02028-ESH (D.D.C. 2010).
[9] Available at *http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm.*

  

had the authority to correct or prevent the violation. Significantly, the FDA asserted that "knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation." Other factors that the FDA will consider include whether the violation is obvious, widespread or serious, involves actual or potential harm to the public, or reflects a pattern of illegal behavior or failure to heed prior warnings. FDA officials are also directed to consider the quality of the legal and factual support for the proposed prosecution and whether the proposed prosecution is a prudent use of agency resources.

**Conclusion**

The OIG and FDA's increased emphasis on pursuing individual liability for fraud and abuse perpetrated by health care entities, along with the severe consequences of exclusion from federal health care programs, create an unprecedented level of exposure for health care industry owners, officers, and managing employees. Indeed, recent enforcement actions brought by the OIG, FDA, and DOJ underscore that owners, officers, and managing employees at health care entities must be vigilant when monitoring the activities of their companies. Thomas Doyle, the special agent in charge of FDA's Office of Criminal Investigations, summarized the trend toward individual liability for corporate fraud and abuse: "pharmaceutical executives will not be able to hide behind a corporate shield when they promote drugs using false or fraudulent information. . . . Pharmaceutical companies do not run themselves, and those who engage in criminal conduct will be held personally accountable."[10]

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[10] See Department of Justice Press Release, available at *http://www.justice.gov/usao/can/press/2009/2009_09_29_harkonen.convicted.press.html.*

## New Enforcement Tools Will Aid Efforts, *from page 1*

HHS Office of Inspector General and DOJ, Peter Budetti, deputy administrator for program integrity at CMS, told the hearing.

"With the tools we have now and are putting into place under the [Patient Protection and Affordable Care Act], we are going to do things that will stop the bulk of fraud," Budetti said. He testified at a hearing of the financial management and federal services subcommittee of the Senate Committee on Homeland Security and Governmental Affairs.

**Spending Cuts**

"We're skating on thin ice" with respect to the amount of debt in the United States, panel Chairman Thomas R. Carper (D-Del.) warned in an opening statement. "We need to look in every nook and cranny to find ways to reduce federal expenditures." Carper pointed to a chart showing that the amount of improper Medicare payments in fiscal year 2010 totaled $47.9 billion, while improper Medicaid payments totaled $22.5 billion.

The panel's ranking member, Scott Brown (R-Mass.), said he found it "amazing we can have that amount of improper payments." Also pointing to the chart's bottom line, Brown said, "People talk about the amount of money Republicans want to cut from the budget. It's right there, folks." The current Republican budget proposal calls for cutting about $60 billion from the budget to fund the government for the rest of the fiscal year.

The optimism expressed by Budetti about the new enforcement tools was echoed by two other witnesses—Gregory Andres, DOJ's acting deputy assistant attorney general, and HHS Inspector General Daniel R. Levinson.

Andres noted that the new law clarifies that a defendant in a health care fraud prosecution "need not be aware of a specific statutory provision in the law" to be convicted of health care fraud.

  

In addition, PPACA directs the U.S. Sentencing Commission to revise sentencing guidelines to allow prosecutors to request sentences based on the amount of fraudulent billings made by a defendant rather than the amount of improper payments received by the defendant, Andres said.

"These important new tools contained in the act are already having a significant impact in assisting our efforts to combat fraud," Andres asserted. Levinson emphasized that the increased "up-front oversight" provisions in the new law will aid HHS in preventing improper payments in the first place.

For example, PPACA authorizes HHS to conduct "more robust" screening procedures for providers and suppliers, to impose temporary enrollment freezes when HHS identifies so-called fraud hot spots, and to initiate provisional periods of enhanced payment oversight for newly enrolled providers and suppliers, as well as heightened disclosure and transparency requirements, Levinson noted.

#### Effective Implementation

Kathleen King, director of GAO's health care section, told the panel that while PPACA provides enhanced statutory authority for HHS, "effective implementation is critical." She said CMS has failed to develop an effective corrective action process for vulnerabilities previously identified by Medicare fee-for-service Recovery Audit Contractors (RACs). Moreover, CMS guidance to states on Medicaid RAC programs "did not include steps to address vulnerabilities through a corrective action process."

Along with her testimony, King provided the panel with a new GAO report, *Medicare and Medicaid Fraud, Waste, and Abuse: Effective Implementation of Recent Laws and Agency Actions Could Help Reduce Improper Payments* (GAO-11-409T). The report is available on the GAO Web site at *www.gao.gov.*

## Increase in Recovery Audit Contractors Raises Concern by Hospital Association

The federal government is relying more heavily on its Recovery Audit Contractor (RAC) program to determine when Medicare overpayments are made, which an official with the American Hospital Association (AHA) March 11 said has prompted the association to develop a strategy to address concerns with the agency that administers the program.

In particular, AHA is concerned with medical necessity reviews and denials. "We need more detail on medical necessity denials and overturned denials," Rochelle Archuleta, AHA's senior associate director of policy, said. "We're going to push [the Centers for Medicare and Medicaid Services] to break out data regarding medical necessity denials and appeals."

Medical necessity audit reviews are designed to determine if a patient was given appropriate medical care and, therefore, whether Medicare payments was appropriate. AHA has questioned if auditors possess the clinical knowledge to determine if patient medical care was both reasonable and necessary.

Archuleta, who spoke at the Fifth National Medicare RAC Summit in Washington, said CMS should review medical necessity denials that have a high rate of being overturned and give better instructions to auditors about what to review and what claims to deny.

  

She said CMS in February raised the cap on additional documentation requests for RACs from 300 per 45-day cycle for large hospitals to 500 per 45-day cycle. AHA, she said, questions whether the RACs have the ability to handle the increased amount of medical records they are being asked to audit.

Archuleta said results from the AHA's most recent RACTrac survey (October-December 2010) show the growing reach of RACs. Medical record requests were up 81 percent from the third quarter of 2010 to the fourth quarter of 2010. There also was a 129 percent increase in denials from the third quarter, she said. Most of the denials, she said, came from complex audit reviews.

### Additional Concerns

Archuleta addressed other AHA concerns with the RAC program, as well, including:

- Hospitals not receiving a letter when a RAC withdraws an audit;
- Lack of explanation regarding the rationale for a claims denial;
- The ability of RACs to process the increase in documentation CMS wants them to review;
- Untimely correspondence from RACs, such as a review results letter being sent to hospitals after the 60-day deadline; and
- Problems with postage reimbursement.

Archuleta said AHA is concerned about additional expansion of the RAC program into Medicare Part C and Medicaid programs. "There are concerns about duplication from multiple auditors when it comes to the Medicaid RACs," Archuleta said. "A number of states already operate their own audit programs." As for Medicare Part C, Archuleta said AHA expressed similar concerns, and she said that Medicare Advantage Plans already bear the responsibility for erroneous payments.

A larger trend by CMS toward the use of data analytics may also be a cause for concern, she said. "With data analytics becoming more popular, will we be facing RACs on steroids?" Archuleta said. "It's going to be hard to push back on the RACs as they are very popular among members of Congress. They see them as an asset."

## Disclosure, Compliance Programs Need Board, Management Buy-In, OIG Official Says

An effective provider compliance plan for handling Medicare disclosure and transparency issues must be supported by both the board of directors and senior management, an official with the Department of Health and Human Services Office of Inspector General said during a March 10 conference.

"To create an effective compliance program, the tone really needs to be set at the top," Mary Riordan, senior counsel in the Office of Counsel to the Inspector General, said. "We want the board to be substantively involved in the compliance program. If the board is scrutinizing the program, it will signal a real commitment."

Riordan spoke during the Third Annual Summit on Disclosure, Transparency, and Aggregate Spend for Drug, Device, and Biotech Companies, held March 9-11 in Washington, D.C. She said providers should be aware of the following disclosure and transparency issues:

  

- Alleged reporting of false or inflated prices for pharmaceuticals;
- Alleged incidences of kickbacks involving payments to physicians;
- Alleged off-label promotions of pharmaceuticals involving the nondisclosure of negative study results; and
- Alleged failures to report any pharmaceutical problems to the Food and Drug Administration.

**Reporting Requirements**

Section 6002 of the Patient Protection and Affordable Care Act also implements new reporting requirements for drug and device manufacturers that require them to disclose any direct payments or transfers to physicians that are over $10. The reporting provision will be implemented in 2013, and results will be open to the public.

During a question-and-answer period after Riordan's presentation, Niall Brennan, acting director of the Centers for Medicare and Medicaid Services Office of Policy, said the office would be responsible for administering the new "physician sunshine" program. No official announcement on the program has been made.

**Senior Management**

Senior management input in compliance programs is essential, Riordan said, a process that is called for in corporate integrity agreements (CIA) that the OIG reaches with providers.

"We ask for compliance program certification from the top management, and in order for them to make an accurate certification, they need assurance from the employees below them," she said. "This process really helps filter the compliance program throughout the organization."

Riordan also said that organizations should tailor compliance programs to their individual businesses. "Take a good look at the risks that are affecting your particular business," she said. "Some key areas to focus on are payments to physicians as well as transparency issues surrounding drug samples."

Other areas to assess for disclosure and transparency compliance, according to Riordan, include all research, publication, and educational activities.

**Compliance Assessments**

She also stressed the importance of ongoing compliance assessments and said that organizations should step back periodically to see if their compliance program is functioning according to plan.

Riordan said that CIAs played an important compliance function, helping organizations understand the consequences of their action, and hopefully resulting in fewer issues being raised in the future. Moving forward, Riordan said she expects to see a continued increase in enforcement actions against drug and device companies.

"There will be a wider scope of allegations, much more nuanced, and there will be more cases against device companies. We'll also continue to see a large number of criminal actions and increasing scrutiny of individuals," she said.

Riordan said that she also has heard, anecdotally, that whistleblower cases against drug and device companies are moving forward even when the Department of Justice chooses not to intervene.

  

# News-At-A-Glance

**CMS AGAIN DELAYS PHYSICIAN SIGNATURE REQUIREMENT:** Although the Centers for Medicare and Medicaid Services (CMS) has not officially withdrawn the requirement that physicians are to sign lab requisitions beginning April 1, the agency in a March 31 memo instructed Medicare contractors not to enforce the requirement. CMS officials have promised that the requirement will be withdrawn but are looking for the appropriate mechanism. Meantime, the delay is being extended indefinitely.

**FTC WITHDRAWS APPEAL OF LABCORP-WESTCLIFF MERGER:** The Federal Trade Commission (FTC) March 23 withdrew its appeal of a court order that left Laboratory Corporation of America free to proceed with its integration of the assets of Westcliff Medical Laboratories into its business (*FTC v. Laboratory Corporation of America*, 9th Cir., No. 11-55293). Originally, the FTC sought an injunction to prevent LabCorp from integrating the companies, pending the outcome of administrative litigation. The agency also decided to withdraw the matter from administrative adjudication. The case was on appeal from the U.S. District Court for the Central District of California. The FTC's complaint, filed in December 2010, alleged that LabCorp's acquisition of Westcliff would lead to higher prices and lower quality in the Southern California market.

**REVOCATION OF LAB'S CERTIFICATE UPHELD:** An administrative law judge for the Department of Health and Human Services Departmental Appeals Board sustained a decision by the Centers for Medicare and Medicaid Services revoking a Texas laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificate because its owner had another CLIA certificate revoked in the previous two years (*Southlake Emergency Care Center v.* CMS). ALJ Joseph Grow found it undisputed that Dr. Charles J. O'Hearn owned and operated both the Southlake Laboratory and the Coppell Laboratory . CMS revoked Coppell Laboratory's CLIA certificate on June 22, 2010. The ALJ rejected Southlake's argument that CMS should not have revoked Coppell's CLIA certificate because O'Hearn closed the lab before the certificate was revoked, finding that the voluntary closure of a lab does not preclude CMS from proceeding with revoking its certificate.









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