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TUESDAY
MAY 28, 2002

CMS takes major step to simplify EMTALA regulations

Agency removes off-campus requirements, but many questions remain, experts say

The Centers for Medicare & Medicaid Services (CMS) made good on its promise to simplify the onerous Emergency Medical Treatment and Labor Act (EMTALA) when it released proposed changes to the much-criticized patient anti-dumping regulation earlier this month. But experts see the agency's effort as a step forward rather than a final solution.

"By and large, the proposed changes are an improvement," says **Lowell Brown**, a partner with Foley and Lardner in Los Angeles, who specializes in this area. "I think they are an intelligent effort to introduce some common sense into what had become a pretty nonsensical situation," he says. "The law had become fairly onerous and difficult and imposed a lot of unnecessary burdens."

The proposed changes are included in CMS' hospital inpatient proposed rule, which was published in the *Federal Register* May 9. "There are some significant changes," says CMS spokeswoman **Ellen Griffith**, who adds that the goal of the revisions is to ensure that the intent of EMTALA still is met but with less burden on hospitals and, in many cases, better care for patients.

Brown says the most import change is the elimination of the off-campus requirements. "This is a big victory for hospitals because we had

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HHS posts recoupment and exclusion records

Last year, the federal government raked in more than $1.7 billion in judgments, settlements, and administrative impositions in health care fraud cases and proceedings, the Department of Health and Human Services (HHS) reported April 30. This marks the largest return to the government since the inception of the national Health Care Fraud and Abuse Control Program, which is funded by the Health Insurance Portability and Accountability Act.

According to HHS, the fifth year of the program witnessed a continuation of the collaborative efforts of federal and state enforcement and oversight

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Using a case study to improve HIPAA readiness

Even for hospitals and other providers attempting to be proactive, preparing for compliance with the Health Insurance Portability and Accountability Act (HIPAA) is no easy task. "Unfortunately, the regulations keep changing," says **Ted Sanford**, clinical professor of anesthesiology and compliance officer at the University of Michigan Health System (UMHS) in Ann Arbor.

Sanford says the first step UMHS took was to assess where the organization stood in terms of HIPAA compliance. As a large health system, the university confronted an organizational chart that included student health services, athletic department, staff benefits, health-related schools, and the Office of Vice President for Research, he says. "There is a lot of personal health information in each of these areas. If you are not just an academic medical center, you may have some campus issues."

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EMTALA changes

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requirements that extended EMTALA to off-campus locations rather indiscriminately," he explains. Where physical therapy, radiology clinics, and similar facilities are concerned, EMTALA currently requires hospitals to have complex protocols in place for contacting the base hospital and transferring patients to neighboring facilities. Under the proposed changes, that would no longer be the case.

Steve Lipton, a partner with Davis Wright Tremain in Seattle, says he also is concerned about the extension of EMTALA for emergency patients who are admitted to the hospital in an unstable condition. What hospitals will face on the inpatient side, he says, is a subset of patients who come out of the emergency department in an unstable condition and then will be covered by EMTALA, he explains. That will raise several questions that are not addressed even in the new regulations.

According to Lipton, one important medical staff issue is whether an on-call physician is required to come to the hospital to perform a consultation for treatment. Brown says that getting physicians to participate in on-call panels is probably the most contentious issue regarding emergency departments and EMTALA in the whole country right now. Worse yet, the new regulations may only complicate the issue.

In short, EMTALA still is a very complicated regulation. Lipton says CMS has not done enough to explain how EMTALA applies to psychiatric patients. For example, he says, what happens if a patient is both medically and psychiatrically unstable when admitted to an acute-care hospital and only the medical condition stabilizes?

Hospitals must pay close attention to EMTALA for a variety of different reasons, says Brown. For one thing, the fines associated with EMTALA violations can be substantial. But he says other problems, such as bad public relations and the resources that are drained by having to respond to a Medicare termination action resulting from an EMTALA violation, can loom just as large. "It is very disruptive and very painful and a very rotten experience to go through," he warns.

The good news for hospitals where complex questions remain is that CMS has invited comment on several areas of the proposed regulation. Brown says CMS has signaled it is not exactly sure how to address certain issues and is likely to take the input it receives seriously. ■

HIPAA readiness

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Sanford and his colleagues also uncovered what he says are some "hidden issues" regarding HIPAA. For example, UMHS contracts for equipment, drugs, and other items that come to the medical center. For that reason, Sanford says, the first thing compliance officers should do is assess the overall structure of their organization.

Another top priority for the health system has been bringing physicians, faculty, and executive staff on board with HIPAA, Sanford reports. He says UMHS decided to educate its managers and executives about HIPAA using a case study that demonstrates the law's impact on clinical issues, patient treatment, and billing transactions as well as research and business operations.

According to Sanford, it is difficult to "throw the law at them" without putting it in some context. However, using a case study can help prompt the thinking that must take place within an entity with regard to HIPAA. UMHS started that process with its executive committee.

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In the UMHS case study, a patient is brought by ambulance to the emergency room of "St. Elsewhere" on May 1, 2003, unconscious with a gunshot wound.

"Here are the questions you have to ask yourself," says Sanford. Can the emergency room treat the patient? Does St. Elsewhere need a business associate agreement with the ambulance company? Can St. Elsewhere report the gunshot wound to the public heath service?

If the patient's family and friends make inquiries, what can they be told? What can his employers be told? What can the emergency room ward clerk tell the news media? Can the patient be listed in the hospital directory?

If the patient has surgery and tests positive for HIV, drugs, and alcohol, can the public health department be told about his HIV status? What can his family be told? "These are all questions that you will have to keep in mind," warns Sanford.

Once the patient recovers, a new set of questions arise, he says. What must St. Elsewhere ask and tell the patient? What about consent? What about his HIV status? Must he be told that the gunshot wound was reported to the local health department?

In the case study, the patient reports prior treatment at other facilities and reports that he has a local physician. Was it a psychiatrist? Can St. Elsewhere obtain his protected health information from another facility or from another physician? What can St. Elsewhere tell the other facility about the patient's condition?

In this scenario, the patient also has some personal information on a web-based site that stores important data. Is it personal health information? Does the hospital require a business associate agreement to see the data? Does the site need to give the patient a notice of privacy and obtain his consent if any of that information is going to be shared?

If the patient's neighbor happens to work in pathology and is able to access information from the patient's records, is that permissible? What should St. Elsewhere do once it learns she has accessed his records without anybody's knowledge? "This is going on daily within your institutions," says Sanford. "There is no doubt about it."

A range of research-related questions may arise as well, says Sanford. If a patient has an interesting case, does St. Elsewhere have to obtain consent from the patient in order to present his case at a morbidity and mortality conference? If a researcher wants to include the patient in his or her records, must the patient's permission be obtained? Does the researcher need permission from the institutional review board (IRB)? Can the IRB waive consent?

Sanford says the scariest issue of all involves laptops and Palm Pilots, many of which are used by medical students. "You are going to have to look at your facility's rules about personal health information and how it is transported and removed from the institution," he says. "These are all issues that are going to have to be on your mind when you implement HIPAA at your institution." ■

HHS records

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agencies to prosecute health care fraud. Several former government attorneys say that trend is likely to continue.

"If anything, I think state Medicaid Fraud Control Units [MFCUs] and state attorneys general are being much more proactive now than in the past with respect to health care fraud enforcement," says former HHS' Office of Inspector General (OIG) Counsel **Howard Young**, now an attorney with Arent Fox in Washington, DC.

Young says state MFCUs have received a lot of training in recent years and are taking a page from the federal government's successful efforts in the area of health care fraud. "They realize that states can also be successful, not only on the criminal side but on the civil side, and they are really increasing their pursuit of these types of cases," he says.

One area Young points to is the area of pharmaceuticals, where many states now are getting out in front of the federal government in terms of pricing issues and Medicaid rebate issues. **Margaret Hutchinson**, assistant U.S. attorney in Philadelphia, says hospitals should pay close

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attention to this trend as well, because the issues being investigated in this area increasingly implicate physicians.

Hutchinson says compliance officers should examine the issues addressed in the TAP Pharmaceutical corporate integrity agreement as a road map for what areas the government is investigating. She says one such area is the government's concern that physician judgement is being compromised by the approach pharmaceutical companies are using to get physicians to prescribe a particular drug.

Was it compromised so much that it resulted in a quality-of-care issue? Was another drug potentially a better choice, but this one was chosen because of the inducements? Those are questions compliance officers must ask, she says.

Former Justice Department attorney **John Bentivoglio**, now an attorney with Arnold and Porter in Washington, DC, says the April 30 report does not reveal any new groundbreaking approaches to cracking down on health care fraud but rather a continued focus on federal state cooperation, reliance on *qui tam* complaints as a basis for the largest settlements, and the continued use of both criminal and civil statutes by the Department of Justice.

Combined with prior-year judgments, settlements, and administrative impositions, HHS also collected more than $1.3 billion.

In addition, more than $1 billion of the funds collected and disbursed in 2001 were returned to the Medicare Trust Fund and another $42.8 million was recovered as the federal share of Medicaid restitution.

The agency also reports that federal prosecutors filed 445 criminal indictments in health care fraud cases last year, and that a total of 465 defendants were convicted for health care fraud-related crimes in 2001. There also were 1,746 civil matters pending, and 188 civil cases filed in 2001.

HHS says it excluded 3,756 individuals and entities from participating in the Medicare and Medicaid programs or other federally sponsored health care programs, most as a result of convictions for crimes relating to Medicare or Medicaid, for patient abuse or neglect, or as a result of licensure revocations. "This record number of exclusion actions is the result of successful collaboration with state Medicaid Fraud Control Units and state licensure boards," says HHS. ■

OIG updates guidance on integrity agreements

The Health and Human Services' (HHS) Office of Inspector General (OIG) last week updated its list of Frequently Asked Questions (FAQ) related to corporate integrity agreements (CIA) that are posted on its web site. But the update mainly tweaks the earlier iteration of the FAQs related to audit requirements for CIAs, and it now appears that the OIG's efforts to quell the storm concerning these agreements have largely succeeded.

The health care industry has been very critical of what it viewed as the overly broad nature of CIAs, notes former OIG Counsel **Howard Young**. But since the release of HHS Inspector General Janet Rehnquist's open letter on Nov. 20, 2001, which made changes in CIA audit provisions, Young says he has not heard very much in the way of criticism. Apart from the audit provisions, CIAs now are more narrowly tailored to the alleged misconduct, he adds. "Those were the two big areas where the OIG faced criticism," says Young, "and they have taken steps to address that."

That does not mean the issue of CIAs has gone away entirely. American Hospital Association (AHA) spokeswoman **Alicia Mitchell** says the issue still ranks high on the Chicago-based association's list of issues. In fact, AHA may release its own guidance to hospitals in this area.

Former Justice Department attorney **John Bentivoglio** says the OIG certainly has eased some of burdens for small providers. But for major cases that involve allegations of widespread wrongdoing, CIAs still can be fairly onerous. He says a case in point is the pharmaceutical industry, where recent CIAs for Bayer and TAP Pharmaceuticals were extremely broad. "I don't see any indication they are going to change that," says Bentivoglio. ■