

Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-08-12

DATE: February 8, 2008

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Hospitals – Revised Interpretive Guidelines for Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Post-anesthesia Evaluations Final Rule.

Memorandum Summary

- The attached interpretive guidelines correspond to the regulatory changes published November 27, 2006 amending Hospital Conditions of Participation (CoPs) pertaining to requirements for history and physical examinations; authentication of verbal orders; securing medications; and post-anesthesia evaluations.
- The Tag numbers have been revised. State survey agencies should not use the temporary Tag numbers identified in the S&C letter of February 23, 2007 (S&C-07-13).
- The interpretive guidelines also include newly-adopted additional changes that were incorporated into the Calendar Year 2008 Outpatient Prospective Payment System (OPPS) regulation. They are effective January 1, 2008.

The interpretive guidelines attached to this memorandum reflect the regulatory changes that were published on November 27, 2006 amending the Hospital Conditions of Participation (CoPs) pertaining to requirements for history and physical examinations; authentication of verbal orders; securing medications; and post-anesthesia evaluations (CMS-3122F, 72 FR 68672). These changes were discussed in an S&C letter published on January 26, 2007 (S&C-07-13; revised 2/23/07).

The interpretive guidelines also reflect the newly-adopted additional changes that were incorporated into the Calendar Year (CY) 2008 Outpatient Prospective Payment System (OPPS) regulation, which was published on November 27, 2007 and were effective January 1, 2008. The revisions are intended to clarify the timeframe requirements for the medical history and physical examination and its update, and the post-anesthesia evaluation requirements for patients undergoing outpatient surgeries and procedures.

Under the CY 2008 OPSS regulation, the Medical Staff CoP at 42 CFR 482.22(c)(5) has been revised to clarify the requirement that the medical history and physical examination, or updated examination, must, regardless of any other timeframe requirements, be completed prior to surgery or a procedure requiring anesthesia services. The appropriate corresponding changes were made to the Medical Records CoP at 42 CFR 482.24(c)(2)(i), the Surgical Services CoP at 42 CFR 482.51(b)(1), and the Anesthesia Services CoP at 42 CFR 482.52(b)(1). In addition, the Anesthesia Services CoP at 42 CFR 482.52(b)(3), pertaining to the post-anesthesia evaluation requirement, requires that a post-anesthesia evaluation must be completed no later than 48 hours after surgery or a procedure requiring anesthesia services. The post-anesthesia evaluation also must be completed in accordance with State laws and with hospital policies and procedures which have been approved by the medical staff and must reflect current standards of anesthesia care. Finally, in order to remove the distinctions between inpatients and outpatients, the paragraph in the Anesthesia Services CoP at 42 CFR 482.52(b)(4) has been deleted.

The Tag numbers in the interpretive guidelines have been revised and in some instances, separate Tags have been consolidated. ASPEN tag number and regulatory text updates have either already been accomplished or are in process. State survey agencies should no longer use the temporary Tag numbers identified in the S&C letter of February 23, 2007.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

If you have additional questions or concerns, please contact David Eddinger at 410-786-3429 or via email at david.eddinger@cms.hhs.gov.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

[replace current SOM text beginning with “A-0191” and up to but not including “A-0192” as follows:]

A-0358

482.22(c)(5) Include a requirement that --

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Interpretive Guidelines §482.22(c)(5)(i)

The purpose of a medical history and physical examination (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 a new or existing co-morbid condition that requires additional interventions to reduce risk to the patient.

The Medical Staff bylaws must include a requirement that an H&P be completed and documented for each patient no more than 30 days prior to or 24 hours after hospital admission or registration, but prior to surgery or a procedure requiring anesthesia services. 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.

An H&P is required prior to surgery and prior to procedures requiring anesthesia services, regardless of whether care is being provided on an inpatient or outpatient basis. (71 FR 68676) An H&P that is completed within 24 hours of the patient's admission or registration, but after the surgical procedure, procedure requiring anesthesia, or other procedure requiring an H&P would not be in compliance with this requirement.

The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Section 1861(r) defines a physician as a:

- *doctor of medicine or osteopathy;*
- *doctor of dental surgery or of dental medicine;*
- *doctor of podiatric medicine;*
- *doctor of optometry; or a*
- *chiropractor.*

In all cases the practitioners included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act attaches further limitations as to the type of hospital services for which a practitioner is considered to be a “physician.”

Other qualified licensed individuals are those licensed practitioners who are authorized in accordance with their State scope of practice laws or regulations to perform an H&P and who are also formally authorized by the hospital to conduct an H&P. Other qualified licensed practitioners could include nurse practitioners and physician assistants.

More than one qualified practitioner can participate in performing, documenting, and authenticating an H&P for a single patient. When performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents. (71 FR 68675)

A hospital may adopt a policy allowing submission of an H&P prior to the patient’s hospital admission or registration by a physician who may not be a member of the hospital’s medical staff or who does not have admitting privileges at that hospital, or by a qualified licensed individual who does not practice at that hospital but is acting within his/her scope of practice under State law or regulations. Generally, this occurs where the H&P is completed in advance by the patient’s primary care practitioner. (71 FR 68675)

When the H&P is conducted within 30 days before admission or registration, an update must be completed and documented by a licensed practitioner who is credentialed and privileged by the hospital’s medical staff to perform an H&P. (71 FR 68675) (See discussion of H&P update requirements at 42 CFR 482.22(c)(5)(ii)).

Surveyors should cite noncompliance with the requirements of 482.22(c)(5) for failure by the hospital to comply with any of this standard’s components.

Survey Procedures §482.22(c)(5)(i)

- Review the medical staff bylaws to determine whether they require that a physical examination and medical history be done for each patient no more than 30 days before or 24 hours after admission or registration by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy. Verify whether the bylaws require the H&P be completed prior to surgery or a procedure requiring anesthesia services.*
- Review the hospital’s policy, if any, to determine whether other qualified licensed individuals are permitted to conduct H&Ps to ensure that it is consistent with the State’s scope of practice law or regulations.*
- Verify that non-physicians who perform H&Ps within the hospital are qualified and have been credentialed and privileged in accordance with the hospital’s policy.*

- *Review a sample of inpatient and outpatient medical records that include a variety of patient populations undergoing both surgical and non-surgical procedures to verify that:*
 - *There is an H&P that was completed no more than 30 days before or 24 hours after admission or registration, but, in all cases, prior to surgery or a procedure requiring anesthesia services; and*
 - *The H&P was performed by a physician, an oromaxillofacial surgeon, or other qualified licensed individual authorized in accordance with State law and hospital policy.*

A-0359

482.22(c)(5) [Include a requirement that --]

(ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Interpretive Guidelines 482.22(c)(5)(ii)

The Medical Staff bylaws must include a requirement that when a medical history and physical examination has been completed within 30 days before admission or registration, an updated medical record entry must be completed and documented in the patient's medical record within 24 hours after admission or registration. The examination must be conducted by a licensed practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P. In all cases, the update must take place prior to surgery or a procedure requiring anesthesia services. The update note must document an examination for any changes in the patient's condition since the patient's H&P was performed that might be significant for the planned course of treatment. The physician or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient's medical record.

If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed (71 FR 68676). Any changes in the patient's condition must be documented by the practitioner in the update note and placed in the patient's medical record within 24 hours of admission or registration, but prior to surgery or a procedure requirement anesthesia services. Additionally, if the practitioner finds that the H&P done before

admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

Survey Procedures §482.22(c)(5)(ii)

- Review the medical staff bylaws to determine whether they include provisions requiring that, when the medical history and physical examination was completed within 30 days before admission or registration, an updated medical record entry documenting an examination for changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration.*
- Determine whether the bylaws require that, in all cases involving surgery or a procedure requiring anesthesia services, the update to the H&P must be completed and documented prior to the surgery or procedure.*
- In the sample of medical records selected for review, look for cases where the medical history and physical examination was completed within 30 days before admission or registration. Verify that an updated medical record entry documenting an examination for any changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration. Verify that in all cases involving surgery or a procedure requiring anesthesia services, the update was completed and documented prior to the surgery or procedure.*

A-0393 [replaces “A202” in current SOM]

§482.23(b)(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.

Interpretive Guidelines §482.23(b)(1)

The hospital must provide nursing services 24 hours a day, 7 days a week. A LPN can provide nursing services if a RN, who is immediately available for the bedside care of those patients, supervises that care.

Exception: §488.54(c) sets forth certain conditions under which rural hospitals of 50 beds or fewer may be granted a temporary waiver of the 24 hour registered nurse requirement by the regional office.

Rural is defined as all areas not delineated as “urbanized” areas by the Census Bureau, in the most recent census. Temporary is defined as a one year period or less and the waiver cannot be renewed.

Survey Procedures §482.23(b)(1)

- Review the nurse staffing schedule for a one-week period. If there are concerns regarding insufficient RN coverage, review the staffing schedules for a second week period to determine if there is a pattern of insufficient coverage. Document daily RN coverage for every unit of the hospital. Verify that there is at least one RN for each unit on each tour of duty, 7 days a week, 24 hours a day. Additional nurses may be required for vacation or absenteeism coverage.
- **Exception:** If the hospital has a temporary waiver of the 24-hour RN requirement in effect, verify and document the following:
 - 50 or fewer inpatient beds;
 - The character and seriousness of the deficiencies do not adversely affect the health and safety of patients
 - The hospital meets all the other statutory requirements in section 1861(e)(1-8).
 - The hospital has made and continues to make a good faith effort to comply with the 24 hour nursing requirement. Determine the recruitment efforts and methods used by the hospitals' administration by requesting copies of advertisements in newspapers and other publications as well as evidence of contact with nursing schools and employment agencies. Document that the salary offered by the hospital is comparable to three other hospitals, located nearest to the facility.
 - The hospital's failure to comply fully with the 24 hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.
 - A registered nurse is present on the premises to furnish the nursing service during at least the daytime shift, 7 days a week.
 - On all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse is in charge.

[replace current SOM text beginning with "A 0210" up to but not including "A-0214" as follows:]

A-0406

482.23(c)(2) 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 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 §482.12(c).

Interpretive Guidelines §482.23(c)(2)

All orders for drugs and biologicals, with the exception of influenza and pneumococcal polysaccharide vaccines, must be documented and signed by a practitioner who is authorized by hospital policy, and in accordance with State law, to write orders and who is responsible for the care of the patient as specified under §482.12(c). In accordance with §482.12(c)(1), practitioners who are authorized to provide care for Medicare patients include:

- A doctor of medicine or osteopathy;*
- A doctor of dental surgery or dental medicine;*
- A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;*
- A doctor of optometry who is legally authorized to practice optometry by the State;*
- A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist;*
- A clinical psychologist as defined in §410.71, but only with respect to clinical psychologist services as defined in §410.71 and only to the extent permitted by law.*

Nurse Practitioners and Physician Assistants responsible for the care of specific patients are also permitted to order drugs and biologicals in accordance with delegation agreements, collaborative practice agreements, hospital policy and State law.

Influenza and pneumococcal polysaccharide vaccines may be administered per physician-approved hospital policy after an assessment of contraindications.

Note: If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care.

In accordance with standard practice, elements that must be present in orders for all drugs and biologicals to ensure safe preparation and administration include:

- Name of patient (present on order sheet or prescription);*
- Age and weight of patient, when applicable;*
- Date and time of the order;*
- Drug name;*

- *Exact strength or concentration, when applicable;*
- *Dose, frequency, and route;*
- *Quantity and/or duration, when applicable;*
- *Specific instructions for use, when applicable; and*
- *Name of prescriber.*

Hospitals are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding orders. Any questions about orders for drugs or biologicals are expected to be resolved prior to the preparation, or dispensing, or administration of the medication.

Survey Procedures §482.23(c)(2)

- *Review the hospital's policy for drug and biological orders. Does it require that orders be in writing and signed by a practitioner who is authorized by hospital policy and in accordance with State law, to write orders and who is responsible for the care of the patient?*
- *Review a sample of open and closed patient medical records. Although the regulation applies to both inpatient and outpatient medical records, the sample should be weighted to include more inpatient records.*
- *Determine whether all orders for drugs and biologicals, with the exception of influenza and pneumococcal polysaccharide vaccines, are written in the patient's medical record 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.*
- *Determine whether all orders for drugs and biologicals contain the required elements.*
- *Verify that the prescribing practitioner has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.*

A-0407

482.23(c)(2)(i) If verbal orders are used, they are to be used infrequently.

Interpretive Guidelines §482.23(c)(2)(i)

Verbal orders, if used, must be used infrequently. This means that the use of verbal orders must not be a common practice. Verbal orders pose an increased risk of miscommunication that could contribute to a medication or other error, resulting in a patient adverse event. Verbal orders should be used only to meet the care needs of the patient when it is impossible or

impractical for the ordering practitioner to write the order or enter it into a computer (in the case of a hospital with an electronic prescribing system) without delaying treatment. Verbal orders are not to be used for the convenience of the ordering practitioner. (71 FR 68679)

Hospitals are expected to develop appropriate policies and procedures that govern the use of verbal orders and minimize their use, such as:

- Describe limitations or prohibitions on the use of verbal orders;*
- Provide a mechanism to ensure validity/authenticity of the practitioner issuing a verbal order;*
- List the elements required for inclusion in the verbal order process;*
- Describe situations in which verbal orders may be used;*
- Define the types of personnel who may issue and receive verbal orders; and*
- Establish protocols for clear and effective communication, verification, and authentication of verbal orders.*

The content of verbal orders must be clearly communicated. All verbal orders must be immediately documented in the patient's medical record and signed by the individual receiving the order. Verbal orders should be recorded directly onto an order sheet in the patient's medical record or entered into the computerized order entry system, if the hospital employs one. CMS expects nationally accepted read-back verification practice to be implemented for every verbal order. (71 FR 68680)

Survey Procedures §482.23(c)(2)(i)

- Are there policies and procedures in place to minimize the use of verbal orders?*
- Interview direct care staff to determine whether actual practice is consistent with verbal order policies and procedures.*
- Review both open and closed patient medical records for the use of verbal orders.*
- Were the policies and procedures for the use of verbal orders followed?*
- Does the number of verbal orders found in the sampled records suggest routine use, which the regulations do not permit? The number of verbal orders is not in itself evidence of noncompliance, but should result in more focused analysis. For example:*
 - Is there a pattern to the use of verbal orders? Some patterns might make sense – e.g., for orders entered between midnight and 7 a.m., it might be plausible that it*

was impossible for the prescribing practitioner to write/computer-enter the order. On the other hand, if one patient care unit has a high proportion of verbal orders, while another does not, this might be a flag for inconsistent implementation of the hospital's policies and procedures for verbal orders.

- Are verbal orders used frequently for certain types of situations, and if so, is it reasonable to assume that it is impossible or impractical for the prescribing practitioners to write/enter the orders in such situations?*
- Do certain practitioners use verbal orders frequently? From the limited number of records sampled it may be difficult to detect trends related to specific practitioners, but if a surveyor finds such evidence, further investigation is warranted to determine if it is evidence of noncompliance.*

A-0408

482.23(c)(2)(ii) *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.*

Interpretive Guidelines §482.23(c)(2)(ii)

A verbal order for drugs and biologicals must be documented in the medical record by a practitioner who is permitted by Federal and State law and hospital policy to accept verbal orders.

Survey Procedures §482.23(c)(2)(ii)

- Determine whether the hospital has policies and procedures governing who is authorized to accept verbal orders.*
- Determine whether the hospital's policies and procedures for acceptance of verbal orders are consistent with Federal and State law.*
- Review open and closed patient medical records containing verbal orders for drugs and biologicals. Determine whether the orders are documented by authorized hospital personnel, consistent with Federal and State law.*
- Interview several direct care staff to determine if they are permitted to take verbal orders for drugs and biologicals, and determine whether such staff have been authorized to do so in accordance with hospital policy.*

Replace current SOM text beginning with “A-0230” up to but not including “A-0235” with the following:]

A-0450

482.24(c)(1) *All patient medical record entries must be legible, complete, 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.*

Interpretive Guidelines §482.24(c)(1)

*All entries in the medical record must be **legible**. Orders, progress notes, nursing notes or other entries in the medical record that are not legible may be misread or misinterpreted and may lead to medical errors or other adverse patient events.*

*All entries in the medical record must be **complete**. A medical record is considered complete if it contains sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers. With these criteria in mind, an individual entry into the medical record must contain sufficient information on the matter that is the subject of the entry to permit the medical record to satisfy the completeness standard.*

*All entries in the medical record must be **dated, timed, and authenticated**, in written or electronic form, by the person responsible for providing or evaluating the service provided.*

- The time and date of each entry (orders, reports, notes, etc.) must be accurately documented. Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries is necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events. (71 FR 68687)*
- The hospital must have a method to establish the identity of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.*
- The hospital must have a method to require that each author takes a specific action to verify that the entry being authenticated is his/her entry or that he/she is responsible for the entry, and that the entry is accurate.*

The requirements for dating and timing do not apply to orders or prescriptions that are generated outside of the hospital until they are presented to the hospital at the time of service. Once the hospital begins processing such an order or prescription, it is responsible for ensuring that the implementation of the order or prescription by the hospital is promptly dated, and timed in the patient’s medical record.

Where a practitioner has written a set of orders or is using a preprinted order set contained on one page, or on several pages, the physician must sign, date, and time each page of orders.

Authentication of medical record entries may include written signatures, initials, computer key, or other code. For authentication, in written or electronic form, a method must be established to identify the author. When rubber stamps or electronic authorizations are used for authentication, the hospital must have policies and procedures to ensure that such stamps or authorizations are used only by the individuals whose signature they represent. There shall be no delegation to another individual.

Where an electronic medical record is in use, the hospital must demonstrate how it prevents alterations of record entries after they have been authenticated. Information needed to review an electronic medical record, including pertinent codes and security features, must be readily available to surveyors to permit their review of sampled medical records while on-site in the hospital.

Any entries in the medical record made by residents or non-physicians that require countersignature by supervisory or attending medical staff members must be defined in the medical staff rules and regulations.

A system of auto-authentication in which a physician or other practitioner authenticates an entry that he or she cannot review, e.g., because it has not yet been transcribed, or the electronic entry cannot be displayed, is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the entry after it was created. In addition, failure to disapprove an entry within a specific time period is not acceptable as authentication.

The practitioner must separately date and time his/her signature, even though there may already be a date and time on the document. For certain electronically-generated documents, where the date and time that the physician reviewed the electronic transcription is automatically printed on the document, the requirements of this section would be satisfied. However, if the electronically-generated document only prints the date and time that an event occurred (e.g., EKG printouts, lab results, etc.) and does not print the date and time that the practitioner actually reviewed the document, then the practitioner must either authenticate, date, and time this document itself or incorporate an acknowledgment that the document was reviewed into another document (such as the H&P, a progress note, etc.), which would then be authenticated, dated, and timed by the practitioner.

Survey Procedures §482.24(c)(1)

- *Review a sample of open and closed medical records.*
 - *Determine whether all medical record entries are legible. Are they clearly written in such a way that they are not likely to be misread or misinterpreted?*

- Determine whether orders, progress notes, nursing notes or other entries in the medical record are complete. Does the medical record contain sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers?
- Determine whether medical record entries are dated, timed, and appropriately authenticated by the person who is responsible for ordering, providing, or evaluating the service provided.
- Determine whether all orders, including verbal orders, are written in the medical record and signed by the practitioner who is caring for the patient and who is authorized by hospital policy and in accordance with State law to write orders.
- Determine whether the hospital has a means for verifying signatures, both written and electronic, written initials, codes, and stamps when such are used for authorship identification. For electronic medical records, ask the hospital to demonstrate the security features that maintain the integrity of entries and verification of electronic signatures and authorizations. Examine the hospital’s policies and procedures for using the system, and determine if documents are being authenticated after they are created.

A-0454

482.24(c)(1)(i) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner, except as noted in paragraph (c)(1)(ii) of this section.

482.24(c)(1)(ii) For the 5 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 under §482.12(c) and authorized to write orders by hospital policy in accordance with State law.

Interpretive Guidelines §482.24(c)(1)(i)

The hospital must ensure that all orders, including verbal orders, are dated, timed, and authenticated promptly. The Merriam-Webster online dictionary defines “prompt” as performed readily or immediately.

Verbal orders are orders for medications, treatments, interventions, or other patient care that are transmitted as oral, spoken communications between senders and receivers, delivered either face-to-face or via telephone.

The receiver of a verbal order must date, time, and sign the verbal order in accordance with hospital policy. CMS expects hospital policies and procedures for verbal orders to include a read-back and verification process.

The prescribing practitioner must verify, sign, date, and time the order as soon as possible after issuing the order, in accordance with hospital policy, and State and Federal requirements.

Authentication of a verbal order may be written, electronic, or faxed. The hospital must have a method for establishing the identity of the practitioner who has given a verbal order, including verification of the author of faxed verbal orders or computer entries.

In some instances, the ordering practitioner may not be able to authenticate his or her verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is "off duty" for the weekend or an extended period of time). In such cases, for a temporary period expiring on January 26, 2012, it is acceptable for another practitioner who is responsible for the patient's care to authenticate the verbal order of the ordering practitioner. CMS provided this temporary exception in order to take account of differences among hospitals in their rate of adoption of electronic medical record systems that would permit the ordering practitioner to easily and efficiently authenticate an order in all circumstances.

- All practitioners responsible for the patient's care are expected to have knowledge of the patient's hospital course, medical plan of care, condition and current status.*
- When a practitioner other than the ordering practitioner signs a verbal order, that practitioner assumes responsibility for the order as being complete, accurate and final.*
- A qualified licensed practitioner, such as a physician assistant (PA) or nurse practitioner (NP), may authenticate a physician's or other qualified licensed practitioner's verbal order only if the order is within his/her scope of practice and the patient is under his/her care.*
- If State law requires that the prescribing practitioner authenticate the verbal orders, a practitioner other than the prescribing practitioner would not be permitted to authenticate the verbal order in that State.*

(71 FR 68682)

Survey Procedures §482.24(c)(1)(i)

- Does the hospital have policies and procedures requiring prompt authentication of all orders, including verbal orders, by the prescribing practitioner or, if permitted under State law, another practitioner responsible for the care of the patient?*
- Do 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?*
- Review orders, including verbal orders, in a sample of medical records. Have orders been dated, timed, and authenticated promptly by the ordering practitioner or another practitioner who is responsible for the care of the patient, as specified under §482.12(c), and who is authorized to write orders by hospital policy in accordance with State law?*

- *Has the receiver of an order, including verbal orders, dated, timed, and signed the order according to hospital policy?*

A-0457

482.24(c)(1)(iii) 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.

Interpretive Guidelines §482.24(c)(1)(iii)

This regulation provides that, if there is no State law designating a specific timeframe for authentication of verbal orders, then such orders must be authenticated within 48 hours.

Authentication of a verbal order represents an opportunity to identify a transcription error and potential risk to patient safety. Prompt authentication of a verbal order enables early identification and correction of an error. CMS does not believe a 30-day timeframe for authentication is consistent with the intent to intercept an error as soon as possible. However, given the lack of data to support a specific timeframe for authentication of verbal orders and the lack of consensus on a timeframe for authentication, CMS will continue to defer to State law, when there is a State law establishing a verbal order authentication timeframe. (71 FR 68684)

However, a State law that substitutes for authentication of the verbal order another mechanism, such as a read-back and verify requirement, where the receiver of the order reads the order back to the ordering practitioner to verify its accuracy, does not qualify for the State law exception. CMS expects hospital policies and procedures for verbal orders to include a read-back and verify process, in addition to specifying a timeframe for authentication of the orders. For example, in a State with a law that requires verification of a verbal order within a specified timeframe only when the read-back and verify process is not used, hospitals in that State would still be required by CMS to authenticate all verbal orders within 48 hours. It does not matter whether the State law also has a separate requirement for completion of the medical record within a specified timeframe, e.g., 30 days. On the other hand, a State law that establishes a 48 hour authentication period for verbal orders where no read-back and verify process was used, but 30 days for verbal orders using read-back and verify does qualify for the State law exception. (71 FR 68684)

Survey Procedures §482.24(c)(1)(iii)

- *Determine whether there is a State law that qualifies for the exception to the 48-hour requirement for verbal order authentication. This should be done in consultation with the Regional Office in advance of the survey.*
- *Determine whether the hospital's policies and procedures for verbal orders include a read-back and verify requirement.*

- *Review verbal order entries in a sample of medical records. Have verbal orders been authenticated within the applicable Federal (48 hours) or State timeframe?*

A-0458

482.24(c)(2) All records must document the following, as appropriate:

(i) Evidence of--

(A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.24(c)(2)(i)(A)

The medical record must include documentation that a medical history and physical examination (H&P) was completed and documented for each patient no more than 30 days prior to hospital admission or registration, or 24 hours after hospital admission or registration, but in all cases prior to surgery or a procedure requiring anesthesia services.

The purpose of an 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 an allergy to a medication that must be avoided, or a co-morbidity that requires certain additional interventions to reduce risk to the patient.

The H&P documentation must be placed in the medical record within 24 hours of admission or registration, but in all cases prior to surgery or a procedure requiring anesthesia services, including all inpatient, outpatient or same-day surgeries or procedures. (71 FR 68676) The H&P may be handwritten or transcribed. An H&P that is completed within 24 hours of the patient's admission or registration, but after surgery or a procedure requiring anesthesia would not be in compliance.

The H&P must be completed and documented by a physician (as defined in section 1861(r) of the Act), oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Section 1861(r) defines a physician as a:

- *doctor of medicine or osteopathy;*
- *doctor of dental surgery or of dental medicine;*
- *doctor of podiatric medicine;*
- *doctor of optometry; or a*
- *chiropractor.*

In all cases the practitioners included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their

authorized scope of practice. In addition, in certain instances the Social Security Act attaches further limitations as to the type of services for which a practitioner is considered to be a “physician.”

Other qualified individuals are those licensed practitioners (such as nurse practitioners and physician assistants) who are permitted by their State scope of practice laws or regulations to conduct a history and physical examination, and who are also formally authorized by the hospital to conduct an H&P.

More than one qualified licensed practitioner can participate in performing, documenting, and authenticating an H&P for a single patient. When performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents. (71 FR 68675)

A hospital may adopt a policy allowing submission of an H&P prior to the patient’s hospital admission or registration by a physician who may not be a member of the hospital’s medical staff or who does not have admitting privileges by that hospital, or by a qualified licensed individual who does not practice at that hospital but is acting within his/her scope of practice under State law or regulation. Generally this occurs where the H&P is completed in advance by the patient’s primary care physician. (71 FR 68675)

When the H&P is conducted within 30 days before admission or registration, an update must be completed and documented by a licensed practitioner who is credentialed and privileged by the hospital’s medical staff to perform an H&P. (71 FR 68675) (See discussion of medical record H&P update requirements at 42 CFR 482.24(c)(2)(i)(B)).

Survey Procedures §482.24(c)(2)(i)(A)

Review a sample of inpatient medical records for various types of patients and outpatient medical records for patients having same day surgery or a procedure requiring anesthesia to determine whether:

- There is an H&P that was done no more than 30 days before or 24 hours after admission or registration, but, for all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure;*
- The H&P documentation was placed in the medical record within 24 hours after admission or registration, but, for all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure;*
- The H&P was performed by a physician, an oromaxillofacial surgeon, or other qualified licensed individual authorized in accordance with State law and hospital policy.*

A-0458

482.24(c)(2) [All records must document the following, as appropriate:]

(i) Evidence of --

(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.24(c)(2)(i)(B)

When an H&P is completed within the 30 days before admission or registration, the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is placed in the patient's medical record within 24 hours after admission or registration, but, in all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure. The examination must be conducted by a practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P.

The update note must document an examination for any changes in the patient's condition since the time that the patient's H&P was performed that might be significant for the planned course of treatment. The physician, oromaxillofacial surgeon or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient's medical record.

If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed. (71 FR 68676) Any changes in the patient's condition must be documented by the practitioner in the update note and placed in the patient's medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services. Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

Survey Procedures §482.24(c)(2)(i)(B)

In the sample of medical records selected for review, look for cases where the medical history and physical examination was completed within 30 days before admission or registration.

- *Determine whether an updated medical record entry documenting an examination for changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration.*
- *Determine whether, in all cases involving surgery or a procedure requiring anesthesia services, the update was completed and documented prior to the surgery or procedure.*

[replace current SOM text beginning with “A-0254” up to but not including “A-0255” as follows:]

A-0502

482.25(b)(2)(i) *All drugs and biologicals must be kept in a secure area, and locked when appropriate.*

Interpretive Guidelines §482.25(b)(2)(i)

A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (for example, ambulatory infusion), they are considered secure. Areas restricted to authorized personnel only would generally be considered “secure areas.” If there is evidence of tampering or diversion, or if medication security otherwise becomes a problem, the hospital is expected to evaluate its current medication control policies and procedures, and implement the necessary systems and processes to ensure that the problem is corrected, and that patient health and safety are maintained. (71 FR 68689)

*All controlled substances must be locked. Hospitals are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area. When a patient care area is not staffed, **both** controlled and non-controlled substances are expected to be locked.*

Generally labor and delivery suites and critical care units are staffed and actively providing patient care around the clock, and, therefore, considered secure. However, hospital policies and procedures are expected to ensure that these areas are secure, with entry and exit limited to appropriate staff, patients, and visitors.

The operating room suite is considered secure when the suite is staffed and staff are actively providing patient care. When the suite is not in use (e.g., weekends, holidays, and after hours), it would not be considered secure. A hospital may choose to lock the entire suite, lock non-mobile carts containing drugs and biologicals, place mobile carts in a locked room, or otherwise lock drugs and biologicals in a secure area. If an individual operating room is not in use, the hospital is expected to lock non-mobile carts, and ensure mobile carts are in a locked room.

(71FR 68689)

This regulation gives hospitals the flexibility to integrate patient self-administration of non-controlled drugs and biologicals into their practices as appropriate. When a hospital allows a patient to self-administer selected drugs and biologicals, the hospital authorizes the patient to have access to these medications. This regulation is consistent with the current practice of giving patients access at the bedside to urgently needed medications, such as nitroglycerine tablets and inhalers. It supports the current practice of placing selected nonprescription medications at the bedside for the patient's use, such as lotions and creams, and rewetting eye drops. Hospitals are expected to address patient self-administration of non-controlled drugs and biologicals in their policies and procedures. This regulation supports hospital development, in collaboration with the medical staff and the nursing and pharmacy departments, of formal patient medication self-administration programs for select populations of patients, including hospital policies and procedures necessary to ensure patient safety and security of medications. The policies and procedures are expected to include measures to ensure the security of bedside drugs and biologicals. They are also expected to address both the competence of the patient to self-administer drugs and biologicals as well as patient education regarding self-administration of drugs and biologicals. (71FR 68689)

Due to their mobility, mobile nursing medication carts, anesthesia carts, epidural carts, and other medication carts containing drugs or biologicals (hereafter, all referred to as "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 carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety. (71 FR 68689)

Medication automated distribution units with security features, such as logon and password or biometric identification, are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to the medications. Such units must be stored in a secure area.

Survey Procedures §482.25(b)(2)(i)

- Review hospital policies and procedures governing the security of drugs and biologicals to determine whether they provide for securing and locking as appropriate.*
- Review hospital policies and procedures governing patient self-administration of drugs and biologicals.*
- Observe whether medications in various areas of the hospital are stored in a secure area, and locked when appropriate.*
- Determine that security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.*

- *Interview staff to determine whether policies and procedures to 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 and biologicals are implemented and effective.*

A-0503

482.25(b)(2)(ii) *Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.*

Interpretive Guidelines §482.25(b)(2)(ii)

All Schedule II, III, IV, and V drugs must be kept locked within a secure area. A secure area means the drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Medication automated distribution units with logon and password/biometric identification are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to Schedule II – V medications.

Mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing Schedule II, III, IV, and V drugs must be locked within a secure area.

Survey Procedures §482.25(b)(2)(ii)

- *Determine whether there is a hospital policy and procedure that requires Schedule II, III, IV, and V drugs to be kept in a locked storage area.*
- *Observe in various parts of the hospital whether Schedule II, III, IV, and V drugs are locked and stored in a secure area.*
- *Determine whether security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.*
- *Interview staff to determine whether policies and procedures to restrict access to authorized personnel are implemented and effective.*

A-0504

482.25(b)(2)(iii) *Only authorized personnel may have access to locked areas.*

Interpretive Guidelines §482.25(b)(2)(iii)

The hospital must assure that only authorized personnel may have access to locked areas where drugs and biologicals are stored.

A hospital has the flexibility to define which personnel have access to locked areas, based on the hospital's needs as well as State and local law. For example, a hospital could include within its definition of "authorized personnel" ancillary support personnel, such as engineering, housekeeping staff, orderlies and security personnel as necessary to perform their assigned duties. The hospital's policies and procedures must specifically address how "authorized personnel" are defined for purposes of this section. It is not necessary for the policy to name specific authorized individuals, but the policy should be clear in describing the categories of personnel who have authorized access, as well as whether there are different levels of access authorized in different areas of the hospital, or at different times of day, or for different classes of drugs and biologicals, etc.

The hospital's policies and procedures must also address how it prevents unauthorized personnel from gaining access to locked areas where drugs and biologicals are stored. Whenever unauthorized personnel have access, or could gain access, to those locked areas, the hospital is not in compliance with this requirement and is expected to re-evaluate and tighten its security measures.

Survey Procedures §482.25(b)(2)(iii)

- *Determine whether there is a hospital policy and procedure defining authorized personnel that are permitted access to locked areas where drugs and biologicals are stored.*
- *Determine whether there is a hospital policy and procedure for limiting access to locked storage areas to authorized personnel only.*
- *Observe whether or not access to locked storage areas is limited to personnel authorized by the hospital's policy.*

[replace current SOM text beginning with "A-0391" up to but not including "A-0392" as follows:]

A-0952

§482.51(b)(1) Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

- (i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.*
- (ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.*

Interpretive Guidelines §482.51(b)(1)

There must be a complete history and physical examination (H&P), and an update, if applicable, in the medical record of every patient prior to surgery, or a procedure requiring anesthesia services, except in emergencies.

- The H&P must be conducted in accordance with the requirements of 42 CFR 482.22(c)(5).*
- The H&P must be completed and documented no more than 30 days before or 24 hours after admission or registration. In all cases, except for emergencies, the H&P must be completed and documented **before** the surgery or procedure takes place, even if that surgery or procedure occurs less than 24 hours after admission or registration.*
- If the H&P was completed within 30 days before admission or registration, then an updated examination must be completed and documented within 24 hours after admission or registration. In all cases, except for emergencies, the update must be completed and documented **before** the surgery or procedure takes place, even if that surgery or procedure occurs less than 24 hours after admission or registration.*

Survey Procedures §482.51(b)(1)

Review a sample of open and closed medical records of patients (both inpatient and outpatient) who have had surgery or a procedure requiring anesthesia.

- Determine whether an H&P was conducted and documented in a timely manner.*
- Determine whether the H&P was conducted in accordance with the requirements of 42 CFR 482.22(c)(5).*
- Determine whether the records of patients who did not have a timely H&P or update indicate that the surgery or procedure was conducted on an emergency basis.*

[replace current SOM text from “A-0419” up to but not including “A-0420” as follows:]

A-1006

482.52(b)(1) A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.52(b)(1)

The pre-anesthesia evaluation must be performed within 48 hours prior to any inpatient or outpatient surgery or procedure requiring anesthesia services. At a minimum, the pre-operative anesthetic evaluation of the patient should include:

- *Notation of anesthesia risk;*
- *Anesthesia, drug and allergy history;*
- *Any potential anesthesia problems identified;*
- *Patient's condition prior to induction of anesthesia.*

Survey Procedures §482.52(b)(1)

- *Review a sample of inpatient and outpatient medical records for patients who had surgery or a procedure requiring administration of anesthesia.*
- *Determine whether each patient had a pre-anesthesia evaluation by a practitioner qualified to administer anesthesia.*
- *Determine that the pre-anesthesia evaluation was performed within 48 hours prior to the surgery or a procedure requiring anesthesia services.*

[replace current SOM text from “A-0421” up to but not including “A-0428” as follows:]

A-1004

482.52(b)(3) A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery 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.

Interpretive Guidelines §482.52(b)(3)

A post-anesthesia evaluation must be completed and documented no later than 48 hours after surgery or a procedure requiring anesthesia services. The evaluation is required any time general, regional or monitored anesthesia has been administered to the patient. American Society of Anesthesiology (ASA) guidelines do not define moderate or conscious sedation as anesthesia. While current practice dictates that the patient receiving conscious sedation be monitored and evaluated before, during and after the procedure by trained practitioners, a postanesthesia evaluation is not required (71 FR 68691)

The evaluation must be completed and documented by any practitioner who is qualified to administer anesthesia. In accordance with §482.52(a), anesthesia must be administered only by:

- *A qualified anesthesiologist;*
- *A doctor of medicine or osteopathy (other than an anesthesiologist);*
- *A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;*
- *A certified registered nurse anesthetist (CRNA), who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or*
- *An anesthesiologist's assistant who is under the supervision of an anesthesiologist who is immediately available if needed.*

Although §482.12(c)(1)(i) provides broad authority to physicians to delegate tasks to other qualified medical personnel, the more stringent requirements of §482.52(b)(3) do not permit delegation of the post-anesthesia evaluation to practitioners who are not qualified to administer anesthesia.

Hospitals would be well advised in developing their policies and procedures for post-anesthesia care to consult recognized guidelines. For example, Practice Guidelines for Postanesthetic Care, Anesthesiology, Vol 96, No 3, March, 2002, provides the recommendations of the American Society of Anesthesiologists for routine post-anesthesia assessment and monitoring, including monitoring/assessment of:

- *Respiratory function, including respiratory rate, airway patency and oxygen saturation;*
- *Cardiovascular function, including pulse rate and blood pressure;*
- *Mental status;*
- *Temperature;*
- *Pain;*
- *Nausea and vomiting; and*
- *Postoperative hydration*

Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

Survey Procedures §482.52(b)(3)

- *Review 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.*

- *Determine whether the evaluation was conducted by a practitioner who is qualified to administer anesthesia.*
- *Determine whether the evaluation was performed within 48 hours after the surgery or procedure requiring anesthesia.*
- *Determine whether current practice guidelines are included as part of the hospital's policies and procedures regarding post-anesthesia recovery and evaluation.*

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