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Weekly News and Analysis on New Enforcement Initiatives and Billing/Documentation Strategies

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Managing Editor
Nina Youngstrom
nyoungstrom@aishealth.com

Associate Editor
Eve Collins

Executive Editor
Jill Brown

New Proposed HHS Regulation Outlines Fraud-and-Abuse Waivers for ACOs

CMS and the HHS Office of Inspector General on March 31 floated a proposal to clear the fraud-and-abuse path for accountable care organizations (ACOs). The proposed "notice," which is not a regulation but will have the force of law when finalized, establishes waivers of the Stark, anti-kickback and civil monetary penalty laws so ACOs can move forward without fear of enforcement.

The waivers were unveiled on the same day that CMS proposed the sweeping regulation spelling out the Medicare shared savings program created by the health reform law. The rule sets the parameters for ACOs, which give providers incentives to work together to treat patients across care settings, including doctors' offices, hospitals, and long-term care facilities.

ACOs may include "ACO professionals" (physicians and hospitals) in group practice arrangements; networks of individual practices of ACO professionals; partnerships or joint ventures between hospitals and ACO professionals; and hospitals employing ACO professionals. CMS says ACOs, which should be clinically integrated, are designed to improve patient outcomes and reduce costs.

Because ACO development could have been impeded by the fraud-and-abuse laws, the health reform law authorized HHS to develop Stark, anti-kickback and civil monetary penalty (CMP) waivers. The Stark law bans Medicare payments to entities for services referred by physicians who have a financial relationship with the entity unless an exception applies, and the anti-kickback law criminalizes payment of remuneration for patient referrals.

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Co-Management Is a Hot New Trend in Physician Ventures, But Beware Stark Risks

Hospitals are jumping all over co-management agreements, which allow them to pay physicians to run a department and improve its quality and efficiency. With CMS effectively killing under arrangements through Stark regulations and some physicians balking at hospital employment, co-management opens a new door to physician-hospital alignment. Because money changes hands, however, hospitals entering into these arrangements need to navigate a fraud-and-abuse minefield.

"Co-management agreements are a hot venture," says Pittsburgh attorney Bill Maruca, with Fox Rothschild. "Physicians are happy with co-management agreements because they don't have to sell their souls and become employees. They can remain independent but get their expertise reimbursed."

Co-management agreements are set up around inpatient and/or outpatient service lines (e.g., cardiovascular services, orthopedic services, gastroenterology, neurosurgery). No two deals are alike, but basically they break down into two types, says Ann Brandt, senior director of HealthCare Appraisers:

continued

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(1) Co-management: the hospital and physicians set up (and jointly own) a limited liability company (LLC). The hospital engages the LLC to manage the service line. Payment is made by the hospital to the LLC for the management services, and after expenses are paid, the remaining money is paid to the owners (hospital and physicians) based on ownership percentages.

(2) Management: The hospital hires a physician group or groups to manage a service line. This is different than under arrangements because the physicians don't provide supplies, staff or equipment.

"These arrangements have grown exponentially over the past five to six years," Brandt says. During those early years, she worked on four or five co-management arrangements in a six-month period. "Now we get five a week. We are working on 40 management and co-management arrangements right now," Brandt says. She hasn't heard of any facing government scrutiny, "but it's probably coming."

The goal of co-management agreements is to get physicians and hospitals on the same page in terms of quality improvement, operational efficiency, patient satisfaction and other goals (e.g., new program development) without taking a Stark, kickback or civil monetary penalty rap.

Arrangements Include Numerous Services

The administrative and management services performed by co-management arrangements include quality assurance and utilization review; hiring and staff oversight; development of policies and procedures; discharge planning; operating and capital budgets; choosing/ordering equipment and supplies; and compliance, according to Mishawaka, Ind., attorney Bob Wade, with Krieg DeVault.

Because hospitals compensate physicians for co-management services, there is a financial relationship between the two parties, which triggers the Stark law, Wade notes. As a result, hospitals must fit their co-management agreements into a Stark exception. Wade says two exceptions apply:

◆ ***Personal services exception:*** A one-year agreement must be set forth in writing, signed by both parties and specify all services that physicians will provide. Compensation must be fair-market value, set in advance, cover all services, unrelated to the volume or value of referrals between the parties and negotiated at arm's length.

◆ ***Fair-market value exception:*** Compensation must be fair-market value and commercially reasonable and set in advance through arm's length negotiations. Compensation can't take into account the volume or value of referrals between the parties, but can vary with the extent of the physicians' services. The deal should further legitimate business interests.

Fair-market value, as usual, is the centerpiece of Stark compliance for hospital-physician relationships. Fair-market value compensation in co-management agreements depends on the extent of management services the physicians are going to perform separate from clinical care that they bill to Medicare and other payers, and the size of the department, Wade says.

To calculate fair-market compensation for co-management agreements, Brandt uses a combination of the market approach and the cost approach. The market approach is based on 39 physician tasks that are the heart of co-management, including efforts to:

◆ ***Monitor and coordinate physician resources in the service line*** and ensure patient safety and operational efficiency.

◆ ***Assist the hospital in implementing,*** monitoring and managing quality assurance and utilization review activities.

◆ ***Develop and update best practice standards*** for the service line (e.g., performance-based benchmarks and monitoring systems).

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The cost approach is less direct. Because it's impossible to figure out the actual costs of a co-management arrangement, how would you price the cost of providing various administrative and management services? HealthCare Appraisers applies an approach based on an analysis by proxy, using benchmark data for medical directors based on the size and scope of sub-service lines. "We believe that the cost approach often underestimates the fair market value range for co-management agreements, while the market approach often overestimates it, so we look at other factors," including the number of facilities and their location in order to apply adjustments (e.g., economies of scale), Brandt says. "Then we blend the cost and market approach to determine fair-market value compensation for the arrangement," she says.

There are two compensation components with management/co-management arrangements: base compensation and incentive compensation. Brandt says the base component should make up about 40% to 60% of physician compensation under co-management agreements. The rest of the money is reserved for incentive pay, she says. When physicians hit certain benchmarks, they get some money, but they don't get full compensation unless the top tier of the performance goal is achieved. Brandt cautions that it's not commercially reasonable to reward physicians for achieving a goal if the overall group is already there. For example, if the hospital has on-time surgery starts 85% of the time, "it's not reasonable to incentivize at 100% for achieving 83%."

Physicians Can Be Rewarded in Many Ways

Physicians may be rewarded for all kinds of performance benchmarks. Hospitals could look to the process of care, outcomes and patient satisfaction measures in CMS's new value-based purchasing program *(RMC 3/28/11, p. 1)*.

Co-management has caught on at Fairfield Medical Center in Lancaster, Ohio, which was looking for a way to work with physicians on quality improvement, Chief Operating Officer Howard Sniderman tells *RMC*. "One of the biggest challenges hospitals have is physician alignment and getting physicians involved in helping us manage departments and make decisions about operations of hospitals. They have too many commitments on their time," he says. The medical-staff members of the 220-bed hospital steered clear of hospital employment, but they wanted to join forces to become more competitive with area hospitals. In response, Fairfield Medical Center entered into several management and co-management agreements. For example, on Feb. 1, the hospital opened its new cardiovascular institute, which is a co-management arrangement with the physicians, Sniderman says.

The emphasis of the cardiovascular services co-management arrangement is on quality and patient satisfaction improvements, using the 39 tasks identified by HealthCare Appraisers, Sniderman says. For metrics, physicians, including primary care and specialists, are addressing standards of care, processes and communication.

Docs Paid Only If Entire Group Succeeds

One performance metric is communication. Primary care physicians in the co-management arrangement complained that they are not kept in the loop after referring patients to cardiologists or other specialists for stress tests and other services. They may not even realize the patient had open-heart surgery until months later, when the patient tells them. So one metric is keeping primary care physicians informed about the cardiologist's recommendations and the results of cardiac procedures.

Other examples of metrics at Fairfield's cardiovascular co-management arrangement:

(1) Reducing congestive heart failure (CHF) readmission rates. Fairfield's 30-day CHF readmission rate is now 21%, and the group's full incentive payment will kick in when it's below 15%. "It's a team effort," Sniderman explains. Part of the reason why CHF patients are readmitted has to do with educating the patient and follow-up visits to their physicians within 48 hours. So in addition to nutritional and medication advice, the physicians in the co-management arrangement will determine how to ensure Fairfield CHF patients are able to schedule an office visit promptly.

(2) Standardizing the way patients with common diagnoses are treated. Among them are chest pain, deep-vein thrombosis and "door-to-balloon time," which refers to the time it takes certain types of patients who need cardiac catheterization to get from the emergency department to the cardiac cath lab. The ideal door-to-balloon time is 90 minutes and Fairfield's goal is achieving that 90% of the time.

In a twist, each physician gets the bonus only if all the physicians collectively achieve the performance metric. In other words, the physicians work together to help improve patient care and to enjoy the spoils of their success together rather than pitting physician against physician. They get part of the bonus for partial success or all of the bonus if they reach the benchmark. And it's not just the doctors. "Everyone's pay depends on how all the doctors in the cardiovascular institute perform," he says.

Sniderman believes the co-management agreement is on solid legal ground. "We are not paying for anything related to patient volumes. We are paying for management services," he says. The LLC even pays hospital staffers for services provided to the co-management

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agreement. "When I go to a meeting for co-management, [the LLC] pays the hospital for my time."

The performance metrics should be updated annually, Brandt notes. Raise the bar as physicians reach each benchmark so they continue to be rewarded for further improvement. Otherwise they are paid incentives for what has become the status quo.

Wade adds that hospitals have to ensure compensation for co-management truly reflects the services performed. "You may have to build in percentage-based compensation," Wade says. "If revenue increases substantially because physicians in a co-management agreement refer patients to the hospital more, you have to make sure they are not paid for the increase in referrals." Suppose a hospital pays a physician group $200,000 a year for co-management services that take only 50 hours of administrative time per year. "That's $4,000 an hour, which is not fair-market value," he says.

The anti-kickback law is also a concern with co-management agreements. They don't fall squarely inside any safe harbors, but the personal services and management contract safe harbors are closest, Wade says.

Contact Brandt at abrandt@hcfmv.com, Sniderman at howards@fmchealth.org and Wade at rwade@kdlegal.com. ✧

Use Adult-Learning Ideas to Make Compliance Training More Effective

If compliance education still consists of lecturing employees about Medicare and giving them stacks of regulations, don't expect their education to stick. Because adults learn differently than children, they are more likely to apply what they learn if training is consensual and factors in their motivation and learning style.

"People need to tailor their training to the ways that adults learn," says physician C.J. Wolf, assistant systemwide compliance officer for the University of Texas System. Education is one of the seven elements of a compliance program, but for many years the emphasis was on ensuring everyone got the basics, and then tracking attendance and quizzing employees pre- and post-training. "The next level is to apply scientific principles of effective training for adults," he says. In his compliance training, Wolf uses the six adult-learning principles developed by Malcolm Knowles, the father of adult learning theory. "I have noticed that compliance people want to vomit up regulatory language [when they train]," Wolf says. "What I think is more effective is to provide context for a rule. Rather than providing the Medicare regulation, present a scenario where that regulation has to be used. This mirrors adult learning principles."

Here's how Wolf uses the six adult-learning tenets in compliance training:

(1) Emphasizing to adult learners why it's important for them to learn something: For example, physicians may question why they should know the particulars of evaluation and management (E/M) coding. So before training a clinical department, Wolf runs physician-specific reports that show the impact of downcoding or upcoding one level of service. "I calculate it for the doctors — I have had cases where it's $13,000 a year [for one physician] and others where it's $40,000," he says. "You have to get in their heads. Why would these doctors accept my invitation to learn about compliance? You have to make it interesting and applicable."

(2) The self-concept of the learner: Unlike children, who need more direction, adult learners are autonomous and self-directed. "Adults want to make some decisions even while you are pointing them in the right direction. If they have to sit through 20 minutes of compliance training, you can at least let them control topics within reason," Wolf says. The planning and the training should be "mutual." For example, the gastrointestinal department at University of Texas System asked Wolf to give a billing and coding compliance presentation. Wolf asked every GI physician to submit two or three questions in advance to ensure he addressed their concerns. "Themes start to appear," Wolf says. "They wanted to know about a CCI edit for a series of colonoscopy codes in the CPT code book. I was able to prepare my training specifically to that issue. That department didn't need to know what a CPT code or correct coding initiative (CCI) edit was. They already knew." If training had been that basic, the time would have been wasted and physicians would be dismissive of future compliance education, he says. Also, training should be "contextual," so Wolf prepared two examples the GI physicians could apply to their work. The examples illustrated when it is and isn't acceptable to bypass the CCI edit. Finally, he says, "allow the learner to direct the discussion. Even if you prepared a monstrous presentation, say 'I would like this to be interactive and meet your needs.'"

(3) The prior concept of the learner: Adult learners carry lots of experience, knowledge and ideas, "which can be a valuable launching pad to teach them," Wolf says. Use familiar images and analogies to make complex material understandable. For example, some people can't find much logic behind the CCI edits. So Wolf uses the analogy of a value meal at a fast-food restaurant. If you order an all-inclusive value meal (e.g., burger, fries, drink), should you pay separately for a root beer? The CCI edits are all about bundling, like a value meal. For modifier 59, if that root beer is ordered as part of the value meal, it shouldn't be paid separately. But what if

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another passenger in the car ordered only root beer? On the receipt it looks like it was double billed. "You need to put modifier 59 because the documentation supports separate ordering of root beer," Wolf says. "But the list of CCI edits is not always logical so you have to look up what Medicare considers included and not included."

(4) Readiness to learn: Do employees want to learn about this issue? Compliance training is mandatory, so employees have to attend. But Wolf also gets training requests, and that usually correlates to greater learning readiness.

(5) Orientation to learning: Wolf says training should be focused on the challenges experienced regularly by employees. With HIPAA, discuss different problems and how to solve them in the context of the privacy and security regulations. For example, if employees are in an elevator and Dr. Silver is chatting about Mrs. Gold's colonoscopy, what would they do? Similarly, Wolf thinks it's less effective to just hand psychiatrists all the local coverage decisions (LCDs) that are relevant to them than it is to present a scenario and discuss which LCDs are triggered. For example, you could say to the psychiatrist, "Here is the note you wrote for Mr. Jones. What does and doesn't meet Trailblazer's LCDs?" Then work through it in a small group setting. Trailblazer, a Medicare administrative contractor, has LCDs for Texas on psychiatry codes and partial hospitalization programs, and they specify the documentation requirements. But without a context for the requirements, psychiatrists may not absorb much. "It is an application of principles, not just teaching the principles," he says.

(6) Motivation to learn: This is a fundamental force in adult-learner success, but people are motivated by different things. Some people are motivated by good performance evaluations, another reason to make compliance effectiveness a factor there. Or departments may be evaluated annually on specific goals (e.g., quality of care, compliance), which serves to motivate the people in that department. "And there are people who inherently have a sense of fairness and fair play, so they want to know the rules on both sides of the game," Wolf says. "They are the most vocal when [others] are not following the rules," whether it's payers or providers. Compliance officers should capitalize on these learners because they help breathe life into compliance. "Who is ultimately responsible for an individual operationalizing compliance? The compliance officer? No," he says. "But it's hard for a lot of compliance professionals to let go."

Applying adult learning principles "can be a real separator" between rote education and the type of change-agent training the government expects, Wolf says. For example, the U.S. Sentencing Guidelines for Organizations states that "(4)(A) The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subparagraph (B) by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities."

Contact Wolf at cwolf@utsystem.edu. ✧

Court Dismisses Case Against GSK Lawyer, But Feds Can Try Again

A federal court on March 23 dismissed an indictment against a former GlaxoSmithKline (GSK) attorney, but left the government an opening to indict her again. The people serving as in-house counsel in health care organizations will especially want to pay attention to the outcome of this case, says one former prosecutor.

The case dates back to 2002 when the FDA asked GSK for documents related to the promotion of its antidepressant drug Wellbutrin to investigate whether the company had promoted it for weight loss, which was a use that was not approved by the FDA. At the time, Lauren Stevens was GSK's vice president and associate general counsel and was in charge of responding to the FDA's requests, according to an opinion by the U.S. District Court for the District of Maryland. She led a team of lawyers to gather the information, the opinion says.

The feds allege that Stevens obstructed the investigation by withholding and concealing documents, and that she falsified and altered other documents. She was charged in November 2010 with one count of obstruction of a proceeding (18 U.S.C. § 1512), one count of falsification and concealment of documents (18 U.S.C. § 1519), and four counts of making a false statement (18 U.S.C. § 1001). The trial was set to begin April 5.

Stevens says she worked with in-house attorneys, plus an outside law firm, to gather the documents, and that she depended in good faith upon their advice in the matter.

It was on this issue, and while the grand jury was considering the case, that the government messed up, the court says. After one of the jurors asked a question about Stevens getting advice and direction from other lawyers, the prosecutors erroneously instructed the grand jury that the advice-of-counsel defense was not relevant during the charging phase of the case.

"[G]ood faith reliance on the advice of counsel negates a defendant's wrongful intent, and is therefore highly relevant to the decision to indict," the court explains. "A proper instruction would have informed the grand jurors that if Stevens relied in good faith on the

advice of counsel, after fully disclosing to counsel all relevant facts, then she would lack the wrongful intent to violate the law and could not be indicted for the crimes charged in the proposed indictment," it says.

The grand juror noticed the "elephant in the room," the court says. "The question went to the heart of the intent required to indict. The incorrect answer either substantially influenced the decision to indict or, at the very least, creates grave doubt as to that decision. Accordingly, dismissal of the indictment is appropriate and required in the interests of justice."

Court Decision Was a Mixed Bag

However, the court's opinion was not entirely in Stevens's favor. It denied her motion to dismiss count 2 (falsification and concealment of documents) as unconstitutionally vague because it would have allowed conviction without proof that she acted with specific wrongful intent; denied her motion to dismiss count 2 as multiplicitous of count 1, which she said violates the Double Jeopardy Clause; and denied another motion to dismiss count 2 for failure to state an offense because the heart of that count was that she wrote letters containing false information, not that she destroyed, altered or falsified pre-existing documents, as the statute says.

The court also says it found no evidence that the prosecutors engaged in "willful prosecutorial misconduct," and the government should get another chance at the case "before a different grand jury that is appropriately instructed." The trial date has been continued until April 26.

An attorney representing Stevens did not respond to *RMC*'s requests for further comment.

This case will interest in-house counsel within health care entities, says former federal prosecutor Norman Bloch, who is now with Thompson Hine. "The people who should be paying attention to this are the in-house lawyers in the health care industry because they routinely receive requests and subpoenas from the government for documents," he tells *RMC*. "Whether they respond on their own or are assisted by outside counsel, in many of these [requests], the language isn't clear and a mistake can be made. Then an innocent mistake could become, 'You deliberately withheld it.'" But courts scrutinize these kinds of cases closely, Bloch notes, and he says that's what the court appeared to do here. "In-house lawyers have a difficult enough job without the specter of criminal prosecution if they rely in good faith on the advice of outside counsel or inadvertently fail to provide documents the government seeks."

Contact Bloch at Norman.Bloch@ThompsonHine.com. ✧

New Waivers Proposed for ACOs

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The CMP at issue imposes a fine on hospitals for using incentives to reduce physician services. Hospitals have financial relationships with referral sources in ACOs and may reward them for performance, which could have spelled trouble under the fraud-and-abuse laws.

The new waiver regulation alleviates many of these concerns, says Washington, D.C., attorney Chris Janney, with SNR Denton. "The proposed waivers are pretty broadly worded," which is helpful, he says. "They will largely protect the various shared-savings distributions from CMS to ACOs and then the downstream distributions from ACOs to participating providers and suppliers."

Janney says CMS and OIG "made a concerted effort to make the rule as efficient and user-friendly as possible, in the sense that they are not analyzing each one and deciding whether to waive each one. Instead, they came up with a set of requirements that will be applicable if you have entered into a shared saving arrangement with CMS."

According to the CMS-OIG notice and solicitation of public comments, waivers are not necessary if ACOs fit inside an existing Stark exception or anti-kickback safe harbor. Waivers will be applied consistently across the fraud-and-abuse laws. Here is a summary of the proposed waiver authority:

◆ ***HHS would waive application of the Stark law*** to distributions of shared savings from CMS to the ACO, its participants, providers and suppliers, "and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO." The goal is to protect financial relationships "created by the distribution of shared savings within the ACO, as well as financial relationships created by a distribution of shared savings outside the ACO" if they relate to the ACO. The waiver won't protect payments to referring physicians outside the ACO unless they're paid for ACO-related functions.

◆ ***HHS would waive application of the anti-kickback statute*** for (1) the ACO's distributions of CMS shared savings to ACO participants, providers and suppliers, and (2) any financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary under the shared savings program that triggers the Stark law if it fits into an exception. Normally, qualifying for a Stark exception doesn't confer kickback immunity.

◆ ***HHS would waive application of the CMP law*** that prohibits hospital payments to physicians to induce reduction or limitation of services for (1) CMS distributions of shared savings to an ACO when it flows from a hospital to a physician if the payments are not knowingly made to in-

duce the physicians to limit medically necessary care and the hospital and physician are ACO participants or ACO providers/suppliers; and (2) any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers necessary for the ACO that triggers the Stark law but qualifies for an exception to it.

While the waivers are useful, they leave questions unanswered, Janney says. For example, what happens when ACOs have both Medicare and commercial patients? Stark is implicated by any financial relationship between a hospital and referring physician, but the waivers only address the Medicare side of the equation. Janney hopes CMS and OIG will tackle this in the final regulation. But he called the waivers a good first step. "Their mantra in all of the rulemaking is how to provide enough flexibility to achieve a particular purpose without opening the door inadvertently to improper and abusive referral arrangements," according to Janney.

Meanwhile, the Department of Justice and the Federal Trade Commission will issue guidance to providers on how they can form ACOs without breaching antitrust laws. In particular, a new antitrust policy statement also issued March 31 describes a "safety zone" for certain participating ACOs. Those that fall within this zone are unlikely to raise competitive concerns. However, ACOs that exceed a share above 50% for any common service that two or more ACOs provide to patients in the same Primary Service Area will be subjected to a 90-day expedited review of ACOs by these agencies.

Read the regulation at www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1. Contact Janney at Christopher.janney@snrdenton.com. ✧

NEWS BRIEFS

◆ **Sens. Max Baucus (D-Mont.) and Orrin Hatch (R-Utah) have asked the HHS Office of Inspector General and CMS to submit quarterly reports to the Senate Finance Committee on their efforts to fight fraud, waste and abuse in Medicare and Medicaid,** according to a March 24 letter. The first report is due May 20. The senators asked for details from CMS, including (1) a breakdown of provider screening by industry segment and by month showing how many applications were screened, the number of entities flagged, and the number denied billing numbers as a result; (2) information on the provider enrollment moratorium such as type of provider, geographic scope and length of the suspension; and (3) an update on projects using technology, such as predictive analytics, to prevent or identify fraudulent claims. To read the letter, go to http://finance.senate.gov.

◆ **A hospital's plan to transport patients for free from physician offices on or near its campus if they need further treatment could violate the anti-kickback statute, but OIG would not impose sanctions,** it says in Advisory Opinion 11-02, released March 24. The service also would not be grounds for imposition of civil monetary penalties, OIG adds. The requestor is a nonprofit, tax-exempt corporation that operates an acute-care hospital with outpatient services. Under the arrangement, an emergency medical technician would pick up patients in a hospital-owned, wheelchair-accessible van and transport them to the hospital's main entrance. The requestor says the service is needed because it has a 108-acre campus with limited parking, and walkways that could be difficult for sick patients to navigate. The hospital would not charge the patients or any third-party payer. OIG says it does not object to the service because (1) it would not limit eligibility to federal health care program beneficiaries, (2) the type of transportation is reasonable, (3) it is offered only locally from physicians' offices on or near the hospital's campus, (4) the service is not advertised, (5) availability of public transportation and parking is limited, and (6) the hospital would not submit claims for the service to any federal health care program. Read the opinion at http://go.usa.gov/2DA.

◆ **CMS made $3.1 million in Part D payments to private prescription drug plans and Medicare Advantage plans in 2007 and 2008 for drugs to treat erectile dysfunction (ED),** OIG says in a report (A-07-10-03143) released March 2. Medicare Part D will pay for ED drugs only when they are prescribed for FDA-approved, medically accepted indications other than ED, such as pulmonary hypertension. CMS told OIG that its drug data processing system did not prevent CMS from accepting drugs used for ED treatment in 2007 and 2008 because the Part D program had an incomplete list of excluded drugs. OIG says CMS should (1) find out whether it can get money back from the drug plans; and (2) strengthen internal controls to ensure that Part D payments for drugs comply with federal requirements by working with the FDA on a list of approved ED drugs, disseminating the list to

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NEWS BRIEFS

the drug plans, and updating the edit used to reject drugs used only for treating ED. CMS concurred with the first recommendation and with the suggestion to update the edit. But the agency told OIG its existing edits eliminate the need to collaborate with the FDA on a list of drugs. Read the report at www.oig.hhs.gov/oas/reports/region7/71003143.asp.

◆ **The U.S. Court of Appeals for the Fourth Circuit on March 28 affirmed a district court's dismissal of a lawsuit challenging the seal provisions of the False Claims Act (FCA).** The American Civil Liberties Union and other groups alleged that the seal provisions violate the First Amendment right of access to judicial proceedings, among other arguments. The court explained that the First Amendment allows access to criminal trials and proceedings, but that right is not absolute, and the Supreme Court has not yet addressed whether this extends to civil trials. In assuming that access does extend to civil cases, the court says access still is not guaranteed because the government has a compelling interest to protect the integrity of ongoing investigations. Also, the seal provisions are narrowly tailored to serve the government's compelling interest because (1) there is a detailed process for initiating and pursuing FCA complaints with a narrow window of time that seals are mandatory (60 days), (2) at the end of the 60-day period, there must be a judicial review, and the feds must demonstrate "good cause" to extend the seal, and (3) the seal limits the relator from publicly discussing the FCA complaint, but not from disclosing the existence of fraud. Read the opinion in *ACLU v. Holder* at http://pacer.ca4.uscourts.gov/opinion.pdf/092086.P.pdf.

◆ **CMS said it will revamp regulations that require physician signatures on lab requisitions,** according to a March 31 listserve e-mail from the press office. "CMS has decided to focus its resources for the remainder of 2011 on changing the regulation that requires signatures on laboratory requisitions because of concerns that physicians, [nonphysician practitioners], and clinical diagnostic laboratories are having difficulty complying with this policy," CMS stated. Industry officials said in February that CMS conveyed it would scrap the requisition signature requirement, which hospitals find impractical *(RMC 2/21/11, p. 4)*. CMS introduced the signature mandate in the 2011 Medicare fee schedule, which took effect Jan. 1, but then delayed enforcement until April 1. Also in the e-mail, CMS said that starting April 1, it will enforce a health reform law requirement for physician face-to-face encounters with patients before they certify their eligibility for home health or recertify eligibility for hospice services.

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