Analysis of November and December 2006 Final Rule Changes to the Medicare and Medicaid Programs Hospital Conditions of Participation

December 2006

The Medicare and Medicaid Programs Hospital Conditions of Participation (COP) were first issued in June 1986. Since then there have been notices of proposed rule making and several minor changes to very specific sections of the COP, most taking place in the 1990s. The COP resides in 42CFR Part 482, and can be found at the Centers for Medicare and Medicaid Services (CMS) Web site at www.cms.hhs.gov/CFCsAndCoPs/06_Hospitals.asp. The changes contained in these two final regulations will impact health information management (HIM) professionals in hospital HIM departments, quality assurance, and compliances. The regulation changes also directly impact physicians, nurses, pharmacists, and other hospital professionals.

2006 Changes

CMS finalized changes to four of the hospital COP requirements in the November 27, 2006 *Federal Register*.[1] These changes affect:

- The completion of the history and physical examination in the medical staff and the medical records services COPs;
- Authentication of verbal orders in the nursing service and the medical record services COPs;
- Securing medications in the pharmaceutical services COP; and
- Completion of the postanesthesia evaluation in the anesthesia services CoP (with assumed documentation in the medical record).

These November 27, 2006 changes become effective on January 26, 2007.

CMS finalized changes to the COP Patients' Rights standards that are contained in the December 8, 2006 *Federal Register*.[2] These changes affect hospital COP:

- Notice of rights;
- Exercise of rights;
- Privacy and safety;
- Confidentiality of patient records;
- Restraint for acute medical and surgical care; and
- Seclusion and restraints for behavior management.

These December 8, 2006 changes become effective on January 8, 2007.

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[1] November 27, 2006 *Federal Register* (Vol. 71, No. 227) can be found under CMS at www.access.gpo.gov/su_docs/fedreg/a061127c.html.

[2] December 8, 2006 *Federal Register* (Vol. 71, No. 236) can be found under CMS at www.access.gpo.gov/su_docs/fedreg/a061208c.html

Order of Analysis

Medicare and Medicaid Hospital Conditions of Participation Final Rule Requirements Published November 27, 2006, and Effective January 26, 2007

The first set of COP changes were published in the November 27, 2006 *Federal Register* beginning at page 71FR68694. While several issues are covered in these changes, it is important to note that CMS continually states that these changes are made to improve the quality and safety of patient care. It can be inferred from CMS' comments that it regards proper and timely documentation and authentication of orders as the key reasons behind most of these changes. Specifically, these COPs covered:

Medical staff

- The medical staff must adopt and enforce bylaws to carry out its responsibilities including:
    - The medical history and physical examination must be completed no more than 30 days before or 24 hours after admission for each patient by a physician, an oromaxillofacial surgeon, or other qualified individual in accordance with state law and hospital policy.
    - The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or before surgery.
    - The hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is complete, and this updated examination must be completed and documented in the patient's medical record within 24 hours after admission.

Nursing Services

- The section addressing the preparation and administration of drugs and biologicals is updated to reflect the section changes on verbal orders.
- A second section notes: "with the exception of influenza and pneumoccal polysccharids vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with state law, and who is responsible for the care of the patient as specified" (under other COP sections).
- If verbal orders are used they are to be used infrequently.
- When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with federal and state law.

Medical Record Services

- The medical record must contain information to justify the admission or continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

- All patient medical record entries must be legible, completed, dated, **timed,** and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.
    - All orders, including verbal orders must be dated, timed, and authenticated promptly by the ordering practitioner, except as noted (immediately below).
    - For the five year period following January 26, 2007, all orders, including verbal orders, must be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified and authorized to write orders by hospital policy in accordance with state law.
    - All verbal orders must be authenticated based upon federal and state law. If there is no state law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours.
- As appropriate, all records must document the following evidence of:
    - A medical history and physical examination completed no more than 30 days before or 24 hours after admission. The medical history and physical examination must be placed in the patient medical record within 24 hours after admission.
    - An updated medical record entry documenting an examination for any changes in the patient's condition when the medical history and physical examination are completed within 30 days before admission. This updated examination must be completed and documented in the patient's medical record within 24 hours after admission.

Pharmaceutical Services

- This section covers the control of drugs and biologicals and requirements for safety and access. There are no specific references to patient records, but this section will affect compliance officer reviews.

Anesthesia Service

- This section covers the delivery of anesthesia services and specifically addresses delineation of preanesthesia and postanesthesia responsibilities.
- With respect to inpatients, a postanesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia, as specified, within 48 hours after surgery.

Additional Details Regarding the November 27, 2006, Medicare and Medicaid Hospital Conditions of Participation Final Rule

Previous Proposed Rules

The final rule published on November 27, 2006, came from a notice of proposed rule making that was published on March 25, 2005 and included proposals originally published in the mid-1990s. CMS does not explain why the change process took so long other than to note other legislation that changed the Medicare and Medicaid programs' priorities.

While the final rule is at the end of a long line of proposals, CMS reiterates several times that it is a renewed emphasis on patient safety and the reduction of medical errors that serves as the basis for these new requirements and motivation for the agency to publish these changes now. Hospital staff,

clinical and administrative, should note this emphasis when addressing the bylaws, policies, and procedures that will need to be redrafted as a result of these changes.

Location of the Rule

This final rule "Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations was published in the *Federal Register* on Monday, November 27, 2006. A copy can be found by going to the *Federal Register* Web site at www.access.gpo.gov/su_docs/fedreg/a061127c.html and looking for the Word or PDF copy under the CMS heading. The revision to the full Medicare and Medicaid Programs Hospital Conditions of Participation is published at 42 CFR Part 482. A copy of the full COP rule is available at the CMS Web site at www.cms.hhs.gov/CFCsAndCoPs/06_Hospitals.asp. This CMS Web page also provides an overview of the COP requirements and links to other resources. At the time of this writing, December 2006, CMS had not yet incorporated these November 27, 2006 into its copy at this Web site (Such changes usually take several weeks.).

Effective Date

The effective date for the conditions in this final rule is January 26, 2007. Training and changes to hospital training should be completed by that date. Given the short time period compliance officers and HIM department heads should consider a written implementation plan so that if the facility is unable to complete changes by the effective date, it can document how soon it will be in compliance.

Compliance

This analysis is meant to help the reader understand the changes and requirements in the November final rule. Compliance officers, HIM directors, and others charged with compliance should not substitute this analysis for a reading of the full rule. The rule, including commentary and other required sections, is 23 pages long.

The final rule refers to federal and state rules or requirements as well as Joint Commission on the Accreditation of Health Organizations (JCAHO)[3] or American Osteopathic Association (AOA) requirements. CMS specifically notes that where state requirements (authorized from state legislation) differ from these federal COP requirements, the state requirements should be followed, unless the hospital has chosen to apply (and state law allows) even stricter requirements (federal requirements or their own).

The final rule also notes that there are some accreditation requirements under JCAHO or AOA accreditation standards that are stricter than these final rules. Hospitals accredited by either of these organizations have elected to abide by these stricter requirements and will be held accountable to them if CMS audits for compliance. Hospital medical staff bylaws, policies and procedures, therefore, should reflect the specific federal, state, and accreditation requirements in place.

The conflict among state rules, federal rules, and accreditation requirements has been an issue for many hospitals. CMS is approaching this issue from the perspective that patient safety should be paramount in the setting of medical staff bylaws, policies, and procedures, however, in the case where

[3] The Joint Commission for the Accreditation of Health Organization's has announced that as of January 2007 it will be known as the "Joint Commission." This analysis used the reference as indicated in the November 27 rule.

state law is more lenient that federal COP rules, CMS must (unlike HIPAA) allow hospitals to set policy under the state law if it so chooses.

CMS Contacts for More Information

CMS supplies three contacts for further questions on the November 2006 final rule:

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NOVEMBER FINAL RULE SECTIONS

I. Legislative and Regulatory Background (71FR68672-73)

The first main section of the November final rule, published in the *Federal* Register, covers some of the history behind these COP changes. It refers to previous proposed rules and the content of the most recent proposed rule, published on March 2005, which can be found at www.access.gpo.gov/su_docs/fedreg/a050325c.html.). This section also covers some of the laws under which the regulations are established. It also notes that compliance is determined by state survey agencies, or the two accreditation bodies (JCAHO or AOA)..

II. Provisions of the Proposed Regulations (71FR68673-74)

The second section provides a historical overview of the changes proposed in the March 2005 notice of proposed rule making. This background provides an understanding of the final rule.

Completion of the Medical History and Physical Examination

CMS explains the concerns raised by various medical groups related to the medical history and physician examination (H&P) including the timing of the physical exam and the acceptance of exams possibly conducted by a family physician who was not granted privileges by the hospital accepting the patient in question. Other concerns related to which medical professionals were qualified to give an exam. Finally, concerns were raised concerning the need to have the H&P posted to the medical record and a second exam to cover any changes that might have occurred between the time of the examination and admission.

The completion of the H&P has both time and date implications. Those receiving the external H&P must ensure that the H&P has been completed in 30 days, or less, before the admission or surgery. If accepted (based on date), the H&P must be place in the record within 24 hours after the time of admission or before surgery (whichever is less time). The November 27 notice goes into detail (see III below) on the need to conduct a review of the patient's conditions upon admission (or before surgery) to determine if the patient's condition has changed. The results of this second exam (or first if no H&P was done before), must be also be place in the record within 24 hours of the admission or before surgery. If the physician finds no change, CMS indicates that this fact can simply be noted in the record. The record should note that the second exam occurred and the findings show no change.

Authentication of Verbal Orders

The proposed revisions broaden the category of practitioner who may authenticate verbal orders. CMS notes that the final rule "responds to healthcare community concerns, reduces regulatory burden, and provides flexibility" for compliance. Verbal orders come from and must be authenticated by physicians, and they are usually received and interpreted by nurses. Therefore, the rule changes affect both medical staff and nursing sections of the COP. While the proposed rule broadens the category of practitioners who can actually provide, authenticate, or receive a verbal order is subject to state law and hospital policy, which can be more restrictive.

In the absence of a more lenient state law, CMS proposed that verbal orders must be authenticated within 48 hours.

Securing Medications

Given that there are no HIM implications in this section, this analysis does not address this section.

Completion of Postanesthesia Evaluation

The final section proposed allowing an individual, qualified to administer anesthesia, to complete and document the postanesthesia evaluation for inpatients. Such an evaluation must be completed within 48 hours, so there is a possibility that the evaluation could be done outside the hospital, and not reported in the hospital's medical record. CMS does not comment on this situation.

III. Analysis of and Responses to Public Comments…(71FR68674-91)

Most final rules carry a section on responses to public comment. They are presented in order of the proposed rule, first comment and then response – the response being the rationale behind what will be the final requirement. Often these responses provide some implied compliance and insight as to how CMS will judge compliance. This analysis highlights only comments the reader should be aware of for understanding or compliance.

A. Medical History and Physical Examination Condition of Participation: Medical Staff (§482.22)

CMS initially proposed changes to expand the timeframe for completion of the medical history and physical examination to 30 days before the admission or within 24 hours after the admission. They also proposed removing language as to the specific physicians who can perform the H&P, relying on state law to determine who can perform the H&P and further, not requiring the preadmission H&P be done by a physician who is credentialed (or privileged) by the hospital in which the admission is taking place. The notice provides four sections of comment and response

Medical Staff	
Concerns	**CMS Response**
H&Ps are frequently conducted by the patient's primary care provider who may not be credentialed and privileged to complete an H&P by the admitting hospital.	CMS deleted the requirement that the H&P be completed by a practitioner credentialed and privileged by the admitting hospital.
The patient's condition might change between the time of the external H&P and the admission.	An update to the H&P should be completed after the patient is admitted.
Who can complete such a post admission H&P.	H&P would be completed by an individual who has been credentialed and privileged by the hospital medical staff to conduct an H&P.
Can the post admission H&P examination be split among qualified staff?	Yes, as long as they are qualified and the findings documented within 24 hours of admission. "We believe it is common practice that the practitioner who performs the H&P will proceed to document and authenticate the H&P as well."
Can CMS provide incentives (via reimbursement) to ensure physicians complete and document the H&P in the timelines required?	CMS indicates that incentives are the hospital's problem. To ensure compliance, CMS suggests hospitals evaluate practitioner performances regarding the requirements as well as hospital policies.
If the H&P exam shows no changes does the exam have to be dictated and transcribed in detail?	No, but a note to the effect that an exam was done and there were no changes needs to be placed in the record. If there are changes they need to be documented.
The proposed rule does not address surgeries undertaken before 24 hours after admission.	This part of rule has not changed "there must be a complete history and physical work-up in the chart of every patient before surgery, except in emergencies. If this has been dictated, but not yet recorded …there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient."
Analysis: The H&P must be completed by a practitioner as designated under state law and not necessarily by a practitioner who has credential (or has privilages) at the admitting hospital. The admitting physician is likewise someone who, under state law and medical staff bylaws, is permitted to practice in the hospital and must complete H&P if nothing has been done within 30 days; or, if one has been done, performs a second exam to determine if there have been any changes in the patient's conditions. If there have been no changes it should be so noted in the record. Presumably, minimal changes can be noted in the chart or a dictated H&P or note can be placed in the record.	

Completion of the History and Physical Timeframe for Completion of a H&P	
Concerns	**CMS Response**
The rule does not address admissions for surgery versus other admissions.	Rule applies to all admissions – an H&P is required for all admissions within 24 hours. An H&P is required for all surgeries, whether inpatient or outpatient.
Posting of H&P in record in 24 hours does not recognize transcription turn around. CMS should use "as soon as possible."	CMS states: "It is fairly routine for an H&P to be performed prior to a planned admission or procedure...the number of dictated H&Ps should be small…when H&P is performed and dictated within 24 hours after admission…(CMS) expects an entry in the medical record stating that the H&P was completed and dictated." These standards are not new and are consistent with JCAHO requirements.
When is an updated note on H&P required?	H&P exams must "conducted prior to admission…internal physician can note that an external H&P was reviewed and there were no changes."
The internal, post-admission H&P exam requirement is redundant	This timeframe [and redundancy] is necessary for patient safety.
Obstetric H&P updates – how and where should this happen?	They are no different other than other H&Ps. The first is done at first prenatal visit and the H&P should be updated for subsequent prenatal visits. "For women who have not had prenatal care before the onset of labor, the H&P must be completed within 24 hours of admission."
Analysis: There has to be an H&P for all admissions and for all surgeries (inpatient or outpatient). The H&P exam completed in the hospital must be documented in the record within 24 hours of the admission. CMS will accept physician notes that indicate the exam was completed and either no change was evident in the patient's condition, or that changes were noted and the exam was completed and dictated. CMS does not accept the fact that dictation turn around could cause the hospital to exceed the 24 hour rule. Insertions in the record of the external H&P, internal H&P, or the exam noted in the regulation should include a time stamp so that compliance can be determined should there be an audit.	

Categories of Providers Permitted to Perform the H&P	
Concerns	**CMS Response**
The proposed rules could limit who is qualified to perform an H&P exam (in the hospital).	CMS states: "We are increasing the pool of individuals who can perform the H&P by allowing other qualified individuals who have been granted privileges by the medical staff in accordance with state law to perform the H&P. For clarification in this final rule, the specific reference to oromaxillofacial surgeons has been retained. However, based on hospital policy and State law, the pool of 'other qualified individuals' can be restricted."
Nurse practitioners (NPs), licensed independent practitioners (LIPs), or other qualified individuals should be allowed to perform H&Ps independently of the MD.	"We want to provide the hospital the flexibility to determine if NPs are included in their lists of practitioners who are qualified to perform the H&P." (No mention is made on the other "qualified individuals," so state law would have to prevail.
Analysis: The hospital and medical staff will need to review the medical staff bylaws related to who can complete an H&P and be specific as to who they consider qualified to complete such a record. It may be helpful for them to review the discussion on pages 71FR68674-68678 of the final rule and all state laws that apply.	

B. Authentication of Verbal Orders Condition of Participation: Nursing Services (§482.23) – Condition of Participation: Medical Record Services (§482.24)

CMS notes and repeats several times, its desire to "strengthen the requirement regarding the infrequent use of verbal orders, "with an exception for orders for influenza and pneumococcal polysaccharide vaccines. Orders can only be accepted by "persons authorized to do so by hospital policy and procedures consistent with federal and state law. There was concern that prescribing practitioners were giving verbal orders and then denying they did so especially in cases of medical error. CMS has asked for public comment and found few cases where this has occurred.

CMS notes that the majority of comments were in favor of the proposed rules. A few commenters disagreed with the proposed rule, but CMS' response was to quote a number of groups and articles relating to the potential for medical error associated with verbal orders. CMS notes: "We expect hospital to have systems in place to enable staff to address patient needs on a timely basis without routinely resorting to the use of verbal orders. We do not specify in regulation that verbal orders must only be used in 'emergent or urgent' situations. We require that if verbal orders are used, they must be used infrequently. We expect that hospital policy and practice would discourage the use of verbal orders as much as possible…Verbal orders are not to be used for the convenience of the ordering practitioner." With this in mind and given the move toward electronic health records, CMS has also recommended a five-year sunset on allowing others to authenticate a verbal order.

Verbal Orders	
Concerns	**CMS Response**
CMS should require that all verbal orders be responded to with the "read-back" process. Some states require such a process.	CMS states that, "we would expect the hospital to implement a 'read-back' verification process when using verbal orders…we expect hospitals to comply with nationally accepted guidelines and standards of practice …" but we have not included the "read-back" verification process in the final regulation text. CMS notes that the "read-back" process is just one of many things the hospital should be doing.
Analysis: Given the urgency for addressing medical errors, we expect CMS and other HHS agencies to take action to ensure that hospitals not only limit verbal orders, but also to use "read-back" and the other standards addressed in the CMS November response (71FR68680), when a verbal order occurs. Since the standards mentioned could change over time and issues related to quality and reductions in medical error are currently being addressed in many arenas, it is likely that CMS did not want to codify particular standards in this rule, since it could have meant extending the comment period for another round.	

Authentication of Verbal Orders	
Concerns	**CMS Response**
Concerns were raised as to the value of a physician authenticating orders one or two days after the order is given and acted upon.	CMS notes that verification can identify problems which would still allow for correction even after 48 hours. CMS emphasizes especially the number of prescription errors that occur with verbal orders.
The proposed rule allows for the verbal order to be authenticated by either the prescribing practitioner or another practitioner who is responsible for the care of the patient as long as the individual is authorized by hospital policy and permitted by the state law to write a specific order. Concerns were raised that this relieved the prescribing practitioner of his or her accountability and responsibility.	"All orders, including verbal orders, must be dated, timed and authenticated promptly by the prescribing practitioner or another practitioner who is responsible for the care of the patient. …A hospital has the flexibility to limit who may authenticate a verbal order and could authorize on the prescribing practitioner to authenticate a verbal order."
Concern was raised that the "other practitioner" may not want to authenticate the order so that the hospital is compliant within the 48-hour requirement.	CMS notes that the flexibility provided in the rule does not mandate a practitioner to authenticate any order he or she did not give. CMS goes on to state: "We expect a practitioner responsible for the care of the patient to have knowledge of the patient's hospital course, medical plan of care, condition, and current status. A practitioner who does not possess this knowledge about a patient

	should not be authenticating verbal orders for this patient."
Concerns	**CMS Response**
CMS was asked to clarify what is meant by the requirement that verbal orders be legible, complete, dated, and timed.	CMS responded: "…all orders, including verbal orders, be legible, complete, dated, timed, and authenticated…it would be necessary for a physician or other practitioner to date and time the authentication of a verbal order. The receiver should clearly record the order directly onto an order sheet in the patient's medical record or enter it directly into the computer. The receiver should date, time, 'read back,' and sign the verbal order according to hospital policy."
Can physicians/practitioner use faxed or electronic signatures as a means to validate verbal orders?	Yes, authentication of a verbal order may occur in writing or electronically. The hospital must have a method to establish the identity of the practitioner who has authenticated a verbal order. Hospital policies should address author verification process for both written and electronic signatures.
What if hospital policy is stricter than the COP?	Hospital policy would prevail and CMS would expect it to be followed.
Can a nurse practitioner or physician assistant verify the verbal order?	Only if they are licensed to write such an order themselves and meet the other conditions about knowledge of the patient noted above.
To be consistent with other state and federal laws, CMS should replace the term "prescribing" practitioner with the term "ordering" practitioner.	CMS agreed.
Analysis: Each hospital should determine who is qualified to authenticate verbal orders and must, along with the medical staff, recognize CMS' desire to see verbal orders used infrequently. Implementation of this section of the rule may provide an opportunity to look at the standards suggested by CMS.	

Sunset Provision	
Concerns	**CMS Response**
CMS recommended that the provision allowing for others than the ordering physician to authenticate a verbal be sunseted in five years. Many commenters believe this was adequate and that technology would provide a means to eliminate verbal orders.	CMS noted the work being done on EMR systems promises a means to eliminate verbal orders and improve patient safety.
Several commenters noted that technology may not be in use within the five year window and were concerned that CMS might not respond in time to meet the sunset date.	CMS agreed that it might have to address this issue in the next five years, acknowledged that not all providers may have technology in place, and agreed that there should not be a gap in the regulation.
Analysis: While most in the industry would like to see verbal orders eliminated, given the potential for medical errors, this may not happen in then next five years. CMS indicates that it will begin to address this issue early (before the five-year period expires) and it should be expected that any change proposed in the next five years will take into account how hospitals are dealing with verbal orders and the results of these rule changes.	

Timeframe for Authentication of Verbal Orders	
The proposed rule indicated that verbal orders must be authenticated based upon federal and state law. If there is no state law that designates a specific timeframe for the authentication of verbal orders, then verbal orders must be authenticated within 48 hours. Most comments indicated acceptance of the CMS proposal.	
Concerns	**CMS Response**
There are no statistics showing the value of a 48-hour timeframe. Hospitals and medical staffs should be permitted to establish their own time frame. Any authentication is after the fact.	CMS notes: "there is little in the literature regarding an appropriate timeframe for authentication of verbal orders, the use of verbal orders is cited as an error-prone process by the JCAHO, ISMP [Institute for Safe Medication Practices]….Authentication of a verbal order is an opportunity to identify a transcription error and minimize risk to patient safety. The goal is to intercept an error as soon as possible."
48 hours is burdensome	CMS notes: "If verbal orders are used, they must be used infrequently. Therefore, practitioners and other hospital staff should not need to expend a great deal of time and energy ensuring that verbal orders are authenticated within 48 hours

Concerns	**CMS Response**
"Repeat and verify" processes enhance patient safety more effectively than a timeframe for authentication.	CMS did not buy the implementation of "repeat and verify" process alone. CMS encourages such a process, but also indicates that the verification process, within 48 hours, does not negate the need for prompt authentication of verbal orders. "Neither of these practices alone can ensure patient safety as effectively as both can when used together."
Several states allow for authentication under varying conditions for as much as up to 30 days after discharge.	CMS notes that prompt authentication has been a COP requirement since the beginning. CMS suggests that states may have misinterpreted the intent of the COP requirements, and further notes that 30 days is not prompt and cannot be seen as reducing medical error. However, in spite of this concern, CMS will accept state law where it is specific to the authentication of verbal orders.
Verbal orders should not be permitted, as many such orders will be unsigned at discharge and seeking such authentication becomes a burden for staff.	CMS notes that it does not believe that it is in the best interest of patient safety to disallow the use of verbal orders. "Even when 100 percent of hospitals…have completely implemented a computerized medical record, and computerized physician order entry, there would still be those situation in which it is impossible or impractical for the prescriber to write the order or enter it in the computer (for example, in medical emergencies, or when the practitioner is scrubbed in the operating room).
CMS should add a provision that waives or delays the time element for medical emergencies.	CMS comments that there will be medical emergencies and "expects" hospitals to have policies and procedures that ensure care is given without delay, but that authentication also take place either by "someone." CMS notes; "It is standard practice for verbal orders to be documented, dated, and timed by someone other than the ordering practitioner, and then authenticated, dated and timed by the ordering practitioner once the patient has been stabilized. It is also standard practice in an emergency situation for the practitioner administering a medication to repeat the verbal order back to the ordering practitioner."

Concerns	CMS Response
A comment was made as to the burden a 48-hour requirement would have on psychiatric hospitals.	CMS notes that such hospitals must abide by the COP requirements if they are a Medicare or Medicaid facility.
Several commenters raised concerns on the burden of the 48 hour rule and its impact on discharges potentially creating longer stays and so forth.	CMS replied that these comments seem to indicate a common use of verbal orders – something CMS is trying to eliminate.

Analysis: CMS wants to eliminate verbal orders as much as possible except in medical emergencies. CMS views verbal orders as a threat to patient safety and continuity of care. While CMS would prefer hospitals be as strict as possible about verbal orders, it allows for a less restrictive compliance when state law specifically sets a longer time period for verification. Now that this COP rule has been finalized, hospital should expect to see patient/public interest groups approach states to change the more lenient rules so that 48 hours becomes the standard. Those accreditation agencies not already requiring a shorter timeframe will likewise do so in the future.

Priority of Requirements:

CMS acknowledges that the COP requirement for timing of authentication of the COP's verbal order may vary depending on state law or accreditation choices. CMS has not taken steps to eliminate the variance (hoping that states will accept CMS' call for a 48-hour maximum for completion of the verbal order). Concern over this variance has been raised for several years within AHIMA's membership. As it stands, when the rule becomes effective the following priorities will exist for hospitals covered under these COPs:

- If the institution is not covered under the Joint Commission or AOA accreditation requirements (meaning that the institution is accredited by the state) and the institution does not have a policy calling for completion of the authentication in less than 48 hours, and there is no state law that specifically addresses the completion of the authentication of verbal order process in a period of time exceeding 48 hours, then the Medicare 48 hour rule will apply.
- If the institution is not covered under the Joint Commission or AOA accreditation requirements (meaning that the institution is accredited by the state) and the institution does not have a policy calling for completion of the authentication in less than 48 hours, and there is a state law specifically permitting completion of the verbal order authentication process for a period of time greater than 48 hours, then the state law would prevail over the COP requirement.
- If the institution is covered under the Joint Commission or AOA accreditation requirements (requirements that are less than 48 hours), and the institution has not developed requirements stricter than those imposed by the Joint Commission, then the Joint Commission or AOA requirements would prevail.
- If the institution is covered under the Joint Commission or AOA accreditation time requirements (requirements that are less than 48 hours), and the institution has developed requirements stricter than those imposed by accreditation, then the institution's stricter requirements would prevail.

No matter which scenario applies to an institution, the institution will be accountable for complying with the scenario it has chosen or is required to follow. Given the increased attention to the issue of patient safety, it is doubtful that accreditation agencies will relax their requirements to fit the COP requirement. For the same reason, CMS' expectation to see states move toward CMS' requirement

will probably hold true, and like the call-back process, institutions may wish to tighten their own requirements if they do not come under the Joint Commission or AOA.

Authentication of Medical Record Entries

CMS proposed minor revisions that would clarify that all patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form.

Concerns	CMS Response
A commenter asked CMS to move away from requiring that all entries be authenticated due to the burden it would impose, noting the burden already in place due to JCAHO requirements.	CMS replied that the authentication of medical record entries is not new – except for the "timed" requirement. CMS states: "We recognize that JCAHO authentication requirements differ from CMS standards. However, Medicare participating hospital must comply with the Medical hospital COPs. JCAHO standard IM.6.10, element of performance number 4 does, in fact, refer to our regulations by stating the "medical record entries are dated, the author identified and, when necessary, according to law, regulation or hospital policy, authenticated, either by written signature, electronic signature, or computer key or rubber stamp."

Analysis: Most readers will not find these requirements new as CMS noted. Medical staff bylaws should reflect these same requirements.

C. Securing Medications Condition of Participation: Pharmaceutical Services (§482.25)

This section, beginning on page 71FR68688, has no bearing on HIM functions and deals with security and access to medications. For this reason we are not providing addition analysis.

D. Completion of the Postanesthesia Evaluation Condition of Participation: Anesthesia Services (§485.52)

CMS proposed, with respect to inpatients, a postanesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia within 48 hours after surgery. Most commenters agreed with the CMS proposal. Since documentation is an issue here, we are noting comments regarding that requirement.

Completion of the Postanesthesia Evaluation

Concerns	CMS Response
What type of anesthesia warrants this follow-up and documentation?	"A postanesthesia evaluation is required any time general, regional, or monitored (this would include deep sedation/analgesia) anesthesia has been administered to the patient." Monitored anesthesia care is defined using ASA guidelines.
What if the patient is discharged before the examination?	If the patient is discharged less than 48 hours after the procedure, completion and documentation of the postanesthesia evaluation is still required. CMS goes on to state "this is the case regardless of whether the procedure is performed on an inpatient or outpatient basis or when the patient is discharged." CMS also notes that many hospitals have policies calling for such an exam in less than 48 hours and it is implied that hospital policy in these cases should be followed.
Analysis: There were several comments and responses related to the clinicians permitted to make such an exam under this rule. If this becomes an issue, refer to pages 71FR68690-91. CMS does not address where or how documentation of the exam should be posted; so, while it is clear that the report would be dated and timed, it is not clear if it has to be in the record of the hospital where the anesthesia was administered, or the location where the exam took place. This is an issue that AHIMA will pursue.	

IV Provisions of the Final Regulations (71FR68991-92)

CMS writes that the final rule responds to the healthcare community's primary concern that current (pre-November 2006) regulations related to completion of the history and physical examination, authentication of verbal orders, storage of medications, and completion of the postanesthesia evaluation are contrary to current medical practice and unduly burdensome. In this section CMS provides the specific changes that will be made within the current hospital COPs at 42 CFR part 482. "Any changes that have been made to clarify or strengthen the provisions that appeared in the March 25, 2005 proposed rule (70 FR 15266) are noted in the following description of the provisions." We have included the text from the *Federal Register* notice for a quick reference.

Section 482.22 Condition of Participation: Medical Staff

Section 482.22(c)(5)

This requirement expands the timeframe for completion of the history and physical examination and broadens who may perform the history and physical examination. It requires that each patient receive a history and physical examination completed no more than 30 days before or 24 hours after admission and documentation be placed in the patient's medical record within 24 hours of admission. A physician (as defined in section 1861(r) of the Act), oromaxillofacial surgeon, or other qualified individual could complete the history and physical examination in accordance with state law and hospital policy. In addition, when a history and physical examination is recorded within the 30 days before admission, the 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.

Several revisions were made to this standard in this final rule. Based on public comments, the following changes were made at Sec. 482.22(c)(5): (1) We retained the specific reference to oromaxillofacial surgeons; (2) we deleted the requirement that practitioners must be granted the privilege to conduct a medical history and physical examination by the medical staff; and, (3) in its place we added the language, “in accordance with State law and hospital policy." The remainder of the standard is being finalized as proposed.

Section 482.23 Condition of Participation: Nursing Services

Section 482.23(c)(2)
This requirement clarifies that, with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is responsible for the care of the patient as specified under Sec. 482.12(c) and authorized to write orders by hospital policy and in accordance with State law. This standard has not been revised and, therefore, is being finalized without change.

Section 482.23(c)(2)(i) and Section 482.23(c)(2)(ii)
These provisions reinforce current requirements that when verbal orders are used, they are to be used infrequently, and be accepted only by persons authorized by hospital policy and procedures consistent with Federal and State law. This standard has not been revised; and, therefore is being finalized without change.

Section 482.24 Condition of Participation: Medical Record Services

Section 482.24(c)(1)
This requirement maintains and reinforces the current regulation for authentication of all medical record entries. It requires that all patient medical record entries be legible, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating a service provided. This standard has not been revised and, therefore, is being finalized without change.

Section 482.24(c)(1)(i)
This provision requires that all orders, including verbal orders, be dated, timed, and authenticated promptly by the ordering practitioner, except as noted in subsection (ii). One minor revision has been made in the final rule based on public comment. The word “ordering" has replaced the word “prescribing." Otherwise, the standard is being finalized as proposed.

Section 482.24(c)(1)(ii)
This provision permits a temporary exception to the requirement that all orders, including verbal orders be dated, timed, and authenticated by the ordering practitioner. For a period of five years beginning with the effective date of this final rule, verbal orders will not need to be signed by the ordering practitioner, but could be authenticated by another practitioner responsible for the care of the patient. One minor revision has been made in this final rule based on public comment. The word “ordering" has replaced the word “prescribing." Otherwise, the standard is being finalized as proposed.

Section 482.24(c)(1)(iii)
This provision specifies that all verbal orders must be authenticated based upon federal and state law. If there is no state law that designates a specific timeframe for the authentication of verbal orders, then verbal orders must be authenticated within 48 hours. This standard has not been revised and, therefore, is being finalized without change.

Section 482.24(c)(2)(i) and Section 482.24(c)(2)(ii)
These requirements have been revised to be consistent with the changes in the Medical staff COP. These regulations specify documentation requirements for history and physical examinations. The two provisions require evidence of either: (1) A medical history and physical examination completed within 30 days before or 24 hours after admission, and placed in the patient's medical record within 24 hours after admission; (2) an updated medical record entry documenting an examination for any changes in the patient's conditions when the medical history and physical examination was completed within 30 days before admission. This updated examination will need to be completed and documented in the patient's medical record within 24 hours of admission. These standards have not been revised and, therefore, are being finalized without change.

Section 482.25 Condition of Participation: Pharmaceutical Services

Section 482.25(b)(2)(i)
This provision specifies that all drugs and biologicals be kept in secure areas, and locked when appropriate. This standard has not been revised and, therefore, is being finalized without change.

Section 482.25(b)(2)(ii)
This provision requires that scheduled drugs (II, III, IV, and V), as outlined in the Comprehensive Drug Abuse Prevention and Control Act of 1970, must be locked within a secure area. This standard has not been revised and, therefore, is being finalized without change.
Section 482.25(b)(2)(iii)
This requirement states that only authorized personnel may have access to locked areas. This standard has not been revised and, therefore, is being finalized without change.

Section 482.52 Condition of Participation: Anesthesia Services

Section 482.52(b)(3)
This requirement permits the postanesthesia evaluation for inpatients to be completed and documented by any individual qualified to administer anesthesia. This standard has not been revised and, therefore, is being finalized without change.

V. Collection of Information Requirements and VI Regulatory Impact (71FR68692-94)

Section V reviews CMS' estimation of the information burden created by the proposed requirements and what must take place to ensure there is no deviance from what would be considered best practice. Section VI is required, and CMS must show if the impact of these new rules would be economically significant. CMS suggests that there will be significant benefits that will outweigh the one time changes some hospitals and medical staffs might have to make. CMS also notes that the final rule will not have a negative impact on the rights, rules, and responsibilities of state, local, or tribal governments.

Part 482 – Conditions of Participation for Hospitals (71FR68694-95)

The final section in the November rule covers little more than a page with the actual 482 rule language changes. We have not provided this language since the requirements have been covered above.

Medicare and Medicaid Hospital Conditions of Participation Final Rule Requirements Published December 8, 2006, and Effective January 8, 2007

The second set of COP changes were published in the December 8, 2006 *Federal Register* beginning on page 71FR71426. The title for these requirements is "Patient Rights;" however, the bulk of the regulation and the discussion in this notice or final rule relate to the use of restraint or seclusion. While many of the requirements in this COP are clinical and administrative, there are sections that relate to patient records and documentation. HIM professionals should be aware of the requirements for this entire COP since documentation will be crucial to any review of clinical compliance and the process of documentation will vary by facility. In brief, this COP revision covers the following rights and standards:

Patient's Rights

- A hospital must protect and promote each patient's rights
    - Standard: Notice of Rights covers information patients or patient's representatives (as designated under state law) must receive as well as the grievance process that must be in place.
    - Standard: Exercise of Rights – covers the patient's right to:
        - Participate in the development and implementation of his or her plan of care;
        - Make informed decisions regarding his or her care;
        - Formulate advance directives;
        - Have a family member or representative as well as family physician promptly notified of his or her admission to the hospital
    - Standard: Privacy and safety covers right to:
        - personal privacy,
        - receive care in a safe setting, and
        - be free from all forms of abuse or harassment.
    - Standard: Confidentiality of **patient records** covers the patient's right to:
        - Confidentiality of his or her clinical records
        - Access information contained in his or her clinical records within a reasonable time frame. The hospital must not "frustrate the legitimate efforts of individuals to gain

access to their own medical records and must actively seek to meet these requests as quickly as its record-keeping system permits."

- Standard: Restraint or seclusion covers:
  - Definitions,
  - When restraint or seclusion may only be used,
  - Type of technique of restraint or seclusion,
  - Who can order restraint or seclusion,
  - Orders for the use of restrain or seclusion must never be written as a standing order or on an as-needed basis (PRN),
  - Notice to attending physician,
  - Timing of restraint or seclusion,
  - Discontinuance of restraint or seclusion,
  - Monitoring of patient under restraint or seclusion,
  - Training requirements,
  - Use or restraint or seclusion to management violent or self-destructive behaviors,
  - State requirements,
  - Face-to-face evaluation
  - Simultaneous use or restraint and seclusion
- Standard: Restraint or seclusion – staff training requirements – documentation of training must be kept in personnel records.
- Standard: Death reporting requirements reporting deaths associated with use of seclusion or restraint includes death within one week after restraint or seclusion and **requires staff to document in the patient's medical record the date and time the death was reported to CMS.**

Additional Details Regarding the December 8, 2006, Medicare and Medicaid Hospital Conditions of Participation: Patient's Rights; Final Rule

Previous Proposed Rules

The final rule published on December 8, 2006, came from a proposed rule presented July 2, 1999. As with the November comments, CMS' reasons for delay are vague, although it is clear that many of the initial comments to the 1999 proposed rule, related to restraints and seclusion, were mixed and did not provide clear guidance to the agency. While the title to this COP is Patient Rights, most of the text is related to the use of restraints and seclusion in a number of settings.

Location of the Rule

This final rule "Hospital Conditions of Participation: Patient's Rights" was published in the *Federal Register* on Friday, December 8, 2006. A copy can be found by going to the *Federal Register* Web site at www.access.gpo.gov/su_docs/fedreg/a061208c.html and looking for the Word or PDF copy under CMS heading. The revision to the full Medicare and Medicaid Programs Hospital Conditions of Participation is published at 42 CFR Part 482. A copy of the full COP rule is available at the CMS Web site at www.cms.hhs.gov/CFCsAndCoPs/06_Hospitals.asp. This CMS Web page also provides an overview of the COP requirements and links to other resources. At the time of this writing, December 2006, CMS had not yet incorporated these November 27, 2006 changes into its copy at this Web site (Such changes usually take several weeks.).

Effective Date

The effective date for the conditions in this final rule is January 08, 2007. This means that any training and changes to hospital training should be completed by that date. Given the very short time period, hospitals should consider a written implementation plan so that if they are unable to complete changes by this date they can document how soon it will be in compliance.

Compliance

This analysis is meant to help the reader understand the changes and requirements that will affect HIM functions, such as record documentation, quality assurance, or compliance. Due to the very specific clinical requirements in this document (50 pages) we are not providing detail on the clinical and administrative requirements associated with the restraint and seclusion sections. HIM professionals responsible for documentation of restraint and seclusion should read this entire regulation to understand what document requirements may be required in the medical or health record.

CMS Contacts for More Information

CMS supplies the following contacts for further questions on the December final rule:

- Patricia Chmielewski, RN, MS (410) 786-6899
- Janice Graham, RN, MS (410) 786-8020
- Monique Howard, OTR/L (410) 786-3869
- Jeannie Miller, RN, MPH (410) 786-3164
- Rachel Weinstein, RN, MPA (410) 786-6775

I. Background (71FR71378-80

The background in the December rule begins by CMS noting that "these standards support and protect patient's rights in the hospital setting; specifically, the right to be free from the inappropriate use of restraint and seclusion with requirements that protect the patient when use of either intervention is necessary." The section covers key statutory provisions, regulatory history, and how CMS came to these final rules and consider restraint and seclusion in settings beyond the hospital.

II. Provisions of the Proposed and Interim Final Rules Regarding Patients' Rights (71FR71380)

The proposed rule (actually an interim final rule) that generated this final rule can be found in the Friday, July 2, 1999 *Federal Register* (Vol. 64, No. 164) which can be found at http://www.access.gpo.gov/su_docs/fedreg/a990702c.html. Provisions first proposed and covered in this 2006 final rule, were also published in 1997. CMS notes that with the exception of the standard for seclusion and restraint, it received few comments on the other requirements for notice of rights, exercise of rights regarding care, privacy and safety, and confidentiality of patient records; accordingly, CMS does not go into great detail on these sections.

III Comments on and Responses to the Provision of the Interim Final with Comment Period (71FR71380-71418)

Given the age of the comments and the fact that most relate to the use of restraint and seclusion, this analysis will skip a review of this section's "comments" and "responses" except where applicable to potential HIM functions. For the reader's information, when a comment or response is noted we have included the page where the discussion resides.

A. General Comments on the Requirements for the Use of Restraint and Seclusion (71FR71380-85)

B. Comments Received on Specific Provisions (71FR71385-71418)

NOTE: **Discussion on "Elimination of Protocols"** (71FR71395) CMS notes that protocols are not banned by the regulation. "A protocol may contain information that is helpful for staff, such as how a restraint is to be applied and monitored. However, a protocol cannot serve as a substitute for obtaining a physician or other LIP order before initiating each episode of restraint or seclusion use…"

NOTE: **Discussion on "Written Modification of the Plan of Care"** (71FR71398) CMS notes that "the regulation does not require that a modification to the patient's plan of care be made before initiating or obtaining an order to the use of restraint or seclusion. The use of a restraint or seclusion intervention should be reflected in the patient's plan of care or treatment plan based on an assessment and evaluation of the patient…" In this final rule, we are specifying that the use of restraint or seclusion be documented in the patient's medical record [and]…we have specified the required elements of documentation under the combined standard."

The combined standard has been revised to require that the use of restraint or seclusion be documented in the patient's medical record, and must contain documentation that includes:

- The one-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others;
- A description of the patient's behavior and the intervention used;
- Alternatives or other less restrictive interventions attempted (as applicable);
- The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and
- The patient's response to the intervention(s), including the rational for continued use of the intervention.

CMS also notes that it has required that when restraint or seclusion is used certain elements must be documented such as date, time, duration, and so forth. Additional elements of documentation, such as name, title and credentials of staff members involved in the procedure should be specified in hospital policy.

NOTE: **Discussion on "Reporting of Death(s) Related to Restraint/Seclusion"** (71FR71415) – CMS has revised the rule to require that the hospital report each 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 information will be relayed to the CMS central office and the State survey agency. This is for deaths that occur while a patient is in restraint or in seclusion or both at the hospital and each death known to the hospital that occurs within one week after restraint (whether physical restraint or drugs used as a restraint) or seclusion, in cases in which it is reasonable to assume that use of restraint or placement in 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. Staff must document in the patient's medical record the date and time the death was reported to CMS (Regional Office).

IV Provisions of the Final Rule (71FR71418-71420)

CMS notes that it is codifying the Patients' Rights COP within the current hospital COPs under Subpart B Administration at Sec. 482.13. The eight standards specified in this final rule establish minimum protections and rights for patients. Any changes that have been made to clarify or strengthen the provisions that appeared in the interim final rule with comment period are noted in the following description of the provisions.

[*To provide some knowledge of this COP, we have included CMS' description of the changes and contents of the rule. Items bolded refer to documentation requirements.*]

Notice of Rights

The first standard, "`Notice of Rights,"' requires the patient or the patient's representative, as permitted by state law, to be informed of the patient's rights prior to furnishing or discontinuing care whenever possible. The standard also requires that the hospital have a grievance process, that the patient be informed of whom to contact to file a grievance, and that the process include specific elements. This standard has not been revised; and therefore is being finalized without change.

[*This standard has been in place in most institutions for some time and should not be new. Hospitals should review their policy, procedures, and practices to ensure this requirement continues to be met.*]

Exercise of Rights

The second standard, "Exercise of Rights," provides the patient the right to participate in the development and implementation of his or her plan of care, and to request or refuse treatment. This standard supports the patient's right to make decisions regarding his or her care and to formulate advance directives and have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with Sec. 489.102 (Requirements for providers). This standard also supports the patient's right to have a family member or representative of his or her choice and his or her physician notified promptly of the patient's admission to the hospital. This standard has not been revised; and therefore is being finalized without change.

[*This standard is also not new to most institutions. Note, however, that the "patient representative" discussed here relates to state law and not the person or individual described in the HIPAA privacy rules. CMS does not address the potential discrepancy that could occur, so it is presumed that hospital staff will recognize the difference in these situations.*]

Privacy and Safety

The third standard, "`Privacy and Safety,"' which includes the right to personal privacy, to receive care in a safe setting, and to be free from all forms of abuse or harassment. This standard has not been revised from the proposed rule (1999); and therefore is being finalized without change.

Confidentiality of Patient Records

The fourth standard, "Confidentiality of Patient Records," provides the patient's right to the confidentiality of his or her records, and to access those records. This standard has also not been revised and is therefore being finalized without change.

[*Again, this COP standard does not acknowledge HIPAA (most likely because current HIPAA privacy rules were written after the comment period for this COP in 1999). While it might be presumed that CMS will accept the HIPAA, or in the case of stricter state requirements, there are no clear assurances at this time that this will be the case. AHIMA will pursue this issue with CMS.*]

Restraint or Seclusion

The fifth standard, "Restraint or seclusion," differs both in content and in application from the standard presented in the interim final rule with comment period. CMS has revised and combined the requirements contained in standards (e) and (f) in the interim final rule into a single, combined standard in the final rule. The final, combined standard (e) applies to the use of restraint, the use of seclusion, as well as the simultaneous use of restraint and seclusion regardless of patient location.

[*As noted elsewhere, individuals charged with ensuring a complete record will need to review this section and existing hospital requirements to ensure the document requirements are understood and followed by staff.*]

Right to be Free from Physical or Mental Abuse, and Corporal Punishment

The revised, combined standard (e) states that all patients have the right to be free from physical or mental abuse, and corporal punishment. It retains the patient's right to be free from restraint or seclusion, of any form, imposed by staff as a means of coercion, discipline, convenience, or retaliation. It also states that restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff, or others and must be discontinued at the earliest possible time.

A significant change from the interim final rule with comment period to this final rule is that standard (e) provides a revised definition of "restraint." In the final rule, we adopted the restraint definition contained in the CHA. A 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 when it is 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. The final rule also 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 (this does not include a physical escort). The seclusion definition contained in the interim final rule with comment period has been retained with minor content revisions. Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Standard (e) also clarifies that seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

[*This section notes a definition change for "restraint." Affected hospitals will have to compare this definition against that used by the COP requirement and make the necessary changes to be in compliance with this rule. CMS does not specifically mention any conflict with state requirements or definitions.*]

Seclusion and Restraint for Behavior Management

All the requirements contained in the current standard (e) "Restraint for acute medical and surgical care" are also contained in the current standard (f) "Seclusion and restraint for behavior management." These requirements have been moved to the combined standard (e) in the final rule. The more stringent requirements contained in the current standard (f), but not in the current standard (e) have also been moved to the combined standard (e) in the final rule. These more stringent requirements are: Time limits on the length of each order, and the one-hour face-to-face evaluation. The final rule clarifies that these two requirements only apply when restraint or seclusion are used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Requirements for the simultaneous use of restraint and seclusion have also been retained in the final rule.

Standard (e) retains the following requirements: Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm; the type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm; and, the use of restraint 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 in accordance with State law.

Standard (e) retains and clarifies the requirement that use of a restraint or seclusion must be in accordance with the order of a physician or other LIP who is responsible for the care of the patient as specified under Sec. 482.12(c) and is authorized to order restraint or seclusion by hospital policy in accordance with State law. **The standard also requires that the restraint or seclusion order never be written as a standing order or on an as needed basis (PRN), and that the attending physician must be consulted as soon as possible if restraint or seclusion is not ordered by the patient's attending physician**. **Standard (e) also sets limits on the length of each order for restraint or seclusion used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others based on the age of the patient, and states that the order may only be renewed in accordance with these limits for up to a total of 24 hours unless superseded by State law that is more restrictive.** After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other LIP (if allowed by State law) must see and assess the patient. Each order for restraint used to ensure the physical safety of the nonviolent or non-self-destructive patient may be renewed as authorized by hospital policy. Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

Further, standard (e) specifies that the condition of the patient who is restrained or secluded must be monitored by a physician, other LIP or by trained staff at an interval determined by hospital policy. The criteria for staff to be considered "trained" are specified under Sec. 482.13(f). In addition, physician and other LIP training requirements must be specified in hospital policy. At a minimum, physicians and other LIPs authorized to order restraint or seclusion by hospital policy in accordance with state law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

A significant change from the interim final rule with comment period to this final rule is that standard (e) has been revised to expand the type of practitioners permitted to conduct the one-hour face-to-face

evaluation. When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other LIP, or a RN or PA trained in accordance with the requirements specified under Sec. 482.13(f), must see the patient face-to-face within one-hour after the initiation of the intervention. This practitioner must evaluate the patient's immediate situation, the patient's reaction to the intervention, the patient's medical and behavioral condition, and the need to continue or terminate the restraint or seclusion. As specified at Sec. 482.13(e)(13), state law (by statute or regulation) regarding the one-hour face-to-face evaluation may be more restrictive than these requirements. If the one-hour face-to-face evaluation is conducted by a trained RN or PA, the attending physician or other LIP who is responsible for the care of the patient as specified under Sec. 482.12(c) must be consulted as soon as possible after completion of the evaluation. Standard (e) clarifies requirements related to the simultaneous use of restraint and seclusion. All requirements specified under standard (e) apply in the simultaneous use of restraint and seclusion, which is not permitted unless the patient is continually monitored face-to-face by an assigned, trained staff member, or continually monitored by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

Finally, standard (e) has been amended to specify elements of documentation. **When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:**

- **The one-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others;**
- **Alternatives or other less restrictive interventions attempted (as applicable);**
- **The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and,**
- **The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.**

When restraint or seclusion is used for violent or self-destructive behavior, documentation must also include findings from the one-hour face-to-face assessment.

[*Hospital document requirements clearly must be examined and revised as needed. Those charged with reviewing the chart for completeness as well as the clinical staff involved will need to be quickly trained in these requirements, if they differ from current hospital medical staff bylaws, policies, or procedures.*]

Staff Training Requirements

Standard (f) is a **new standard** that addresses staff training requirements. A patient has a right to the safe implementation of restraint or seclusion by trained staff. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with hospital policy.

In addition, standard (f) states that the hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require restraint or seclusion;
- The use of nonphysical intervention skills;

- Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition;
- The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
- Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
- 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 one-hour face-to-face evaluation; and,
- The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

[*The documentation of staff training is to be included in personnel records and NOT the medical record. HIM staff affected by these rules should be trained or be the trainers.*]

Reporting Requirements for Deaths

Standard (g) is a **new standard** that addresses reporting requirements for deaths associated with the use of restraint or seclusion. The hospital must report to CMS each death that occurs while a patient is in restraint or in seclusion at the hospital, occurs within 24 hours after the patient has been removed from restraint or seclusion; or each 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 placement in seclusion contributed directly or indirectly to a patient's death. For the purposes of this regulation, “reasonable to assume” includes, but is not limited to deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation. Each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. **Staff must document in the patient's medical record the date and time the death was reported to CMS.** Although we have modified some of the provisions to address public comments, these modifications do not lessen protections afforded patients who are restrained or secluded.

[*HIM staff will have to determine how and where this will be documented as well as the process for such documentation that could occur after discharge.*]

V. Collection of Information Requirements and VI Regulatory Impact (71FR71420-26)

Similar to the previous rule this section is CMS’s estimation of impact of these regulations. CMS notes that costs will vary and that potentially there are initial and on going training costs associated with the restraint or seclusion requirements.

Part 482 – Conditions of Participation for Hospitals (71FR71426-28)

Since we did not have sufficient detail in the regulation to discuss the conditions of participation, we have included below the conditions that will impact HIM professionals and comments that have not been previously made. Numbers used refer to the numbers used in the *Federal Register* notice and therefore may not be sequential.

§482.13 Condition of Participation: Patient Rights

A hospital must protect and promote each patient's rights.

Standard: **Notice of rights**

1. A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.
2. The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:
    a. The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.
    b. The grievance process must specify time frames for review of the grievance and the provision of a response.
    c. In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

Standard: **Exercise of rights.**

1. The patient has the right to participate in the development and implementation of his or her plan of care.

2. The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

3. The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with Sec. 489.100 of this part (Definition), Sec. 489.102 of this part (Requirements for providers), and Sec. 489.104 of this part (Effective dates).

4. The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of admission to the hospital.

Standard: **Privacy and safety.**

1. The patient has the right to personal privacy.

2. The patient has the right to receive care in a safe setting.

3. The patient has the right to be free from all forms of abuse or harassment.

Standard: **Confidentiality of patient records**.

1. The patient has the right to the confidentiality of his or her clinical records.

2. The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

Standard: **Restraint or seclusion**.
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 or 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.

1. Definitions.
    - A 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 when it is 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 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 (this does not include a physical escort).
    - Seclusion is 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.

5. The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under

Sec. 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

6. Orders for the use of restraint or seclusion must never be written as a standing order or on an as-needed basis (PRN).

8. Unless superseded by State law that is more restrictive--
(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:
(A) 4 hours for adults 18 years of age or older;
(B) 2 hours for children and adolescents 9 to 17 years of age; or
(C) 1 hour for children under 9 years of age; and
(ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under Sec. 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.
(iii) Each order for restraint used to ensure the physical safety of the nonviolent or non-self-destructive patient may be renewed as authorized by hospital policy.

16. When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:
(i) The one hour face-to-face medical and behavioral evaluation 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.

Standard: **Restraint or seclusion: Staff training requirements.**

The patient has the right to safe implementation of restraint or seclusion by trained staff.

Standard: **Death reporting requirements**:

Hospital must report deaths associated with the use of seclusion or restraint.

1. The hospital must report the following information to CMS:
(i) Each death that occurs while a patient is in restraint or seclusion.
(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
(iii) Each 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 placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in the context includes, but is not limited to deaths related to restriction of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

2. Each death referenced in this paragraph must be reported to CMS by telephone no later than close of business the next business day following knowledge of the patient's death.

3. Staff must document in the patient's medical record the data and time the death was reported to CMS.

Updates

As noted in a few comments above, these two final rules have been issued after some delay in the rule-making process at CMS. There are a few areas that need clarification and we expect that this will come from CMS over time, including inquiries that AHIMA is making (as noted). Up dates to this analysis will be modified as more information is received. In addition, AHIMA members can receive information on updates by reading notices in AHIMA's weekly ***e-Alert***. Readers should also check the CMS COP Web site as it will soon be updated to reflect these changes and should carry any additional clarifications in responses to questions.