AMERICAN HEALTH CONSULTANTS

COMPLIANCE HOTLINE™

THE NATION'S ESSENTIAL ALERT FOR HEALTH CARE COMPLIANCE OFFICERS

MONDAY
JULY 8, 2002

CMS guidance offers scant clarification on EMTALA regs

Guidance doesn't resolve issue of EMTALA's physician on-call requirements

The Centers for Medicare & Medicaid Services (CMS) last month issued guidance aimed at answering nagging questions about inconsistent regional enforcement of the Emergency Medical Treatment and Active Labor Act's (EMTALA) physician on-call requirements. But health care attorneys say the two memoranda released June 13 could spell trouble for hospitals. "The memoranda contain no 'bright line' guidance, and providers will need to be very cautious in applying the information in the documents," asserts **David Vukadinovich** of Foley and Lardner in Los Angeles.

The two memoranda — one in the form of a Q&A and the other addressing the issue of physicians being on call simultaneously at more than one hospital — closely follow a proposed rule on EMTALA issued by CMS May 9. In that proposal, the agency mainly reiterated its long-standing interpretation regarding on-call coverage requirements.

According to Vukadinovich, neither the June 13 memoranda nor the May 9 proposed rule provides any clear-cut guidance for hospitals. "Although the June 13 memoranda frequently uses appealing words and phrases, such as 'flexibility' and 'all relevant factors,' to describe CMS's policy toward this issue, hospitals and medical staffs should be

*See **On-call requirements**, page 2*

Grassley presses CMS on anti-kickback enforcement

Sen. Charles Grassley (R-IA) is investigating reports from *qui tam* attorneys who claim the U.S. Department of Justice (DOJ) is putting health care fraud prosecutions on the back burner. Grassley, the ranking Republican on the Senate Finance Committee and author of the amendments that essentially resurrected the False Claims Act in the mid-1980s, is specifically targeting the Centers for Medicare & Medicaid Services (CMS) Administrator Tom Scully and the DOJ for lax enforcement of False Claims Act anti-kickback cases.

In a June 25 letter to Health and Human

*See **False Claims Act**, page 4*

Overpayment disclosures still pose risk for hospitals

When it's published, the Centers for Medicare & Medicaid Services' (CMS) final regulation on overpayments likely will be the most significant development yet regarding the controversial practice of disclosing Medicare overpayments. But compliance professionals and health care attorneys should bear in mind that not every question about overpayments is included in the proposed regulation and that the government has not yet decided how an overpayment will be defined, says **Greg Luce**, a partner with Jones Day in Washington, DC. In addition, it's not certain when CMS might publish a final overpayment regulation.

Luce says the bottom line is that the government is committed to voluntary disclosure, and providers have learned a lot about that process. "A voluntary disclosure is one of the most important defensive measures that you can take," he

*See **Overpayment disclosures**, page 3*

On-call requirements

Continued from page 1

cautious in revising their on-call policies," he warns.

Vukadinovich says the new guidance, which does not carry the weight of a regulation, mainly provides broad criteria for hospitals to consider when making these decisions. As a result, he predicts, CMS surveyors likely will maintain broad discretion in issuing deficiencies.

The Q&A states that CMS does not require physicians to provide on-call coverage 24 hours per day, 365 days per year. It explains that if a hospital is unable to provide a certain service to its patients because of a lack of on-call coverage, the hospital may appropriately transfer the patient. But Vukadinovich says the Q&A merely indicates that the degree of on-call coverage should be based on "the capability of the institution and the well-being of the patient."

Gregory Cochran, an attorney with Foley and Lardner's San Francisco office, says the Q&A addresses the closely related issue of how frequently physicians must be on call by explaining that CMS expects hospitals to provide services based on the availability of physicians required to be on call. However, CMS goes on to say that this availability depends on such factors as practice demands, vacations, and days off, as well as on the financial means of the hospital, he adds.

The Q&A also explains that CMS allows flexibility in providing coverage and that such an exemption does not, by itself, violate EMTALA, "as long as the exemption does not affect patient care adversely." However, a surveyor might not approve a senior staff exemption if patient needs were not met, Cochran says. "The Q&A memo does not provide any further guidance about how a hospital's exemption practices might be deemed to affect patient care adversely," he explains.

"One could argue that even one less specialist available to emergency patients has an adverse effect on patient care, especially if the absence of that physician requires the hospital to transfer more patients for stabilizing treatment," Cochran adds. "By stating that exemption policies do not *per se* violate EMTALA, this portion of the Q&A memo is helpful but leaves important unanswered questions."

CMS also addresses the issue of physicians being on call at more than one hospital within a geographical area. Cochran says the agency emphasizes in both memoranda that when an on-call physician is available simultaneously at more than one hospital, each of the hospitals involved must know that, and they must have policies and procedures to follow when an on-call physician is unable to respond because he or she has taken a call at another facility.

CMS simply states that hospitals "must meet the needs of patients who present for emergency care," Cochran notes. In the opinion of a surveyor, that could be a very high standard, he cautions.

In what Vukadinovich calls one of the only "straightforward pronouncements" offered by CMS, the Q&A states group names may not be used to identify an on-call physician. "Hospitals who are relying on groups to provide call coverage will need to consider modifying their approach," he says.

"The Q&A memo expressly disavows the 'Rule of Three,'" Vukadinovich adds. Some hospitals have used the "Rule of Three," which requires full coverage for a specialty whenever there are at least three physicians in that specialty on the staff.

"CMS explains that no specific ratio will be determinative of a hospital's obligation to provide coverage," he says. However, the additional language included in the memo allows considerable discretion for surveyors and does not give hospitals concrete guidance, he says. ■

Compliance Hotline™ is published every two weeks by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. *Compliance Hotline*™ is a trademark of American Health Consultants®.

SUBSCRIBER INFORMATION
Please call **(800) 688-2421** to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call **(404) 262-5536**. Our customer service hours are 8:30 a.m. to 6 p.m. EST.

Overpayment disclosures

Continued from page 1

says. But he warns that it does not prevent any subsequent claim by the government under the False Claims Act or other criminal or civil penalty statutes.

Luce says the key is to make sure the disclosure is done in a way that does not result in a course of action that leads to fines, interest, or other consequences.

He points out that if and when CMS' proposed regulation takes effect, it will not be the first self-disclosure regulation. In addition, many questions, such as when the overpayment took place and whether there is a pending adjustment such as an open cost report, are not addressed by those regulations.

When providers are considering a voluntary disclosure, the starting point is the legal obligations imposed, rather than the latest pronouncement from a carrier or a retrospective review in the form of a fraud alert by the Health and Human Services Office of Inspector General (OIG), Luce asserts.

"What is needed is a disciplined and studied determination of whether the law requires the repayment," Luce explains. "That kind of disciplined study is not found in the latest CMS regulation."

For example, the proposed regulation requires repayment within 60 days but does not say when the determination was made, he says. It also fails to address waiver of liability issues if a reasonable mistake took place that could not have been avoided by a reasonable interpretation or application of the regulations.

Rick Ward, of the law firm Ropes and Gray in Boston, says the problem is that the fundamental distinction between inadvertent errors, negligence, and reckless disregard often are blurred. "Those distinctions determine a number of potential problems for anyone who deals with the Medicare program," he says.

According to Ward, health care attorneys and hospitals must determine if an overpayment is simply an error and whether it even rises to the level of a civil false claim much less a criminal false claim. He points out that while federal statute requires disclosure of any overpayment, failing to disclose is not a crime.

"If you can honestly conclude that it does not obligate you to disclose, that does not mean you are not going to disclose," he asserts.

Ward argues that CMS would not be proposing a regulation requiring repayment if it believed that obligation already existed. That said, Luce and Ward say the risks are too great not to return the overpayment. "There are too many opportunities for people to file *qui tam* cases," Ward says. In addition, the government probably will stumble across the overpayment anyway.

According to Ward, the rules for reimbursement, overpayment, and recoupment often are overlooked by government agencies attempting to ferret out fraud.

"They have blurred the distinction between clear cases of fraud and second guessing what the actual Medicare rules mean," he says. "It is only when you know that you have an overpayment that you should think about disclosing, but it is not required by law."

"The simple reality is you do have money that does not belong to you, and the right thing to do is to give it back, even if there is not a criminal statute that requires you to do so," Ward points out.

The OIG's guidance regarding overpayment can be helpful, Luce says. But it is only guidance, he cautions, not a mandate. Moreover, the OIG's protocol does not apply in all repayment and disclosure circumstances. Hospitals often will have to deal with the Department of Justice and possibly a state Medicaid Fraud Control Unit.

"The key here is to make sure that everything you say is absolutely truthful," Luce says. "By that, I mean each sentence in your letter would on its own stand alone as a truthful statement." Some of the criminal investigations Luce has confronted actually have addressed not the conduct disclosed but the nature of the disclosure, he reports.

Finally, paying back the absolute minimum that might be due usually is not a good idea, Luce says. If providers give a range that includes a high and a low and pay the midrange, that is probably the safest route, he says. ■

False Claims Act

Continued from page 1

Services Secretary Tommy Thompson and the DOJ, Grassley wrote that recent comments by Scully raise concerns about efforts to change or modify enforcement policy that could undermine the False Claims Act. He pointed to a recent Senate hearing in which Scully said DOJ's prosecution decisions regarding a specific False Claims Act case were "beyond comprehension." It was learned later that Scully was referring to the massive HCA settlement, Grassley claimed.

However, several seasoned observers say Grassley's investigation largely is a function of his protective instincts concerning the False Claims Act. "Grassley takes great ownership interest in the False Claims Act," says **Marie Infante**, a health care attorney with Mintz Levin in Washington, DC.

Infante says she sees no relaxation in health care anti-fraud efforts. She says the real question is whether the government is prosecuting less fraud or if there is just less fraud to prosecute.

"I certainly don't see DOJ being at all lackadaisical in its enforcement of the False Claims Act in the context of health care," says **Bill Sarraile**, a health care attorney with Arent Fox in Washington, DC. "From the provider perspective, there are still ongoing concerns about providers being too aggressive."

Sarraile argues that CMS generally has been supportive of DOJ's efforts. For example, he notes that in the final Stark II rules, CMS articulated that a violation of Stark can be a violation of the False Claims Act. "That gave the Department of Justice a better basis to proceed with those kind of cases," he says.

Grassley maintains that his concerns go beyond the case against HCA to general policy matters regarding kickback schemes and the False Claims Act. "My primary concern is that there be no policy changes at DOJ or HHS that could weaken or undermine efforts to police and punish kickbacks under the FCA," he asserts.

Grassley's memo concludes with a number of questions to be investigated:

- "What meetings has Tom Scully had with DOJ officials to discuss Anti-kickback Act or Stark Act cases?"
- "With whom and when did he meet?"
- "Are there memos or background information regarding these discussions?"
- "Why has DOJ requested an inventory of all Kickback and Stark Act civil cases?"
- "In *US ex rel Thompson v. Columbia HCA,* the Department of Justice filed an amicus brief supporting the principle that these violations could and should be subject to False Claims Act prosecutions. Has this position changed at all?"
- "In the Thompson case, HCFA [now CMS] provided a declaration, which said that a hospital's certification that it is not offering kickbacks or other financial inducements is serious and is material to the hospital's continued participation as a Medicare provider. Is this no longer CMS' position?"
- "If it still is CMS' position, does CMS continue to support use of the False Claims Act as a vehicle to prosecute kickback and Stark Act violations?"
- "What, if any, qualms does CMS have about this kind of approach?" ■

HHS approves physician ASC arrangement

The Health and Human Services Office of Inspector General (OIG) approved an arrangement June 14 for a physician to become the sole investor in, and sole owner of, a freestanding, Medicare-certified, single-specialty ambulatory surgical center (ASC). The physician would derive at least one-third of his medical practice income from endoscopic procedures that he performs within his office or at one of the local hospitals.

The advisory opinion is "a very straightforward application of the ASC safe harbor without any complicated wrinkles," says health care attorney **Bill Sarraile** of Arent Fox in Washington, DC. "From that perspective, I think it was a very easy opinion."

According to Sarraile, physicians and hospitals both are very concerned about the potential kickback implications of joint-venture ASC configurations. "What is interesting about this arrangement is that it was a single doctor rather than a joint-venture situation," he says. ■