



# practical health law

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Perspectives on health care legal issues

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# There are new CoPs on the beat

## What you need to know about hospital conditions of participation

**O**n Jan. 26, 2007, the Centers for Medicare and Medicaid Services (CMS) added some muscle to the rules on hospital conditions of participation (CoPs). The final regulations apply to history and physical examinations (H&Ps), authentication of verbal orders, securing medications, and post-anesthesia evaluations. CMS's goal? To increase patient safety and reduce treatment errors.

### History and physical exams

The CoP for H&Ps has been revised to allow an H&P to be completed no more than 30 days before admission or within 24 hours after admission. Previously, the rule allowed an H&P to be completed no more than seven days prior to admission or within 48 hours after admission.

The admitting physician may delegate completion of the H&P to another practitioner qualified by state law and hospital policy to complete H&Ps. But both are responsible for ensuring that the exam is completed accurately and documented in the medical record.

If an H&P is completed no more than 30 days before admission, the physician must update the H&P within 24 hours after admission, reflecting the change in the patient's condition necessitating hospitalization. A time and dated entry in the medical record may be entered if the update is dictated — but not entered into the medical record — within 24 hours of admission.

### Authentication of verbal orders

The revised CoP for authentication of verbal orders is designed to decrease medical errors and provide greater flexibility in the authentication process. Under the previous rule, telephone or oral orders had to be authenticated as soon as possible by the prescribing practitioner.

Unless otherwise specified by state law, all verbal orders must be authenticated within 48 hours. Authentication time frames prescribed by state law are, however, subject to certain limits. For



example, CMS has stated that time frames of greater than 30 days aren't acceptable.

The new rule requires that all orders, including verbal ones, be timed. (The previous rule required dated and authenticated but not timed orders.) Additionally, CMS has temporarily broadened the class of individuals that may authenticate an order. For the five-year period beginning Jan. 26, 2007, an order may be authenticated by either the ordering practitioner or another practitioner involved in the patient's care. After the end of this five-year period, all orders must be authenticated by the ordering practitioner.

The intent isn't to *increase* the use of verbal orders. On the contrary, hospitals are expected to *limit* their use of verbal orders to situations where it's impossible or impractical for the practitioner to write the order in the medical record.

### Securing medications

Before the new regulations, all drugs and biologicals were to be kept in a locked storage area, which proved difficult for anesthesiologists and other health care providers who needed to access them quickly.

The new requirements allow storage of drugs and biologicals in a secure area that is "locked when appropriate." The regulatory commentary suggests that an area in which staff are actively providing patient care or preparing to receive patients would generally be considered a "secure area." A medication will be considered secure if unauthorized persons are prevented from obtaining access.

Additionally, self-administration medications may be kept at a patient's bedside. The hospital, however, must ensure that only the patient or authorized individuals have access to them.

CMS expects each hospital to implement policies and procedures that address how medications are stored; patient education on appropriate storage, use and self-administration of medication; and the completion of a competency evaluation of patients' self-administration.

### Postanesthesia evaluations

Under the new CoPs rules, postanesthesia evaluations may now be completed and documented by "any individual qualified

to administer anesthesia." Previously, only the individual who actually administered the anesthesia was permitted to complete the evaluation.

CMS has indicated that this revision offers greater flexibility and reduces regulatory burden for hospitals and anesthesia practitioners while maintaining patient safety.

### CoPs enforce the law

Each of these CoPs reflects Medicare's *minimum* standards. However, hospitals must ensure that their compliance efforts also address state laws and regulations as well as applicable accrediting body guidelines. <

## Investigations result in both civil and criminal charges

**H**ealth care providers and administrators are responsible for ensuring that all patients receive quality care. A lack of such care can lead to both civil and criminal liability. Here are just a few examples of recent investigations that have resulted in charges of civil and criminal violations — against not only the individuals providing the care, but also the administrators who oversee the facility's operations.

### Release of homeless woman

The Los Angeles City Attorney charged Kaiser Foundation with civil and criminal violations for allegedly discharging a homeless woman onto the streets of L.A. The criminal complaint contained two charges: one for false imprisonment, one for dependent adult endangerment.

In California, any person who knows or should reasonably know that a person is an elder or a dependent adult, and who willfully causes or permits that person to be placed in a situation which endangers his or her health, commits false imprisonment. Kaiser has issued an apology since the event and immediately revised its policies to ensure this type of incident doesn't occur again.

The civil charges included unlawful and unfair business practices and failure to comply with state law regarding discharge planning and procedure. The law requires hospitals to provide an appropriate postdischarge plan for each patient.

### Second-degree murder

Two nurses and a physician were arrested last year for allegedly giving morphine and Versed, a drug used to produce drowsiness and relieve anxiety, to patients in the aftermath of Hurricane Katrina. The patients were being cared for at a long-term acute care center leasing space within a New Orleans hospital that was left without power and flooded during the storm. Four of the residents died during the aftermath of the storm.

An investigation by the Louisiana Attorney General's Medicaid Fraud Control Unit resulted in enough information to charge the defendants with four counts of second-degree murder.

### Neglect of a patient

A nurse at a Wisconsin hospital was charged with neglect of a patient, causing great bodily harm. The nurse mistakenly administered to a patient a medication used for epidural nerve

## State Operations Manual changes

Nursing home administrators and directors of nursing must pay careful attention to Medicare regulations. These regulations are designed to provide effective and safe care to all nursing home residents. Facilities that adhere to Medicare guidelines will not only perform well during surveys, but are also more likely to avoid placing residents in dangerous situations.

CMS recently made several revisions to the *State Operations Manual*. One new F-Tag was issued, and several F-Tags were reorganized:

- > Tag F334: Influenza and Pneumococcal Immunizations was issued.
- > Tags F329, F330 and F331 have been consolidated under Tag F329: Unnecessary Drugs.
- > Tags F425, F426 and part of F427 have been consolidated under Tag F425: Pharmacy Services.
- > Tags F428, F429 and F430 have been consolidated under Tag F428: Drug Regimen Review.
- > Tags F431, F432 and the other part of F427 have been consolidated under Tag F431: Pharmacy Service Consultation and Labeling and Storage of Drugs and Biologicals.

The Interpretive Guidelines for each F-Tag have been revised to reflect the changes. Please update your policies and procedures to address these changes, if necessary. Watch for additional changes, such as these, so that you stay in compliance with the regulations and continue to provide safe and effective care.

blocks. The prescribed medication for the patient was penicillin. If convicted, the nurse could face a maximum penalty of six years' imprisonment and/or a fine of \$25,000.

The error occurred despite the hospital's efforts to reduce medication errors by reviewing whether the medication was the prescribed medication, given to the correct patient, at the correct time, in the correct dosage via the correct route. The hospital was cited for six violations of state and federal regulations. It avoided penalties by updating its policies and procedures and educating staff accordingly.

### Cover-up of poor care

The former administrator of a nursing home in Pittsburgh was sentenced to five years in prison for attempting to defraud Medicare and Medicaid

by altering records to cover up poor resident care. She allowed the quality of care to deteriorate to the point that one resident was assaulted by a staff member and suffered a broken hip, and another resident died after wandering out of the building in the middle of the night.

The ex-administrator was also ordered to pay a fine of \$50,000. The nursing home, which is now closed, was ordered to pay a fine of \$490,000.

### Fraud

The former CEO of American Healthcare Management pled guilty to attempting to defraud Medicare and Medicaid by receiving federal funds for nursing home care that wasn't provided.

The CEO intentionally reduced the staffing and care at 11 nursing homes in Missouri. The home's residents suffered as a result: Many were dehydrated and malnourished and had large bedsores. One resident was found walking across a six-lane interchange near the nursing home. Family members of another resident found her covered in ants.

The prosecutor recommended 18 years' imprisonment and a fine of \$29,000 for the CEO's conduct. The total fine for him and American Healthcare Management could be close to \$1 million.

### Fulfilling patient care responsibilities

Administrators and directors of nursing homes and hospitals may be concerned that regulations and conditions of Medicare and Medicaid participation are becoming more and more cumbersome. But the cases referenced here demonstrate that the regulations and rules are in place for one purpose: to ensure high-quality patient care.

To make sure your health care facility continues its good track record of patient care, scrutinize your staff and your policies and procedures. Then make any changes necessary for you to be confident your facility is fulfilling its patient care responsibilities. <

# EHR and e-prescribing systems

## Proper donations are essential

**E**lectronic health record (EHR) and e-prescribing systems are becoming increasingly prevalent and are an important component of the new technology of health care delivery. Many physicians, however, find the technology's prohibitive expense a significant barrier to implementing it. Hospitals are typically better equipped to afford the technology, but donating it to physicians can raise both Stark law and antikickback statute issues.

The Stark law prohibits physician referrals of Medicare and Medicaid patients to an entity with which that physician has a financial relationship, and the antikickback statute prohibits any individual or entity from offering, paying, soliciting or receiving remuneration to induce or reward the referral of business reimbursable by a federal health care program.

The Centers for Medicare and Medicaid Services and the Office of Inspector General have issued rules that create new legal protections for donations of technology for EHR and e-prescribing systems. Both donors and recipients of this technology must ensure that their arrangements are structured in compliance with these rules to avoid Stark law and antikickback statute violations.

### EHR systems

To comply with federal guidelines, make sure all donations are handled as follows:

**Donation of items and services.** A health care entity may donate software necessary for use predominantly in the creation, maintenance or transmission of EHRs when the record is used for diagnosis or treatment. Under the new Stark law rules, donations can be made only to physicians, while the antikickback statute rules allow donations to be made to *any provider* of health care goods or services.

Donated software may have additional functionality, such as billing or scheduling, so long as the predominant use is to create, maintain or transmit an EHR.

The software must include e-prescribing capabilities that are compliant with Medicare Part D and interoperable — that is, it must be able to exchange information with other software systems. A certifying body (recognized by the Secretary of Health and Human Services) must determine whether the software is interoperable. Software training, maintenance, secure messaging and help desk services may be part of the donation. Hardware, storage devices and staff needed to transfer records into the system, however, may not be included in the donation.

**No strings attached to donations.** The donor may not limit the donation's use or attempt to control the physician's business by restricting the system's communication with other entities. Moreover, the donation may not be conditional upon the referral of business by the physician.



The donor also may not base the physician's eligibility for the donation on the volume or value of his or her referrals. There are, however, criteria that may be used to determine eligibility for a donation:

- > Number of prescriptions a physician writes regardless of payor,
- > Size of the physician's practice,
- > Number of hours the physician practices medicine, and
- > Medical staff membership, if applicable.

The donor must allow the EHR system to be used for all patients no matter who pays for those services.

**Share the costs.** For any donation of EHR systems and services, the donor may only provide up to 85% of its total cost. The recipient must pay for the remaining 15%, and the donor may not finance the recipient's portion. Considering the substantial cost of implementing an EHR system, the donor and physician should consider this expense when discussing a donation.

### E-prescribing systems

Although the exception and safe harbor rules for e-prescribing systems are essentially the same as those for EHRs, there are slight differences:

**Donations of items and services.** Donated software must include only those functions that are "necessary and used solely" for e-prescribing.

And, unlike with EHRs, hardware *can* be included as part of the donation.

Moreover, hospitals may donate software and/or hardware to physicians who are members of the hospital's medical staff. Group practices may donate to practice members. And prescription drug plan sponsors and Medicare Advantage organizations may donate to pharmacists or pharmacies participating in that network.

**Cost sharing.** Again, unlike with EHRs, cost sharing isn't necessary for e-prescribing systems; the entire cost may be donated.

### Other things to think about

All donors should realize that they must not know, or deliberately ignore, the fact that the recipient already has equipment or services equivalent to the items or services to be donated.

All donations must be documented in a written agreement that includes the items and services provided, their cost, and the recipient's contribution to the total cost.

### Guidance for implementation

EHR and e-prescribing capabilities will soon become the norm in hospitals and physician practices. The exceptions and safe harbors explained above can help you navigate a safe course when implementing or donating a system. <

# Consent forms: Stay informed on necessary disclosures

**A**s electronic health records emerge and hospital forms are converted into standardized electronic versions, it's important to remember that consent forms are a different breed and shouldn't be standardized with lists of complications, side effects and "check the box" procedures.

### Make it personal

An effective consent form should provide the patient with enough information so that he or she can understand the nature of his or her disease or ailment, the proposed treatment, the expected outcome from the treatment, the risks associated with the treatment, any reasonable alternatives to

the treatment, and the prognosis for the disease without the benefit of the treatment.

For the consent form to be effective, the practitioner must also explain the proposed treatment in layman's terms and disclose any potential effects. Some patients may be unaware of even the simplest adverse reactions. Allow the patient to ask questions, because he or she may not understand medical terminology or the implications posed by the disease.



### Cover everything

There are several means you can use to ensure you're providing sufficient information on the consent form. Think of it like this: What information would a reasonable physician provide? What type of information does an average patient need to make an informed decision? What type of information does a *particular* patient need to make an informed decision?

Or simply check with your state's governing board. Some states have codified the requirements for establishing informed consent.

Medicare- and Medicaid-participating providers should be aware that an effective surgical consent form requires even more detailed information than general consents to treatment require. The recently revised Interpretive Guidelines for executed surgical consent forms require the following:

- > Patient's name and signature, or the patient's legal guardian's, when appropriate,
- > Hospital name,

- > Specific surgical procedures,
- > Risks,
- > Alternative procedures, treatments or therapies,
- > Date and time of consent,
- > Statement that the procedure was explained to the patient or guardian,
- > Signature of the professional person witnessing the consent, and
- > Name and signature of the person explaining the procedure to the patient or guardian.

The Interpretive Guidelines also require the name of the practitioner performing the procedure or important aspects of the procedure, as well as the names of practitioners other than the primary surgeon/practitioner and significant surgical tasks that they will perform, to be included on the consent form. Significant tasks include harvesting grafts, dissecting tissue, removing tissue, implanting devices and altering tissue.

### Don't go with the status quo

Avoid the temptation to use preprinted consent forms that require only signatures by the physician and the patient or guardian. If you must use them, at a minimum, consider leaving blank spaces for the physician to fill in the diagnosis, procedure, adverse effects of the particular procedure and patient condition. Possible side effects of most procedures, such as bleeding, scarring and death, can be listed on the document so long as the physician has ample space to fill in adverse effects given the patient's co-morbidities, risk factors or other unique circumstances.

## *Avoid the temptation to use preprinted consent forms.*

### Full disclosure benefits all

Make sure you use consent forms that cover all the bases, including (at a minimum) the revised Interpretive Guidelines, and also fully cover the consent form with your patients before the procedure. You and your patients will benefit from the full disclosure. <

## A message to our clients and friends:

Hall Render is pleased to provide you with this issue of *Practical Health Law*. This newsletter will be sent to you bi-monthly compliments of our health law attorneys; each issue will also be housed in the **Articles and Newsletters** section of [www.HallRender.com](http://www.HallRender.com).

We understand the value of good information when making sound business decisions. *Practical Health Law* is written by Hall Render's health law attorneys, each with extensive experience handling the legal issues of health care providers. We trust the information in each issue will be a valuable resource. Our attorneys stand ready to respond promptly to your questions and needs; please contact us if there are specific topics you'd like to see addressed.

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