G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Labs Get Delay on Physician Signature Requirement

Clinical laboratories are breathing a small sigh of relief after the Centers for Medicare and Medicaid Services (CMS) announced Dec. 21, 2010, that it would delay for three months enforcement of the physician signature requirement on laboratory requisitions. The requirement was to have taken effect Jan. 1, 2011.

In a statement posted on its Web site, CMS said that because many physicians, nonphysician practitioners, and clinical laboratories may not be aware of, or understand, the policy, it will focus in the first calendar quarter of 2011 on developing educational and outreach tools to educate those affected. As these tools become available, CMS says it will post the information on its Web site and use the other channels it has to communicate with providers to ensure the information is widely distributed. The agency will not begin enforcing the requirement until April 1.

While the clinical laboratory community had hoped for a repeal of the requirement—or at least a delay of one year—groups representing labs say they are grateful for a three-month reprieve.

Continued on page 2

Turning up the Heat: 10 New Reasons to Tune Up Your Laboratory Compliance Program

With the federal government and private payers stepping up enforcement actions against health care providers, this is a good time for clinical laboratories to update their compliance programs to meet the new challenges of health care reform, advises David Gee, an attorney with Garvey Schubert Barer (Seattle). Gee spoke at Washington G-2 Reports' annual LabCompete Sales and Marketing Conference, held Dec. 8-10 in Las Vegas.

"Health care providers have been, and continue to be, the target of criminal, civil, and administrative enforcement actions," noted Gee. "Federal and state officials are intent on purging fraud and abuse from the health care delivery system. The targeting of clinical laboratories and other health care providers is driven by the perception that fraud is rampant in the health care system and must be eradicated."

Still not convinced? Gee lists 10 reasons why you should be concerned:

Continued on page 9

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Inside this issue

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Labs Get Delay, *from page 1*

"Implementation on Jan. 1, 2011, would have resulted in a crisis in access to laboratory services for the nation's seniors," said the American Clinical Laboratory Association (ACLA) in a statement issued Dec. 21. "ACLA maintains that the policy is unworkable and is committed to working with CMS to examine a feasible alternative approach to meeting CMS's objective of ensuring that laboratory requisitions are appropriately documented."

How Did We Get Here?

A rule adopted by CMS in 2000 established the policy that there are alternatives to physicians signing laboratory requisitions. This policy was reiterated in numerous communications from CMS as recently as March 2010, according to ACLA. In a surprising turnabout in this policy, CMS in July proposed requiring a physician signature on all laboratory requisition forms. The agency then finalized this policy in its final rule implementing changes to the 2011 Medicare physician fee schedule.

In its proposal, CMS stated that the new requirement would eliminate uncertainty about whether documentation was required, would not increase the burden on physicians because "it is our understanding that physicians are already annotating the medical record or signing the paperwork provided to the laboratory," and would minimize compliance problems for labs during audits.

Labs and groups commenting on the proposal noted that the requirement would increase the burden not only on physicians but also on labs, which have no way of enforcing the requirement and are the only provider at financial risk if the requisitions are not signed.

Part of the confusion about the new policy has to do with establishing the difference between a requisition and an order, explained Peter Kazon, an attorney with Alston & Bird (Washington, D.C.). Kazon spoke on this issue Dec. 16 during a webinar sponsored by Washington G-2 Reports.

According to CMS, a requisition is the "actual paperwork, such as a form, that is provided to a . . . laboratory that identifies the test or tests to be performed for a patient." Physicians are not actually required to use a requisition. Instead, they can use an "order," which CMS defines as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed." An order could be an annotated medical record or a documented telephone request—in this case the policy is not implicated. If the order is a written document, then it must be signed by the treating physician or practitioner.

"In other words, it doesn't really matter what you call it," says Kazon. "If it's on paper, then it has to be signed by the doctor."

What Does This Really Mean?

The new policy raises—but does not necessarily answer—a number of questions about implementation. Kazon and Alan Mertz, president of ACLA, addressed some of the more common questions during the Dec. 16 webinar.

What is the impact of this rule on electronic or telephonic orders?

CMS states that this requirement does not apply to telephone or electronic orders. For a telephone order, both the treating physician, or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records.

Does this affect test requirements for anatomic pathology services paid for on the physician fee schedule (PFS), rather than the clinical lab fee schedule (CLFS)?
It's unclear what CMS is saying here. CMS states that it is not changing its policy with regard to signature requirements of other types of services, such as those paid based on the PFS. In last year's proposed "clarification," CMS said it was not addressing questions related to physician pathology services. Kazon advises that once this policy goes into effect, labs should plan on getting a signature on all written orders for laboratory services, regardless of whether they are paid based on the CLFS or PFS.

What happens if a lab bills without a signed requisition?
CMS says you need a physician signature to have a valid order. If you don't have a valid order, then it raises the very substantial questions about whether a laboratory should bill for the service.

Can a laboratory go back to a physician to obtain a signature if the requisition comes in unsigned?
It appears likely. In certain circumstances, CMS has permitted laboratories to obtain an "attestation statement" signed by the physician to support that he or she ordered certain testing (see Transmittal 327, issued March 10, 2010). However, this is a key issue that CMS will have to clear up prior to implementation.

What will the likely impact of this rule be on nursing homes?
It seems likely that this rule could have a significant impact on labs that specialize in servicing nursing home patients. In many instances, nursing homes order tests after a telephone consultation with the patient's physician. Because this physician is usually not on site, it will make it difficult for the nursing home to obtain a signature prior to ordering the test. Also, this difficulty is magnified because often testing is ordered based on a standing order, which may cover a plan of care for the patient. If the standing order is otherwise valid, and signed by the physician, then it is possible that that could serve as the order, although CMS has not spoken to that issue. However, according to Kazon, CMS has been dismissive of the concerns raised by nursing home labs, even though this could be a particularly difficult area in which to apply the new physician signature rules.

Are stamped signatures permissible on requisitions?
No. In transmittal 327, CMS states that a signature must be handwritten or electronic. Stamped signatures are not permissible.

The CMS statement announcing the delay is available at *www.cms.hhs.gov/ClinicalLabFeeSched/*.

Detroit Medical Center to Pay $30 Million to Resolve Referral Allegations

An operator of several hospitals in Michigan will pay $30 million to the federal government to settle allegations of violating the False Claims Act and other laws, the Department of Justice (DOJ) said in a Dec. 30 announcement.

DOJ said that Detroit Medical Center (DMC) engaged in improper financial relationships with referring doctors. Detroit Medical Center, according to DOJ, is a nonprofit company that owns and operates hospitals and outpatient facilities in Detroit. The government said the medical center agreed to pay $30 million to resolve allegations of violating FCA as well as the anti-kickback statute and the Stark self-referral law.

According to DOJ, the Stark law and anti-kickback law restrict the financial relationships that hospitals may have with doctors who refer patients to them. "Most of the relationships at issue in this matter involved office lease agreements and independent contractor relationships that were either inconsistent with fair market value or not memorialized in writing," DOJ said in its release.

DOJ said that the government learned of the statutory violations from DMC itself, which discovered improper financial relationships with a number of physicians as it prepared for a sale to hospital company Vanguard Health Systems Inc. "We applaud the hospital leadership's decision to come forward voluntarily to disclose these issues to the government," U.S. Attorney for the Eastern District of Michigan Barbara McQuade said.

The Detroit Medical Center operates 10 hospitals and institutes, including the Children's Hospital of Michigan and Detroit Receiving Hospital.

13% of Physicians Own or Lease High-Tech Equipment, Study Says

Thirteen percent of physicians in community-based, physician-owned practices own or lease three or more kinds of advanced technology medical equipment, potentially increasing the incentive to self-refer patients for medically unnecessary services, according to a December data bulletin from the Center for Studying Health System Change (HSC).

The bulletin contained findings from the HSC's *2008 Health Tracking Physician Survey*, funded by the Robert Wood Johnson Foundation, which involved more than 4,700 physicians. The findings were based on a sample of 2,750 physicians in community-based, physician-owned practices.

Of the sampled physicians, 29 percent reported owning or leasing equipment for noninvasive procedures, 25 percent said they owned or leased laboratory services equipment, 22 percent owned or leased X-ray equipment, 17 percent owned or leased advanced imaging equipment, and 11 percent owned or leased invasive procedure equipment.

"Policy makers have long been concerned that physicians with ownership or other financial interests in medical facilities and equipment would make more referrals than medically necessary," the bulletin said. "[A] substantial body of research indicates that physician ownership of facilities and equipment does affect referral patterns."

The physician self-referral law, or Stark law, prohibits referrals of Medicare and Medicaid patients to entities with which physicians or their immediate family members have a financial relationship if the referral is for the furnishing of designated health services. However, the in-office ancillary services exception allows physicians to provide certain services in their offices that normally would be prohibited under the Stark law.

"Given the growing evidence that physician self-referral contributes to unnecessary and costly care, policy makers might reconsider the broadness of the in-office ancillary service exemption to the Stark law," the bulletin said, citing a series of articles in the December issue of *Health Affairs.*

The bulletin said that reimbursing physicians for the entire episode of care, as opposed to using the current fee-for-service model, could reduce financial incentives to self-refer. Sharing the cost of care with the physician could also help reduce excessive self-referral, the bulletin said.

The HSC data bulletin is at *www.hschange.org/CONTENT/1172/.*

COMPLIANCE
PERSPECTIVES

The Recovery Audit Contractor Program: What Can Laboratories and Pathologists Expect?

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The Centers for Medicare and Medicaid Services (CMS) Recovery Audit Contractor (RAC) program is now operational nationwide. Laboratories and pathologists should begin to prepare now for increased auditing activity. Should a provider be faced with a RAC denial and overpayment demand, such a determination can be appealed. This article will outline the fundamentals of the RAC program and will set forth key issues of which all providers should be aware to challenge RAC denials.

RACs: The Beginning

Section 306 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directed the Department of Health and Human Services (HHS) to initiate a three-year demonstration program using RACs. The demonstration began in 2005 in the three states with the highest Medicare expenditures: California, Florida, and New York. In 2007, the demonstration expanded to include Massachusetts, South Carolina, and Arizona. The purpose of the RAC demonstration program was to determine whether the use of RACs would be a cost-effective way to identify and correct improper payments in the Medicare program.

The RAC demonstration program proved highly "cost effective." Over the three-year demonstration, the RACs identified more than $1.03 billion in improper payments. The vast majority of this amount, 96 percent, constituted alleged overpayments. CMS estimates that the RAC demonstration program cost approximately 20 cents for each dollar returned to the Trust Funds.[1]

RACs: The Expansion

Section 302 of the Tax Relief and Health Care Act of 2006 made the Medicare RAC program permanent and required its expansion nationwide by no later than 2010. CMS divided the nation into four regions and assigned a Medicare RAC contractor to each:

- Diversified Collection Services Inc. is the RAC for Region A, comprising the northeastern states;
- CGI Technologies and Solutions Inc. is the RAC for Region B, comprising the midwestern states;
- Connolly Consulting Associates Inc. is the RAC for Region C, comprising the southern states; and
- HealthDataInsights Inc. is the RAC for Region D, comprising the western states.[2]

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[1] *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration,* at p. 15, June 2008, *available at http://www.cms.hhs.gov/RAC/Downloads/RAC_Demonstration_Evaluation_Report.pdf.* This report was updated as CMS compiled additional appeals data. Updated reports are *available at www.cms.hhs.gov/RAC.*

[2] *Id. Note that the RAC Expansion Schedule, available at https://www.cms.gov/RAC/Downloads/RAC%20Expansion%20Schedule%20Web.pdf, identifies the four RAC regions, labeled A, B, C, and D.*

RACs: The Future

In addition to the existing Medicare RAC program, which applies to Medicare Parts A and B, Section 6411 of the Patient Protection and Affordable Care Act requires the RAC program to expand to Medicare Advantage claims (Part C), Medicare Prescription Drug claims (Part D), and Medicaid claims.[3] As the rules associated with this expansion are not yet finalized, this article will focus upon the existing Medicare RAC program.

RACs: The Review Process

CMS compensates RACs on a contingency-fee basis, based upon the principal amount collected from (or the amount repaid to) a provider or supplier.[4] The contingency fee percentages range from 9 percent to 12.5 percent.[5] Because of this compensation arrangement, the RACs are highly incentivized to find improper payments upon review.

The RACs may attempt to identify improper payments resulting from incorrect payments, noncovered services (including services that are not reasonable and necessary), incorrectly coded services, and duplicate claims.[6]

The RACs have discretion in determining which claims to review; however certain limitations are in place. For example, RACs may not may review claims at random. They must use "data analysis techniques" to identify claims likely to be overpayments, a process called "targeted review." Additionally, RACs may only review claims paid on or after Oct. 1, 2007. As time passes, the RACs will be prohibited from reviewing claims more than three years past the date of initial determination.[7]

Types of Reviews

RACs engage in two types of claim reviews to identify improper payments: "automated review" and "complex review." An automated review is a review of claims data without a review of the records supporting the claim. Generally speaking, RACs may conduct automated reviews only in situations where there exists both (1) a certainty that the service is not covered or is incorrectly coded and (2) a written Medicare policy, article, or coding guideline applicable to the claim. RACs also may use automated review, even if there is no specific Medicare guidance on point, in "clinically unbelievable" situations or when identifying duplicate claims or pricing mistakes.[8]

A complex review consists of a review of medical or other records and is used in situations where there is not certainty that a claim involves an overpayment.[9] In summary, the RAC complex review process is as follows:

- RACs are authorized to (1) visit a provider's location to view or copy medical records or (2) request that such records be securely transmitted to the RAC for review.[10] The RAC Web sites contain detailed guidelines for records submission.[11] Importantly, requested records must be returned within 45 days. It is imperative that providers timely respond to RACs' requests for medical records. If a RAC does not receive requested medical records within 45 days, it is authorized to

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[3] *See* Medicaid RAC Proposed Rule, *available* at 75 Fed. Reg. 69037 *et seq*. (Nov. 10, 2010); *see also* Medicare Parts C and D Proposed Rule, *available at* 75 Fed. Reg. 81278 et seq. (Dec. 27, 2010).

[4] RAC Statement of Work, *available at http://www.cms.hhs.gov/RAC/10_ExpansionStrategy.*asp#TopOfPage..

[5] *See https://www.fbo.gov/index?s=opportunity&mode=form&id=5c8c7d4b00249ba579d4d77d64bd0aea&tab=core&_view=1&cck=1&au=&ck=.*

[6] RAC Statement of Work, *available at http://www.cms.hhs.gov/RAC/10_ExpansionStrategy.*asp#TopOfPage.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] *http://www.cms.gov/RAC/Downloads/RACcontactinfo.pdf.* Additionally, CMS has placed limits on the number of records a RAC may request from a given provider per 45-day period. These limitations are published on the CMS RAC Web site, *available at http://www.cms.gov/RAC/03_RecentUpdates.asp#TopOfPage.*

render an overpayment determination. Providers failing to timely respond to RACs' medical records requests could lose appeal rights with respect to these claims.[12]

- In conducting reviews, RACs are required to comply with national coverage determinations (NCDs), coverage provisions in interpretive manuals, national coverage and coding articles, local coverage determinations (LCDs), and local coverage and coding articles.[13] The RACs also are authorized to develop internal guidelines to assist their reviewers to conduct claims reviews.[14]
- Generally speaking, a RAC must complete complex reviews within 60 days from receipt of the requested medical records.[15] Following its review, the RAC will issue a letter to the provider setting forth the findings for each claim.[16] The claim will be adjusted on a recovery audit, and a demand letter will be issued.
- Alleged overpayments identified by the Medicare Part A or B RACs may be appealed through the Medicare appeals process.

How Should Providers Prepare for a RAC Audit?

Although providers cannot prevent RAC audits from happening, they can prepare for increased claims scrutiny and RAC activity. It is advised that providers assign an audit point person, responsible for the following tasks:

- Regularly monitoring guidance documents educating providers regarding the types of claims subject to RAC reviews, including the RACs' Web sites and guidance documents such as the OIG Work Plan (note that, to date, the RACs have approved the numerous issues for review impacting both hospital-based and office-based providers.[17] The OIG Work Plan for 2011 includes laboratory test unbundling by clinical laboratories as well as general trends in laboratory utilization as issues that will be monitored and potentially audited during fiscal year 2011[18]);
- Implementing compliance efforts targeted toward compliance risk areas;
- Responding to record requests within the required timeframes; and
- Monitoring appeals deadlines and properly working up appeals to challenge denials in the appeals process.

How to Appeal Claims Denials Made by RACs

Before engaging in the Medicare appeals process, providers subject to a RAC denial may wish to engage in a "discussion period" with the RAC. According to CMS:

The discussion period offers the opportunity for the provider to provide additional information to the RAC to indicate why recoupment should not be initiated. It also offers the opportunity for the RAC to explain the rationale for the overpayment decision. After reviewing the additional documentation submitted the RAC could decide to reverse their decision. A letter will go to the provider detailing the outcome of the discussion period. You always contact the RAC for this option. The timeframe is between day 1 and 40 and will begin with receipt of the demand letter for automated review and from receipt of the review results letter for complex review. The timeframe ends on day 40.[19]

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[12] According to the RAC Statement of Work, if a provider appeals this type of claim denial, "the appeals department **may, at CMS direction**, send the claim to the RAC for reopening under certain conditions" (emphasis in original). However, the carrier or intermediary is not required to send the claim to the RAC for reopening. *See RAC Statement of Work, available at http://www.cms.hhs.gov/RAC/10_ExpansionStrategy.asp#TopOfPage.*

[13] RAC Statement of Work, *available at http://www.cms.hhs.gov/RAC/10_ExpansionStrategy.asp#TopOfPage.*

[14] *Id.*.

[15] Id.

[16] Id.

[17] Links to the Recovery Audit Contractor Web sites, with listed approved issues, are available from the CMS RAC Web site: *http://www.cms.hhs.gov/RAC.*

[18] The 2011 OIG Work Plan is available at http://oig.hhs.gov/publications/workplan/2011/.

[19] *See https://questions.cms.hhs.gov/app/answers/detail/a_id/9994/~/what-is-the-difference-between-the-rac-discussion-period-and-the-rebuttal-and.*

If the discussion period does not prove effective, Medicare Part A or B RAC denials may be appealed using the standard Medicare appeals process:

- **Stage 1: Redetermination.** The first level in the appeals process is redetermination. There is no amount-in-controversy requirement. Providers must submit redetermination requests in writing within 120 calendar days of receiving notice of initial determination.

- **Stage 2: Reconsideration.** Providers dissatisfied with a redetermination decision may file a request for reconsideration to be conducted by a Qualified Independent Contractor (QIC). There is no amount-in-controversy requirement. This second level of appeal must be filed within 180 calendar days of receiving notice of the redetermination decision. Significantly, providers must submit a "full and early presentation of evidence" in the reconsideration stage. When filing a reconsideration request, a provider must present evidence and allegations related to the dispute and explain the reasons for the disagreement with the initial determination and redetermination. Absent good cause, failure of a provider to submit evidence prior to the issuance of the notice of reconsideration precludes subsequent consideration of the evidence.

- **Stage 3: Administrative Law Judge (ALJ) Hearing.** A provider dissatisfied with a reconsideration decision may request an ALJ hearing. The request must be filed within 60 days following receipt of the QIC's decision and must meet the amount-in-controversy requirement.

- **Stage 4: Medicare Appeals Council Review.** The fourth level of appeal is the Medicare Appeals Council (MAC) review. A MAC review request must be filed within 60 days following receipt of the ALJ's decision. Among other requirements, a request for MAC review must identify and explain the parts of the ALJ action with which the party disagrees. Unless the request is from an unrepresented beneficiary, the MAC will limit its review to the issues raised in the written request for review.

- **Stage 5: Federal District Court.** The final step in the appeals process is judicial review in federal district court. A request for review in district court must be filed within 60 days of receipt of the MAC's decision and meet the amount-in-controversy requirement.

Strategies for Appealing Claims Denials

Once a provider receives a claim denial made by a RAC, it is important that the provider aggressively pursue appealing the denial through the Medicare appeals process. Experienced health care legal counsel can assist providers with appeals to ensure all available substantive challenges and legal theories are utilized. Experienced counsel will submit an appeal brief or position statement that advocates the provider's position and raises applicable legal challenges, which may include the legal theories of waiver of liability, provider without fault, and challenges to any statistical extrapolation.

Conclusion

All providers, including clinical laboratories and pathologists, should be ready for increased Medicare auditing activity. Providers should act now to get systems in place to prepare for RAC records requests and possible claim denials and to evaluate their compliance with Medicare guidelines. Should a provider be subject to RAC denials, effective strategies are available that can be successfully employed in the appeals process.

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Turning up the Heat, *from page 1*

1 You Are a Target

The government has new tools and motivation to go after health care fraud. The Patient Protection and Affordable Care Act (PPACA), signed into law March 23, 2010, raises the government's financial commitment to fighting health care fraud in 2011 to $1.7 billion. In addition, PPACA toughens sentencing for criminal activity, enhances Medicare screening and enrollment requirements, encourages increased sharing of data across government, expands overpayment recovery efforts, and provides greater oversight of private insurance abuses. The new law also raises the bar for health care providers who seek to avoid liability for inadvertent noncompliance and limits the entry of new providers.

PPACA comes on the heels of last year's Fraud Enforcement Recovery Act (FERA), as well as the Health Care Fraud Prevention and Enforcement Action Team (HEAT), an aggressive interagency task force created last year by Attorney General Eric Holder and Health and Human Services Secretary Kathleen Sebelius to combat Medicare and Medicaid fraud.

2 More Prosecution Resources

Past successes lead to more enforcement. More than $25 billion has been recovered under the FCA since 1986, 18 billion since 1996, $3 billion in 2010. The government recovers $6 for every $1 spent. The HHS Office of Inspector General (OIG) has approximately 500 investigators and 75 attorneys (versus 14 attorneys 25 years ago). The Department of Justice has 24 prosecutors (versus six just four years ago). The increase in prosecution resources naturally leads to more enforcement actions, said Gee, who quoted a tweet from Sen. Charles Grassley (R-Iowa): "When you are a hammer, you think everything is a nail."

3 Front-End Focus

The government is shifting focus of health care fraud enforcement from recovery of illegal payments to preventing questionable payments on the front end. PPACA authorizes more stringent processes and requirements, with the goal of preventing enrollment by unethical health care providers. PPACA also provides for enhanced oversight, such as prepayment reviews, shared information databases, unscheduled and unannounced site visits, and payment suspension pending the completion of an investigation.

As required by PPACA, CMS recently issued proposed regulations governing the Medicare, Medicaid, and Children's Health Insurance Program enrollment process for providers and suppliers. In setting screening requirements, the proposed regulations group health care providers into three categories of risk for fraud, waste, and abuse: limited, moderate, and high. Publicly traded providers (including laboratories) are designated "limited risk," as are physicians and physician groups. Privately owned independent clinical laboratories are deemed "moderate" risk for screening purposes.

4 New Self-Policing Requirements

PPACA creates a clear obligation to report and repay overpayments, thus removing any doubt whether an inadvertent overpayment must be repaid. An overpayment is defined as any Medicare or Medicaid funds that a person receives or retains to which the person, after "applicable reconciliation," is not entitled.

Laboratories must report and return overpayments to the appropriate agency no later than 60 days after the date the overpayment was "identified." Additionally,

PPACA requires providers and suppliers to provide in writing the reason for the overpayment. Unfortunately, the law does not define what the term "identified" means, nor does it state what meaning is attached to the term "after applicable reconciliation"; therefore, it is difficult to know when the 60-day notice period begins or end, said Gee.

5 PPACA Is a Game Changer

The FCA was amended in 2009 to remove some of the language that had been used by criminal defense lawyers to avoid FCA convictions. The changes essentially redefined what constitutes a knowing violation of the law. As amended, the FCA defined "knowing" to mean that the provider (1) had applicable knowledge of the information, (2) acted in deliberate ignorance of the truth or falsity of the information, or (3) acted in reckless disregard of the truth or falsity of the information. PPACA defines the terms "knowing" and "knowingly" in other provisions of the law by adopting the definition under the FCA. This is a significant change, explained Gee.

For example, it is likely that courts will interpret the FCA as now allowing a conviction when a provider retains monies that it received from a private company, even if the provider did not realize that the private company received some portion of those monies from the government. In addition, this change will also make it easier for the government to obtain a conviction under the anti-kickback statute (AKS) since the law changed the standard of proof such that ignorance of the AKS is no longer an excuse.

PPACA's clarification of the relationship between the AKS and the FCA also makes AKS claims subject to qui tam suits and FCA penalties (treble damages and civil penalties of $5,500-$11,000 for each false claim) as well as AKS penalties (up to five years in prison, a $25,000 criminal fine, a $50,000 civil fine, and exclusion).

6 Qui Tam Lawsuits Made Easier

Under PPACA, it will be easier for qui tam relators to bring FCA lawsuits for a number of reasons. First, the government is now authorized to share civil investigative demand (CID) information with relators. Under prior law, qui tam lawsuits were dismissed if the claims were based on publicly disclosed information. PPACA provides that the court will allow the case to go forward if the government opposes dismissal. Therefore, relators are no longer required to have direct knowledge of the FCA violations and do not even need to be an original source of the information. Finally, the amendments protect whistleblowers who disclose information to the government after a public disclosure but before officially filing a complaint.

PPACA also reversed court decisions that held that state and local government proceedings involving the behavior underlying the qui tam lawsuit (e.g., employment litigation, shareholder suits, etc.) could not form the basis of a qui tam suit. Thus, these types of decisions will no longer result in a dismissal of a qui tam action.

Finally, PPACA narrows the FCA's "public disclosure bar," which prevents plaintiffs from bring a qui tam lawsuit if the lawsuit is based upon the public disclosure of allegations or transactions via certain defined sources. Qui tam suits are now only prohibited by the public disclosure bar if the public disclosure of allegations or transactions occurs via a federal hearing in which the federal government is a party; a congressional report or federal audit, report, or investigation; or a news media report.

7 Expanded Investigative Tools

The use of CIDs has been expanded. A potent tool for investigators examining violations of the FDA since 1986, CIDs can include requests for documents, demands for depositions, or interrogatories. Prior to PPACA, only the attorney general was authorized to issue CIDs. After PPACA, the law allows the attorney general to delegate this authority. CIDs are also accompanied by two new punches: (1) failure to allow the OIG timely access to requested materials or testimony will be punished by a $15,000 per day penalty, and (2) those who fail to maintain and provide HHS access to documents can be excluded.

Likely Core Elements of a Compliance Program

1. Establishment of a chief compliance officer and compliance committee (with a direct reporting relationship between the compliance officer and the board).
2. Written standards of conduct (a code of conduct) and written policies and procedure pertaining to specific areas of health care operation.
3. Education and training programs for affected employees.
4. A process for receiving complaints.
5. A system to respond to allegations of improper conduct and impose appropriate discipline.
6. An auditing/monitoring mechanism.
7. A plan for promptly responding to detected offenses and implementing corrective action.

8 New Stark Self-Referral Disclosure Protocol

PPACA required HHS (in cooperation with the OIG) to establish a self-referral disclosure protocol (SRDP) to be used by health care providers and suppliers to report violations of the Stark law. In exchange for self-disclosure, the secretary of HHS is authorized to reduce the amount owed for Stark violations. While PPACA established a deadline of 60 days for returning an overpayment, if an SRDP is filed, the 60-day obligation will be suspended until a settlement agreement is entered, the provider or supplier withdraws form the SRDP, or CMS removes the provider of services or supplier from the SDRP. On Sept. 23, 2010, HHS issued the SRDP and posted it on the Internet (*www.cms.hhs.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf*).

9 Officers and Managers Are Targets Too

In order to effect organization change, the government has frequently chosen to hold corporate officers responsible for company missteps. This is exactly what the HHS OIG has announced it intends to do in the health care industry, noted Gee. Thus, not only is an organization subject to civil and criminal liability based on its policies and procedures, its officers, high-level managers, and employees are also exposed to personal responsibility. In the absence of specific statutory authority, state and federal prosecutors and regulators routinely have relied on two legal theories to hold individuals responsible for the organization's conduct: (1) accomplice liability and (2) the "responsible corporate officer" doctrine. In April 2010 at the Health Care Compliance Association's Annual Compliance Institute, IG Daniel Levinson made clear that his agency will hold responsible corporate officials accountable for health care fraud (*http://oig.hhs.gov/testimony/docs/2010/HCCAIGKeynoteSummary.pdf*).

10 Compliance Programs Are Now Required

While in the past compliance programs have been voluntary (though recommended), PPACA makes a compliance program mandatory as a condition of enrollment in federal health programs. Those compliance programs must contain certain "core elements." Gee anticipates that the new "core elements" will be based, in part, on existing OIG compliance guidance and the elements of a compliance plan as set out in the federal sentencing guidelines (*see box*). Providers and suppliers with robust compliance processes will inevitably need to adjust existing compliance programs, said Gee, while those whose compliance plans are simply gathering dust on a shelf will likely need to put new compliance processes in place.

LAW REPEALS FRAUD PROVISION: President Obama has signed into law the Medicare and Medicaid Extenders Act of 2010 (H.R. 4994), which repeals a fraud provision from the Patient Protection and Affordable Care Act, in addition to delaying for one year a 25 percent cut in the Medicare reimbursement rate for physicians. The repealed provision, contained in Section 6502 of PPACA, would have mandated exclusions by state Medicaid agencies in cases where the individual or entity owned or managed an entity that had not returned Medicaid overpayments, had been suspended or excluded from Medicaid, or had been affiliated with an individual or entity that had been excluded from the program. The Medicaid exclusions were to have gone into effect on Jan. 1, 2011.

HEALTH SPENDING SLOWS: Health care spending in the United States grew 4 percent to $2.5 trillion in 2009, the slowest rate of growth in the five decades during which records have been kept, according to a report by federal analysts released Jan. 5. The economic recession "profoundly influenced" health spending in 2009, according to the report by analysts in the Office of the Actuary at the Centers for Medicare and Medicaid Services. "Many consumers decreased their use of health care goods and services partly because they had lost employer-based private health insurance coverage, and partly because their household income had declined," the report said. The annual report will be published in the January edition of the journal *Health Affairs*. The historically low health spending growth rate reflects a deceleration in private health insurance spending growth, a decline in spending on structures and equipment, and slower out-of-pocket spending growth, according to the report. The slowdown was partially offset by other areas, such as increased Medicaid enrollment that fueled higher spending growth and increased prescription drug spending growth. Health care spending grew 4.8 percent in 2008, the second-lowest rate of growth in the past 50 years. Despite the slowdown, the share of the gross domestic product consumed by health care spending rose 1 percentage point due to a decline in the current-dollar GDP.

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