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CMS CHANGES REQUIREMENTS REGARDING HOSPITALS' USE OF RESTRAINTS AND SECLUSION

On December 8, 2006, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule that updates the hospital Condition of Participation on Patients' Rights and contains standards that ensure minimum protections of a patient's physical and emotional health and safety (the "Final Rule"). Prior to the Final Rule, there were two separate standards regarding the restraint and seclusion of patients receiving acute medical and surgical care and of patients requiring behavior management. The Final Rule not only combines the two restraint standards into one standard that applies to *all* patients regardless of the purpose of the restraint, but also expands the definitions of "restraint" and "seclusion," adds new requirements regarding patient evaluations and documentation of the restraint and/or seclusion and expands the requirements for staff training and the reporting of deaths of patients who are or have been restrained or secluded. The Final Rule became effective January 8, 2007 and is available by clicking here.

Definition of Restraint and Seclusion

Under the Final Rule, "restraint" is any manual method, physical, or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication that is used 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. The Final Rule clarifies that a "restraint" does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm.

"Seclusion" is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. The Final Rule clarifies that "seclusion" may only be used for the management of self-destructive behavior.

Patient Evaluation

Prior to the Final Rule, a physician or licensed independent practitioner was required to see the patient and evaluate the need for restraint or seclusion within one hour after the initiation of the intervention. The Final Rule specifies that a physician, other licensed independent practitioner, or a registered nurse or physician assistant who has been trained to evaluate the need for restraint or seclusion, must perform a face-to-face evaluation within one hour after the restraint or seclusion was initiated for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. This standard is less restrictive than the prior CMS rule in that it allows registered nurses and physician assistants to perform the evaluation, but is more restrictive than the Joint Commission's standard which requires a licensed independent practitioner or his or her designee to evaluate the patient in person within four hours of the initiation of restraint or seclusion for patients who are eighteen or older and within two hours for children and youth who are seventeen and younger.

The Final Rule further provides that during the face-to-face evaluation, the practitioner should evaluate the patient's immediate situation, reaction to the intervention, medical and behavioral condition and need to continue or terminate the restraint or seclusion. If the evaluation is conducted by a trained registered nurse or physician assistant, the practitioner performing the evaluation must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as soon as possible after the completion of the face-to-face evaluation.

Documentation

CMS previously mandated no specific documentation requirements with respect to the use of restraint or seclusion. The Final Rule provides that when restraint or seclusion is used, there must be documentation in the patient's medical record of (i) the face-to-face medical and behavioral evaluation within one hour of initiation of restraint or seclusion, if restraint or seclusion is used to manage violent or self-destructive behavior; (ii) a description of the patient's behavior and the intervention used; (iii) alternatives or other less restrictive interventions attempted, as applicable; (iv) the patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and (v) the patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

Staff Training Requirements

Prior to the Final Rule, CMS required all staff who had direct patient contact to receive ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms and situations that traditionally had been treated through the use of restraint or seclusion.

The Final Rule provides that prior to initiating the use of restraint or seclusion, staff must be trained and be able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion. Specifically, based on the needs of the patient population, the staff should have knowledge of: (i) techniques that identify staff and patient behaviors, events and environmental factors that may trigger circumstances that require the use of a restraint or seclusion; (ii) the use of nonphysical intervention skills; (iii) the use of the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition; (iv) the safe application and use of all types of restraint or seclusion used in the hospital, including training on how to recognize and respond to signs of physical and psychological distress; (v) clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary; (vi) monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs and any special requirements specified by hospital policy associated with the required face-to-face evaluation; and (vii) the use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

The Final Rule also requires that individuals providing staff training be educated, trained and have experience in techniques used to address patient behaviors. As such, hospitals must document in the trainers' personnel records that the training and demonstration of competency were successfully completed.

Death Reporting Requirements

Hospitals were previously required to report to CMS any death that occurred while a patient was restrained or in seclusion, or where it was reasonable to assume that the patient's death was a result of restraint or seclusion. Under the Final Rule, hospitals are now required to report to CMS: (i) any death that occurs while a patient is in restraint or seclusion; (ii) any death that occurs within twenty-four hours after the patient has been removed from restraint or seclusion; or (iii) any death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or deaths related to chest compression, restriction of breathing, or asphyxiation.

Any death that is reportable to CMS must be reported by telephone no later than the close of business on the next business day following knowledge of the patient's death, and the

date and time that the death was reported to CMS must be documented in the patient's medical record.

The Final Rule is intended to promote protection of patients' physical and emotional health and safety. State laws may contain additional or different requirements regarding seclusion and restraints. In light of the substantive changes that have been made to requirements for the use of restraint and seclusion, health care facilities and providers must revise their policies and procedures accordingly. If you need assistance interpreting the Final Rule or revising policies and procedures in accordance with the Final Rule, please contact a member of Robinson & Cole's Health Law Group.

CMS RELEASES FOUR REVISED HOSPITAL CONDITIONS OF PARTICIPATION

On November 27, 2006, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule that revises four of the current conditions of participation ("CoP") that hospitals must satisfy to participate in the Medicare and Medicaid programs ("Final Rule"). Specifically, revisions were made to the CoPs for the history and physical ("H&P") examination procedures, authentication of verbal orders, storage of medications and completion of post-anesthesia evaluations. The Final Rule became effective January 27, 2007 and is available by clicking here.

History and Physical Examination

Previously, an H&P examination had to be performed on each patient no more than seven (7) days before or forty-eight (48) hours after an admission by a doctor of medicine or osteopathy, or for patients admitted for oromaxillofacial surgery, by an oromaxillofacial surgeon granted privileges by the medical staff in accordance with state law. Under the Final Rule, each patient must receive an H&P examination no more than thirty (30) days before or twenty-four (24) hours after admission by a physician, oromaxillofacial surgeon, or other qualified practitioner who has been granted these privileges in accordance with hospital policy and state law.

If it has been more than thirty (30) days since the patient's last H&P examination, a new H&P examination must be performed. If the H&P examination was completed within thirty (30) days of admission, a hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is completed within twenty-four (24) hours after admission, but prior to any surgical or other procedure requiring an H&P examination.

Authentication of Verbal Orders

Prior to the Final Rule, only the prescribing practitioner was allowed to authenticate a verbal order after the order was given. For the five-year period following the Final Rule's effective date, the category of practitioners who may authenticate verbal orders is broadened to include any practitioner responsible for the care of the patient and authorized to write orders according to hospital policy and state law. All verbal orders must be authenticated within forty-eight (48) hours after the order is given.

Storage of Medications

The previous regulation required that all drugs and biologicals be kept in a locked storage area. The Final Rule loosens the regulation by allowing non-controlled substances to be stored in an unlocked secure area, but specifies that only authorized personnel may have access to the locked areas.

Post-Anesthesia Evaluation

Previously, only the practitioner who administered the anesthesia during a procedure could perform the post-anesthesia evaluation of a patient. In order to give hospitals and anesthesiology departments more flexibility in ensuring timeliness of post-operative anesthesia care, the Final Rule provides that a post-anesthesia evaluation can be performed by any practitioner qualified to administer anesthesia, regardless of his or her involvement in the procedure, within forty-eight (48) hours after the procedure.

The changes specified in the Final Rule are intended to reflect current medical practice and reduce the regulatory burden on hospitals. If you need assistance interpreting the Final Rule or revising policies and procedures in accordance with the Final Rule, please contact a member of Robinson & Cole's Health Law Group.

CMS CHANGES HOSPITAL OBLIGATIONS REGARDING DISCHARGE RIGHTS

On November 27, 2006, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule setting forth new requirements for a hospital's notice to inpatient Medicare beneficiaries of their discharge rights ("Final Rule"). Currently, hospitals are required to provide Medicare beneficiaries (i) the Important Message from Medicare ("IM"), which explains hospital discharge rights and discharge appeal rights and (ii) a separate Hospital-Issued Notice of Non-coverage ("HINN") to any Medicare beneficiary expressing dissatisfaction with an impending hospital discharge. Under the Final Rule, the IM and HINN are combined into one notice ("Revised IM") and hospitals are required to follow specific timelines when a beneficiary disagrees with the discharge decision and requests an expedited determination from the applicable quality improvement organization ("QIO"). The Final Rule takes effect July 1, 2007 and is available by clicking here.

Discharge Notification

The current IM only informs inpatient Medicare beneficiaries of their discharge rights as a hospital patient. Under the Final Rule, the Revised IM has been expanded to include: (i) a beneficiary's rights as a hospital inpatient, including the right to benefits for inpatient services and for post-hospital services; (ii) a beneficiary's right to request an expedited determination of the discharge decision including a description of the process and the availability of other appeals processes if the beneficiary fails to meet the deadline for an expedited determination; (iii) the circumstances under which the beneficiary will be liable for charges for continued stay in the hospital; (iv) a beneficiary's right to receive additional detailed information regarding the procedures a QIO must follow pursuant to a

beneficiary's request for an expedited determination; and (v) any additional information required by CMS.

The Final Rule further specifies that hospitals will have to provide, explain and have the beneficiary (or his or her health care representative) sign the Revised IM within two calendar days of admission and provide a copy of the signed Revised IM to the beneficiary no later than two calendar days prior to discharge, if two or more days have passed since it was signed. The Revised IM must be provided to Medicare*and* Medicare Advantage beneficiaries.

If a beneficiary refuses to sign the Revised IM, the date of refusal will be treated as the day the beneficiary was notified of his or her rights.

Request for Review

Under existing law, beneficiaries who disagree with the discharge decision have the right to an expedited determination by the applicable QIO. The expedited appeal process currently requires that a beneficiary submit the request, in writing or by telephone, by noon of the first working day after he or she receives written notice that the hospital has determined that the hospital stay is no longer necessary.

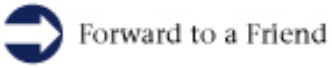
Under the Final Rule, a beneficiary can make the request for an expedited review up until the day of discharge. A beneficiary who fails to make a timely request for an expedited determination and remains in the hospital after the discharge date may be held responsible for charges incurred after the discharge date. In addition, when a QIO notifies a hospital that a beneficiary has requested an expedited determination, the hospital must deliver a detailed notice to the beneficiary as soon as possible, but not later than noon of the day after the QIO's notification. The detailed notice must include: (i) a detailed explanation of why the services are either no longer reasonable and necessary or are otherwise no longer covered; (ii) a description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including information about how the beneficiary may obtain a copy of the Medicare rule, instruction, or policy; (iii) facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case; and (iv) any other information required by CMS.

Upon notification by the QIO of the request for an expedited determination, the hospital must also supply all information necessary for the QIO to make its expedited determination, no later than noon of the day after the QIO notifies the hospital of the request. The hospital must also provide the beneficiary, upon request, with a copy of, or access to, any documentation that it sends to the QIO, including written records of any information provided by telephone, no later than the close of business of the first day after the material is requested by the beneficiary. The hospital is allowed to charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary.

The Final Rule expands a hospital's obligations to notify inpatients of their discharge

rights. If you need assistance interpreting the Final Rule or revising policies and procedures in accordance with the Final Rule, please contact a member of Robinson & Cole's Health Law Group.

Robinson & Cole's Health Law Group includes:



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