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**42 CFR Part 482
Medicare and Medicaid Programs;
Hospital Conditions of Participation; Final
Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

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Medicare and Medicaid Programs; Hospital Conditions of Participation; Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations

AGENCY: Centers for Medicare & Medicaid Services (CMS), DHHS.

ACTION: Final rule.

SUMMARY: In this rule, we finalize changes to four of the current requirements (or conditions of participation (CoPs)) that hospitals must meet to participate in the Medicare and Medicaid programs. Specifically, this final rule revises and updates our CoP requirements for: Completion of the history and physical examination in the medical staff and the medical record 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. We also respond to timely public comments submitted on the proposed rule published in the March 25, 2005 *Federal Register* (70 FR 15266). The changes specified in this final rule are consistent with current medical practice and will reduce the regulatory burden on hospitals.

DATES: Effective Date: These regulations are effective on January 26, 2007.

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I. Legislative and Regulatory Background

A. General

On March 25, 2005 we published a proposed rule in the *Federal Register* entitled “Medicare and Medicaid Programs; Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations” (70 FR 15266). In that document, we presented our proposals to: (1) Expand the timeframe for completion of the history and physical examination to 30 days and expand the number of permissible professional categories of individuals who may perform the history and physical examination; (2) require that all orders, including verbal orders, be dated, timed, and authenticated by a practitioner responsible for the care of the patient. In the absence of a State law specifying the timeframe for authentication of verbal orders, verbal orders would need to be authenticated within 48 hours; (3) require that all drugs and biologicals be kept in secure areas, and locked when appropriate; and, (4) permit the postanesthesia evaluation for inpatients to be completed and documented by any individual qualified to administer anesthesia. This action was initiated in response to broad criticism from the medical community that the current requirements governing these areas are burdensome and do not reflect current practice.

Previously, we published a proposed rule in the December 19, 1997 *Federal Register* (62 FR 66726), entitled

“Medicare and Medicaid Programs; Hospital Conditions of Participation (CoPs); Provider Agreements and Supplier Approval” which specified our proposal to comprehensively revise the entire set of hospital CoPs. The CoPs are the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients.

Sections 1861(e)(1) through 1861(e)(8) of the Social Security Act (the Act) define the term “hospital” and list the requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the Act specifies that a hospital must also meet such other requirements as the Secretary of Health and Human Services (the Secretary) finds necessary in the interest of the health and safety of the hospital’s patients. Under this authority, the Secretary has established in regulations, at Part 482, the requirements that a hospital must meet to participate in the Medicare program.

Compliance is determined by State survey agencies (SAs) or accreditation organizations. The SAs, in accordance with section 1864 of the Act, survey hospitals to assess compliance with the CoPs. The SAs conduct surveys using the State Operations Manual (SOM) (Centers for Medicare & Medicaid Services (CMS) Publication No. 7). The SOM contains the regulatory language of the CoPs as well as interpretive guidelines and survey procedures that give guidance on how to assess provider compliance. Under § 489.10(d), the SAs determine whether a hospital meets the CoPs and make corresponding recommendations to us about a hospital’s certification, (that is, whether a hospital has met the standards required to provide Medicare and Medicaid services and receive Federal and State reimbursement).

Under section 1865 of the Act, hospitals that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association (AOA), and other national accreditation programs approved by us are deemed to meet the requirements in the CoPs. All Medicare- and Medicaid-participating hospitals are required to be in compliance with our CoPs regardless of their accreditation status.

B. Finalizing Provisions of the December 19, 1997 Proposed Rule (62 FR 66726)

In the December 19, 1997 proposed rule (62 FR 66726), we proposed to revise all CoPs specified in Part 482. While our initial intention was to

finalize the December 19, 1997 proposed rule in its entirety, delays within CMS (then the Health Care Financing Administration (HCFA)) led us to re-evaluate this objective in light of concerns expressed by providers that we move forward with certain final rules in the interest of public health and safety. Our strategy to address CoPs considered of particular urgency by providers was to finalize or “carve-out” specific CoPs as separate final rules. To date, we have published the following hospital CoPs: Organ, Tissue and Eye Procurement CoP (see the June 22, 1998 final rule (63 FR 33856); Patients’ Rights (see the July 2, 1999 interim final rule (64 FR 36069); Anesthesia Services-CRNA supervision (see the November 13, 2001 final rule (66 FR 56762); Fire Safety Requirements for Certain Health Care Facilities (see the January 10, 2003 final rule (68 FR 1374); and, Quality Assessment Performance Improvement (see the January 24, 2003 final rule (68 FR 3435).

Beginning in 2003, we began to develop a final rule to address public comments provided on the December 19, 1997 proposed rule for the following four requirements: (1) Completion of a history and physical examination in the medical staff and the medical record services CoPs; (2) authentication of verbal orders in the nursing service and the medical record services CoPs; (3) securing medications in the pharmaceutical services CoP; and (4) completion of the postanesthesia evaluation in the anesthesia services CoP.

Our decision to carve out these four requirements in this final rule has evolved in large measure as a result of our continuing dialogue with the health care community. Through various CMS-sponsored provider forums such as the Physicians’ Regulatory Issues Team (PRIT) (a team of subject matter experts who work within the government to reduce the regulatory burden on Medicare participating physicians), our open door forums, and written correspondence by a variety of organizations and individuals, we were made aware that providers overwhelmingly believe that the existing regulations for these requirements no longer reflect current health care practice. In addition, public comments received on the December 19, 1997 proposed rule strongly supported the revisions we proposed for these selected CoPs.

C. Changes as a Result of the Enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was enacted. Section 902(a) of the MMA specifies that the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), is required to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. Section 902 further provides that the timeline may vary among different regulations, but shall not be longer than 3 years except under exceptional circumstances.

Although we do not believe that this law operates retroactively, out of an abundance of caution, we are applying the provisions of section 902(a) of the MMA to this rule since our publication of the December 19, 1997 rule was not finalized. Had section 902(a) of MMA not been enacted, the CoP provisions stipulated in the March 25, 2005 proposed rule would have been stipulated in a final regulation. However, with the passage of section 902 of the MMA, we believe it was in the spirit of the legislation to publish a new proposed regulation and subsequent final rule.

This final rule finalizes provisions set forth in the March 25, 2005 proposed rule (70 FR 15266 through 15274). In addition, this final rule has been published in the **Federal Register** within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that this final rule is in accordance with the Congress’ intent to ensure timely publication of final regulations.

II. Provisions of the Proposed Regulations

On March 25, 2005 we published a proposed rule (70 FR 15266) in the **Federal Register** entitled “Medicare and Medicaid Programs; Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations.” This proposed rule responded to the health care community’s primary concern that the current regulations are contrary to current health care practice and unduly burdensome. In order to be consistent with current health care practice, reduce regulatory burden, and ensure patient safety and quality care, we proposed

revising aspects of the current medical staff, nursing services, medical record services, pharmaceutical services, and anesthesia services CoPs. Below we summarize and discuss our proposed changes to these conditions and requirements.

As discussed in section I of the preamble to the proposed rule, we proposed the following changes:

A. Completion of the Medical History and Physical Examination

These proposed revisions would expand the timeframe for completion of the history and physical (H&P) examination to 30 days and expand the number of permissible categories of individuals who may perform the H&P. They address ongoing concerns expressed by the American Medical Association (AMA) and the American Podiatric Medical Association, Inc. (APMA), related to the timeframe for completion, as well as who is permitted to complete the history and physical examination. We proposed to revise the current medical staff requirement at § 482.22(c)(5) to specify that a 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 (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law, and that the medical history and physical examination must be placed in the medical record within 24 hours after admission. We also proposed revising the current Medical Records CoP at § 482.24(c)(2)(i) to reflect that a medical history and physical examination must be completed no more than 30 days before or 24 hours after admission, and placed in the patient’s medical record within 24 hours after admission. We also proposed revising § 482.22(c)(5) and § 482.24(c)(2)(i) to require that when a medical history and physical examination is completed 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 current condition is completed. This updated examination must be completed and documented in the patient’s medical record within 24 hours after admission.

B. Authentication of Verbal Orders

These proposed revisions broaden the category of practitioners who may authenticate orders. It responds to health care community concerns, reduces regulatory burden, and provides flexibility for hospitals in meeting the

requirements for authentication of verbal orders.

We proposed to retain and revise the current requirement for authentication of medical record entries at § 482.24(c)(1). This proposed provision stated that all patient 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. Additionally, we proposed retaining the current requirement that all orders, including verbal orders, must be dated, timed, and authenticated promptly by the prescribing practitioner, with the exception being that from the effective date of the final rule, to 5 years following the effective date of the final rule, 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 as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law, even if the order did not originate with him or her.

We proposed revising § 482.23(c)(2)(ii) to require that all verbal orders must be authenticated based upon Federal and State law, and relocating it to § 482.24(c)(1)(iii). We further proposed that if there is no State law that designates a specific timeframe for authentication of verbal orders, verbal orders must be authenticated within 48 hours. We also proposed to revise related nursing service requirements at § 482.23(c)(2) that address documentation of orders for drugs and biologicals.

We proposed 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 authorized to write orders by hospital policy in accordance with State law, and who is responsible for the care of the patient as specified under § 482.12(c).

We proposed retaining the current requirements at § 482.23(c)(2)(iii) that state that when verbal orders are used, they are to be used infrequently. We also proposed retaining the current requirement at § 482.23(c)(2)(i) that when verbal orders are used, they must only be accepted by persons that are authorized to do so by hospital policies and procedures consistent with State and Federal law.

C. Securing Medications

The proposed revision addresses health care community concerns, provides flexibility for hospitals in determining control of nonscheduled drugs and biologicals, and would be more patient-focused and outcome-oriented than the current requirement. We proposed to revise the provision at § 482.25(b)(2) to require that all drugs and biologicals be kept in a secure area, and locked when appropriate. We proposed that 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. We further proposed that only authorized personnel may have access to locked areas.

D. Completion of the Postanesthesia Evaluation

We proposed revising the requirement at § 482.52(b)(3) to permit an individual qualified to administer anesthesia to complete and document the postanesthesia evaluation for inpatients.

III. Analysis of and Responses to Public Comments and Final Decisions Made on the March 25, 2005 Proposed Rule

In response to the proposed rule published in the March 25, 2005 **Federal Register**, we received a total of 609 timely comments from individuals, providers, national and regional health care professional associations and advocacy groups, State and local health organizations, labor unions, health care law firms, and others. Summaries of the public comments received and our responses to those comments are set forth below under the appropriate subject headings.

We also received comments on issues outside the scope of this proposed rule. These comments will not be addressed in this final rule.

A. Medical History and Physical Examination

Condition of Participation: Medical Staff (§ 482.22)

In response to the industry's concern that timeframes for completion of the medical history and physical examination (H&P) are too stringent, we proposed revisions that broaden the timeframe for completion of the patient's medical history and physical examination and entry into the patient's medical record, and broaden whom may perform such an examination. In the March 25, 2005 proposed regulation, we expanded the timeframe to state that the medical history and physical examination must be completed no more than 30 days before or 24 hours

after admission for each patient. We also proposed removing the reference to specific physicians who can perform the medical history and physical examination, and instead stated it must be performed by a physician (as defined in section 1861(r) of the Act), or other qualified individual who has been granted these privileges by the medical staff in accordance with State law. We also proposed that the medical history and physical examination must be placed in the patient's medical record within 24 hours after admission. We added that when the medical history and physical examination is completed within 30 days before admission, we proposed that the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is completed. Finally, we stated that this updated examination must be completed and documented in the patient's medical record within 24 hours after admission.

Comments and responses to these proposed changes are separated into four major categories: Medical staff, completion of the H&P, timeframes for completion of the H&P, and categories of providers permitted to perform the H&P.

Medical Staff

Comment: A significant number of commenters identified the granting of privileges to conduct an H&P as problematic in both rural and urban areas. Commenters stated that the H&P is 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.

A commenter stated that the requirement for a pre-operative H&P to be completed only by a physician credentialed by the medical staff at a particular hospital is onerous and does not add value to the operative process for the patient. Instead, the commenter believes that a physician who is credentialed by a JCAHO-accredited hospital should be capable of performing this function.

Response: We understand that it is often the patient's primary care provider who completes the patient's H&P before an elective admission or procedure in both urban and rural areas. We also understand that this provider may or may not be credentialed and privileged by the admitting hospital. Based on public comments, in this final rule we have deleted the requirement that the H&P be completed by a practitioner credentialed and privileged by the admitting hospital.

If a patient's H&P is completed before admission to the hospital, an updated examination must be completed and documented in the patient's medical record within 24 hours after admission, but before a surgical procedure. This update to the H&P would be completed after the patient is admitted to the hospital by a physician, oromaxillofacial surgeon or other qualified individual who has been granted these privileges by the medical staff in accordance with State law. Therefore, if the H&P was completed by the patient's primary care provider, the H&P would be reviewed, the patient would be examined, and the H&P would be updated by an individual who has been credentialed and privileged by the medical staff to conduct an H&P. If upon review, the H&P done before admission is found to be 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 a new H&P within 24 hours after admission, but before a surgical procedure. The practitioner completing the update is responsible for ensuring that the H&P documented in the medical record is complete and accurate.

Comment: A commenter requested that CMS clarify whether performance, documentation and authentication of the H&P can be split among qualified staff or must these functions be performed by a single individual. The commenter recommended that CMS clearly identify the individual who is ultimately responsible for the H&P documentation and integrity.

Response: We believe it is standard practice to perform the H&P before a planned admission. Thus, if the H&P is done before admission, an update note will be needed which we expect would be done by a practitioner qualified to do the H&P. The hospital would be held responsible for ensuring a complete and accurate H&P is documented in the patient's medical record in accordance with the required timeframes.

Additionally, more than one qualified practitioner can participate in performing, documenting, and authenticating the H&P for a single patient. However, 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. In those instances when performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P, ultimately, will be responsible for the integrity of its contents.

Comment: One commenter asked that CMS continue to allow delegation of all or part of the H&P to other practitioners. This commenter also recommended that CMS confirm that the completed H&P can be authenticated by another practitioner responsible for the care of the patient. The commenter further stated that this is especially important when the H&P is dictated, but the author cannot authenticate between the time the H&P is physically placed on the medical record and the end of the 24 hours following admission. The commenter stated that a dictated medical record entry usually indicates the time dictated, transcribed, and signed. The commenter further asked if a practitioner would be required to indicate the time the undersigned H&P was physically placed in the medical record or whether the signature of the responsible practitioner serves as the time stamp.

Response: This requirement does not affect the physician's ability to delegate performance of the H&P to other qualified practitioners. The physician does not necessarily have to perform the H&P himself. However, the physician is responsible for ensuring that it is done, and complete. The completed H&P would be authenticated by the practitioner who conducted the H&P, and as applicable, the physician who delegated the performance of the H&P.

If the H&P is performed when the patient arrives at the hospital and the H&P is not placed on the medical record immediately following completion, we expect the practitioner who conducts the H&P to document in the patient's medical record that the H&P was completed and dictated within 24 hours following admission. Authentication includes dating and timing of a medical record entry. Therefore, it is not necessary to document the time the H&P was physically placed in the medical record.

Comment: One commenter requested that CMS align the physician and practitioner incentives to ensure timely and accurate completion of H&Ps. The commenter recommended that CMS address actions to be taken by the hospital staff if an H&P is not completed or received within the proposed standard timeframe. Additionally, the commenter stated that guidance to prohibit practitioners from billing for professional services rendered during an inpatient admission in the absence of a timely, accurate H&P would be helpful.

Other commenters thought it would be very difficult to enforce a timeframe for updating the H&P. Instead, these commenters stated that they see no reason to require documentation in the

form of an update note if there has been no change in the patient's condition. Instead, they believe CMS should align its regulations regarding the update note with the JCAHO requirements for an update just prior to beginning a procedure only if there have been changes to the patient's condition since the H&P was done. One commenter further stated that this would maintain the update when necessary, but not require additional processing when nothing more is required or of benefit.

Another commenter stated that despite supporting the timeframe proposed for completion of the H&P, they were still concerned that hospitals are required to ensure that an updated medical record entry, documenting an examination for any changes in the patient's condition be completed within 24 hours after admission. The commenter asked how completely documented must a physical examination be in order to document a change in a patient's condition. The commenter also asked if a statement signed by the physician stating that "no change" has occurred in the patient's condition would be satisfactory. The commenter further stated that to provide safe patient care, but be less burdensome to those who perform H&Ps, it would be more appropriate to require a medical record entry documenting a re-examination of the patient and their condition.

Response: Payment issues are out of the scope of this regulation. Thus, we will not specifically address this commenter's payment related concerns. However, hospitals have the flexibility to implement incentives or other systems and processes necessary to ensure timely completion and documentation of an H&P and update examination. The hospital is responsible for ensuring compliance with hospital policies, as well as, State and Federal regulations.

We expect hospitals to evaluate the practitioner's performance regarding the requirements as well as hospital policies and procedures through mechanisms such as QAPI and peer review as part of the credentialing and privileging process. If a hospital is not in compliance with the H&P requirements, we expect the hospital to take the necessary corrective action to ensure compliance. Non-compliance could lead to termination from the Medicare & Medicaid programs.

Regarding timely performance, documentation, and authentication of the H&P and update note, a physician, oromaxillofacial surgeon, or other qualified individual is expected to review the H&P that was completed

before admission, see the patient, and conduct an assessment to determine if there have been any changes since the H&P was completed. If there are no changes to the H&P as written, the physician can simply document an update note stating that the H&P has been reviewed, that the patient has been examined, and that the physician concurs with the findings of the H&P completed on the specified date. If there are changes in the H&P examination, we would expect the changes to be documented in the patient's medical record as well. The update note could include language such as concurrence with the H&P conducted on the specified date "with the following additions and/or exceptions."

Comment: One commenter recommended that instead of requiring that an update be conducted "within a maximum of 24 hours after admission" if the H&P was completed within 30 days before admission, that CMS modify the language to state, "at time of admit" since surgery or a procedure could be done before the 24 hour timeframe.

Response: The current requirement at § 482.51(b)(1) states, "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 in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient." This current requirement has not changed and applies to all patients undergoing surgery or other procedures that require an H&P. We note that the update note could be done sooner than 24 hours after admission. We would expect hospital policies and procedures to address this issue.

Comment: Numerous commenters support all proposed changes and believe the revised requirements for admission H&Ps would provide flexibility to better meet patient needs.

Response: We thank them for their support.

Completion of the H&P

Comment: One commenter stated we need to clarify that the proposed H&P revisions apply to inpatient admissions only. The commenter recommends eliminating wording that limits H&P requirements to just "patients admitted only for oromaxillofacial surgery" and requests additional clarification explaining the extent to which the H&P applies to patient admissions regardless of the services or procedures performed. Additionally, the commenter recommended additional clarification regarding the term "admission."

Instead, the commenter suggests that CMS clarify in the final rule whether the requirement only applies to inpatient admissions, specific types of admissions, all admissions and/or outpatient surgery, and/or diagnostic and therapeutic procedures.

Response: For the purposes of this requirement, the term "admission" applies to any admission. An H&P is required for all admissions. An H&P is required prior to surgery as well as prior to other procedures that require an H&P based on current standards of practice and hospital policy regardless of whether care is being provided on an inpatient or outpatient basis.

Comment: One commenter agreed with the completion of the H&P no more than 30 days before or 24 hours after admission. However, the commenter suggests modifying placement of the H&P in the medical record from 24 hours to "as soon as possible" due to the transcription turn around time of 24 hours. In agreement with this commenter, another commenter stated that requiring the H&P to be placed on the medical record within 24 hours after admission would force hospitals to staff transcription services 7 days a week which would be extremely difficult to do in small rural hospitals. The commenter believes this would result in increased cost with no increase in reimbursement for these small rural hospitals.

Response: We expect that practitioners and hospitals will make every effort to meet this requirement through the timely performance of the H&P and by maintaining transcription services and other systems that support this effort. However, in current medical practice, it is fairly routine for an H&P to be performed prior to a planned admission or procedure. As a result, the number of dictated H&Ps should be small. However, when the H&P is performed and dictated within 24 hours after admission, we would expect an entry in the patient's medical record stating that the H&P was completed and dictated. Hospital policies and procedures should address the process and timeframes for transcription, authentication, and placement of a dictated H&P into the medical record. The hospital must ensure that these policies and procedures are being followed.

The 24 hour timeframe establishes a clear and measurable guideline. Stating "as soon as possible" would allow too much flexibility and possibly lead to the H&P being placed in the chart well after 24 hours which could potentially impact patient care. These revised standards are consistent with the

JCAHO's requirements that have been in place for several years.

As the field of medical information technology advances to the common use of electronic medical records, it will be more probable that this reduced timeframe will become routine practice in hospital settings that may not be in compliance already. We believe there will be less need for transcription services replaced by more on-screen documentation.

Comment: A commenter requested further clarification as to what point between 30 days and the patient's admission does it become necessary to update the medical record regarding the patient's condition. The commenter requested that we reword the regulation to indicate that anything greater than "X" days prior to admission must be updated. The commenter further asked if the H&P is conducted 24 hours before admission, based on the proposed rule, would an update still be required.

Response: An update note is required when the H&P is conducted prior to admission. This update can be brief as long as the update adequately addresses any changes in the patient's medical condition since the H&P was conducted. It would be adequate for the physician to make an entry in the patient's medical record stating 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.

Comment: An organization applauded CMS for proposing to codify the medical H&P requirements with guidance previously issued by CMS in a January 28, 2002 memorandum to the Associate Regional Administrators and the State Survey Agency Directors. The purpose of this memorandum was to clarify our policy with respect to the application of regulatory provisions for hospital admission and presurgical H&P requirements and guidance regarding the timing of the H&P for hospital admissions. They stated the proposed changes would also align the CoPs with standards used by the JCAHO, which, heretofore, has been an ongoing source of conflict for hospitals creating confusion, and needless additional work. However, the commenters seek clarification as to whether the requirement will remain a standard within the CoP at the proposed § 482.24(c) entitled "Content of record."

Response: We appreciate the commenter's support. Yes, the proposed 482.24(c) will continue to address the regulatory language regarding the requirements under the CoP: Medical record services.

Timeframe for Completion of H&P

Comment: Many commenters expressed support for the proposed H&P timeframe revisions.

Response: We appreciate this support.

Comment: A commenter supports the use of timeframes; however, the commenter stated this would result in a disconnect between the CMS's requirements and the JCAHO's existing 24 hour requirement. The commenter further expressed the concern that if the H&P is done within 30 days of admission and there is a need to update, this may lead to patient dissatisfaction due to the redundancy of the requirement for updating the H&P.

Response: We recognize there may be redundancy in the information that was gathered at the time of the initial assessment and the completion of an updated assessment. However, we believe this timeframe is necessary for patient safety to ensure that a procedure or admission is still appropriate based on the patient's current condition.

The JCAHO's standards must meet or exceed our requirements in accordance with section 1865(e)(9) of the Act. In this case, the JCAHO standards are more stringent than our requirements. JCAHO requires the H&P to be completed within no more than 24 hours of an inpatient admission. If the H&P was completed within 30 days before the patient was admitted or readmitted, updates on the patient's condition since the assessment(s) are recorded at the time of admission.

Additionally, in the event of there being patient dissatisfaction with the redundancy of performing an update procedure, we believe educating the patient regarding the necessity and importance of performing this update for their safety should help to reduce dissatisfaction expressed by the occasionally dissatisfied patient.

Comment: A commenter requested that CMS specifically address the updating requirements for obstetric H&Ps. The commenter requested CMS to define how and where this update should happen for obstetric H&Ps.

Response: The update requirement for obstetric patients would be no different than the update requirements for other medical services. However, for women who have had prenatal care, an H&P would be conducted on the first prenatal visit. An update note would then be documented at each subsequent prenatal care visit. The next update note would be documented at the onset of labor. For women who have not had prenatal care before the onset of labor, the H&P must be completed within 24 hours of admission.

Comment: A commenter opposed the proposed revisions stating the proposed requirements would create undue burden and expense for rural hospitals. The commenter stated that there is a shortage of physicians and other health care professionals in their rural state which challenges the providers in that area in delivering safe, quality patient care. The commenter further stated that many of the surgical patients are referred by their local family physician and come from more than sixty miles from the healthcare center. The commenter stated that many times the family physician provides an H&P that is done more than 24 hours in advance of the surgery. The commenter is concerned that, in those instances, when it is not possible to have a current H&P on the chart before surgery, the physician is responsible for performing an update to the H&P would charge additional costs to the patient and possibly "resent" that an update is requested.

Response: The requirement at § 482.22(c)(5) has been changed to remove reference to "who has been granted these privileges by the medical staff." It is our desire that the expansion of who may perform the H&P would lessen the burden associated with meeting this requirement. Additionally, we would expect the hospital to address in its policies and procedures the practice of accepting the H&P completed by a practitioner who has not been granted these privileges by the hospital's medical staff.

Regarding the issue of an additional physician seeking reimbursement for performing the H&P, we would expect that the performance of an H&P would be provided if necessary. Reimbursement issues are beyond the scope of this regulation.

Categories of Providers Permitted To Perform the H&P

The current medical history and physical examination requirements, including who is permitted to complete the history and physical examination, has continued to be a point of contention among various provider groups. Specifically, while podiatrists have expressed concern that doctors of podiatric medicine are currently not permitted to perform a history and physical examination, oromaxillofacial surgeons have been concerned that the lack of specific reference to oromaxillofacial surgeons in the regulation language could result in their loss of current privileges to perform the H&P.

We received 342 comments regarding the proposed revision to adopt the

definition of "physician" at section 1861(r) of the Act and the removal of the specific reference to oromaxillofacial surgeons. Commenters were evenly split. Nearly 48 percent of the commenters supported the proposed change, while over 52 percent of commenters opposed the proposed change.

One group of commenters supported the definition of physician which includes doctors of medicine or osteopathy, doctors of dental surgery, or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors. These commenters believe that specific reference to these practitioners would result in increased access to care while protecting patient health and safety.

The other group of commenters stated that in the specific context of eligibility to perform a complete H&P, which should be based on documented education, training, and current competence, they believe the use of this definition may be misinterpreted by hospital medical staffs and governing bodies. As a result, commenters believe the hospital medical staffs around the country may feel compelled to change the bylaws to grant such privileges only to those "commonly known" to have requisite training in history and physical exam (that is, MD and DO—allopathic and osteopathic) medical doctors. The commenters further stated that limitations or withdrawal of privileges for H&P exam for oromaxillofacial surgeons would limit access for many maxillofacial trauma, head and neck pathology, and reconstruction patients who need the services of an oral surgeon. Instead, the commenters believe that specific reference to oromaxillofacial surgeons must be retained in the final regulation to ensure that they continue to be recognized by the medical staff as qualified to perform the H&P.

Many commenters who expressed opposition to the proposed revision stated the SSA definition might cause hospital medical staffs to exclude trained DMD or DDS. They suggest the definition be expanded to include other degreed professionals that are trained to perform H&Ps. Many commenters who opposed the revised language instead suggested the language read, "a doctor of medicine or osteopathy, oral and maxillofacial surgeons, and those accredited to perform H&Ps".

Podiatrists were in support of being permitted by regulation to perform H&Ps, stating that podiatric physicians are, by education and training, capable of performing a comprehensive H&P for any of their patients. These commenters

referenced their 4 year educational requirements for podiatric students and the Council on Podiatric Medical Examination (CPME) publication 120, Standards and Requirements for Accrediting Colleges of Podiatric Medicine (April 2000) and CPME publication 320, Standards (July 2003). Additionally, several commenters discussed how participation in the medicine and medical subspecialty training resources requires that podiatric residents perform a minimum number of comprehensive medical histories and physical examinations.

Response: It is not our intent for this revised change to lead to a reduction in the pool of professionals who are qualified to perform the H&P. Instead, in an effort to reduce burden, 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.

Comment: A commenter expressed concern stating that § 482.22 should read, "nurse practitioners (NPs), licensed independent practitioners (LIPs), or other qualified individuals should be allowed to perform H&Ps independently of the MD." The commenter elaborated by stating that due to current work hour limitations on residents in acute hospitals, H&Ps are currently being performed by NPs. The commenter stated that H&Ps are frequently billed to Medicare under the "shared care" rules instead of under the NP's own Medicare provider number, thus, providing a great cost saving to Medicare. Instead, the commenter believes the proposed language is restrictive, in turn, creating barriers to care for Medicare beneficiaries and increased cost to Medicare.

Another commenter voiced a lack of support over the expansion of the proposed rule to allow "other qualified individuals who have been granted these privileges by medical staff in accordance with State law." The commenter references and supports the AMA's beliefs that the best interests of hospitalized patients are served when admission history and physical exams are performed by a physician, recognizing the "portions" of the histories and physical exams may be delegated by the physician to others whose credentials are accepted by the medical staff.

Response: Again, it was not our intent to exclude practitioners who are believed to be appropriately trained and qualified to perform the H&P. We are aware that NPs, especially in rural settings have been an invaluable resource in performing H&Ps as a rule of practice. Thus, 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.

B. Authentication of Verbal Orders

Condition of Participation: Nursing Services (§ 482.23)

We proposed revisions to strengthen the requirement regarding the infrequent use of verbal orders. We proposed 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 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). In addition, we proposed that if verbal orders are used, they are to be used infrequently and must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

In the proposed rule, we stated that authentication requirements enhance patient safety and serve to protect practitioners carrying out verbal orders by preventing those giving the orders from later denying the order was given. We requested public comment on whether recurring problems exist with prescribing practitioners denying that they gave a verbal order after the verbal order was carried out. We also requested public comment on the perceived impact of this proposed rule on this potential issue.

Comment: Several commenters stated that ordering practitioners only occasionally or rarely deny giving a verbal order. One commenter stated that there are anecdotal reports that this problem continues to occur, especially if an incorrect or incomplete order appears to contribute to patient morbidity or mortality, and stated that it is problematic for nurses when a practitioner does deny giving a verbal order. One commenter stated that their State health department and hospital association conducted a comprehensive study and found no examples of prescribing practitioners denying that

they gave a verbal order after the verbal order was carried out when the order was repeated back to them.

One commenter stated that these revisions address a recognized problem for RNs who frequently find that they are dealing with unsigned or denied verbal orders and clarifies when and how verbal orders are to be documented. The commenter stated that these revisions would support increased collaboration of the health care team and promote safe, effective patient care.

Response: Denial of verbal orders does not appear to be a frequently occurring problem for the commenters. We agree, however, that it is problematic any time a prescribing practitioner denies giving a verbal order, particularly after the verbal order has been carried out. A denial jeopardizes the trust necessary in collaborative relationships among members of the health care team and may jeopardize patient safety and quality care as well. Therefore, it is necessary that this final rule clarifies when and how verbal orders are to be documented and authenticated.

Comment: The majority of commenters supported the requirement that if verbal orders are used, they should be used infrequently. Commenters commended CMS for recognizing the critical importance of minimizing the use of verbal orders. One commenter stated that CMS should require hospitals and practitioners to take steps to limit the use of verbal orders, in the absence of electronic health record and computerized physician order entry technologies.

A few commenters did not support this requirement. One commenter stated that the use of verbal orders is a common practice and certainly not infrequent. The commenter recommended that this requirement be tested with practicing physicians in both rural and urban hospitals. The commenter stated that verbal orders can comprise 100 percent of orders received at night in rural areas as well as other times when the patient's condition warrants and the physician is not physically available or capable of secure electronic communication.

Another commenter stated that in order to provide more timely, appropriate, and patient-focused care, the use of verbal and/or telephone orders in the hospital has increased, and could be viewed as being used in circumstances that a regulatory agency may not consider "urgent or emergent." The commenter further stated that patient lengths of stay have declined dramatically over the past decade and, therefore, require more frequent changes

in orders and more immediate response to patient's expressed needs while hospitalized. This commenter recommended that CMS broaden its interpretation of "emergent or urgent" to recognize that verbal orders are needed to ensure the provision of timely, appropriate and patient-focused care and that verbal orders are often necessary from a service delivery perspective for patients and families. The commenter further stated that it is often necessary to secure verbal orders in order to change diet or activity orders, secure changes to therapy orders to better meet the needs of the patient, and obtain medication orders in response to patient response or non-response to ordered medication regimens, particularly with respect to pain management.

Response: The use of verbal or telephone orders is cited as an error-prone process by the American Society of Health-System Pharmacists (ASHP)¹, the Institute of Safe Medication Practices (ISMP)², the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)³, and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)⁴. These nationally recognized organizations recommend that the use of verbal orders be minimized as much as possible. In addition, minimizing the use of verbal or telephone orders was a key 2003 JCAHO National Patient Safety Goal.

The use of verbal orders poses an increased risk of miscommunication that could result in an adverse event, including a medication error, for the patient. The NCC MERP reports that confusion over the similarity of drug names accounts for approximately 25 percent of all medication errors.⁵ The ISMP described safety issues related to the use of verbal orders in the January

24, 2001 issue of *Medication Safety Alert!*⁶

"Verbal orders offer more room for error than orders that are written or sent electronically. The interpretation of what someone else says is inherently problematic because of different accents, dialects, and pronunciations. Background noise, interruptions, and unfamiliar terminology often compound the problem. Once received, verbal orders must be transcribed as a written order, which adds complexity and risk to the ordering process. The only real record of the verbal order is in the memories of those involved. When the recipient records a verbal order, the prescriber assumes that the recipient understood correctly. No one except the prescriber, however, can verify that the recipient heard the message correctly. If a nurse receives a verbal order and subsequently calls it to the pharmacy, there is even more room for error. The pharmacist must rely on the accuracy of the nurse's written transcription of the order and the pronunciation when it is read to the pharmacist.

Sound-alike drug names also impact the accuracy of verbal orders. There are literally thousands of name pairs that can easily be misheard. For example, we have received scores of error reports where verbal orders for "Celebrex 100 mg PO" were misheard as "Cerebyx 100 mg PO." Drug names are not the only information prone to misinterpretation. Numbers are also easily misheard. For example, an emergency room physician verbally ordered "morphine 2 mg IV," but the nurse heard "morphine 10 mg IV" and the patient received a 10 mg injection and developed respiratory arrest. In another case, a physician called in an order for "15 mg" of hydralazine to be given IV every 2 hours. The nurse, thinking that he had said "50 mg," administered an overdose to the patient who developed tachycardia and had a significant drop in blood pressure."

If verbal orders are used, they must be used infrequently. This means that the use of verbal orders must not be a common practice. This is not a new requirement. The requirement for the infrequent use of verbal orders has been part of the hospital CoPs since 1986. We expect this requirement to be reflected in hospital policy as well as in actual practice. We expect hospitals to implement practices that minimize the use of verbal orders regardless of whether or not the hospital has implemented electronic health record and/or computerized physician order entry technologies. We do, however, strongly support the adoption and implementation of these technologies. If the use of verbal orders in a hospital is common practice, the hospital could be cited as being out of compliance with the Medicare hospital CoPs.

We recognize that there are occasional situations in a hospital, regardless of a

rural or urban setting, when the use of a verbal order is necessary. We also recognize that a practitioner responsible for the care of the patient may not necessarily be available on site during the night or always have access to electronic communication to issue a written order. However, every effort should be made to minimize the use of verbal orders given the risks to patient safety when verbal orders are used. The use of verbal orders should be limited to those situations in which it is impossible or impractical for the prescriber to write the order or enter it into a computer. Verbal orders are not to be used for the convenience of the ordering practitioner.

We agree that "timely, appropriate, and patient-focused care" is important. We also recognize that patient length of stay has decreased and may necessitate more frequent order changes and more immediate response to patient needs. However, we do not agree that these factors necessarily translate into the need for the frequent use of verbal orders. We expect hospitals 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.

Comment: The majority of commenters cited and endorsed the 2003 JCAHO National Patient Safety Goal—"For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the order or test result 'read-back' the complete order or test result." Commenters also cited the related JCAHO requirement that hospitals "implement a process for taking verbal or telephone orders or receiving critical test results that require a verification 'read-back' of the complete order or test result by the person receiving the order or test result" (IM 6.50, EP 4) and recommended that CMS consider including this requirement in the CoPs. One commenter stated that a regulatory requirement would further enhance the ability of nurses to clarify verbal orders without seeming to be personally confrontational to physician and practitioner colleagues who issue such orders to nurses. One commenter stated that their State law requires that a verbal order be repeated back to the prescribing practitioner and verified.

¹ American Society of Hospital Pharmacists. ASHP guidelines on preventing medication errors in hospitals, *Am J Hosp Pharm* 1993; 50:305-14. http://www.ashp.org/bestpractices/MedMis/MedMis_Gdl_Hosp.pdf.

² Smetzer J, Cohen MR. Instilling a measure of safety into those "whispering down the lane" verbal orders." *ISMP Medication Safety Alert! Acute Care Edition*, 2001; 6:1-2. <http://www.ismp.org/Newsletters/acute-care/articles/20010124.asp>.

³ 2003 JCAHO National Patient Safety Goals: practical strategies and helpful solutions for meeting these goals. *Joint Commission Perspectives on Patient Safety*. 2003; 3:1-11. <http://www.jcrinc.com/subscribers/patientsafety.asp?durki=3746#goal2>.

⁴ National Coordinating Council for Medication Error Reporting and Prevention. Recommendations to reduce medication errors associated with verbal medication orders and prescriptions. February 20, 2001. <http://www.nccmerp.org/council/council2001-02-20.html>.

⁵ *Ibid*, National Coordinating Council for Medication Error Reporting and Prevention.

⁶ *Ibid*, Smetzer J, Cohen MR.

This commenter stated that this practice has reduced errors and has increased communication and patient safety.

One commenter stated that verbal orders have generally been instituted well before authentication of the order can occur and stated that the possibility exists that harm could occur to the patient before it is recognized through an authentication procedure. The commenter strongly recommended that CMS consider including JCAHO's National Patient Safety Goal that requires the "read-back" of the verbal order to ensure that the order is heard correctly to reduce the likelihood of patient harm. The commenter states that this intervention is real-time and more likely to ensure the safety of patients as opposed to the authentication of the verbal order well after the verbal order has already been implemented.

Response: We agree that the "read-back" verification process is a critical step in preventing medication errors and ensuring patient safety when verbal orders are used. We strongly support this practice as a national safety patient goal and expect hospitals to be actively working toward the achievement of this goal. However, "read-back" verification of a verbal order is just one critical measure designed to minimize errors and ensure patient safety.

Authentication of verbal orders is another critical measure. Both of these important processes are supported by organizations such as the NCC MERP and ASHP. As part of a hospital's efforts to implement the JCAHO National Patient Safety Goals for Hospitals, as well as other nationally accepted guidelines and standards of practice, 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, such as the "read-back" verification process, to ensure patient safety and minimize medical errors regardless of whether they are contained in the regulatory text of the CoPs. Therefore, we have not included the "read-back" verification process in the final regulation text.

Comment: One commenter stated that the proposed rule would benefit from adding the detail found in the ASHP "Guidelines on Preventing Medication Errors in Hospitals".

Response: We expect hospitals to follow standards of practice and nationally accepted guidelines, such as those published by ASHP. However, given the number of standards of practice and practice guidelines that exist nationally, it would be impossible to include and maintain a complete, up-

to-date set of standards and practices in the regulatory text. Clinical practice continuously evolves based on research findings, technology developments, and the needs of specific patient populations. Just because a practice standard or guideline is not contained in the regulation text does not mean that CMS does not support it.

Several organizations, including ASHP, have published nationally accepted guidelines targeted at reducing medication errors and provide specific recommendations regarding the use of verbal orders. These guidelines serve as a strong foundation upon which hospitals can develop safe policies and practices. They include:

- ASHP, "Guidelines on preventing medication errors in hospitals," 1993. http://www.ashp.org/bestpractices/MedMis/MedMis_Gdl_Hosp.pdf;
- ISMP, Medication Safety Alert! Acute Care: "Reducing 'at-risk behaviors'," October 7, 2004. <http://www.ismp.org/Newsletters/acute/articles/20041007.asp?ptr=y>
- ISMP, Medication Safety Alert! Acute Care, "Instilling a measure of safety into those 'whispering down the lane' verbal orders," January 24, 2001. <http://www.ismp.org/MSArticles/VerbalOrders.html>; and,
- NCC MERP, "Recommendations to reduce medication errors associated with verbal medication orders and prescriptions," February 20, 2001. (<http://www.nccmerp.org/council/council2001-02-20.html>).

Authentication of Verbal Orders

We proposed revisions that would broaden the category of practitioners who could authenticate orders. We proposed that all orders, including verbal orders, must be authenticated promptly by the prescribing 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 for a period of 5 years following the effective date of this final rule.

Comment: The vast majority of commenters voiced strong support for these proposed changes. Commenters welcomed the flexibility represented in these changes, and agreed that an authentication requirement is necessary to protect the health and safety of patients and to ensure quality, accountability and overall integrity of medical services rendered. One commenter stated that authentication of any type of orders in the hospital setting serves three distinct purposes that should be included in policy consideration: (1) Authentication is

used to document and hold accountable the prescribing physician/practitioner for the medical necessity of the services ordered; (2) authentication is used to validate that hospital staff received, transcribed and performed orders appropriately, and (3) authentication is used to document that practitioners reviewed the patient medical record, findings and other relative documents when making medical decisions and interpretations.

Another commenter stated strong agreement with CMS that this verbal order authentication requirement increases accountability for the service provided and verifies that the entry is complete and accurate. The commenter stated that the necessity for this requirement is evidenced by a JCAHO study indicating that most organizations (84 percent) cited a breakdown in communication, most often (67 percent) with or between physicians, as one of multiple root causes leading to a sentinel event, defined by JCAHO as "an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof." The commenter stated that by the very nature of clinical practice in an Emergency Department, verbal orders are an essential component of emergency care, especially when a patient's condition rapidly deteriorates. The commenter stated that authentication of verbal orders enhances patient safety and minimizes the risk of medical errors by ensuring that the interdisciplinary communication that naturally occurs between practitioners in a busy Emergency Department environment is correct, complete, and implemented as intended to ensure positive patient outcomes. The commenter stated that such orders also enhance personal accountability of practitioners who issue and receive verbal orders and further augment provider performance by revealing potential discrepancies before inadvertent miscommunications can cause harm to patients.

Commenters welcomed the proposed rule that would allow verbal orders to be dated, timed, and authenticated by the prescribing practitioner or another practitioner responsible for the care of the patient. One commenter stated that this approach reflects the needs of medical practice today and does not raise quality of care concerns. A commenter stated that the proposed changes at § 482.23(c)(2) and § 482.24 are both consistent with current hospital practices and help to clarify how hospitals and their staff must comply with the CoPs. The commenter further stated that in those cases when a practitioner gives an order, and then is

“off duty,” it is appropriate that a practitioner other than the ordering practitioner be allowed to authenticate the order.

Response: We appreciate the support. We agree that the authentication of verbal orders is critical to patient safety and quality care.

Comment: One commenter did not agree that patient safety is compromised if a physician order is not authenticated and requested an example of such an occurrence. The commenter also asked how patient safety is enhanced by signing a verbal order the next day or the next week, and stated that the physician is responsible whether the verbal order is signed or not. Another commenter stated that he understands the perspective taken by CMS related to the importance of authentication of verbal orders from a provider accountability and hospital risk management standpoint; however, the commenter does not believe that authentication of verbal orders necessarily translates to improved patient safety and quality.

Response: We agree that the practitioner giving a verbal order is responsible for the order whether it is authenticated or not. However, incomplete or incorrectly transcribed verbal orders present a risk to the patient's health and well being. If a verbal order for a one-time medication is not documented completely and accurately, patient harm can occur. Prompt correction of this verbal order can identify the error and ensure that appropriate patient follow up occurs as soon as possible. It can also be used to identify and correct related practice issues. Therefore, even though a verbal order may be authenticated after the order has already been implemented, authentication is important. If a verbal order for an ongoing medication is not documented completely and accurately, an ongoing medication error could occur and compromise the patient's health and well being. Prompt authentication of this verbal order could avoid ongoing medication errors. In addition to identifying and correcting the error, any necessary patient follow up as a result of the error can be implemented as soon as possible. Therefore, we believe that the authentication of verbal orders impacts patient safety and quality of care.

Comment: One commenter stated that the proposed changes regarding verbal order authentication appears to place all the accountability and liability on the hospital personnel or facility-based professional who carry out the orders—including orders that the prescribing or ordering physician/practitioner may

have issued unnecessarily or incorrectly. The commenter stated that he acknowledges that medical errors can occur due to documentation errors and has included in hospital bylaws safeguards requiring counter-signatures by the prescribing or ordering physician/practitioner within a defined time period. The commenter requested that CMS reconsider its position on eliminating the counter-signature by the prescribing or ordering physician/practitioner on verbal orders and recommends that CMS maintain requirements for the prescribing or ordering physicians/practitioners to authenticate their verbal orders to ensure their accountability for ordered services (for example, attestation to medical necessity), but provide for greater flexibility by allowing other physician group members or physician employed non-physician practitioners to countersign on behalf of the prescribing physician. The commenter stated that this maintains the appropriate “accountability” for the service by the prescribing or ordering physician/practitioner.

Response: This revised requirement does not, in any way, relieve the prescribing practitioner of his or her accountability and responsibility for the ordered service. The intent of the proposed revisions to the verbal order authentication requirements is to maximize the hospital's flexibility while maintaining patient safety and an appropriate level of accountability for both the hospital and prescribing practitioner for services rendered to the patient. We proposed that 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 as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law. Under this proposed rule, hospitals would no longer be burdened by the requirement that verbal orders must be signed by the practitioner who gave the order. Any practitioner responsible for the care of the patient who is authorized by hospital policy and permitted by State law to write a specific order would be permitted to authenticate a verbal order, even if the order did not originate with him or her. This could include permitting other physician group members or non-physician practitioners to countersign on behalf of the prescribing physician based on hospital policy as recommended by the commenter. A hospital has the flexibility to limit who may authenticate

a verbal order and could authorize only the prescribing practitioner to authenticate a verbal order.

Comment: A commenter stated that many individuals are not comfortable signing another's orders and incurring the responsibility for the validity of the order. Another commenter expressed doubt that the proposed change to allow another provider caring for the patient to sign a verbal order for the prescribing provider would be held in high regard by the provider community. The commenter stated that they have multiple care providers with teaching services, and residents covering off-shifts, hence the utilization of telephone orders. The commenter stated that each provider may not necessarily see the patient in person. Finally, the commenter stated that the shorter length of stay also adds to the complexity of maintaining a signed hard-copy chart.

Response: The proposed provision provides hospitals and practitioners the flexibility of permitting a verbal order to be authenticated promptly by the prescribing practitioner or another practitioner 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. However, this regulation does not require a practitioner responsible for the care of the patient to authenticate a verbal order that he or she did not give. Ultimately, the prescribing practitioner is responsible for authenticating the verbal order. A hospital has the flexibility to develop policies and practices to implement this regulation in a manner that makes sense for their hospital based on the needs of the patient population served. When a practitioner authenticates a verbal order that he or she did not give, the practitioner accepts responsibility for the order and is validating that the order is complete, accurate, and final based on the patient's condition. 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.

When verbal orders are used, they must be used infrequently regardless of the patient's length of stay. When multiple practitioners are responsible for the care of a patient, there should be even fewer instances when verbal orders are necessary. Orders should be documented directly in the medical record by the prescribing practitioner either in writing or electronically. The use of verbal orders should be limited

to those situations in which it is impossible or impractical to write the order or enter it into the computer. Verbal orders are not to be used for the convenience of the ordering practitioner.

Comment: One commenter stated that he does not support anyone other than the ordering practitioner authenticating verbal orders because it partially alleviates the ordering practitioner's accountability for the work he or she does. The commenter stated that only the ordering practitioner knows what their intentions were for a patient, not another practitioner.

Response: We do not agree that the ordering practitioner's accountability for a verbal order is in any way decreased if another practitioner authenticates the order. When a practitioner authenticates a verbal order that he or she did not give, the practitioner accepts responsibility for the order and is validating that the order is complete, accurate, and final based on the patient's condition. We also do not agree that only the ordering practitioner knows what their intentions were for the patient when giving the verbal order. 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. We believe that a practitioner with this knowledge can safely evaluate the completeness and accuracy of a verbal order. If a practitioner does not possess this knowledge about a patient, the practitioner should not be authenticating a verbal order for the patient. If the practitioner has questions or concerns about the order, we would expect them not to authenticate the order and contact the prescribing practitioner to resolve any questions or concerns as soon as possible.

Comment: One commenter requested clarification on what is meant by the requirement that verbal orders be legible, complete, dated and timed, and whether or not it is necessary for a physician to date and time the authentication of a verbal order.

Response: This final regulation requires that all orders, including verbal orders, be legible, complete, dated, timed, and authenticated. Therefore, 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. The prescriber or another

practitioner responsible for the care of the patient must then verify, sign, date and time the order as soon as possible in accordance with hospital policy, and State and Federal requirements.

Comment: One commenter requested clarification as to whether prescribing physicians/practitioners can use faxed or electronic signatures as a means to validate verbal orders.

Response: Faxed or electronic signatures could be used to authenticate a verbal order. 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. This would include verification of the author of faxed verbal orders or computer entries. We would expect that hospital policies would address author verification processes for both written and electronic signatures.

Comment: One commenter stated that discrepancies between the proposed rule and the current interpretive guidelines raise the question of whether hospitals which have recently effected policy and procedural changes to comply with the new interpretive guidelines would be required to make further changes in order to comply with new rules. The commenter also requested clarification regarding the temporary 5-year exception to one aspect of the authentication requirements and whether hospitals would need to make still further changes upon termination of the exemption period.

Response: Hospitals participating in the Medicare and Medicaid program are expected to comply with current CoPs. When a final rule is published, an effective date for the revised requirements is identified in the final rule. Upon the effective date, hospitals participating in the Medicare and Medicaid program are expected to comply with the new requirements. In addition, the interpretive guidelines will be revised based on the final rule.

If CMS does not make the exemption permanent, then the individual ordering practitioner must authenticate his own verbal order. Hospitals are free, however, to maintain the more stringent requirement that verbal orders must be authenticated promptly by the prescribing practitioner and not permit another practitioner responsible for the care of the patient to authenticate verbal orders.

Comment: One commenter stated that they are seeking to balance patient safety, "common practice," and administrative problems associated with verbal orders. The commenter stated that from an administrative perspective,

they appreciated the approach of allowing other qualified practitioners to sign an order and resolve some of the administrative barriers. However, the commenter stated concern that there are legal liabilities to such a practice that run contrary to the philosophy of patient safety, and that the proposed change may be illegal in some States. The commenter requested that if legality is not an issue that the requirement be modified to indicate that the qualified practitioners have some relationship to the patient's care, the medical service, or the medical practice. The commenter stated that to enhance patient safety, the practitioner should be more narrowly defined to ensure that he or she has the knowledge of the case, or service, to evaluate an order before signing it.

Response: State laws may be more stringent than Federal requirements. If State law requires that the prescribing practitioner authenticate verbal orders, a practitioner other than the prescribing practitioner would not be permitted to authenticate verbal orders in that State. As proposed, this final rule requires that verbal orders be signed by the prescribing 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. We expect a practitioner responsible for the patient's care to have knowledge of the patient's hospital course, medical plan of care, condition and current status.

Comment: One commenter requested clarification as to whether a physician assistant or nurse practitioner who has prescriptive authority under State law is allowed to co-sign a physician's order.

Response: A physician assistant or nurse practitioner may only authenticate verbal orders written by a physician or other licensed independent practitioner that they have authority to write themselves as determined by hospital policy in accordance with state law. For example, some hospitals limit who may give orders for certain types of drugs or therapies. If a physician assistant or nurse practitioner is not permitted by hospital policy to order a specific drug or therapy, he or she would not be permitted to authenticate a verbal order for such a drug or therapy. Hospitals have the flexibility to limit who may authenticate verbal orders.

In addition, a physician assistant or nurse practitioner may only authenticate verbal orders for a patient for whom they have physician delegated responsibility. Like all practitioners responsible for the care of the patient, a physician assistant or nurse

practitioner would be expected to have knowledge of the patient's hospital course, medical plan of care, condition and current status. With this knowledge, a practitioner can safely evaluate the completeness and accuracy of a verbal order.

Comment: A commenter requested that in the proposed § 482.24(c)(1)(i) and § 482.24(c)(1)(ii), CMS replace the term "prescribing" practitioner with the term "ordering" practitioner in keeping with Federal and State laws on prescriptive authority, current hospital practice and CMS objectives.

Response: We agree. In this final rule, we are replacing the term "prescribing" with the term "ordering" at § 482.24(c)(i) and § 482.24(c)(1)(ii).

Sunset Provision

We proposed limiting the length of time that a practitioner other than the prescribing practitioner would be permitted to authenticate an order. We proposed that for the 5-year period following the effective date of the final rule, 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 as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.

Comment: Several commenters supported the 5-year sunset provision. One commenter stated that the 5-year timeframe is reasonable and should allow adequate time for evaluation. A few commenters stated that it will provide greater flexibility while health information technology continues to evolve to the point where the originating physician may authenticate his or her own orders in an efficient manner. Another commenter stated that the 5-year temporary provision provides hospitals with flexibility while maintaining an appropriate level of accountability. One commenter stated that the American Health Information Management Association is actively working with healthcare systems, vendors and others to promote the adoption of a standard electronic health record and the capability for all orders to be immediately authenticated, as they are dictated or written, electronically.

Response: We appreciate the support of these commenters and the work being done to promote the use of electronic medical record systems.

Comment: Several other commenters did not support the 5-year sunset provision. One commenter expressed concern that the proposed 5-year exception would expire prior to the technology actually being widely

available and used. The commenter recommended replacing the 5-year sunset language with "until such time as health information technology is sufficient to allow the originating physician to authenticate his or her own orders in an efficient and non cost-prohibitive manner."

Another commenter shared the current administration's interest in implementing electronic medical records. However, the commenter stated that it is highly unlikely that all hospitals in any given State would be able to afford to implement health information technology fully within the next 5 years. This commenter strongly urged CMS to authorize the authentication of verbal orders by practitioners who meet the specified criteria without any time limitation. The commenter stated that CMS can then assess after 5 years whether the implementation of health information technology has occurred and revise regulations at that time if necessary. The commenter stated that, otherwise, hospitals unable to implement health information technology would experience undue administrative burden in 5 years.

A few commenters expressed concern about a potential gap between the expiration of the exception and the publication of new regulations. One commenter recommended revising the provision as follows: "exception is 5 years from the effective date following the date of the final rule, or the publication of new requirements, whichever comes later." Another commenter emphasized the need to re-evaluate the 5-year "temporary exception" period in a systematic and timely manner. The commenter recommended that CMS begin planning this evaluation at least 12 months before the end of the 5-year period to allow for adequate time to assess the availability and capability of electronic health records and hospital information systems.

Response: We appreciate the health care community's support of health information technology. We understand that the implementation of this technology requires an investment of hospital resources and that the rate of health information technology adoption and full implementation in hospitals varies across the country. We agree that this provision may need to be revised in 5 years based on the level of health information technology adoption and implementation at that time. We also agree that a policy decision must be made within a timeframe that avoids a gap between the expiration of the

exception and the publication of a new regulation, if necessary.

Timeframe for Authentication of Verbal Orders

We proposed revisions that would clarify the timeframe for authentication of verbal orders. We proposed 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.

Comment: Many commenters supported the proposed rule as written. Other commenters stated that they support the proposed change that all verbal orders must be authenticated based upon Federal and State law, but did not support the proposed 48 hour timeframe for authentication of verbal orders in the absence of a State law that designates a specific timeframe for the authentication of verbal orders. One commenter stated that he was unable to identify any study to support the theory that the 48-hour rule has any significant impact on preventing patient harm. Another commenter stated that while they would still prefer to allow "hospitals and their medical staffs to establish their own policies on authentication of verbal orders," they supported the application of the 48-hour timeframe only to those States that do not currently have a timeframe in place for the verification of such orders.

Another commenter stated that a timeframe for the authentication of verbal orders adds no value because if an order is issued and carried out promptly, as it should be, signing the order after the fact does nothing to reverse any misadventure that may have occurred due to an unsigned order. Several commenters stated that the 48-hour timeframe is burdensome for physicians, nurses and medical records staff.

Response: We appreciate the support we received from commenters. Although 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, NCC MERP and ASHP. 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. Prompt authentication of a verbal order enables early identification and correction of an error. Early identification and correction of an error enables the practitioners to minimize or eliminate the risk to patient safety posed

by incomplete or incorrectly transcribed verbal orders.

As discussed previously, verbal orders can be given for a variety of patient interventions, including medications and biologicals that direct staff to provide both onetime and ongoing patient care and treatments. If a verbal order for a onetime medication is not documented completely and accurately, patient harm can occur. Authentication of this onetime verbal order can identify the error and ensure that appropriate patient follow up occurs as soon as possible. Therefore, even though a verbal order may be authenticated after the order has already been implemented, authentication is important. If a verbal order for an ongoing medication is not documented completely and accurately, an ongoing medication error could occur and compromise the patient's safety and well being. Authentication of this verbal order could avert ongoing medication errors. In addition to identifying and correcting the error, any necessary patient follow up as a result of the error can be implemented as soon as possible. Therefore, we believe that the authentication of verbal orders impacts patient safety and quality of care.

We do not agree that the 48-hour timeframe is unnecessarily burdensome. 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. However, if a hospital is not in compliance with this requirement and the use of verbal orders is routine or commonplace, compliance with this 48-hour requirement could seem daunting.

We have also broadened the current requirement that states that verbal orders must be authenticated by the prescribing practitioner. This final rule provides hospitals flexibility by allowing a verbal order to be authenticated by the prescribing 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 for a period of 5 years. The next time the prescribing practitioner or another practitioner responsible for the care of the patient assesses the patient or documents information in the patient's medical record, a verbal order should be authenticated. In an acute care setting, opportunities exist throughout the course of 48 hours for a verbal order to be authenticated by one of these practitioners.

Comment: Many commenters stated that the "repeat and verify" process for verbal orders enhances patient safety more effectively than a timeframe for authentication of verbal orders after the service has been provided once or many times. Other commenters stated that if a verbal order is repeated and verified and considered acceptable by the ordering practitioner, the order need not be authenticated until the medical record is closed. Commenters further stated that if a verbal order is not repeated and verified, it should be authenticated within 48 hours. Several commenters stated that their State law permits verbal orders that follow the "repeat and verify" process to be signed within 30 days of discharge; if the "repeat and verify" process is not implemented, verbal orders must be authenticated within 48 hours. One commenter stated that their State law requires repetition and verification of verbal orders if a physician does not want to authenticate within 48 hours.

Response: We agree that the "repeat and verify" process for verbal orders enhances patient safety. We expect hospital policies and practices to implement this practice when verbal orders are used regardless of whether the physician wants to authenticate the order within 48 hours. Implementation of this nationally recognized safe practice should not be hampered by practitioner convenience or preference. However, the "repeat and verify" process is just one critical measure designed to minimize errors and ensure patient safety when verbal orders are used. Authentication of verbal orders is another critical measure. Both of these important processes are supported by organizations such as the NCC MERP and the AHSP. Implementation of the "repeat and verify" process 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.

Comment: One commenter stated that their State law, which permits a 30-day timeframe for authentication of verbal orders if the "repeat and verify" process is followed, is acceptable and does not jeopardize patient care. A commenter requested clarification regarding whether a State law providing for a 30-day timeframe for the authentication of verbal orders if the order is "repeated and verified" is acceptable. A few commenters requested clarification of what is meant by the word "promptly."

Response: We are not aware of any data that would support the commenter's statement that a 30-day timeframe for authentication of verbal

orders is acceptable and does not jeopardize patient care. We are also not aware of any data that define a specific timeframe for the authentication of verbal orders. Although authentication of verbal orders is supported by national organizations such as NCC MERP and ASHP, neither of these organizations specifies a timeframe for authentication of verbal orders.

The prompt authentication of all medical record entries, including verbal orders, has been a requirement for hospitals since 1986 (§ 482.24(c)(1)). The Merriam-Webster online dictionary⁷ defines "prompt" as performed readily or immediately. A 30-day timeframe for authentication of verbal orders would not be consistent with this requirement. 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. Early identification and correction of an error enables the practitioners to minimize or eliminate the potential risk to patient safety. A 30-day timeframe for authentication is not consistent with the intent to intercept an error as soon as possible.

It is possible that some States misinterpreted the intent of the Medical Records CoP at § 482.24(c)(2)(viii). This provision requires final diagnosis with completion of medical records within 30 days following discharge. It was not our intent for this requirement to support authentication of verbal orders 30 days following the patient's discharge. This requirement addresses a specific issue and does not negate the requirement for prompt authentication of all medical record entries, including verbal orders, at § 482.24(c)(1) or other specific timeframe requirements found in other CoPs. For example, the H&P examination must be placed in the patient's medical record within 24 hours after admission. A hospital would be noncompliant if the H&P examination was not placed in the medical record until 30 days following discharge. Likewise, if the postanesthesia evaluation was not completed and documented within 48 hours of surgery, a hospital would be found noncompliant.

However, given the lack of data supporting a specific timeframe for authentication of verbal orders, the lack of consensus on a timeframe for authentication of verbal orders (as evidenced by the wide variability of timeframes specified in State law from

⁷ The Merriam-Webster Online Dictionary. <http://www.merriamwebster.com/dictionary/promptly>.

24- to 48-hours up to 30 days after discharge), and many public comments stating support for deferring to State law on this issue, we have finalized this provision as proposed. We will continue to defer to State law on this issue. In the absence of a State law, verbal orders must be authenticated within 48 hours. As hospitals continue to adopt health information technologies, the prompt authentication of all medical record entries, including verbal orders, will become less burdensome for hospitals.

Comment: A few commenters stated that they support the current requirement that verbal orders for the administration of drugs or biologicals must be signed or initiated by the prescribing practitioner as soon as possible. Another commenter stated that current authentication requirements for prescribing practitioners may appear to be burdensome. However, the commenter stated that they do not believe the requirements are burdensome in their nature, but rather, are burdensome because the current requirement language, "as soon as possible" sets an arbitrary standard that cannot be operationalized or enforced. The commenter recommended that CMS define a "reasonable" timeframe for verbal orders to be documented, authenticated, and counter-signed in the patient medical record that is enforceable and can be incorporated into hospital policy and procedure. The commenter stated that since CMS is considering an H&P to be evident in the medical record within 24–48 hours, he recommended that CMS apply the same time standard for verbal orders.

Response: We appreciate the support for authentication of verbal orders as soon as possible. We agree that 48 hours is a reasonable and enforceable timeframe for authentication of verbal orders. It clarifies the current expectation of "as soon as possible" and supports patient safety. Therefore, we have finalized this provision as proposed. All verbal orders must be authenticated based upon Federal and State law. In the absence of a State law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours.

We agree that current requirements are not necessarily burdensome. Hospital burden related to verbal order authentication can be minimized. Hospitals must evaluate current practices and policies, and implement measures that minimize the use of verbal orders. If a hospital permits the routine, frequent use of verbal orders, not only is the hospital out of compliance with the CoPs, but the

hospital has created a tremendous authentication burden. The use of verbal orders should be limited to those situations in which it is impossible or impractical for the prescribing practitioner to write the order either manually or electronically. These situations should become even less frequent as hospitals implement electronic medical record and computerized physician order entry systems. As hospitals minimize the use of verbal orders, they will also minimize the burden associated with their authentication. In addition, when it is necessary to use a verbal order, this final rule gives hospitals more flexibility in terms of who may authenticate the verbal order.

Comment: A commenter stated that establishing a 48-hour requirement would not change the fact that some verbal orders would continue to be unsigned at discharge and health information management staff will continue to expend resources chasing physicians to sign orders. Instead, the commenter recommended that no verbal orders be allowed if CMS wants to put teeth in its rules. The commenter stated that patient safety would be improved by the physician actually writing the order, typing it into an email, faxing an order, or using a computerized order entry system.

Response: We acknowledge the fact that establishing a 48-hour requirement may not eliminate unsigned verbal orders. However, the use of verbal orders must not be commonplace. We agree that the use of technology such as computerized physician order entry, fax and email should be used to minimize the use of verbal orders whenever possible. However, we do not believe it is in the best interest of patient safety to disallow the use of verbal orders. Even when 100 percent of hospitals in the nation have completely implemented a computerized medical record and computerized physician order entry, there would still be those situations 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). Thus, the need for verbal orders would continue to exist.

Comment: In contrast, another commenter recommended that CMS add further provisions that waive or delay the "time" element on verbal orders during a "medical emergency" when staff are not able to stop and document orders without jeopardizing the patient's health. A possible solution would be to allow for an independent scribe to document verbal orders in

those instances and then have the physician/practitioners sign, date, and time once the patient is stabilized.

Response: We agree the use of verbal orders is often necessary during a medical emergency. We would expect the hospital to have policies and procedures that ensure that the necessary emergency care is provided to the patient without delay and appropriate documentation of emergency care. In an emergency situation, 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.

Comment: One commenter stated disagreement with the 48-hour authentication requirement due to the additional burden on physicians in residential facilities located in a psychiatric hospital. Current regulations require a patient to be seen by their attending physician as required by the condition of the patient. The medical staff is only expected to see their patients once or twice weekly. The requirement to sign verbal orders within 48 hours would negate the once to twice weekly expectation these physicians have scheduled themselves to for many years. The commenter stated that many residential facilities must be compliant with the CMS hospital regulations.

Response: Psychiatric hospitals participating in the Medicare and Medicaid programs must comply with the hospital CoPs. If a residential unit is considered a unit of a hospital, the unit must comply with the hospital CoPs. If verbal orders are used, they must be used infrequently. The final rule permits verbal orders to be authenticated by the prescribing practitioner or another practitioner who is responsible for the care of the patient.

The current regulation text cited by the commenter is contained in the specialty requirements for psychiatric hospitals at § 482.61. Section 482.61(d) states:

"Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the

treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan."

This standard addresses the frequency of progress notes. It does not address the frequency of physician visits. Even if the attending physician does not see the patient on a daily basis, we would expect another practitioner responsible for the care of the patient to be in attendance in a hospital setting. How often the medical staff is required to see a patient is determined by the patient's condition and hospital policy. In the situation described by the commenter, hospital policy may need to be revised to ensure compliance with the CoPs and State law.

Comment: One commenter recommended that we consider specifying a calendar day timeframe for verbal order authentication instead of in hours.

Response: The revised regulations now include timing of verbal order authentication. This supports a requirement for a verbal order authentication timeframe in 48 hours versus two calendar days. A timeframe stated in calendar days could be ambiguous and unclear, and could vary from situation to situation and hospital to hospital. For example, a verbal order is documented on a Wednesday at 12 noon. A 48-hour timeframe for authentication would clearly require that the verbal order be authenticated by 12 noon on Friday. Conversely, calendar days are less clear. In the previous example, it would be less clear when the verbal order must be authenticated. The outside timeframe for two calendar days could be interpreted as 12 noon Friday, or as 12 midnight Friday. Our intent is to ensure consistency in the timeframe for authentication of verbal orders. Therefore, we have retained the 48-hour timeframe for authentication of verbal orders in the final rule.

Comment: A few commenters asserted that the 48 hour authentication requirement for verbal orders would place undue burden on the hospital and physician in both urban and rural areas. One commenter stated that members of the medical staff asserted that the 48 hour authentication requirement for verbal orders would cause significant "bottle-necking" at time of discharge and would increase length of stay. The commenter stated concern that any order not signed within 48 hours might become invalid and cause problems with insurance fraud. The commenter also stated that this would eliminate their ability to electronically complete this portion of the medical record. The commenter stated that a major concern

is with the non-compliance with regard to "verbal orders" (telephone and verbal) today as measured using the expectation of 30 days. The commenter stated that compliance with the 48-hour limit would be extremely difficult, adding to their already high non-compliance rate. The commenter also stated that shorter lengths of stay add to the complexity of maintaining a signed hard-copy chart. Another commenter stated that while they understand the value of authentication of orders, the 48-hour time frame for authentication of verbal orders would be very difficult to meet in rural areas as they were working with limited resources and have a very small medical staff.

A few commenters stated that the 48-hour requirement would be burdensome in outpatient hospital physical therapy settings where there is less contact with and less supervision from the attending physician, and treatment is often begun with a verbal order. These commenters requested that this proposed requirement be limited to inpatient settings or that the current language requiring prompt authentication of verbal orders be maintained.

Response: The fundamental issue raised by these commenters is the apparent routine use of verbal orders. We agree that the routine use of verbal orders and their subsequent authentication could create a tremendous burden for both the hospital and practitioners regardless of an urban or rural setting. However, this is a costly burden created by the hospital and practitioners who tolerate the routine use of verbal orders in their daily practice and the resulting risk to patient safety.

The use of verbal orders is nationally recognized as an error prone process that poses an increased risk of miscommunication that could result in adverse effects, including medication errors, for patients. If verbal orders are used, they must be used infrequently. This means that the use of verbal orders must not be a common practice. This is not a new requirement. The requirement for the infrequent use of verbal orders has been part of the hospital CoPs since 1986. We expect that this requirement be reflected in hospital policy as well as in actual practice. If the use of verbal orders is common practice, the hospital is out of compliance with the CoPs. Current ordering practices in the hospital should be evaluated and measures implemented to minimize the use of verbal orders.

We recognize the challenges that a decreased patient length of stay presents and that more frequent order changes and more immediate response to patient

needs may be necessary. However, we do not agree that these factors necessarily translate into the need for the frequent use of verbal orders. We expect hospitals 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. A hospital's concern about potential insurance fraud issues is another reason for hospitals to minimize the use of verbal orders. We recognize that there are times when verbal orders are necessary, but their use must be infrequent. The use of verbal orders should be limited to those situations in which it is impossible or impractical for the prescriber to write the order or enter it into the computer. Verbal orders are not to be used for the convenience of the ordering practitioner. Hospital policy and practice should discourage the use of verbal orders as much as possible. When it is necessary to use a verbal order, this final rule gives hospitals more flexibility in terms of who may authenticate the verbal order.

We do not see why this requirement would eliminate a hospital's ability to complete this portion of the medical record electronically. In fact, this requirement could serve as an impetus for a hospital to adopt and implement information technology such as electronic medical record and computerized physician order entry systems.

Finally, the hospital CoPs apply to both inpatient and outpatient settings. It would not be in the best interest of patient health and safety to exempt any particular provider or patient care setting in a hospital from this requirement. Everyone providing patient care is accountable for safe care.

Comment: A few commenters stated that in the absence of State law, hospital policy should prevail, and recommended that CMS delete a specific time frame as to when hospitals must ensure authentication of verbal orders. One commenter stated that CMS should also require that hospital policies and procedures identify which types of orders, such as orders for high-alert medications, may warrant more timely authentication than orders that do not carry the same risk of patient harm.

Response: All verbal orders need to be authenticated to support continuity of care and patient safety. It is not logical to require authentication for only select "high-alert" medications. What is high risk for one patient may not be high risk for another patient. In addition, errors can be made in the documentation of a verbal order. A verbal order that is incorrectly documented may result in

the wrong medication being administered or the correct medication being administered via the wrong route or at the wrong dose. These errors pose a risk to a patient regardless of whether or not the medication is considered to be a "high-alert" medication.

Hospitals do, however, have the flexibility to develop policies that are more stringent. A hospital may decide that verbal orders cannot be given or accepted for certain types of high risk drugs. For example, many hospitals do not permit verbal orders for chemotherapeutic agents. Additionally, many hospitals already require that verbal orders be authenticated within 24 hours.

Comment: One commenter stated that in some States in which the law does not provide a specific timeframe, the law would have to be amended through a statutory or regulatory amendment process which takes time. In the meantime, hospitals would have to make changes to comply with the new 48-hour rule, and then change again to the timeframe designated in their new State rule. The constant changing of procedures is confusing to staff, and presents an unnecessarily burdensome challenge to hospitals.

Response: Whether or not a hospital needs to implement changes in policy and procedure as a result of this final rule will vary from hospital to hospital. It is not uncommon for current hospital policies to be more stringent and require that verbal orders be authenticated within 24 hours. In addition, individual States may or may not choose to amend their laws based on this final rule. If a State chooses to adopt a timeframe for the authentication of verbal orders that is longer than 48 hours, a hospital can choose to maintain a more stringent timeframe in their policy. Conversely, if a State chooses to adopt a more stringent timeframe, hospital policy may not be more lenient and policy changes would be necessary. Hospitals are expected to maintain compliance with State and Federal regulations as well as their own policies at all times.

Comment: One commenter stated that the language proposed under § 482.24(c)(1)(iii) should be corrected to read: "All verbal orders must be authenticated based upon Federal or (not 'and') State law." The commenter stated that as currently written, it is not possible for hospitals to comply with both Federal and State law if State law is different than 48 hours.

Response: As a general rule, when Federal and State law are different, we expect a hospital to comply with the more stringent requirement. However, in this provision, the Federal

requirement of 48 hours is only applicable in the absence of a State law that designates a specific timeframe for the authentication of verbal orders. Therefore, we have finalized the provision as proposed.

Comment: One commenter stated concern about current interpretive guidelines and urged CMS to cease implementation of the new interpretive guidelines related to the authentication of verbal orders.

Response: Current interpretive guideline revisions are beyond the scope of this rule. However, when these final regulations are effective, the interpretive guidelines will be revised accordingly to reflect the final regulations.

Section 482.24 Condition of Participation: Medical Record Services

We proposed adding "timed" to the existing medical records documentation requirements. We proposed that 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.

Comment: A few commenters objected to the requirement that all medical record entries be timed and requested that this requirement be deleted. Some commenters acknowledged that timing of all entries in the patient record is good practice, but not the current standard of practice for such things as progress notes by professionals other than nursing. One commenter stated that this requirement would be difficult for hospitals to comply with unless the medical record is computerized. A commenter who strongly objected to timing all medical record entries stated that currently, health care providers time only those medical record entries that require timing for clinical reasons, that is, blood draws. This commenter stated that there is no clinical need to time basic progress notes and that this requirement would also create an issue for nursing flow sheets with check boxes that are not timed. This commenter asserted that this requirement significantly increases administrative burden. Another commenter requested clarification of the preamble language in the March 25, 2005 proposed rule (71 FR 15270) regarding § 482.24(c)(1)(i). The commenter indicated that this proposed provision would require that all orders, including verbal orders, be dated, timed, and authenticated promptly by the prescribing practitioner, with few exceptions, and recommended that the

word "timed" be deleted from the final rule or that it be clarified to state that the requirements to time the entry applies only to the authentication of verbal orders.

Response: The timing of medical record entries is crucial for patient safety and quality of care. Timing applies to all medical record entries, not just to the authentication of verbal orders. This would include orders, progress notes, procedure notes, patient assessments, H&Ps, etc. Timing establishes when an order was given, when an activity, intervention, treatment, or procedure occurred, or when an activity, intervention, treatment or procedure is to take place. 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.

Authentication of Medical Record Entries

We 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.

Comment: One commenter requested that CMS move away from requiring that all entries be authenticated due to the burden it would impose. The commenter stated that the JCAHO requires authentication, at a minimum, for H&Ps, operative reports, consults, discharge summaries and other entries in accordance with law or regulation and hospital policy. The commenter stated that if CMS requires authentication for all entries, they support the 5-year exception to accommodate advancements in health information technology and the plan to re-evaluate these advances prior to the end of the 5-year period.

Response: The requirement that all medical record entries be authenticated is not a new requirement. This requirement has been in place since 1986. The proposed requirement that all medical record entries be timed is the only substantive proposed change to this particular provision. We do not believe that retaining this requirement adds additional burden as hospitals have been subject to this requirement for a significant period of time. Hospitals have incorporated the authentication of all medical record entries as part of standard operating procedures. As discussed throughout this preamble, authentication is a critical measure that supports patient safety. We expect authentication

requirements to become less of an issue as hospitals continue to implement health information technologies, including an electronic medical record.

We recognize that JCAHO authentication requirements differ from CMS standards. However, Medicare participating hospitals must comply with the Medicare hospital CoPs. JCAHO standard IM.6.10, element of performance number 4 does, in fact, refer to our regulations by stating that “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.”

C. Securing Medications

We proposed revisions to provide hospitals with greater flexibility in terms of storage of non-controlled substances. These proposed revisions are in response to concerns expressed by the medical community related to carts containing medications as well as medications kept at the patient's bedside. We proposed that all drugs and biologicals must be kept in a secure area, and locked when appropriate. We proposed that 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, and that only authorized personnel may have access to locked areas.

Comment: Anesthesia professionals as well as other commenters overwhelmingly supported these proposed revisions, particularly as it relates to anesthesia carts in the operating room and labor and delivery. Commenters stated that the proposed changes address concerns of the medical community, provides flexibility for hospitals in determining control of nonscheduled drugs and biologicals, and is more patient-focused and outcome-oriented than the current requirements. Commenters stated the proposed language would help to ameliorate patient safety and practical anesthesia practice concerns as well as help to ensure that medications are not accessible to those persons who might tamper with, abuse and/or distribute these medications. A commenter stated that this revision is consistent with the “ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control”⁸ document which states,

“Storage is an important aspect of the total drug control system * * * Storage areas must be secure: Fixtures and equipment used to store drugs should be constructed so that drugs are accessible only to designated and authorized personnel.” Commenters stated that the proposed changes will provide hospitals flexibility in determining which non-controlled drugs and biologicals need to be stored in locked areas versus which can be stored in secured and monitored areas that are only accessible to authorized hospital personnel.

Several commenters stated that the current regulation is too restrictive and has led to unnecessary and redundant security requirements for anesthesia personnel resulting in delays in care. Several commenters stated that there has never been any question that controlled drugs must be locked. However, the commenters stated that locking non-controlled medication on top of or in anesthesia carts between cases in a busy operating room is a threat to patient safety. Commenters stated that emergency carts and anesthesia carts need to be readily available in order to treat patients in imminent danger. The commenter stated that emergency carts should be sealed, for example, tamper-evident, but never locked. Commenters stated that delayed access to needed medications could be lethal. Commenters listed broken locks, lost keys, and forgotten combinations or security codes among the shortcomings of equipment used to lock anesthesia medications. One commenter stated that there is an inherent conflict between accessibility and security. One commenter stated that he supported the proposed revision in light of technology advances such as omniceils and pixus.

Response: We appreciate the strong support of commenters on these proposed revisions. We acknowledge that there can be a conflict between accessibility and security. We agree that it is critical for resuscitation drugs to be readily accessible and available when needed for patient care. We also recognize the need to set up anesthesia and other carts in advance preparation for use in the operative or labor and delivery suites. This practice is supported by the ASA. See the ASA Position Statement approved by the ASA Executive Committee, October 2003, entitled “Security of Medications in the Operating Room,” <http://www.asahq.org/clinical/LockedCartPolicyFinalOct2003.pdf>.

The intent of these revisions is to enhance patient safety and minimize delays in care. However, patient safety can also be at risk when drugs or biologicals are missing or not readily

available for patient care. The security of drugs and biologicals is essential to patient safety. All controlled substances must be kept locked. Therefore, we expect hospitals to implement and maintain appropriate safety mechanisms to control drugs and biologicals to ensure the health and safety of its patients. We agree that technology, such as Omniceils and Pixus medication storage units, assists hospitals in controlling drugs and biologicals.

Comment: Several commenters requested clarification of the definition of “authorized personnel.” Commenters stated that the definition of “authorized personnel” needs to include ancillary support personnel such as engineering, housekeeping staff, orderlies and security when needed to perform their assigned duties. One commenter stated that hospitals should have the latitude to determine who authorized persons are based on State law and local conditions.

Response: This final rule provides hospitals with the flexibility to define which personnel have access to locked areas based on their own needs as well as State and local law. The definition of “authorized personnel” should be addressed in hospital policies and procedures. Hospitals may or may not choose to include the categories of staff mentioned by commenters in their definition of “authorized personnel.”

Comment: Several commenters requested clarification of “secure area.” Commenters stated that they considered the operating room, delivery room, or similar critical care area to be secure locations when in use. One commenter agreed that areas restricted to authorized personnel would generally be considered “secure” under the proposed revisions. This commenter recommended that the regulations require that access to operating room suites be strictly limited to authorized persons. Another commenter supported the statement in the preamble of the proposed rule that secure areas would be those areas where “patients and visitors are not allowed without the supervision or presence of a healthcare professional.”

Response: The goal of this provision is to provide hospitals flexibility in the storage of non-controlled drugs and biologicals when delivering patient care, and the safe guarding of drugs and biologicals to prevent tampering or diversion. An area in which staff are actively providing patient care or preparing to receive patients, that is, setting up for procedures before the arrival of a patient, would generally be considered a “secure area.” For example, the operating room suite

⁸ American Society of Hospital Pharmacists. ASHP technical assistance bulletin on hospital drug distribution and control. *Am J Hosp Pharm.* 1980;37:1097-103. http://www.ashp.org/bestpractices/drugdistribution/Distrib_TAB_Hosp.pdf.

would be considered secure when the suite is staffed and staff are actively providing patient care. When the entire suite is not operational or otherwise not in use, for example, weekends, holidays, and after hours, the suite would not be considered secure. When the suite is closed or otherwise not in use, we would expect all drugs and biologicals to be locked. A hospital may choose to lock the entire suite, lock non-mobile carts containing drugs and biologicals, lock mobile carts containing drugs and biologicals within a locked room, or otherwise lock drugs and biologicals within a secure area. When individual operating rooms are closed or otherwise not in use, we would expect a hospital to lock non-mobile carts containing drugs and biologicals and lock mobile carts containing drugs and biologicals within a locked room. Generally, labor and delivery suites and critical care units are staffed and actively providing patient care around the clock, and would be considered secure areas. In addition, we expect hospital policies and procedures to ensure that these areas are secure with entry and exit limited to appropriate staff, patients, and visitors. All controlled substances would need to be locked within a secure area regardless of whether a patient care area is staffed or actively providing patient care.

A medication is considered secure if unauthorized persons are prevented from obtaining access. Medications should 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 medication security 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.

Comment: One commenter cited the current interpretive guidelines that if an anesthesia cart, nursing or other "cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart." The commenter requested that CMS clearly state that the final rule does not require direct monitoring of an unlocked anesthesia cart in an operating suite that is in use.

Another commenter stated that medication carts should remain locked or in line of sight of a licensed practitioner, but should not require additional security.

Response: This final rule does not address interpretive guidelines. The interpretive guidelines will be revised once this rule is finalized. This final rule requires that all drugs and biologicals be secure, and locked when appropriate. We expect hospital policies and procedures to address the security and monitoring of any carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety.

Comment: Commenters agreed that a hospital must monitor issues related to medication security, and reassess and modify its systems and process as needed.

Response: We appreciate the support. We would expect hospitals to reevaluate their policies, procedures, systems and processes related to the safe storage of all drugs and biologicals periodically, regardless of whether there is evidence of tampering or diversion.

Comment: One commenter requested that CMS give more guidance as to what "locked when appropriate" means.

Response: All controlled substances must be locked. We expect all non-controlled substances to be locked when a patient care area is not staffed. Hospitals have the flexibility to determine the most effective way to safeguard non-controlled drugs and biologicals when they are not locked. We expect hospitals to develop, implement and evaluate policies, procedures and practices to keep medications and biologicals secure and to minimize the risk of tampering and diversion as much as possible. Hospitals may choose to keep all non-controlled drugs and biologicals locked at all times. Hospitals may choose to keep non-controlled drugs and biologicals secure when a patient care area is staffed. We expect that hospitals would tighten their security measures when there is evidence of tampering or diversion of any drugs or biologicals. We realize that the security of drugs and biologicals cannot be guaranteed. However, for the safety of patients and quality of care, hospitals need flexibility regarding the security of non-controlled substances.

Comment: Commenters strongly supported the proposed provision related to patient self-administration of medication at the bedside citing standard medical practice that allows urgently needed medications to be available at the patient's bedside.

Commenters stated that the current requirements are burdensome and potentially harmful to patients when medications, such as nitroglycerine and inhalers cannot be accessed in a timely and effective manner. One commenter requested clarification of whether patients are considered "authorized" to keep non-controlled medications at the bedside.

One commenter stated that JCAHO defines self-administration as including instances when a patient independently uses a medication. The commenter stated that the JCAHO standards on self-administration outline the safe and accurate administration of medication including patient education on dosage, frequency, route of administration and monitoring of potential side effects. The commenter recommended that CMS revise the CoP to specifically address the acceptability of patient self-administration of drugs and biologicals.

Response: This final rule gives hospitals the flexibility to integrate patient self-administration of drugs and biologicals into their practice as appropriate. This final rule is consistent with the current practice of giving patients access to urgently needed medications, such as nitroglycerine tablets and inhalers, at the patient's bedside. 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. Finally, this final rule supports hospitals in the development of formal patient medication self administration programs for select populations of patients in collaboration with the medical staff, nursing, and pharmacy that include the development of the necessary hospital policies and procedures to ensure patient safety and security of medications.

We would expect hospital policies and procedures to address patient self-administration of medications. When a hospital allows a patient to self-administer medication, the hospital authorizes the patient to have access to these medications. We expect hospitals to implement measures to secure bedside medications. We agree that self-administration includes those instances where a patient independently uses a medication. Hospital policies and procedures should address competence of the patient to self-administer medications, patient education regarding self-administration of medications including elements outlined by JCAHO standards, as well as measures to secure medications at the bedside.

Comment: One commenter requested that sodium chloride solution in the form of saline flush and respiratory saline be exempt from the standards. The commenter stated that these items are completely innocuous, and are excipients, rather than medications.

Response: It is not in the best interest of patient safety to exempt any drug or biological from this requirement.

Although a saline flush or respiratory saline may have an extremely low risk of diversion, the possibility of tampering exists. It may not be necessary to lock these items but they must be secured. We also acknowledge that it may be common practice for clinicians to carry items such as these on their person. Therefore, we would expect hospital policy to address the security of these items as well.

In summary, no changes were made to the proposed regulations based on public comment. The regulations have been finalized as proposed.

D. Completion of the Postanesthesia Evaluation

We proposed that, with respect to inpatients, a postanesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia within 48 hours after surgery.

Comment: Anesthesia professionals as well as other commenters overwhelmingly supported this proposed revision. Commenters stated that implementation of the proposed change would give hospitals greater flexibility in meeting the needs of patients, ensure high quality patient care, and impose less burden than the current requirement. One commenter stated that this is a change that the ASA has been seeking for some time. Another commenter stated that this proposed revision “gives hospitals and anesthesiology departments much needed flexibility to deploy anesthesiologist, anesthesiologist assistants and nurse anesthetists so as to ensure the highest quality and timeliness of postoperative anesthesia care.” One commenter stated that the 48-hour timeframe is reasonable and allows hospitals to determine which patients need to be evaluated sooner due to risk factors such as age, comorbid medical conditions, anticipated post-procedure length of stay, and the patient experience during the surgical or interventional procedure and immediately post-procedure.

Response: We appreciate the support of commenters. We agree that this change provides more flexibility and decreases burden for hospitals and anesthesia professionals while maintaining patient safety. The 48 hour

timeframe for completion and documentation of the postanesthesia evaluation is an outside parameter. As commenters stated, individual patient risk factors may dictate that the postanesthesia evaluation be completed and documented sooner than 48 hours. This should be addressed by hospital policies and procedures.

Comment: One commenter recommended that the CoP be modified to state, “within 48 hours or before discharge, whichever comes first.” The commenter also recommended that consideration be given to determine if any non-surgical procedures may require a postanesthesia assessment.

Response: A postanesthesia evaluation is required any time general, regional or monitored (this would include deep sedation/analgesia) anesthesia has been administered to the patient. ASA guidelines define monitored anesthesia care as “a specific anesthesia service for a diagnostic or therapeutic procedure. Indications for monitored anesthesia care include the nature of the procedure, the patient’s clinical condition, and/or the potential need to convert to a general or regional anesthetic.”⁹ The type of procedure, surgical or non-surgical, is not necessarily the determining factor.

If the patient is discharged less than 48 hours after the procedure, completion and documentation of the postanesthesia evaluation is still required. This is the case regardless of whether the procedure is performed on an inpatient or outpatient basis or when the patient is discharged. There are many factors that may require that the postanesthesia evaluation be done in less than 24 hours post-procedure, such as an outpatient procedure, the patient’s condition and length of stay. Obviously, the postanesthesia evaluation must be done before the patient is discharged. Hospital policies and procedures approved by the medical staff should address the completion and documentation of the postanesthesia evaluation. This is consistent with the current anesthesia services CoP at § 482.52(b)(4) which states “with respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff” must be provided for each patient.

Comment: One commenter stated that many patient-related anesthesia issues can best be handled by a pharmacist.

The commenter recommended that CMS consider a pharmacist qualified to assist in completing postanesthesia evaluations.

Response: This standard requires that the postanesthesia evaluation be completed by an individual qualified to administer anesthesia as specified in § 482.52(a). A pharmacist is not generally qualified to administer anesthesia. However, if a patient experiences a problem with a medication, a pharmacist can be consulted. We expect individuals administering anesthesia to use the pharmacist as a clinical resource. We expect pharmacists to participate in the care of patients and assist in evaluating patients post-procedure as needed. However, a pharmacist’s evaluation would not meet this requirement.

Comment: One commenter stated that he did not support anyone other than the professional who administered the anesthesia to complete the postanesthesia evaluation. The commenter stated that the anesthesiology professional who administered the anesthesia is most familiar with the patient and should be held accountable.

Response: We agree that the professional who administered anesthesia is most familiar with the patient. However, other practitioners qualified to administer anesthesia can safely perform a postanesthesia evaluation and determine the patient’s response to and recovery from anesthesia. In addition to the practitioner’s own anesthesia knowledge base and expertise, the practitioner also has access to all of the patient’s medical records for information regarding the patient’s pre-, intra-, and post-operative status.

Comment: One commenter supports the proposed change, but stated concern that it may create unnecessary confusion when applied to procedures requiring conscious sedation.

Response: A postanesthesia evaluation is required anytime general, regional or monitored (this would include deep sedation/analgesia anesthesia has been administered to the patient). ASA guidelines do not define moderate or conscious sedation as anesthesia.¹⁰ The practitioner administering the conscious sedation may or may not be trained to administer

⁹ American Society of Anesthesiologists. Position on monitored anesthesia care. (Approved by the House of Delegates on October 21, 1986, and last amended on October 25, 2005) <http://www.asahq.org/publicationsAndServices/standards/23.pdf>.

¹⁰ American Society of Anesthesiologists. “Continuum of depth of sedation, definition of general anesthesia and levels of sedation/analgesia,” ASA Standards, Guidelines and Statements (Approved by ASA House of Delegates on October 13, 1999, and amended on October 27, 2004), <http://www.asahq.org/publicationsAndServices/standards/20.pdf>.

anesthesia. Certainly, current practice dictates that the patient receiving conscious sedation be monitored and evaluated before, during and after the procedure by trained practitioners. However, a postanesthesia evaluation would not be required when the administration of conscious sedation does not require a practitioner qualified to administer anesthesia.

Comment: One commenter stated that he supports broadening the standard for who can perform the postanesthesia evaluation but believes the proposed language does not go far enough. The commenter recommended that the language be broadened to allow physician delegation to a qualified provider to the extent permitted by State law. The commenter stated that this would allow anesthesiologists to delegate the postanesthesia evaluation and report to qualified physician assistants whom they supervised. The commenter stated that the proposed language and the parallel language regarding preanesthesia reports unnecessarily limit the ability of physicians to delegate to qualified physician assistants. The commenter cited the broad delegation authority afforded medical doctors and doctors of osteopathy at § 482.12(c)(1)(i):

“Every Medicare patient is under the care of: A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State’s regulatory mechanism.);”

The commenter stated that when rules confer both a broad authority as found at § 482.12(c)(1)(i), and a more narrowly defined authority at § 482.52, it is often not clear which provision is meant to prevail.

Response: The commenter is correct in that the requirement at § 482.12(c)(1)(i) applies to all CoPs. However, individual CoPs often provide qualifiers that limit this authority, as is the case in this situation. The revision at § 482.52 states that the postanesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia as specified in paragraph (a) of this section. A physician assistant is not specified in paragraph (a) as an individual qualified to administer anesthesia. A physician assistant does not have the required education, training and experience to administer anesthesia or to conduct a comprehensive evaluation of a patient recovering from anesthesia. Therefore, a physician is not permitted to delegate the completion and documentation of the postanesthesia evaluation to a

physician assistant or any other individual not qualified to administer anesthesia.

IV. Provisions of the Final Regulations

This final rule responds to the health care community’s primary concern that current 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 order to be consistent with current medical practice, reduce burden, and ensure patient safety, we are revising the current Medical staff, Nursing services, Medical record services, Pharmaceutical services, and Anesthesia services CoPs. These changes are made with respect to completion of the history and physical examination, authentication of verbal orders, securing medications, and completion of the postanesthesia evaluation. We believe that these issues are particularly burdensome to hospitals and it is in the best interest of patients and quality care for us to move forward with these changes.

For these reasons, we are codifying these changes 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.

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 § 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 § 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 5 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

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the following sections of this document that

contain information collection requirements:

Section 482.22 Condition of Participation: Medical Staff

Paragraph (c) requires that a hospital have bylaws that include specified information. This rule revises some of the contents required in the bylaws.

The burden associated with these requirements is the time spent in drafting the bylaws regarding performance of the H&P, the update examination, and documentation of both. We believe that this requirement reflects customary and usual business practice. Thus, the burden is not subject to the PRA in accordance with section 1320.3(b)(2). In addition, we estimate that there are fewer than 10 new hospitals per year that would have to comply, on a one-time basis, with this requirement; information collection requirements affecting fewer than 10 entities are exempt from the PRA.

Section 482.23 Condition of Participation: Nursing Services

Paragraph (c) of this section requires that with the exception of influenza and pneumococcal polysaccharide vaccines, which can be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals be documented and signed by a practitioner who is authorized to write orders by hospital policy in accordance with State law, and who is responsible for the care of the patient as specified under § 482.23(c).

The burden associated with these requirements is the time spent by the practitioner in documenting and signing orders. We believe that these requirements reflect customary and usual business and medical practice. Thus, the burden is not subject to the PRA in accordance with § 1320.3(b)(2).

Section 482.24 Condition of Participation: Medical Record Services

Paragraph (c) of this section requires that 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. 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 as specified under § 482.12(c) 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, then verbal orders must be authenticated within 48 hours.

Records must include evidence of a medical history and physical examination completed no more than 30 days before or 24 hours after admission, and placed in the patient's medical record within 24 hours of admission.

The burden associated with these requirements is the time spent in signing and dating medical record entries and in placing evidence of a history and physical examination in the patient's records. We believe that these requirements reflect customary and usual business and medical practice. Thus, the burden is not subject to the PRA in accordance with § 1320.3(b)(2).

Section 482.52 Condition of Participation: Anesthesia Services

Under paragraph (b)(3) of this section, with respect to inpatients, a postanesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia within 48 hours after surgery.

The burden associated with these requirements is the time spent in documenting the evaluation. We believe that these requirements reflect customary and usual medical practice. Thus, the burden is not subject to the PRA in accordance with § 1320.3(b)(2).

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to the Office of Management and Budget (OMB) for its review of these information collection requirements.

If you would like to comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Melissa Musotto, CMS-3122-F Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, CMS-3122-F, carolyn_lovett@omb.eop.gov. Fax (202) 395-6974.

VI. Regulatory Impact

We have examined the impact of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA)

(September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in costs/savings any one year). This final rule would impose minimal additional costs on hospitals. In fact, hospitals may realize some minimal cost savings. We believe the cost of implementing these provisions borne by hospitals would be limited to a one time cost associated with completing minor revisions to portions of the medical staff bylaws, and policies and procedures related to the requirements for history and physical examinations, authentication of verbal orders, securing medications, and postanesthesia evaluations, as well as communicating these changes to affected staff. The changes contained within this final rule are consistent with current practice, would decrease existing burden, and would provide hospitals with more flexibility in meeting CoP requirements.

Although we believe that implementation of this final rule will result in greater efficiencies for hospitals, we do not believe that the final changes will result in significant savings near the \$100 million threshold. We believe these benefits will offset the implementation costs that a hospital would incur, and, therefore, be budget neutral. Therefore, we have determined that it is not considered a major rule and no RIA is required. There are no final requirements for hospitals to initiate new processes of care, reporting, or increases in the amount of time spent providing or documenting patient care services. However, we lack data to quantify the effects of this final rule. We invited public comment on the impact on hospitals and practitioners. However, we did not receive any comments.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having receipts of \$6 million to \$29 million or less

annually (65 FR 69432). For purposes of the RFA, all hospitals are considered to be small entities. However, the nature of this final rule is such that no additional regulatory burden will be placed upon hospitals. Instead, burden would be decreased for hospitals by this final regulation. Therefore, no regulatory relief options are considered.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We do not anticipate that the operations of a substantial number of small rural hospitals will be significantly impacted.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this final rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. However, we lack data to quantify the effects of this final rule on small entities or small rural hospitals. We invited public comment on the impact of the proposed rule on small entities and small rural hospitals. We did not receive any comments on the impacts presented, thus, we have finalized this rule as proposed. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in aggregate, or by the private sector, that exceeds the inflation adjusted threshold of \$110 million. This final rule would place no additional burden for implementation on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this final rule and have determined that it would not have a negative impact on the rights, rules, and responsibilities of State, local or tribal governments. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule.

List of Subjects in 42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, part 482 as set forth below:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395hh).

■ 2. Section 482.22 is amended by—

■ A. Republishing paragraph (c) introductory text.

■ B. Revising paragraph (c)(5) to read as follows:

§ 482.22 Condition of participation: Medical staff.

* * * * *

(c) Standard: Medical staff bylaws. The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

* * * * *

(5) Include a requirement that a medical history and physical examination be completed no more than 30 days before or 24 hours after admission for each patient by a physician (as defined in section 1861(r) of the Act), 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. When the medical history and physical examination are completed within 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. This updated examination must be completed and documented in the patient's medical record within 24 hours after admission.

* * * * *

■ 3. Section 482.23 is amended by—

■ A. Republishing paragraph (c) introductory text.

■ B. Revising paragraph (c)(2) to read as follows:

§ 482.23 Condition of participation: Nursing services.

* * * * *

(c) Standard: Preparation and administration of drugs. Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

* * * * *

(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).

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

(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.

* * * * *

■ 4. Section 482.24 is amended by—

■ A. Republishing paragraph (c) introductory text.

■ B. Revising paragraph (c)(1).

■ C. Republishing paragraph (c)(2) introductory text.

■ D. Revising paragraph (c)(2)(i).

The revisions read as follows:

§ 482.24 Condition of participation: Medical record services.

* * * * *

(c) Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(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.

(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.

(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.

(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.

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

(i) Evidence of—

(A) 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's medical record within 24 hours after admission.

(B) 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.

* * * * *

■ 5. Section 482.25 is amended by—

■ A. Republishing paragraph (b) introductory text.

■ B. Revising paragraph (b)(2) to read as follows:

§ 482.25 Condition of participation: Pharmaceutical services.

* * * * *

(b) Standard: Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

* * * * *

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

(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.

(iii) Only authorized personnel may have access to locked areas.

* * * * *

■ 6. Section 482.52 is amended by—

■ A. Republishing paragraph (b) introductory text.

■ B. Revising paragraph (b)(3) to read as follows:

§ 482.52 Condition of participation: Anesthesia services.

* * * * *

(b) *Standard: Delivery of services.* Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and postanesthesia responsibilities. The policies must ensure that the following are provided for each patient:

* * * * *

(3) With respect to inpatients, a postanesthesia evaluation must be

completed and documented by an individual qualified to administer anesthesia as specified in paragraph (a) of this section within 48 hours after surgery.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774,

Medicare—Supplementary Medical Insurance Program)

Dated: June 27, 2006.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: August 11, 2006.

Michael O. Leavitt,
Secretary.

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