G2 Compliance Report

G2 INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

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Labs Advised to Prepare for End Of Pathology TC Grandfather Protection

Independent clinical laboratories should begin preparing for the end of the pathology grandfather protection, which is set to expire June 30 of this year, advises Peter Kazon, an attorney with Alston & Bird and counsel to the American Clinical Laboratory Association (ACLA).

While ACLA and other groups, including the College of American Pathologists, are continuing to push for a further extension of the grandfather protection, Kazon warned that labs should be ready July 1 to bill hospitals for the technical component (TC) of pathology services provided to hospital inpatients and outpatients.

Kazon discussed the expiration of the grandfather protection during a March 27 webinar sponsored by G2 Intelligence and ACLA. Judging by questions asked by webinar participants, it appears that many labs are confused about exactly what the expiration will mean for them.

The grandfather protection has allowed certain independent laboratories to bill Medicare directly for the TC of pathology services provided to hospital patients. It applies to hospital-lab arrangements in effect

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Massachusetts Lab to Pay $20 Million To Resolve Medicaid Kickback Case

Calloway Laboratories Inc. (Woburn, Mass.) will pay $20 million to resolve allegations that it engaged in an elaborate kickback scheme that resulted in millions of dollars in payments by the state Medicaid program for unnecessary drug screens, according to Massachusetts Attorney General Martha Coakley.

Calloway Laboratories and two of its top executives were indicted by a state grand jury in July 2010 on 42 counts of Medicaid fraud, Medicaid kickbacks, and larceny. Prosecutors alleged that the company and its executives between 2005 and 2007 engaged in a pervasive kickback scheme involving two straw companies that funneled kickbacks to "sober houses" and paid middlemen and a medical office to illegally obtain drug screening business reimbursed by the state's Medicaid program.

The indictments also alleged that the company falsely billed MassHealth for urine screening services that were not ordered by a doctor or authorized prescribers for a medically necessary purpose as

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Pathology TC Grandfather Protection, *from page 1*

as of July 22, 1999, the date when Medicare officials first proposed to eliminate the direct billing, saying hospitals already receive payment for the TC as part of their DRG payments.

This protection was eliminated as part of the Middle Class Tax Relief and Job Creation Act of 2012, signed into law Feb. 22, 2012. According to Kazon, Congress decided to eliminate the protection for several reasons: (1) concern about the fact the Medicare was paying twice for the same services, (2) concern that the Centers for Medicare and Medicaid Services did not really know which hospitals qualified as "covered hospitals," and (3) elimination of the protection would save $50 million per year.

What Should the Lab Do?

1. Let the hospital know that effective July 1, 2012, the lab will be billing the hospital for the TC of pathology services provided to hospital patients.
2. Negotiate the terms on which the lab will provide the TC.
3. Sign an agreement to that effect.

Effective July 1, all independent labs must bill the hospital for the pathology TC, which also means they will need to negotiate the rate with the hospital. For inpatient services, no additional payment will be received by the hospital because the TC is considered to be included in the DRG. For outpatient services, the TC is separately billed and paid under the outpatient prospective payment system (OPPS). Under the OPPS, the hospital will be paid based on APC 0342, 0343, 0344, and 0433. Because they will receive less for the TC than the labs receive for the same service, hospitals will have incentive to negotiate a lower rate with labs.

According to a survey conducted several years ago by Health Care Development Services (Highland Park, Ill.), hospitals typically pay 40 percent to 55 percent of the Medicare physician fee schedule rates for TC services they purchase from independent labs.

Kickback, Stark Implications

Does a laboratory have to bill the hospital for the TC? Yes, says Kazon, who notes that not billing the hospital could implicate both the anti-kickback law and the Stark self-referral law.

"If a laboratory fails to bill the hospital for the TC, then the hospital is getting something of value at no charge," he explains. "According to the OIG, giving a service to a referrer for no cost or below market value can raise serious questions under the anti-kickback law. It could also create a compensation arrangement under the Stark self-referral law."

"14-Day Rule"

Labs should pay careful attention to how the pathology billing requirement interacts with Medicare's "14-day rule," says Kazon. The 14-day rule requires that for biopsy specimens collected in the hospital, the date of service (DOS) depends on when the test is ordered. If the test is ordered 14 days or more after the patient is discharged from the hospital, then the DOS is the date the test is performed. Since the patient is not a hospital patient on that DOS, the hospital bundling rules do not apply and the service can be billed to Medicare.

If the test is ordered 13 days or less after the patient is discharged, the DOS is the date the specimen is collected, explains Kazon. Since the patient is a hospital patient on that DOS, the hospital bundling rules do apply and the service must be billed to the hospital.

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Lawmakers Want FDA to Address Concerns Over 'Research Use Only' Guidance

A group of House Republicans in a letter to Food and Drug Administration (FDA) Commissioner Margaret Hamburg raised a variety of concerns about the content and implementation process of a draft guidance regarding the definition of "research use only" diagnostic devices.

According to the lawmakers, FDA in the draft guidance disregarded current law and significantly departed from any prior agency regulations. The letter, sent March 19, was signed by Republican members of the House Energy and Commerce Committee, including health subcommittee chairman Joseph Pitts (Pa.) and Reps. Michael Burgess (Texas), Cathy McMorris Rodgers (Wash.), and Brian Bilbray (Calif.).

The guidance in question, *Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions*, was issued June 1, 2011. FDA said the guidance is intended to clarify the types of in vitro diagnostic (IVD) products that are properly labeled "for research use only" (RUO) or for "investigational use only" (IUO).

According to FDA, RUO and IUO IVD products are distinctive in that they are devices that may themselves be used in research or investigations on human samples that eventually may lead to their clearance or approval for clinical diagnostic use, and they also may be marketed for and used in the research and investigation of other FDA-regulated products.

According to the lawmakers, the draft guidance "appears to represent a disregard for current law" on the definition of intended use. In the guidance, FDA indicates that "actual use" will be a factor in the agency's analysis of intended use.

Thus, the manufacturer of an IUO IVD product is not necessarily the sponsor of a clinical investigation that uses such an IVD product in a study. The manufacturer of such a product may legally distribute the product commercially without FDA premarket review, as long as the distribution is only for investigational use.

FDA said it was concerned about the increasing illegal use of RUO or IUO tests for clinical purposes.

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According to the lawmakers, the definition of intended use is essential to the interpretation of the Federal Food, Drug, and Cosmetic Act (FFDCA), as it determines whether a product is a drug or device as well as if it is being marketed off-label. The addition of actual use as a factor in this analysis "has significant consequences" not only for IVD products labeled for research use only or for investigational use only "but also for all FDA regulated products," the lawmakers wrote.

Manufacturer Enforcement, CLIA

Under the guidance, if a manufacturer learns that its laboratory customers are using a product marked as RUO or IUO for clinical purposes, it should immediately stop selling to those customers. If a manufacturer learns that a laboratory to which

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it sells its RUO-labeled IVD product is using it in clinical diagnosis, "it should halt such sales," the agency said in the guidance.

By requiring manufacturers to "police end users of their products," the lawmakers said FDA "appears to further exacerbate this disregard of current law."

The guidance appears to force RUO and IUO manufacturers to police their clinical laboratory customers so the FDA can further expand its regulatory reach.

Prior to publication of the draft guidance, lawmakers said FDA was satisfied with a certification from customers acknowledging the RUO products were not being used for clinical purposes. However, to comply with the draft guidance, lawmakers said "manufacturers must now conduct surveillance on their customers. . . . [U]nder this requirement, manufacturers, rather than the FDA, would enforce [FFDCA]."

The lawmakers also expressed concerns over the "apparent policy shift" that gave rise to the guidance. According to the lawmakers, the draft appears to extend the regulatory reach of FDA into clinical labs, which are currently overseen by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA).

"The guidance appears to force RUO and IUO manufacturers to police their clinical laboratory customers so the FDA can further expand its regulatory reach," the lawmakers wrote. Instead of extending its regulatory outreach, the FDA should respect congressional intent, focus on its core mission, and prevent duplicative efforts by enabling CMS to enforce CLIA, the letter said.

Warning Letter Example, Seeking Answers

The lawmakers said they were especially concerned with how quickly FDA appeared to be implementing the guidance. Although the agency stated that it was a nonbinding guidance not for implementation, the lawmakers said FDA cited the guidance in a warning letter only two weeks after the public comment period closed.

"Given the substantial negative stakeholder comment and the fact the FDA represented the draft guidance as nonbinding and not for implementation, we question how and why the FDA implemented the draft guidance document so rapidly," the lawmakers said.

The lawmakers requested by April 9 answers to other questions as well, including:

- Why did FDA not provide a transition period for companies to come into compliance with the draft guidance?
- An explanation of how the utilization of "intended use" comports with established legal precedent;
- An explanation of the legal basis for forcing manufacturers to enforce the FFDCA;
- Whether and how the agency intends to respond to public comments received; and
- Has FDA conducted an economic impact assessment to determine the effect of the new requirements on laboratories, manufacturers, and innovation?

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G2 INTELLIGENCE

COMPLIANCE PERSPECTIVES

Critical Elements of Compliance Sales Training

Peter Francis is president of Clinical Laboratory Sales Training LLC.

When a laboratory hires or assigns someone to market its lab services, the lab should undertake at least one important educational duty within the first few days of the new employee's start on the job: review of laboratory sales compliance rules, regulations, and policies. Nothing should interfere with this initial education. Even if the representative has come from another lab where compliance had been part of the instructional component, it nonetheless remains important for the new employer to provide this training, either through in-house resources or from outside of the company.

Intense Government Focus on Health Care

The reason why this becomes so important is, in part, because of the spotlight the government has directed to uncover health care fraud and abuse. In 2011, there were a record number of criminal and civil cases filed and record-breaking financial settlements reported: $2.4 billion in health care-related settlements and judgments under the False Claims Act alone. In addition, all signs point to more enforcement activity. The Department of Justice's fiscal year 2013 budget request includes an additional $71.7 million over FY 2012 for health care fraud enforcement efforts.

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There exist key laws that people must understand before engaging in conversations with health care professionals and their respective staff. The laws are the False Claims Act, anti-kickback statute, the Stark law, and applicable state laws. These broad statutes affect such topics as in-office phlebotomy, client supplies, leasing space in a doctor's office, electronic medical record donations, nonmonetary compensation, and custom profiles. While this article is not an exhaustive compliance overview, it will examine a few key points with which marketing people should be fully cognizant. Proper training should be more expansive than the content of this document.

False Claims

The False Claims Act remains the government's most powerful civil enforcement tool. It can result in liability, for example, when a provider (1) bills a government health insurance program for services that were not provided, (2) submits a claim for reimbursement that contains false information to a government health insurance program, or (3) seeks reimbursement from a government health insurance program for medically unnecessary services. While this may seem to affect the billing department more than the sales function, it is important to understand that the government has seen numerous cases in which marketers have sought to persuade providers to change ordering patterns, or to request unnecessary services, and such conduct can implicate the False Claims Act.

Anti-Kickback

The anti-kickback statute is of paramount importance to employees in marketing

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positions. This statute specifically states that a person may not knowingly or willfully offer, pay, solicit, or receive remuneration to induce, or to recommend or arrange for, referrals of Medicare or Medicaid patients or items of services provided to such patients. The statute is broad and it applies to individuals and entities on both sides of a prohibited transaction.

Stark

The Stark law addresses issues that are similar to those that underlie the anti-kickback statute. It is often referred to as the "Stark self-referral prohibition" because it says that a physician may not refer a Medicare patient to a clinical lab with which the physician (or an immediate family member) has a financial relationship. A financial relationship is either an ownership interest or a compensation arrangement. There are several important points within this law that sales representatives must understand.

One of these points is the provision of nonmonetary compensation to physicians. For calendar year 2012, labs may provide nonmonetary compensation (e.g., lunches, note pads, pens, mugs) to physicians (who order laboratory tests for Medicare beneficiaries) worth up to $373 per physician. Thus, laboratories should keep track of the amount of money spent on each physician for lunches and other giveaway items to confirm they are meeting the law's requirements. In addition, all of the following conditions must be met:

- The compensation cannot be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.
- The compensation may not be solicited by the physician or the physician's practice (i.e., employees and staff members).
- The compensation arrangement does not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission.

The second bullet above is breached for one main reason: ignorance by both the field rep and the physician's office staff. A ubiquitous statement emanating from a doctor's office is, "If you bring in lunch, you can see the doctor." But this statement creates Stark law issues. The field person may offer to bring in lunch, but not the other way around.

Anti-Kickback and Stark

Another area covered by the both the anti-kickback statute and the Stark law and subject to certain exceptions from the prohibitions established by these laws is assistance with the purchase of qualifying forms of electronic health record (EHR) software. Congress directed that the Department of Health and Human Services (HHS) develop these exceptions to encourage EHR proliferation.

As a result of these HHS-created exceptions, labs may donate up to 85 percent of the cost of the EHR software, but the office must pay the remaining 15 percent. Sales reps (and donating labs) must understand this requirement: the donation cannot be contingent upon referrals. In other words, there is no quid pro quo. If the lab donates toward the EHR software, it "sits-on-the-hook" for the gift. The physician's office may decide not ever to refer testing to the donating lab or to change laboratory vendors and to refer to a different lab, and the donating lab may not ask for a refund or discontinue making payments.

In addition to the 15 percent payment rule for physicians, there are several other requirements that must be met for the exceptions to apply. For example, the EHR

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software must be certified as interoperable (i.e., connect with others), there needs to be a written and signed contract, and the physician cannot already have equivalent items or services. If an EHR contract has already been signed, it is best to talk to legal counsel if the client requests a donation after the fact. Also, a lab should seek legal advice if it has been approached after a new EHR has been installed and the client suddenly requests a donation. There are many grey areas surrounding this issue of EHR donations. Another one relates to the question of whether a lab may pay for annual EHR maintenance fees. Again, seeking appropriate counsel equals the best policy. As it stands now, the law for EHR donation terminates on Dec. 31, 2013. However, the law was enacted in August 2006, and several things have occurred since then (e.g., meaningful use incentives, slow EHR adoption, recommendations to make the safe harbor donation permanent, etc.). Stay tuned.

State Laws

Field marketers must also be familiar with state laws to which they are subject. State laws can supersede federal laws. For example, New York state has banned EHR donations. Some states have direct-bill laws (i.e., no doctor billing) while others have anti-markup and truth-in-billing laws. Consequently, representatives must be trained on the rules and regulations that apply in the states in which they are marketing and selling.

Penalties

The punishment for violation of these laws can be criminal, civil, and administrative. Conviction for a single violation under the anti-kickback statute may result in a fine up to $25,000 and imprisonment for up to five years. And—a point not always understood by salespeople—depending upon the situation, not only does the laboratory become entangled, but also the client and, possibly, the field rep. A violation of the False Claims Act can result in up to $11,000 in penalties for each false claim for reimbursement submitted to a government health care program. In addition to that penalty, damages can equal three times the amount wrongfully paid in reimbursement. Exclusion from the federal programs for both the lab and the client can also occur. Depending on circumstances, cases can be brought under both the False Claims Act and the anti-kickback statute.

Due to the direct contact between salespeople and their clients and prospects, field reps should always be sensitive to the laws regulating conduct between those who refer (physicians) and those who receive referrals (e.g., labs) and labs should implement compliance programs to reduce the likelihood of violation of the fraud-and-abuse laws.

The federal government is not the only entity that can initiate lawsuits against labs. Private insurance companies can also bring suit. The bottom line is this—offering kickbacks and submitting false claims can lead to detrimental consequences for labs.

Summary

Due to the direct contact between salespeople and their clients and prospects, field reps should always be sensitive to the laws regulating conduct between those who refer (physicians) and those who receive referrals (e.g., labs) and labs should implement compliance programs to reduce the likelihood of violation of the fraud-and-abuse laws. The penalties for violation of these laws can be extremely severe. As a result, every laboratory should conduct yearly training to ensure that those individuals who interface with clients and prospective customers fully understand these laws and the consequences that can come from violating them.

The author wishes to thank Hope Foster from Mintz, Levin in Washington, D.C., for review of this manuscript. *Peter Francis, president of Clinical Laboratory Sales Training LLC, provides sales training and coaching for the reference laboratory industry. He has authored over 30 articles focused on selling within the laboratory industry. For more information, visit www.clinlabsales.com or contact Francis at 410-299-6562.*

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New Study on Self-Referral Supports Closing Loophole

A new study by researchers at Georgetown University supports efforts by lab and pathology industry groups to close the loophole in the Stark law that permits self-referral to in-office pathology laboratories.

The long-awaited study, funded by the American Clinical Laboratory Association (ACLA) and the College of American Pathologists (CAP), compared Medicare billings and prostate cancer detection rates over a three-year period by practices with a financial interest in the pathology lab doing the test versus those without a direct financial interest. The study was conducted by noted health economist Jean Mitchell, Ph.D., and published in the April issue of *Health Affairs*.

Results of the study support the premise that the practice of physician self-referral for diagnostic imaging and pathology services leads to increased use and escalating health care expenditures with little or no benefit to patients. The study found that:

- On average, self-referring urologists billed Medicare for 72 percent more anatomic pathology specimens than physicians who did not benefit financially from ordering more tests, and
- The prostate cancer detection rate per biopsy episode was significantly higher for men who had the biopsy performed by non-self-referring urologists.

The study concluded that "self-referral of prostate surgical pathology leads to increased utilization and higher Medicare spending but lower cancer detection rates. The findings support eliminating the exception that permits physicians to self-refer to in-office pathology laboratories. Both government and commercial insurers could reduce health care spending substantially by adopting measures to restrict self-referral."

Ancillary Services Exception

The Stark law includes an exception related to in-office ancillary services (IOAS) that allows physicians and group practices to self-refer or insource designated health services, including diagnostic imaging, physical therapy, and anatomic pathology. Although self-referral for advanced imaging has been widely studied, the consequence of self-referral on the use of other ancillary services has received little attention. This study addresses the impact of self-referral on Medicare payment for anatomic pathology services, specifically biopsies to detect prostate cancer. Both CAP and ACLA have long supported elimination of the IOAS exception.

"The implications of Dr. Mitchell's study are clear," said Stanley Robboy, M.D., FCAP, CAP's president. "Self-referral has created an incentive to spend millions and millions of dollars without any data showing that this practice benefits patients."

"This study suggests that men are at heightened risk of unnecessary and costly prostate cancer biopsies when under the care of a physician who benefits financially through self-referral," said Alan Mertz, president of ACLA. "This is a serious unintended consequence of a legal loophole that needs to be corrected immediately by Congress."

The Stark law was intended to eliminate the financial conflicts of interest by prohibiting physicians from referring Medicare and Medicaid patients to health care entities in which the physician has a financial interest. The IOAS exception was included in the Stark law to facilitate the performance of on-site services that could aid in the immediate diagnosis and treatment of patients while they were still present in the doctor's office. However, surgical pathology services almost never are performed during the patient visit given the amount of time necessary to prepare and analyze the specimens.

The full report is available online at *www.healthaffairs.org*.

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Massachusetts Lab to Pay $20 Million, *from page 1*

required by law. The scheme "was one of the most egregious abuses of the Medicaid program our office has handled," Coakley said in a statement.

Under the agreement, Calloway will enter into a three-year compliance and monitoring program, with annual site and record audits, and will no longer employ or use as consultants the two accused executives, Arthur Levitan, former chief executive officer, and Patrick Cavanaugh, former chief operating officer.

The settlement resolves the 21 corporate indictments brought against Calloway Laboratories. The AG's office continues to prosecute the remaining 21 indictments against the individuals involved in the case.

This agreement is the seventh settlement resulting from an ongoing industrywide investigation by Coakley's Medicaid Fraud Division into urine drug tests billed by independent clinical laboratories to the state Medicaid program. To date, this investigation has returned approximately $30 million to the state Medicaid program and resulted in numerous criminal indictments. G2

Colorado Governor Signs Direct Billing Law

Colorado Gov. John Hickenlooper (D) has signed into law direct billing legislation that protects patients from having a "mark up" charge added to their laboratory bill by an ordering physician.

Effective Jan. 1, 2013, the Colorado law ensures that patients are billed for anatomic pathology services only by the pathologist performing or supervising the service. In addition, any person receiving a bill in violation of the direct billing law may maintain an action to recover the actual amount paid for the bill.

Prior to the March 22 signing, the legislation unanimously passed both the state's House of Representatives and the Senate. G2

CMS Delays Place of Service Code Changes

The Centers for Medicare and Medicaid Services (CMS) is delaying until Oct. 1 its revised instructions on assigning place-of-service (POS) codes for services paid under the Medicare physician fee schedule and for certain services furnished by independent labs.

The agency had planned to implement the changes April 1 (Transmittal 2407). But in announcing the delay in Transmittal 2435 (March 29), the agency said this would give it time to address questions raised about the national POS policy change, including how it would affect pathology service claims.

This is welcome news to the College of American Pathologists (CAP), which sought a delay, noting that the change would significantly alter how pathologists code for POS and that more time and clarifications are needed to minimize the impact on operations.

CAP further noted that if implemented April 1, the change would have caused major confusion in how Medicare contractors process claims submitted by independent labs under the "grandfather" protection. With the change now postponed until Oct. 1, independent laboratories can continue to bill and be paid without interruption for the technical component (TC) of pathology services furnished to "grandfathered" hospitals until July 1, when the TC provision is set to expire.

In the revised instructions, CMS is proposing that:

- The POS code shall be for that setting in which the beneficiary is receiving inpatient care (POS code 21) or outpatient care (POS code 22) from a hospital.

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- Pathologists who work from their office or laboratory and receive specimens from hospitals must use POS 21 or 22; claims using POS 11 (physician's office) or 81 (independent lab) will be denied.

The purpose is to ensure that claims paid by Medicare contractors are always paid at the correct facility or nonfacility rates, CMS said. This responds to concerns raised by the Office of Inspector General about the volume of claims for services reported as occurring in the office POS when the services were actually provided in an outpatient hospital or ambulatory service center which are paid at the nonfacility rate, rather than the lower facility rate.

In addition to calling for the POS implementation delay, CAP also recommended that CMS include in instructions to contractors various clarifications specific to pathology services, including pathology examples, and that pathologists be allowed to use the POS 11 code for procedures performed on archived specimens or on a confirmatory or secondary opinion consultation.

CMS Has Received $805,000 in Self-Referral Disclosure Settlements

The Centers for Medicare and Medicaid Services (CMS) has settled seven cases under its self-referral disclosure protocol (SRDP) since the process was implemented in September 2010, resulting in more than $800,000 being returned to the federal government, a CMS official said at a conference March 29.

Troy Barsky, director of CMS's Division of Technical Payment Policy, said CMS submitted a report to Congress March 23 detailing the results of the process from Sept. 23, 2010, when CMS posted the SRDP to its Web site, through March 20.

CMS has received 151 disclosures submitted under the SRDP, with the bulk coming from hospitals, he said. Barsky, who spoke at the American Health Lawyers Association's Institute on Medicare and Medicaid Payment Issues, said disclosed violations have included:

- Personal services arrangement issues;
- Nonmonetary compensation issues;
- Office space rental issues; and
- Physician recruitment issues.

Barsky said many of the disclosed self-referral violations have been procedural in nature, involving administrative errors as opposed to outright fraud.

Out of the 151 SRDPs CMS has received, 20 are on administrative hold, 61 await requested information, three have been referred to law enforcement, 51 are under CMS review, nine have been withdrawn by the disclosing entity, and seven have been settled, Barsky said.

Authorized by PPACA

The SRDP was authorized by Section 6409 of the Patient Protection and Affordable Care Act. It is intended to give providers a process to self-report potential violations of the physician self-referral statute, or Stark law. The Stark law prohibits physician referrals of Medicare and Medicaid patients to entities with which physicians or their immediate family members have a financial relationship.

Prior to the CMS SRDP, providers could self-report Stark violations to the Department of Health and Human Services Office of Inspector General. But on March 24, 2009, OIG announced it would accept only self-reported disclosures associated with violations of the anti-kickback statute.

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How to Prepare a Disclosure

Attorney Thomas S. Crane, with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC in Boston, also addressed the topic of SRDPs and said preparation is essential. "Before you prepare materials for a[n] SRDP, make sure you've done a very thorough investigation," he said. "Credibility is key above all else."

Crane also said providers should consider the scope of a potential Stark law violation before entering an SRDP. "For nominal infractions, it may make more sense to take your situation to your Medicare Administrative Contractor, instead of entering a[n] SRDP," Crane said.

Crane said providers should understand that submitting a disclosure under the SRDP does not release them from potential civil monetary penalties or False Claims Act cases. "Only the Department of Justice or the OIG can do that," he said. In addition, Crane said, providers preparing to enter into an SRDP should avoid making any legal admissions. "You should characterize your SRDP as being for settlement purposes only," Crane said.

The CMS SRDP is at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.*

CMS Official Says 26 States Have Awarded Medicaid RAC Contracts

Twenty-six states have awarded Medicaid Recovery Audit Contractor (RAC) contracts, three months after the program's official implementation date, a Centers for Medicare and Medicaid Services (CMS) official said during a March 29 conference.

The remaining states either have not yet awarded a RAC contract or have been granted a limited exception to the RAC requirement, Angela Brice-Smith, acting director of CMS's Medicaid Integrity Group, said during the American Health Lawyers Association's Institute on Medicare and Medicaid Payment Issues.

"We've allowed exceptions for all the territories and for some states," Brice-Smith said. "The exceptions have been for a year or two and have been given to states with a low Medicaid Payment Error Measurement Rate (PERM), for example." She said a quarter of the 26 states with Medicaid RACs have begun reviewing claims, with some just beginning and some further along in the process.

The Medicaid RAC program was established by Section 6411 of the Patient Protection and Affordable Care Act, with the intent of identifying underpayments and overpayments within the Medicaid program and recovering the overpayments. CMS released a final rule on the program in September 2011, with an implementation date of Jan. 1, 2012.

Performance Metrics

As Medicaid RACs get up and running, Brice-Smith said, CMS will provide information on the status of individual state RACs, as well as on overall performance metrics.

"We're planning to use our state Medicaid RACs at-a-glance Web page to show who the RAC is for each state, including contact information," she said, adding that the enhanced Web page will most likely be available this summer.

In addition, Brice-Smith said, CMS will begin collecting performance metrics for the Medicaid RAC program in the fall. She said the information will be available to the public by winter. She said CMS has engaged with the states numerous times over the creation of states' RAC programs and will continue to do so. The program is still evolving, but Brice-Smith said communications between Medicaid RACs and providers could improve.

"I've seen some letters between Medicaid RACs and providers that could be better, such as by clearly identifying where the letters are coming from," Brice-Smith said.

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News-At-A-Glance

OIG'S MORRIS TO RETIRE: Lewis Morris, chief counsel to Department of Health and Human Services (HHS) Inspector General Daniel R. Levinson, retired from his position effective April 1, and Greg Demske, previously assistant inspector general for legal affairs, assumed Morris's position. Over the course of his 10 years as OIG chief counsel, Morris was instrumental in pushing for increased health care fraud enforcement and compliance, according to industry leaders. Morris, who has been with the HHS Office of Inspector General for 27 years, was selected by then Inspector General Janet Rehnquist to become chief counsel in October 2002, replacing D. McCarty Thornton. Prior to becoming chief counsel, Morris served as the HHS assistant inspector general for legal affairs, among other positions within the OIG. Demske joined the counsel's office in September 1990 as a staff attorney. He became the administrative and civil remedies branch chief in October 2002 and assistant inspector general for legal affairs in 2005.

OIG QUESTIONS BILLING FOR IDTFS: Twenty geographical areas accounted for 11 percent ($76 million) of all Medicare Part B payments for independent diagnostic testing facility (IDTF) services in 2009, even though only 2 percent of IDTF beneficiaries lived in the areas, according to a report from the Department of Health and Human Services Office of Inspector General released March 15. The report, Questionable Billing for Medicare Independent Diagnostic Testing Facility Services (OEI-09-09-00380), also found that 18 percent of IDTF claims in the 20 high-utilization core based statistical areas (CBSAs) had at least two questionable characteristics, such as lacking a corresponding claim from a referring physician, compared with 8 percent of IDTF claims in all other CBSAs. A CBSA is defined by the OIG as being anchored around a city with a population of 10,000 or more. The OIG prepared the report in response to previous work on IDTFs that determined they are prone to fraud, waste, and abuse, including 2007 testimony from the Centers for Medicare and Medicaid Services that it had denied $163 million in IDTF claims and terminated Medicare billing privileges for 83 IDTFs in Los Angeles.

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