

MEDICARE COMPLIANCE

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

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CMS Revises Position on Standing Orders, Clarifies Physician Signature Stamp Ban

CMS in late October backed off its restrictions on standing orders and clarified its position on physician signature stamps, which have a sort of split personality under Medicare.

In an Oct. 24 survey and certification letter to states (S&C-09-10), CMS said the timing of physician orders should not be a “barrier to effective emergency response.” If necessary, emergency-room nurses can begin treating a patient pursuant to standing orders/protocols as long as a signed physician order specific to that patient is placed in the patient’s medical record as soon as possible, CMS said. This is a big relief for hospitals, which had been unnerved by a February survey and certification letter (S&C-08-12) that essentially prevented nurses from initiating patient care until a physician signed the order.

Barbara Tomar, director of federal affairs for the American College of Emergency Physicians (ACEP), says the Medicare conditions of participation for hospitals permit the use of standing orders, so it came as a surprise early this year that CMS was suddenly telling state surveyors — who evaluate CoP compliance for CMS — that hospitals can’t invoke written protocols or standing orders without first obtaining a physician order. The February letter stated, “If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient’s care.”

That set off alarm bells. For one thing, provider groups were worried about patient safety, says Tomar. “The concern was that nurses wouldn’t, for example, be able to administer aspirin to a patient with chest pain or Tylenol to a child with febrile seizures on arrival at the emergency department” without summoning a physician, who might be knee-deep in a trauma case, she says. “This just bogged things down” in the emergency department, she contends.

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RAC Program Is On Hold While GAO Weighs Protests by Two Vendors That Lost Bids

The national rollout of the recovery audit contractor program is temporarily on ice while the Government Accountability Office (GAO) reviews protests about the RAC contractor selection process filed by two vendors that lost the competition.

On Nov. 1, PRG-Schultz USA, Inc., and Viant, Inc., which lost the bidding wars for lucrative RAC contracts, separately asked GAO to recommend that CMS conduct a do-over of the RAC selection process. GAO has 100 days to decide if the vendors make a persuasive case that CMS erred when it didn’t choose them as RACs, explains Michael Golden, managing associate general counsel at GAO. During this time, CMS must impose a “stop-work order” on the four winning RAC contractors until GAO’s decision comes down.

continued

Managing Editor

Nina Youngstrom

Associate Editor

Eve Collins

Editor

Angela Maas

Executive Editor

James Gutman

But RACs delayed will not be RACs denied, hospital officials agree. Congress mandated the expansion of the RACs nationwide after a three-year pilot program, and CMS views them as an effective method for identifying payment errors, so there's no question the RACs will be back. "You can't stop worrying about the RACs. The government is convinced this is a good way to [recover] money, and especially during this economy, they're not going to shy away from it," contends Boston attorney Larry Vernaglia, who is with Foley & Lardner LLP.

Either the protests will fail, and the RACs will get to work in a few months, or the contracting process will be reopened, and the national RAC program will take longer to get off the ground — but the latter scenario is less likely.

The suspension came down about one month after CMS formally announced the national RAC rollout by naming the four vendors that won the contracts — and just four days after CMS posted a schedule of site visits

to numerous states to prepare hospitals there for the RAC launch. CMS pledged to meet with hospitals (and bring RAC representatives) before the first medical-record requests hit the streets. In a sense, the posting of the site-visit schedule was a concrete sign that the audits would begin. And then, bam — the RACs were stopped in their tracks by the protest.

Delay Gives Firms More Time to Prepare

"The fact that RACs are being held up because contractors are fighting over the contracts doesn't give us any hope there will be more reasonableness on the part of the RACs. But at least we will have more time to organize our approach and our response to RAC medical-records requests and to review different kinds of software being developed to track and oversee the RAC response process," says Nickie Braxton, compliance officer for Hartford Hospital and Healthcare Corp. in Connecticut.

Ironically, the RAC suspension was set in motion the moment when CMS announced the four contractors, says Washington, D.C., attorney David Ralston, who is with Foley & Lardner. CMS would also have sent a letter to the losers saying they didn't get a RAC contract. That notification triggers their right to a "debriefing" by CMS so that the vendors can get a sense of why they lost the RAC bids, he explains. This gives the vendors enough information to decide whether to file a protest with GAO. If and when they do, the case will be assigned to a GAO attorney for review. GAO reviews are intended to ensure integrity in the contracting system, he says.

Only one in five protests wins the support of GAO, Golden and Ralston say.

Thirty days after the protest is filed with GAO, CMS submits all procurement records to GAO and the vendors' lawyers under a protective order. That may give the attorneys for a losing vendor more ammunition for the protest, Ralston says. Vendors might argue that CMS unfairly evaluated their proposals because it failed to consider fully the vendors' positive points or gave too much consideration to its negative points. In a press release, PRG-Schultz said it "understands from CMS that it received one of the highest technical scores, but it was not awarded a contract because it ultimately did not have the lowest contingency fee bid in any region." According to Ralston, what this probably means is that the vendor is challenging the best value trade-off performed by CMS, in which CMS appears to have chosen the lower technically ranked, but also lower-cost, proposal. PRG-Schultz would argue that the CMS trade-off decision was flawed because PRG-Schultz offered greater value that more than offset its additional cost, he says.

Protests are common with high-value contracts, Ralston says. "In the vast majority of contracts, there

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aren't any protests," he adds. Vendors fear alienating the government agencies whose business they vie for, he maintains. In this case, he says, RAC contracts are quite valuable and too good to pass up, considering that they will yield contingency fees on potentially hundreds of millions of dollars a year.

If the protest is denied, CMS can immediately lift the stop-work order, says Ralston. Meanwhile, the vendor also gets "a second bite at the apple," he says. If unhappy with the outcome, the vendor can try again to get the contract decision overturned by the U.S. Court of Federal Claims in Washington, D.C. However, the RAC program would resume unless the vendor got an injunction from the court to stop it, he says. If the vendor loses in this court, it has one final chance to win back the RAC contract: the U.S. Court of Appeals for the Federal Circuit.

Vernaglia says providers may see this development as a stay of execution, the same way they perceived the Federal Trade Commission extension for compliance with the "Red Flag Rules," which require an identity theft-prevention program (*RMC 10/27/08, p. 7*). But with the RACs, it won't change the October 2007 look-back date, which means even if RACs have to start later, they still will audit claims paid as far back as that date. "Any delay is good for hospitals from a planning perspective," he asserts. "It allows more time to get ready for RAC audits. If the first letters had dropped in January, a lot of hospitals would have been unprepared."

Hospitals should spend this unexpected time cushion auditing their processes to (1) identify past areas of vulnerability that they might need to proactively report, and (2) flag areas for process improvements to ensure medical-necessity compliance and coding accuracy moving forward, recommends Robert Corrato, M.D., president and CEO of Executive Health Resources in Pennsylvania.

Contact Ralston at dralston@foley.com. ♦

Establish Set of Procedures for Responses to Federal Investigation

It's 6 a.m., and FBI agents have just shown up at the doors of some hospital employees, determined to find out what they know about certain physician financial relationships. The employees immediately call the compliance officer, pursuant to a company policy that requires them to inform corporate officials of visits from federal agents. So far, so good. But there are many things to consider as an investigation unfolds, including the information that organizations should convey to employees about investigations and the nature of cooperation that will go over well with the government.

The landscape has changed somewhat because of two August developments. For one thing, there is less pressure on organizations to waive attorney-client privilege. The Department of Justice (DOJ) on Aug. 28 announced it had revised its Principles of Federal Prosecution of Business Organizations (*RMC 9/8/08, p. 1*). In one major change, DOJ says corporations can get credit for self-disclosing misconduct without waiving attorney-client privilege.

On the same day, the U.S. Circuit Court of Appeals for the Second Circuit affirmed the dismissal of indictments against 13 KPMG employees on the grounds that DOJ pushed KPMG to stop paying their legal fees. The court ruled in *U.S. vs. Stein* that the KPMG employees' Sixth Amendment right to counsel was violated and that dismissal of the indictments was the only viable alternative.

But the essential themes remain the same: The more effective compliance programs are, the better they are at uncovering potential violations. That raises the stakes for internal investigations, an organized response to government investigators and insight into what the government wants from companies during the investigative process.

Set Up Procedure for Dealing with Subpoenas

Organizations should have written procedures for responding to the various scenarios that may happen with law enforcement, said former federal prosecutor Robert Nicholson, now with the law firm Broad and Cassel. If an organization receives any kind of DOJ subpoena, "that may mean that someone in law enforcement has taken enough interest in you to have opened an investigation. If so, they probably aren't just going to go away. It probably means a likelihood of double or treble damages or even criminal damages," he says.

It's essential to have a procedure to deal with subpoenas. Make sure they are sent to a central authority in the organization (e.g., general counsel, compliance officer). That person can tell the FBI agent, "Thank you. We will pass this [subpoena] on to counsel, who will be in touch with you to arrange for production," he says.

When it's a search warrant, "that means [the feds] have convinced a federal magistrate or other judicial officer there is probable cause to believe your organization has engaged in criminal behavior," he explains. "Immediately outside counsel must come in, and you need to do significant triage." A search warrant means agents can come on the scene without delay and seize records, which is why organizations should have a plan in place in advance in preparation for this event, says Nicholson.

continued

Compliance officers and/or legal counsel should be contacted quickly, and the search warrant should be shown to legal counsel immediately, he says. Law enforcement should not be obstructed or hindered in any way. Send home all non-essential personnel. "Ideally, you have an employee monitoring the search by the agency," Nicholson says. The employee can direct agents to items they plan to seize according to their search warrant and point out when agents are headed toward off-limits territory (e.g., the filing cabinet with privileged legal documents).

Tell rank-and-file employees they have the right, but not the obligation, to talk to law enforcement. If they decide to speak up, let the employees know the organization will supply a lawyer. "You should not be perceived as trying to obstruct, hinder or delay communications with law enforcement," says Nicholson. "But you are allowed to tell them you will provide them with a lawyer."

Officers Should Have Counsel Before Talking

However, corporate officers and key personnel (e.g., senior management) should not talk to law enforcement without corporate counsel. "What they say can be imputed to the corporation for civil and criminal purposes. They may make a statement that will constitute an admission against the organization, so there are additional protections provided to the organization in that context," he says.

Nicholson adds that it's a good idea to interview employees — with counsel present — before they meet with the government. But make sure employees know their conversation is privileged only with respect to the company. "Employees should know when they are being interviewed as part of the internal investigation that the interview may be disclosed, and they could have culpability," he says.

Amy Berne, chief of the civil division for the U.S. Attorney's Office for the Northern District of Georgia, and Nicholson emphasize that employees must be warned against making documents disappear — and there should be no "wink, wink" about it. Nicholson says document destruction can "turn what is nothing more than an administrative, civil or maybe nascent criminal investigation into something more complex" and potentially damaging to the company. He suggests sending an e-mail to all employees, managers and board members stating that no document gets destroyed until the investigation is over and reminding them there are substantial penalties for doing so.

Once an organization receives a subpoena or search warrant, should it conduct its own internal investigation to get its arms around any alleged violation? There is no one-size-fits-all answer to this question. Suppose

you immediately start probing, and find and fix systemic problems. Do you reveal the results of the investigation to the government? "You want to go down that path very slowly," he says. "Don't obstruct the investigation, but I don't know that you want to rush in and do a full disclosure." However, maybe a full disclosure is exactly what the doctor ordered if, for example, the internal investigation found that the violation resulted from one or a small group of rogue employees, Nicholson says. "Excise that tumor from the organization, and hopefully that will give you an advantage in negotiations with the government," he says. "You can take the position that '[the rogues] acted outside the scope of their employment, it wasn't for the benefit of the corporation, and we have an effective compliance program.' You are trying to save the corporation at the expense of people who did wrong."

Berne says a thorough internal investigation of potential violations is essential to ensuring that organizations report to the right party. "If you do a limited investigation and decide it's just a mistake and report it to the fiscal intermediary rather than DOJ or the Office of Inspector General, but later it becomes apparent that there is possible fraud and it comes to the attention of the U.S. attorney," it doesn't make you look good to the government, she says. "If it's a potential False Claims Act [violation], you go to the U.S. attorney or OIG Self-Disclosure Protocol."

DOJ Considerations for Fraud Case

Berne described factors that DOJ considers in whether to pursue a health care fraud case against a corporation:

- ◆ *The seriousness of the offense.*
- ◆ *The pervasiveness of wrongdoing.*
- ◆ *The history of similar conduct by the corporation.*
- ◆ *The timeliness of voluntary disclosure.*
- ◆ *The corporation's response to the realization it is being investigated.* Does the corporation provide blanket legal representations for "everyone they ever dealt with in the world? That doesn't look to us like full cooperation," says Berne. "And how do they respond to our subpoena? Do they send 500 boxes of totally irrelevant documents first, and wait to give us key documents that we are requesting a year later? That's not cooperation." Also, how do corporations under investigation assert attorney-client privilege regarding documents? Do they claim every document is privileged just because the attorney's name is cc'd "when that is not necessarily the case? Do they identify the culprits involved, and will they let us interview employees? Do they do investigations internally and offer to disclose the findings? It all depends on how you respond to our inquiries and

whether you're indicating you really want to cooperate and want to disclose and help us get to the resolution or if you try to make it more difficult for us to get to the facts," Berne explains.

For more information, contact Nicholson at rnicholson@broadandcassel.com. ✧

Standing Orders and Protocols: Challenges, Tips for Improvement

The relief over CMS's October survey and certification letter (S&C-09-10), which rescinded its requirement that physicians sign orders before nurses can start applying standing orders and protocols in the emergency room (see story, p. 1), underscores the important role that standing orders play. But there are other compliance challenges facing hospitals with protocols, standing orders and preprinted order sets, says Cheryl Rice, corporate director for corporate responsibility at Catholic Healthcare Partners.

"The use of protocols, order sets and standing orders should be reserved for emergency or high-intensity, urgent situations, where quick action by caregivers can mean the difference between life and death or disability," she says. "In clinical situations where patients are stable [or having] scheduled services, protocols, order sets and standing orders can be used to ensure uniformity in care. But there should be the expectation that the physician who is present is providing an upfront review of the patient and is able to render a timely upfront order to implement a protocol." She says staff should look at their protocols, order sets and standing orders, determine which are for emergencies and which are for routine care, and then write a policy addressing this.

Rice describes the challenges hospitals face in using protocols and standing orders and offers ideas for improvement:

(1) Protocols or standing orders not supported by evidenced-based medicine. Rice suggests that as part of protocol/standing-order development, hospitals require retention of the supporting evidence-based documentation for the life of the protocol. "That way, if challenged on the merits or rationale of the protocol, staff has documentation," she says. Also, protocols/standing orders should be reviewed annually to ensure that measures are still current to medical advances and acceptable practice.

(2) Lack of physician involvement in decision making and follow-up of protocols/standing-orders activation. The Medicare conditions of participation (CoP) and the recent CMS survey and certification clarification continue to support physician involvement in patient care even when a protocol or standing order is invoked.

"Unfortunately, many facilities and providers take the attitude that once a protocol is in place, everything can go on auto-pilot without any additional physician interface or decision making," Rice says. "This attitude puts nursing and ancillary staff in a position that implicates scope-of-practice concerns — particularly when protocols are based upon diagnosed medical conditions."

She says that the HHS Office of Inspector General (OIG) and CMS have expressed concerns about scope-of-practice issues where nursing and ancillary staff are being asked to perform patient assessments, look at signs and symptoms, and then apply diagnosis-based clinical protocols based on their observations rather than on physician-based observation. In essence, the nursing and ancillary staffers are diagnosing the patient, which is typically beyond the state scope of practice and licensure of a registered nurse or technician.

Physicians Are Still in Charge

Rice says staff members need to keep in mind that CMS still considers all hospital services as "incident to" the physician's services, which implies physician review of the patient. "CMS is quite clear in the hospital CoP and the recent survey and certification clarification that the physician is still responsible for ensuring a contraindication review is performed, documenting an order, rendering their personal authentication to orders and entries, rendering a diagnosis or impression, and providing overall management of the patient's treatment." Rice says facilities should consider developing clear protocol/standing-order policies and procedures that outline (1) when it is and is not appropriate to apply a protocol/standing order, (2) where in the protocol process that physician review of the patient should be performed and documented, and (3) what supporting documentation is needed within the medical record by ancillary staff and the physician to properly document the need for implementation of the protocol.

(3) Preprinted order sets need to have underlying documentation that supports overall medical necessity for the individual interventions/service. CMS stated in the survey and certification letter that the preprinted order sets should be reviewed and approved by the medical staff and include date, time and authentication. One problem often associated with preprinted orders is the lack of physician documentation (e.g., diagnoses, signs and symptoms) within the medical record that supports the underlying necessity for each test or service listed on the protocol, says Rice. CMS has specific national coverage determinations (NCDs) and local coverage determinations (LCDs) that outline specific diagnoses, signs and symptoms, frequency limits and often historic treatments that must be documented by the physician before a specific service is covered. "Often facilities will

generate preprinted order sets with a laundry list of services, but fail to include space for the physician to document the medical necessity for each test and/or fail to instruct the physician to document the medical necessity of the order elsewhere in the medical record," Rice says. "Facilities follow the protocol only to receive a denial for lack of medical necessity due to lack of physician documentation."

She says facilities should review current LCD and NCD documents for each test or service listed on a preprinted order sheet if available. Along with the date, time and signature, preprinted order sheets should include space for the physician to document medical diagnoses, signs and symptoms and/or rationale for implementation of order sets, or it should include instructions on where to document supporting diagnostic information.

Contact Rice at clrice@health-partners.org. ✦

CMS Eases Standing-Order Controls

continued from p. 1

Also, compliance officers worried that the medical necessity of the treatment could be challenged if the physician order wasn't timed to indicate it was signed before treatment began.

So provider groups, including ACEP, the Emergency Nurses Assn. and the American Hospital Assn., met with CMS to explain their concerns, Tomar says. Finally, the revised letter was issued late last month. CMS said it dropped the language about requiring a physician order before treatment from the survey and certification letter and the online edition of the *State Operations Manual Hospital Appendix A*. The letter now just states that "with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of

contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under §482.12(c)."

Medical Necessity Still Issue for Some Hospitals

But medical necessity is an issue still for hospitals in Washington state and Alaska, says Houston attorney Nancy LeGros, who is with the law firm King & Spalding. Noridian, their fiscal intermediary (FI), has a local coverage decision (LCD) that says standing orders don't support medical necessity for individual patients, she notes. The LCD states that "Medicare does not accept such 'standing orders' as supporting medical necessity for the individual patient as is required by law," Noridian says. That means hospitals must have an order in place for that specific patient for that service, LeGros says. Noridian distinguishes between recurring orders (e.g., for wound treatment), which are acceptable because they are written for a specific patient, and standing orders, she says.

It's not completely clear whether other FIs have similar LCDs, but none surfaced during a preliminary search, LeGros adds.

Cheryl Rice, corporate director of corporate responsibility for Catholic Healthcare Partners, "applauds CMS for the clarification" but advises hospitals to take a close look at three aspects of the letter before they expand the use of standing orders or protocols:

(1) *CMS is not eliminating the historic original text of 482.23(c)(2)*, which maintains the need for a physician order for drugs and biologicals administered as part of a protocol with the exception of vaccines for influenza and pneumonia. The patient still must undergo an assessment of contraindications before a drug or biological is administered as part of a protocol.

(2) *CMS is balancing patient safety and benefit against transparency and integrity* for clinical documentation, Rice says. In the letter, CMS says it expects "to see that the standing order had been entered into the order entry section of the patient's medical record as soon as possible after implementation of the order (much like a verbal order would be entered), with authentication by the patient's physician." Like verbal orders received by hospital staff, CMS is still expecting physicians to authenticate in a timely manner (within 48 hours or sooner under state law). "My interpretation of this passage is that CMS is simply changing the timing of the order documentation to make the patient first priority in those situations where there is the potential for patient deterioration," she says.

(3) *CMS indicated that it believes that protocols have bedside benefits* by allowing care to be delivered more quickly as patient conditions warrant, Rice says. "How-

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ever, CMS goes on to state that the significant merit of expeditious delivery of care brought on by the appropriate use of standing orders or protocols can be counteracted by equally significant 'potential harm' to patients if you have staff who are routinely making clinical decisions outside of their scope of practice," Rice says. For example, non-physician staff could invoke protocols without physician review of the patient, she notes (see story, p. 5 for suggestions on improving standing orders and protocols).

Stamps: Payment Ban, Not CoP Ban

The waters remain muddy on physician signature stamps. In the letter, CMS reiterated the payment ban on signature stamps (*RMC 5/19/08, p. 1*), but noted that there is no prohibition in the CoP on the use of signature stamps. So apparently hospitals won't get cited for a deficiency if a surveyor finds a signature stamp, but an auditor will deny payment, according to Transmittal 248 (Change Request 5971).

"CMS appears to allow rubber stamp authentication under the CoP as means of authentication — when done under proper controls (e.g., attestation on file indicating only the physician will apply the signature stamp)," says Rice. However, for all intents and purposes, they should be eighty-sixed from the hospital because, as the CMS letter says, "some payers, including Medicare, may not accept such stamps as sufficient documentation to support a claim for payment."

It's frustrating that the hospital CoP continue to allow physician stamps, says Rice. That contradicts current manual citations and recent manual changes that were implemented "to make a consistent policy of 'no signature stamps' across health care entities," she notes. And CoP for other types of providers (e.g., durable medical equipment, home health, hospice) bar signature stamps.

Rice sent a memo to relevant managers in her health system that signature stamps are no longer acceptable. "Since any and all of the documentation within our hospital medical record is subject to review for medical necessity and coverage consideration by Medicare and other payers, the use of rubber stamp signatures is prohibited for documents maintained within the medical record," she says. "That includes such items as individual entries (e.g., patient assessments, progress notes, discharge summaries), orders, clinical results and interpretative reports."

Because the signature stamp ban has potentially painful recoupment consequences, Rice says hospital staff and physicians should get a better grasp of what documents and entries are considered part of the permanent medical record and support pre- or post-medical reviews, Rice says.

To understand the definition of the permanent medical record, they can consult the health information man-

agement department, medical staff bylaws and hospital policy and procedures.

Medicare additional documentation requests are a good source for understanding what is subject to pre- and post-medical payment reviews (other payers' ADRs will help as well if they follow Medicare's signature stamp ban). "Most of the Medicare fiscal intermediaries, carriers or Medicare administrative contractors have a medical review section on their contractor Web sites that outline the medical review process and ADR request," Rice says. She notes that ADR requests are not limited to documents in the medical record. Sometimes reviews include an itemized list of charges and the patient bill.

Contact Rice at clrice@health-partners.org, Tomar at btomar@acep.org and LeGros at nlegros@kslaw.com. View the letters at www.cms.hhs.gov/SurveyCertificationGenInfo. ✧

CMS Retracts Ban on Standing Orders

This is a quick summary of the classifications from CMS's Oct. 24 survey and certification letter (see story, p. 1).

Memorandum Summary

A. Standing Order Clarification: We are clarifying a portion of S&C-08-12 and S&C-08-18, issued on February 8 and April 11, 2008 respectively, regarding use of standing orders in hospitals. The use of standing orders must be documented as an order in the patient's medical record and signed by the practitioner responsible for the care of the patient, but the timing of such documentation should not be a barrier to effective emergency response, timely and necessary care, or other patient safety advances.

B. Future Directions: We express our interest in working with the professional community to advance safe practices and develop a common understanding of both best practices and important operational definitions as they pertain to standing orders, preprinted order sets, and effective methods to promote evidence-based medicine.

C. Signatures on Order Sets: We are also clarifying the circumstances under which signatures are required on pre-printed order sets.

D. Use of Rubber Stamps: We add an information-only note to the Guidance as an alert to note that some payers, including Medicare, do not accept the use of rubber stamps for payment purposes. The Conditions of Participation (CoPs), however, do not prohibit such use.

NEWS BRIEFS

◆ **The Ferrell-Duncan Clinic, a Springfield, Mo., physicians group, reached a \$1 million civil settlement with the government to resolve allegations that it filed improper Medicare claims stemming from prohibited financial arrangements with Cox Medical Centers**, the U.S. Attorney's Office said Oct. 30. Since 1996, its arrangements with Cox "induced physicians to refer patients to Cox" and violated the Stark law and anti-kickback statute, the feds say in a prepared statement. According to the settlement, the clinic had medical directorship agreements with Cox that were not in writing, paid more than fair-market value and paid based on the volume of referrals. Ferrell-Duncan also had a physician services agreement with Cox that included revenue earned from drugs and durable medical equipment (DME) in the salary calculation, the settlement says. The clinic has entered a corporate integrity agreement with OIG. It denies liability and settled only to avoid the delay, uncertainty, inconvenience and expense of litigation. A spokesperson for Ferrell-Duncan could not be reached for comment. Cox Medical Centers paid \$60 million in August to settle False Claims Act allegations that were based on Stark and anti-kickback violations (*RMC 8/4/08, p. 4*). Visit www.usdoj.gov/usao/mow.

◆ **A lack of criteria on evidence needed to reinstate suppliers whose Medicare privileges have been revoked has led to a number of DME suppliers in south Florida having their privileges revoked, reinstated and then revoked again**, OIG says in an Office of Evaluations and Inspections report (OEI-03-07-00540) posted Oct. 31. Almost half of the 491 DME suppliers whose Medicare privileges were revoked last year as part of a fraud crackdown appealed the revocations and received hearings. Of the 243 that appealed, 91% (222) were reinstated. Two-thirds (148) of the 222 suppliers that had their billing privileges reinstated have subsequently had those privileges revoked again or inactivated. OIG recommends that CMS strengthen its appeal process by developing criteria on evidence to reinstate suppliers. CMS agreed, but asked OIG for specific suggestions. OIG says CMS should "develop a list of evidence that it believes would support a decision to overturn various reasons for revocation and that such evidence should be germane to the reason for revocation." In April 2007, OIG conducted unannounced site visits of more than 1,000 DME suppliers in three Florida counties (*RMC 4/9/07, p. 4*). Since March 2008, a strike force has convicted more than

100 people. Visit AIS's Government Resources at the Compliance Channel at www.AISHealth.com; click on "OIG Office of Evaluations and Inspections."

◆ **A Canadian court has frozen the assets of Peter Rogan, the former owner of Edgewater Medical Center who was ordered to pay \$64 million to the U.S. government**, a court document shows. The Supreme Court of British Columbia issued a worldwide Mareva injunction so that Rogan and his wife cannot dispose of their assets. The injunction was sought by a creditor, but stems from the Medicare fraud case filed in 2002 that contended Rogan was responsible for Edgewater's submission of false Medicare and Medicaid claims. A judge in the U.S. District Court of the Northern District of Illinois ruled from the bench that Rogan should pay \$64.25 million, and an appeals court upheld that decision. Rogan now lives in Canada. The U.S. attorney's office later charged him with perjury and obstruction (*RMC 6/16/08, p. 4*). Visit www.courts.gov.bc.ca and search the judgments for "Rogan."

◆ **Two people involved with separate HIV infusion clinics in Miami were sentenced to prison for their roles in a multimillion dollar scheme that defrauded Medicare**, the U.S. Attorney's Office for the Southern District of Florida said Nov. 4. Miami physician Ronald Harris, M.D., was sentenced to 84 months in prison. He pleaded guilty in August to conspiracy to cause the submission of false claims and to pay health care kickbacks, conspiracy to commit health care fraud and submitting false claims to Medicare. He was the medical director of two Miami-area HIV clinics and told investigators that the facilities were "operated for the sole purpose of committing Medicare fraud," the feds explain. He approved nearly \$26.2 million in fraudulent billings, officials say. Harris was ordered to pay more than \$9.8 million in restitution to the Medicare Trust Fund. Also sentenced was Mariela Rodriguez, who received 70 months in prison after pleading guilty in August to conspiracy to commit health care fraud and making false declarations to a federal grand jury. Rodriguez admitted that her clinic billed for \$11.3 million in unnecessary HIV medication. She also told investigators that the facility she ran was opened so that the owners could defraud Medicare. This case is related to an overall scheme that involved 11 clinics in south Florida and defrauded Medicare of about \$119 million, the feds say (*RMC 9/15/08, p. 8*). Visit www.usdoj.gov/usao/fls.

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