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March 13, 2008

Hospitals Take Note: CMS Issues New Interpretive Guidelines for Several Hospital Conditions of Participation

It is not always easy to determine what information, procedures or documentation state surveyors will examine during the course of a Medicare certification survey. However, the Centers for Medicare and Medicaid Services (CMS) has given compliance officers a valuable tool for anticipating surveyors' moves in the State Operations Manual (SOM). The SOM is available on the CMS websiteⁱ and contains both regulatory citations to the Hospital Conditions of Participation (CoP) as well as CMS' Interpretive Guidelines for the CoP.

The Interpretive Guidelines serve as guidance for the state survey agencies that conduct Medicare certification surveys. The Guidelines contain background information describing the purpose and anticipated effect of the CoP standard, but more importantly from a compliance standpoint, the Interpretive Guidelines also include a list of the survey procedures that state surveyors are supposed to follow to check for CoP compliance. By examining these Guidelines, Hospitals can anticipate state survey targets, prepare more effective compliance programs and maximize their chances of a positive survey outcome.

On February 8, 2008, CMS issued

long awaited Interpretive Guidelines regarding several changes to the Hospital Conditions of Participation CMS issued in late 2006ⁱⁱ. The 2006 amendments addressed Hospital CoP relating to history and physical examinations, authentication procedures for verbal orders, securing medications and conducting post-anesthesia evaluations.ⁱⁱⁱ This article is intended to provide hospitals with an overview of these Guidelines and, in turn, help hospitals determine whether they are in compliance with the amended CoP.

History and Physician Examinations

I. The CoP Standard

As a condition of Medicare participation, CMS requires that hospitals complete and document a medical history and physical examination (H&P) for each patient no more than 30 days before or 24 hours after admission or registration.^{iv} In all cases, an H&P must be completed prior to surgery or any other procedure requiring anesthesia services, even if such a procedure is performed within 24 hours of admission or registration. The H&P must be completed by a physician, oromaxillofacial surgeon, or other qualified licensed individual in accordance with state law and hospital policy.



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If the H&P examination was performed prior to hospital admission or registration, an H&P “update” must be completed and documented by a licensed practitioner who is credentialed and privileged by the hospital’s medical staff within 24 hours of admission or registration and in all cases before surgery or a procedure requiring anesthesia.^v

II. The Interpretive Guidelines

As most hospital personnel would expect, the Interpretive Guidelines explain that the purpose of the H&P is to determine whether there is anything in the patient’s overall condition that would affect the planned course of the patient’s treatment, such as a medication allergy or new or existing co-morbid condition. The Guidelines also include additional information that may not be readily apparent from the H&P CoP, including:

- An H&P is required prior to surgery and other procedures requiring anesthesia services regardless of whether that care is provided on an inpatient or outpatient basis.
- An H&P that is completed within 24 hours of admission or registration, but after the surgical procedure, would not be in compliance with this CoP.
- The H&P timing requirement must be included in the Hospital’s medical staff bylaws.
- The H&P may be handwritten or transcribed, but always must be placed within the patient’s medical record within 24 hours of admission or registration or prior to surgery or a procedure requiring anesthesia, whichever comes first.
- More than one qualified practitioner can participate in performing, documenting and authenticating an H&P for a single patient; however, the practitioner who authenticates the H&P will be held responsible for its contents.

The Guidelines also provide additional information regarding the H&P update requirement. Specifically, the Guidelines require that hospitals perform an updated examination of the patient, including any changes in the patient’s condition, within 24 hours after admission or registration, and in all cases prior to surgery or a procedure requiring anesthesia services. The update must meet certain requirements, including:

- The update note must document an examination for any changes in the patient’s conditions since the H&P was performed.
- If the practitioner performing the update finds no change in the patient’s condition he or she may indicate in the patient’s medical record that the H&P was reviewed, that the patient was examined and that no change has occurred.
- If the reviewing practitioner finds that the original H&P was incomplete, inaccurate or otherwise unacceptable, the practitioner may disregard the existing H&P and conduct and document a new H&P examination in the patient’s medical record.

III. Survey Procedures

The Interpretive Guidelines require that the state surveyors utilize the following procedures to ensure compliance with the H&P requirement:

- The surveyors will review your medical staff bylaws to determine whether they require that an H&P be completed for each patient no more than 30 days before or 24 hours after admission or registration. The bylaws must specify that the H&P is to be conducted by a physician, oromaxillofacial surgeon or other qualified licensed individual in accordance with state law and hospital policy. Additionally, the



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surveyors will assess whether the bylaws require that the H&P be, in all cases, completed prior to surgery or a procedure requiring anesthesia.

- The surveyors will examine your hospital's policy regarding what other qualified individuals, if any, are permitted to conduct H&Ps.^{vi} Specifically, they will ascertain whether your policy is consistent with your state's scope of practice laws and regulations.
- The surveyors will verify that all non-physicians who perform H&P within the hospital are qualified and have been credentialed and privileged to do so in accordance with hospital policy.
- The surveyors will verify that where the H&P was conducted within 30 days prior to admission or registration, the hospital's bylaws require an update by a credentialed and privileged individual within 24 hours of admission or registration and in all cases prior to surgery or a procedure involving anesthesia.
- Finally, the surveyors will review a sample of inpatient and outpatient medical records to ensure all timing and personnel requirements are met. The surveyors will also look for cases where the medical history was completed within 30 days before admission or registration to determine whether a timely and complete H&P update was performed.

Authentication of Verbal Orders

I. The CoP Standard

Under the amended CoP regarding verbal orders, CMS cautions that if verbal orders are used in the hospital they are to be used infrequently.^{vii} All orders, including verbal orders, must be dated, timed and authenticated promptly by the ordering practitioner or another practitioner who is responsible for the care of the patient and authorized to write orders by hospital policy in accordance with

state law.^{viii} Verbal orders must be authenticated based upon federal and state law. If there is no state law that designates a specific timeframe for authentication, verbal orders must be authenticated within 48 hours.^{ix}

II. The Interpretive Guidelines

The Interpretive Guidelines clarify that all orders for drugs and biologicals, including verbal orders, must include a standard set of information designed to ensure safe preparation and administration, including:

- The name of the patient (presence on the order sheet or prescription is sufficient);
- The age and weight of the patient (when applicable);
- The date and time of the order;
- The drug name;
- The exact strength or concentration;
- The dose, frequency, route, quantity and duration;
- Specific instructions for use (when applicable); and
- The name of the prescriber.

The Interpretive Guidelines also clarify that verbal orders should not be used in common practice. CMS directs that verbal orders should only be used to meet patient care needs when it is impossible or impractical for the ordering practitioner to write the order or enter it into a computer without delaying treatment. Verbal orders are not to be used for the convenience of the ordering practitioner.

All verbal orders must be immediately documented on an order sheet in the patient's medical record or entered into the computerized order entry system and must be signed by the individual receiving the order. CMS also expects that all hospitals will employ a nationally accepted read-back verification practice for every verbal order.



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Prescribing practitioners must verify, sign, date and time all orders, including verbal orders, as soon as possible after issuing the order. Authentication of a verbal order may be written, electronic or faxed. If the ordering practitioner is not able to authenticate his or her verbal order, it is acceptable for another practitioner who is responsible for the patient's care to authenticate the verbal order.^x When a practitioner other than the ordering practitioner authenticates an order, that practitioner assumes responsibility for the order as being complete, accurate, and final.

- Describe limitations or prohibitions on the use of verbal orders;
- Provide a mechanism to ensure the validity and authenticity of the practitioner issuing a verbal order;
- List the elements required for all verbal orders and describe appropriate procedures for giving and receiving such orders;
- Describe the limited situations in which verbal orders may be used;
- Define the types of personnel who may issue and receive verbal orders; and
- Establish protocols for the effective communication, verification and authentication of verbal orders.

III. Survey Procedures

To ensure compliance with the CoP governing verbal orders, CMS has directed state surveyors to:

- Review your hospital's policies and procedures regarding verbal orders to ensure they minimize use of verbal orders and meet all stated documentation requirements.
- Review orders, including verbal orders, in a sample of medical records to ensure they were properly dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient and authorized to write orders by hospital policy and in

accordance with state law.

- Interview direct care staff to determine whether actual practice is consistent with the hospital's verbal order policies and procedures and whether staff accepting verbal orders have been authorized to do so under hospital policy.
- Review both open and closed patient medical records for the use of verbal orders to determine whether the number of verbal orders found in the sampled records suggests routine use or reveals that the hospital's policies and procedures regarding verbal orders were not followed.
- Determine whether the hospital has policies and procedures governing who is authorized to accept verbal orders. Surveyors will then review open and closed patient medical records containing verbal orders to determine whether the orders were dated, timed and signed by authorized hospital personnel.
- Determine whether the hospital's policies and procedures for verbal orders include a "read back and verify" process where the receiver of the order reads back the order to the ordering practitioner to verify its accuracy.
- Determine whether there is a state law specifying a verbal order authentication time period and review verbal order entries in a sample of medical records to ensure they have been authenticated within the applicable state timeframe, or within 48 hours if no state timeframe has been established.

Securing Medications

I. The CoP Standard

CMS requires as a condition of participation that all drugs and biologicals be kept in a secure area and locked when appropriate.^{xi} Drugs listed in Schedules II, III, IV and V (controlled substances) must be kept locked within a secure area^{xii} and hospitals must ensure that only



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authorized personnel have access to locked areas.^{xiii}

II. The Interpretive Guidelines

The Interpretive Guidelines explain that a “secure area” means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Areas restricted to authorized personnel only, as well as areas in which staff are actively providing care to patients or preparing to receive patients would generally be considered secure.

The Guidelines generally permit hospitals flexibility in the storage and safeguarding of drugs and biologicals. The Guidelines do contain certain required security features. For example, mobile medication, anesthesia and epidural carts must be locked in a secure area when not in use. Hospital policies and procedures are expected to address the security and monitoring of all carts in all patient care areas. Additionally, even though automated medication distribution units with security features are considered to be locked, these units must be stored in a secure area. Further, the Guidelines state that if there is evidence of tampering or diversion the hospital is expected to elevate its current medication control policies and procedures to ensure that the problem is corrected.

The Guidelines also grant hospitals flexibility to define which personnel will have access to locked areas based on the hospital’s needs as well as state law. The hospitals policies and procedures must set forth what personnel will be permitted access to locked areas. The policies should also address whether different levels of access are authorized in different areas of the hospital, at different times of day or for different classes of drugs and biologicals. The policies and procedures must also address what mechanisms the hospital will employ to prevent unauthorized personnel from gaining access to locked areas.

The Interpretive Guidelines clarify that the drug security CoP is not intended to interfere with patients’ appropriate self-administration of non-controlled drugs. Patients may be still be given bedside access to urgently needed medications, such as nitroglycerine tablets or inhalers, or nonprescription medications, such as lotions, creams or rewetting eye drops. Hospitals are expected to address patient self-administration of non-controlled drugs and biologicals in their policies and procedures. The policies should include measures to ensure the security of bedside drugs and biologicals, procedures for assessing the patient’s competence to self-administer, and patient education regarding self-administration policies and procedures.

III. Survey Procedures

In order to ascertain whether hospitals are properly securing medications, CMS has instructed state surveyors to:

- Review hospital policies and procedures governing drug and biological security, patient self-administration and storage of controlled medications in locked areas.
- Review hospital policies and procedures defining what personnel are authorized to access locked areas where drugs and biologicals are stored.
- Observe whether medications in various areas of the hospital are stored in secure areas and locked when appropriate.
- Determine whether security features in automated medication distribution units are implemented and actively maintained.
- Interview staff to determine whether policies and procedures that restrict access to authorized personnel are implemented and effective.
- Interview patients and staff to determine whether policies and procedures regarding patient self-administration of drugs are implemented and effective.



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Post-Anesthesia Evaluations

I. The CoP Standard

CMS requires that a post-anesthesia evaluation be completed and documented by an individual qualified to administer anesthesia no later than 48 hours after surgery or a procedure requiring anesthesia services.^{xiv} The post-anesthesia evaluation is intended to verify anesthesia recovery and must be completed in accordance with state law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

II. The Interpretive Guidelines

The Interpretive Guidelines instruct that a post-anesthesia evaluation is required any time general, regional or monitored anesthesia has been administered to a patient. The Guidelines clarify that although current practice dictates that patients receiving conscious sedation be monitored and evaluated during and after procedures, post-anesthesia evaluations are not required for these patients.

The post-anesthesia evaluation must be completed and documented by a practitioner who is qualified to administer anesthesia including a qualified anesthesiologist; a doctor of medicine or osteopathy; a dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under state law; a certified registered nurse anesthetist (CRNA) who is under the supervision of the operating practitioner or of an anesthesiologist; or an anesthesiologist's assistant who is under the supervision of an anesthesiologist. Post-anesthesia evaluations may not be performed by practitioners who are not qualified to administer anesthesia.

The Guidelines encourage hospitals to consult recognized professional guidance when developing their

policies and procedures for post-anesthesia care. Specifically, the Guidelines point to the Practice Guidelines for Postanesthetic Care published by the American Society of Anesthesiologists, which contains recommendations for post-anesthesia monitoring and assessment of respiratory function, cardiovascular function, mental status, temperature, pain, nausea and vomiting, and postoperative hydration.^{xv} The Guidelines also caution that depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

III. Survey Procedures

State surveyors will ascertain compliance with the post-anesthesia evaluation requirement by:

- Reviewing a sample of medical records for patients who had surgery or a procedure requiring anesthesia to determine whether a post-anesthesia evaluation was written for each patient, whether such evaluation was performed within 48 hours after the surgery or procedure, and whether the evaluation was conducted by a practitioner who is qualified to administer anesthesia.
- Reviewing your hospital's policies and procedures regarding post-anesthesia recovery and evaluation to determine whether the hospital has incorporated current practice guidelines.

Summary

Before your next state survey, take the time to make sure that your hospital is in compliance with these newly updated CoP standards. Look over your medical staff bylaws, review your policies and procedures and check with legal counsel to ascertain any changes in state law. Conduct an internal audit of patient records to



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determine whether all documentation and authentication requirements have been met and interview house staff to ascertain whether policies and procedures are being followed. CMS has given hospitals a valuable way to anticipate state surveyor's moves. Make sure your hospital utilizes the Interpretive Guidelines contained in the State Operations Manual to their fullest potential.

For more information about the new CMS Interpretive Guidelines please contact Mary C. Malone or Rachel J. Suddarth at (804) 967-9604, or by email mmalone@hdjn.com or rsuddarth@hdjn.com. Additional information about Hancock, Daniel, Johnson & Nagle, P.C. is available on the firm's website at www.hdjn.com.

- ⁱ The State Operations Manual is available at <http://www.cms.hhs.gov/Manuals/IOM/list.asp>.
- ⁱⁱ CMS published the new Interpretive Guidelines in a Memorandum to State Survey Agency Directors. A copy of the memorandum is available at <http://www.cms.hhs.gov/surveycertificationgeninfo/downloads/SCLetter08-12.pdf>.
- ⁱⁱⁱ The CoP amendments were published at 72 Fed. Reg. 68672 (Nov. 27, 2006).
- ^{iv} 42 C.F.R. § 482.22(c)(5)(i).
- ^v The H&P update requirements are set forth at 42 C.F.R. § 482.22(c)(5)(ii).
- ^{vi} For example, the H&P may be conducted by a Nurse Practitioner or Physician Assistant if permissible under state law and hospital policy.
- ^{vii} 42 C.F.R. § 482.23(c)(2)(i).
- ^{viii} 42 C.F.R. § 482.24(c)(1)(i), -(ii).
- ^{ix} 42 C.F.R. § 482.24(c)(1)(iii).
- ^x This practice is only permissible if there is no state law requiring that the prescribing practitioner authenticate his or her own verbal orders.
- ^{xi} 42 C.F.R. § 482.25(b)(2)(i).
- ^{xii} 42 C.F.R. § 482.25(b)(2)(ii).
- ^{xiii} 42 C.F.R. § 482.25(b)(2)(iii).
- ^{xiv} 42 C.F.R. § 482.52(b)(3).
- ^{xv} See American Society of Anesthesiologists, Practice Guidelines for Postanesthetic Care, 96 ANESTHESIOLOGY 742 (March 2002).

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