

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

CMS Issues Two Final Rules Revising Hospital Conditions of Participation

January 10, 2007

On Monday, November 27, 2006,¹ and on Friday, December 8, 2006,² the Centers for Medicare & Medicaid Services (CMS) issued final regulations amending several Conditions of Participation (CoPs) that apply to hospitals participating in the Medicare program. The areas of patient care affected by the changes to these CoPs are: (1) history and physical (H&P) examinations (addressed in the Medical Staff and Medical Record Services CoPs); (2) verbal orders and medical record entries (addressed in the Nursing Services and Medical Record Services CoPs); (3) security of medications (addressed in the Pharmaceutical Services CoP); (4) post-anesthesia evaluations (addressed in the Anesthesia Services CoP); and (5) restraints and seclusion (addressed in the Patient Rights CoP).

Selected highlights of these final rules are discussed in this Update. The revisions affecting the first four patient care areas identified above are effective January 26, 2007. The revisions affecting restraints and seclusion show an effective date in the Federal Register of January 8, 2007, despite the fact that CMS' press release regarding this latter rule states that the effective date is February 6, 2007.

H&P Examinations (Medical Staff and Medical Record Services CoPs): The currently effective CoP requires that H&Ps must be performed no more than seven days prior to admission or 48 hours after admission. The current CoP also limits who can perform H&Ps to doctors of medicine and osteopathy or, for patients admitted only for oromaxillofacial surgery, to maxillofacial surgeons granted privileges to perform H&Ps in accordance with state law.

The revised CoP changes the time requirements for H&Ps as well as the categories of individuals who can conduct an H&P. Under the final regulation, H&Ps must be completed within 30 days before hospitalization or within 24 hours after admission. If the H&P is completed before admission, a hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is completed and documented in the patient's medical record within 24 hours after admission.

¹ 71 Fed. Reg. 68672 et seq. (November 27, 2006).

² 71 Fed. Reg. 71378 et seq. (December 8, 2006).

In addition, H&Ps may be performed by physicians, oromaxillofacial surgeons, **or other qualified individuals** in accordance with state law and hospital policy. Moreover, the qualified practitioner performing an H&P prior to admission need not be credentialed and privileged by the admitting hospital. This revision will allow a patient to submit an H&P conducted prior to hospitalization by such patient's primary care provider, even if the provider is not credentialed and privileged by the admitting hospital. However, CMS makes clear in its commentary accompanying the new rule that, in such event, the required update to the H&P upon the patient's admission would be performed by a qualified practitioner who has been granted these privileges by the admitting hospital.

Verbal Orders and Medical Record Entries (Nursing Services and Medical Record Services CoPs): The final rule, while reinforcing that verbal orders must be used infrequently, broadens the categories of practitioners who can authenticate verbal orders. Under the final rule, all orders, including verbal orders, must be dated, timed, and authenticated promptly either by the prescribing practitioner (as in the current rule) or, for a period of five years following the effective date of the final rule, by another practitioner who is responsible for the care of the patient as specified under 42 CFR 482.12 (the Governing Body CoP). The time frame for authentication of verbal orders is 48 hours, unless state law designates a different specific time frame (under the current rule, the time frame for authentication is simply "as soon as possible").

The revised CoP also reinforces current requirements that verbal orders should be accepted only by persons authorized by hospital policy and procedures that are consistent with both state and federal law. Finally, the revised rule adds the requirement that all medical record entries (including all verbal orders and other orders) be "timed" in addition to being complete, legible, dated, and authenticated. CMS notes that many hospitals already require timing of medical record entries.

Security of Medications (Pharmaceutical Services CoP): The current CoP states that all drugs and biologicals must be kept in a locked storage area. The revised CoP relaxes this requirement somewhat (except with respect to Schedule II, III, IV, and V drugs), stating that all drugs and biologicals must be kept in a secure area and locked "when appropriate." CMS notes that a "secure area" is one where hospital staff are actively providing patient care or preparing to receive patients. Further, these operational areas must limit entry and exit to appropriate staff, patients, and visitors. CMS emphasizes that secure areas should not be readily accessible to unauthorized personnel.

The revised CoP continues to require that Schedule II, III, IV, and V drugs be kept locked and also requires that the locked area be a "secure" area. Under the revised CoP, only authorized personnel may have access to the locked areas. CMS declined to define "authorized personnel" because the term should be addressed in hospital policies and procedures. Consequently, CMS notes that hospitals may choose whether to include ancillary support personnel such as housekeeping staff and security personnel in the facility's definition of "authorized personnel."

Post-anesthesia Evaluations (Anesthesia Services CoP): The current CoP requires the individual who administers anesthesia to an inpatient to perform and document a post-anesthesia follow-up report. The revised CoP allows any individual qualified to administer anesthesia to perform and document the post-anesthesia evaluation within 48 hours after surgery. CMS revised this CoP in order to reduce the burden on hospitals and anesthesia professionals while maintaining patient safety.

Restraints and Seclusion (Patient Rights CoP): In a separate final rule, CMS has revised in several respects the standards regarding restraints and seclusion. First, due to confusion between the

application of the former standard entitled “Restraint for acute medical and surgical care” and the former standard entitled “Restraint and seclusion for behavior management,” CMS has now combined these two standards into one standard, applicable to all instances of restraint and seclusion regardless of the patient’s location, entitled “Restraint or seclusion.”

Second, the final regulation revises the language regarding who can order restraints or seclusion. Previously, the language required that the order be made by any physician or other licensed independent practitioner (LIP) “permitted by the State and hospital to order seclusion and restraint.” The new language requires not only that the physician or other LIP be authorized to order restraints and seclusion under hospital policy and state law, but also that such physician or other practitioner “be responsible for the care of the patient as specified under § 482.12(c).”

Since the referenced section requires every Medicare patient to be under the care of a doctor of medicine or osteopathy, or, under specified limited circumstances, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, a chiropractor, or a clinical psychologist, it is somewhat unclear as to whether other categories of LIPs are now foreclosed from ordering restraints and seclusion, even if they would otherwise be permitted to do so under state law and hospital policy. Clarification of this ambiguity may be necessary from CMS since CMS states in the final rule: “It is not our intent to interfere with State laws governing the role of physician assistants, advanced practice registered nurses, or other groups that in some States have been authorized to order restraint and seclusion” Note that, in any event, Section 482.12(c)(1)(i) preserves the ability of a doctor of medicine or osteopathy to delegate tasks to other qualified health personnel to the extent recognized under state law or a state’s regulatory mechanism. Presumably, then, any LIP who has been delegated patient care tasks by the physician in charge and who is otherwise authorized under state law would be able to order restraints and seclusion for such patient.

Third, the final regulation expands the category of practitioners who may conduct patient evaluations within one hour of the initiation of a restraint or seclusion. Currently, CMS requires that a patient be evaluated face-to-face by a “physician or other licensed independent practitioner.” The revised CoP expands that list to include a trained registered nurse (RN) or physician assistant (PA) trained in accordance with the requirements of the rule. The final rule does stipulate, however, that when an RN or PA performs the one-hour-rule evaluation, the RN or PA must consult the attending physician or other LIP treating the patient as soon as possible after the evaluation.

The final regulation also imposes a requirement for documentation of certain elements in the patient’s medical record upon any event of restraint or seclusion, which CMS believes to be “usual and customary recordkeeping practice,” and expands and strengthens the staff training requirements. The revised CoP also clarifies when a healthcare facility must report the death of a patient associated with the use of restraints or seclusion. Each death that occurs during or within 24 hours of a patient’s removal from a period of restraint or seclusion must be reported to CMS. Additionally, hospitals must report to CMS known deaths that occur within one week after restraint or seclusion where it is “reasonable to assume,” as defined in the final rule, that use of restraint or placement in seclusion contributed directly or indirectly to the patient’s death. Hospitals must make such reports by telephone no later than the close of business the next business day following knowledge of the patient’s death.

If you would like assistance in developing policies to meet any of the above guidelines, or if you have any questions about this *Health Law Update*, please contact one of the Bass, Berry & Sims attorneys in our Healthcare Practice Area, listed at the end of this Update.

Bass, Berry & Sims Healthcare Attorneys

H. Stanford Adams, Jr.
(615) 742-7775
sadams@bassberry.com

Renard François
(615) 742-7792
rfrancois@bassberry.com

Pooneh Ghiassi
(615) 742-7782
pghiassi@bassberry.com

J. James Jenkins, Jr.
(615) 742-6236
jjenkins@bassberry.com

Leslie Maclellan
(615) 742-7818
lmaclellan@bassberry.com

Shannon Pinkston
(615) 742-7727
spinkston@bassberry.com

Catherine J.B. Sloan
(615) 742-7789
csloan@bassberry.com

Leigh Walton, Chair
(615) 742-6201
lwalton@bassberry.com

H. Lee Barfield, II
(615) 742-6202
lbarfield@bassberry.com

Valere B. Fulwider
(615) 742-7742
vfulwider@bassberry.com

Anna Grizzle
(615) 742-7732
agrizzle@bassberry.com

Nancy S. Jones
(615) 742-6239
njones@bassberry.com

Claire F. Miley
(615) 742-7847
cmiley@bassberry.com

Cynthia Y. Reisz
(615) 742-6283
creisz@bassberry.com

Danielle M. Sloane
(615) 742-7763
dsloane@bassberry.com

Elizabeth S. Warren
(615) 742-7719
ewarren@bassberry.com

Philip F. Berg
(615) 742-7908
pberg@bassberry.com

Clevonne M. Gaillard
(615) 742-7769
vgaillard@bassberry.com

Angela Humphreys
(615) 742-7852
ahumphreys@bassberry.com

David King
(615) 742-7890
dking@bassberry.com

T. Scott Noonan, Co-Chair
(615) 742-6273
snoonan@bassberry.com

Scott B. Shanker
(901) 543-5932
sshanker@bassberry.com

Krista Thornton
(615) 742-7734
kthornton@bassberry.com

The materials contained herein have been abridged from the statutory sources and should not be construed or relied upon for legal advice. Readers are urged to consult legal counsel concerning particular situations and specific legal questions.

To ensure compliance with requirements imposed by the IRS, we inform you that this message is not intended to be used, and cannot be used, by the addressee or any other person for the purpose of avoiding penalties that may be imposed under the Internal Revenue Code.

NASHVILLE Downtown
AmSouth Center
315 Deaderick St. · Ste. 2700
Nashville, TN 37238-3001
(615) 742-6200

KNOXVILLE
1700 Riverview Tower
900 S. Gay St.
Knoxville, TN 37902
(865) 521-6200

MEMPHIS
The Tower at Peabody Place
100 Peabody Place · Ste. 900
Memphis, TN 38103-3672
(901) 543-5900

NASHVILLE Music Row
29 Music Square East
Nashville, TN 37203-4322
(615) 255-6161