Recent Changes to Medicare Conditions of Participation for Hospitals

Jan 30 2007

Practice Area: Health Law

In late 2006, the Centers for Medicare and Medicaid Services ("CMS") published three final rules revising hospitals' requirements for participating in the Medicare program. The first rule, published November 27, 2006 revises certain requirements in the hospital conditions of participation ("CoPs") relating to completion of history and physical examinations, authentication of verbal orders, securing medications, and completion of post-anesthesia examinations. This rule becomes effective on January 26, 2007. The second rule, also published November 27, 2006, modifies the requirements for notifying hospital inpatients who are Medicare beneficiaries of their discharge appeal rights, and becomes effective July 1, 2007. The third rule, published December 8, 2006, regarding patients' rights, regulates the appropriate use of restraint and seclusion and became effective on January 8, 2007. Several interpretive questions remain, and CMS has indicated that specific guidance will be issued in revised survey guidelines. In the meantime, hospitals should be revising policies and notices where needed, and for restraint and seclusion rules, conducting training, in order to comply with the new rules.

The Wisconsin Office of Quality Assurance has published three charts comparing the new to the previous Medicare CoPs. These charts can be used by hospitals to track the details of the rules.

Completion of the History and Physical Examination
CMS expanded the timeframe in which the History and Physical Examination ("H&P") of a patient must be completed, allowing greater flexibility for hospitals and practitioners. Previously, pre-admission H&Ps had to be completed no more than seven days prior to admission (though CMS had introduced some flexibility in guidance). Under the new rule, the H&P may be completed 30 days prior to an admission.When a pre-admission H&P is used, the rule requires that that patient's medical record be updated with any changes in the patient's condition within 24 hours of admission. If there is no change, the practitioner need only note that he or she reviewed the H&P, examined the patient, and did not detect any change to the patient's condition. When there is no pre-admission H&P, the H&P must be completed no more than 24 hours after an admission. Hospitals must comply with federal, State, and local law in establishing timeframes for a H&P.Wisconsin law notes that a H&P "shall be completed promptly," but does not specify a timeframe for the completion of an initial H&P, so the final rule should be adopted as hospital policy. If the patient is undergoing surgery, the H&P must be in the medical record prior to the procedure, except in an emergency. This is consistent with Wisconsin law.

CMS also increased the number of permissible categories of individuals who may perform a H&P by deleting the requirement that a practitioner performing the H&P be credentialed and privileged by the admitting hospital. The final rule allows a H&P to be performed by "a qualified individual in accordance with State law and hospital policy."

Authentication of Verbal Orders
Consistent with the previous rule, the final rule requires that all orders, including verbal orders, must be legible, complete, dated and authenticated by the practitioner responsible for the patient. The final rule includes an additional requirement that the patient medical record entries be timed and authenticated based on federal and State law. With respect to orders for drugs and biologicals, verbal orders are to be used infrequently. In the absence of a State law specifying the timeframe for authentication of verbal orders, verbal orders must be authenticated within 48 hours.

Under this new requirement, all hospitals must consider State law to determine their obligations. Not all states include a specific number of hours. For example, the Wisconsin Administrative Code, at HFS 124, requires authentication of a verbal order within 24 hours, but the state has used various waivers to expand that requirement. The current waiver requires authentication for drug and biological orders within 48 hours, and other orders may be authenticated "promptly." Since the word "promptly" does not designate a specific timeframe, the practitioner must authenticate all orders within 48 hours of receipt in Wisconsin.

For a five-year period following January 26, 2007, all orders, including verbal orders, must be dated, timed, and authenticated promptly by the "ordering practitioner or another practitioner who is responsible for the care of the patient." This revision allows practitioners to authenticate orders when the ordering physician is unavailable. The rule does not supersede other potentially more restrictive State laws. For example, HFS 124 in Wisconsin requires that verbal and telephone orders shall be authenticated by the "prescribing member of the medical staff." Wisconsin's Bureau of Quality Assurance has interpreted this to mean that hospitals may develop medical staff by-laws policies delineating circumstances under which a physician, who is a member of the medical staff, may sign verbal or telephone orders, with the understanding that the signing physician is then professionally and legally responsible for the treatment and medication prescribed under the order.

Securing Medications
The final rule requires that all drugs and biologicals must be "kept in a secure area and locked when appropriate," with only authorized personnel having access to the locked areas. Also, all controlled substances must be kept locked within a secure area. When individual nonmobile and mobile carts containing drugs and biologicals are not in use, they should be placed in a locked room. The previous rule required that all drugs and biologicals, including non-controlled substances, be kept in a locked storage area. The final rule adds the term "when appropriate," to provide hospitals with greater flexibility to determine which non-controlled drugs and biologicals need to be stored in locked areas as opposed to storage in a secure, monitored area that is only accessible to authorized hospital personnel. Again, State law may be more restrictive. For example, in Wisconsin, HFS 124.15(4)(b)(3) requires that special locked storage spaces be provided to meet the legal requirements for storage of alcohol and prescription drugs, including controlled substances.

Completion of Post-Anesthesia Evaluations
The final rule allows any individual qualified to administer anesthesia to complete and document post-anesthesia evaluations for inpatients within 48 hours after surgery. Under the previous rule, the post-anesthesia evaluation had to be completed by the individual administering anesthesia to the patient. The CoP also allows an individual qualified to administer anesthesia to perform a pre-anesthesia evaluation within 48 hours prior to surgery. Hospitals must consider State law to determine state requirements, and abide by the more restrictive regulations. For example, Wisconsin law requires that a postanesthetic follow up examination be conducted by the person who administered the anesthesia and recorded within 48 hours after surgery, under HFS 124.20(3)(b).

However, a pre-anesthesia evaluation may be completed by a person qualified to administer anesthesia, with findings recorded within 48 hours before surgery.

In Wisconsin, under HFS 124, individuals qualified to administer anesthesia include a qualified anesthesiologist, physician anesthetist, dental anesthetist, podiatrist or a registered nurse anesthetist (under supervision as defined by medical staff policy). The hospital, on recommendation of the medical staff, shall designate persons qualified to administer anesthetics and shall determine what each person is qualified to do.

Notification of Hospital Discharge Appeal Rights
Effective July 1, 2007, CMS will require a two-step discharge notice process for all Medicare hospital inpatients; this includes original Medicare beneficiaries as well as those enrolled in Medicare Advantage and other Medicare health plans. Critical access hospitals must also furnish this notice. A revised version of the Important Message from Medicare ("IM") must be provided to the beneficiary or beneficiary's representative at or near admission, but no later than 2 calendar days following admission. The hospital must deliver the original to the patient and keep a copy. Delivery is valid if patient signs and dates the IM, but if the patient refuses to sign, the hospital may annotate to indicate the refusal, and date the notice. CMS will release a revised IM notice prior to the July 1, 2007 effective date for this rule. A notice was published in the Federal Register on January 5, 2007 requesting comments on the revised version IM (CMS-R-193).

The second step in the process is that hospitals must deliver a copy of the signed and dated notice to the beneficiary prior to discharge but no more than 2 days before discharge. Follow up notice is not required if the initial delivery and signing of the IM took place within 2 days of discharge. "Discharge" is defined as the formal release of a beneficiary or enrollee from the inpatient hospital. A beneficiary requesting a Quality Improvement Organization Review must receive a more detailed notice (also to be provided by CMS). The revised IM will replace the Hospital Issued Notice of Noncoverage (HINN) used at the end of a hospital stay when a patient disputes a discharge decision. This does not include HINN notices used under other circumstances. The Notice of Discharge and Medicare Appeal Rights (NODMAR) will be discontinued.

Restraints and Seclusion
CMS finalized the Patients' Rights CoP, and revised several portions of what had been an interim rule, particularly with respect to restraints and seclusion. The final rule no longer contains separate sections for "acute medical and surgical care" and "behavior management" and the restraints and seclusion aspects of the rule were combined into one standard at § 482.13(e): "All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint and seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time."

The definition of restraint was revised to include, "Any manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his arms, legs, body, or head freely" or a "drug or medication used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition." A restraint does not include devices such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods involving the physical holding of a patient for the purpose of conducting routine exams or tests, protecting the patient from falling out of bed, or permitting the patient to participate in the activities without the risk of physical harm (this does not include a physical escort). Restraint may only be imposed to ensure the immediate physical safety of the patient, staff member, or others. Seclusion is defined as the "involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving." Seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff member, or others.

Restraint or seclusion may only be used when less restrictive interventions have been determined as ineffective to protect the patient or others from harm. The use of restraints or seclusion must be in accordance with a "written modification to the patient's plan of care, and implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy and State law." An order for restraint or seclusion must never be written as a standing order or on an "as needed" basis.

The rule permits seclusion or restraint only "in accordance with the order of a physician or other licensed independent practitioner… authorized by the State and hospital to order restraint or seclusion." If the patient's attending physician did not order the restraint or seclusion, the attending physician must be consulted as soon as possible. Hospitals must refer to their medical staff bylaws and State law to determine practitioner scopes of practice.When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff member, or others, the patient must be seen face-to-face within one hour after the initiation of the intervention by a physician, or other licensed independent practitioner, or a Registered Nurse ("RN") or Physician Assistant ("PA") trained in accordance with specific criteria in the new rule. If the face-to-face evaluation is conducted by a RN or PA, the RN or PA must consult the attending physician or licensed independent practitioner as soon as possible after the evaluation. State law may be more restrictive. The final rule also states, "After 24 hours…a physician or other licensed independent practitioner who is responsible for the care of the patient…and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient." At that time, an order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed in accordance with certain time limits for certain age groups. The order may only be renewed for up to 24 hours, as authorized by hospital policy, unless superseded by more restrictive State law.

The restrained or secluded patient must be monitored by a physician, other licensed independent practitioner or staff that has completed specified training criteria. The final rule adds that monitoring must occur face-to-face by trained staff or by using both video and audio equipment (equipment must be in close proximity to the patient), when there is simultaneous use of restraint and seclusion. Continual monitoring cannot happen solely from outside the room, and staff must enter the room periodically to monitor the patient. State laws may contain additional requirements.

The final rule outlines the documentation that must be included in the patient's medical record at § 482.13(e)(16).When restraint or seclusion is used, there must be documentation in the patient's medical record of the one-hour face-to-face evaluation, alternatives, or less restrictive interventions imposed, the patient's condition or symptoms warranting restraints/seclusion, the patient's response to the interventions used, and the rationale for continued use of the intervention. The documentation must also show the basis for any simultaneous use of seclusion and restraint.

Staff training requirements have been expanded from the previous rule to include detailed specifications. Under the revised rule at § 482.13(f), "The patient has the right to safe implementation of restraint or seclusion by trained staff." The revised training requirements address the following broad areas: training intervals, training contents, trainer requirements, and trainer documentation. Before performing any of the activities in § 482.13, staff must be trained and able to demonstrate competency in application of restraints, implementation of seclusion, monitoring, assessment, and providing care to a patient in seclusion or restraint. The training must also occur on a periodic basis consistent with hospital policy, and hospitals must document in the staff personnel records that the training and demonstration of competency were successfully completed. Section 482.13(f)(2), details the minimum content of training programs.

Under the revised CoP, hospital policies should:

- Establish appropriate restraint and seclusion techniques, in accordance with State Law.
- Specify which practitioners are authorized to order seclusion or restraint, in accordance with State Law.
- Determine restraint order renewal time periods for non-violent and non-self-destructive patients.
- Determine intervals, special requirements, and authorized practitioners (in accordance with State Law) to monitor the patient's condition.
- Specify how face-to-face monitoring will be documented in the patient's record.
- Establish training requirements for staff members, including intervals for periodic training updates.

The final rule also modified death reporting requirements. The revised rule states, "Hospitals must report deaths associated with the use of seclusion or restraint." A hospital must report to CMS each death that occurs while a patient is in restraint or seclusion at the hospital, or that occurs within 24 hours after the patient has been removed from restraint or seclusion, and each death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that the use of restraints or seclusion contributed directly or indirectly to a patient's death. A hospital's failure to report a death to CMS, as required by the final rule, could subject the hospital to termination of its provider agreement. Hospitals must review State law to determine any additional reporting requirements. In Wisconsin, hospitals must report any such death to the CMS Regional Office by telephone no later than the close of business the next business day following knowledge of the patient's death. This is in addition to the report required by State statute mandating that hospitals report to the Office of Quality Assurance (OQA) within 24 hours when there is reasonable cause to believe that the death was related to the use of physical restraint or a psychotropic medication, or suicide in a psychiatric unit of a hospital.

The final rule requires that the patient be notified of the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Hospitals may bundle this notification with existing required notices, or notify the patient by posting forms in the admissions office/emergency room.
