

procurement organizations (OPOs), including multiple new outcome and process performance measures based on donor potential and other related factors in each service area of qualified OPOs.

The proposed rule includes comprehensive conditions for coverage for OPOs that would replace the OPO existing conditions for coverage. The proposed rule contains multiple new technical, structural, and performance requirements, including new procedures for re-certification of OPOs and new outcome performance measures based on organ donor potential. Due to the large number of proposed new requirements and the technical nature of the proposed outcome performance measures, we are extending the comment period to ensure sufficient time for the public to review and comment on the proposed requirements. Therefore, we are extending the public comment period for an additional 60 days, until June 6, 2005.

Authority: Sections 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-g, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273). (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 14, 2005.

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

Approved: March 18, 2005.

Michael O. Leavitt,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS-3122-P]

RIN 0938-AM88

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: Proposed rule.

SUMMARY: In this proposed rule, we propose revisions to four of the current hospital conditions of participation (CoPs) for approval or continued participation in the Medicare and Medicaid programs. We are proposing changes to the CoP requirements related to: Completion of a 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. These proposals respond to concerns within the medical community that the current Medicare hospital CoPs are contrary to current practice and are unduly burdensome. The changes specified in this proposed rule are consistent with current medical practice and will reduce the regulatory burden on hospitals.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 24, 2005.

ADDRESSES: In commenting, please refer to file code CMS-3122-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3122-P, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Patricia Chmielewski, (410) 786-6899. Jeannie Miller, (410) 786-3164.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-3122-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, (410) 786-9994.

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I. Legislative and Regulatory Background

A. General

In the December 19, 1997 **Federal Register** (62 FR 66726), we published a proposed rule entitled “Medicare and Medicaid Programs; Hospital Conditions of Participation (CoPs); Provider Agreements and Supplier Approval” (HCFA-3745-P) 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 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 Social Security Act (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. Therefore, accredited hospitals are not routinely surveyed by SAs for compliance with the CoPs but are deemed to meet most of the hospital CoPs based on their accreditation. (See 42 CFR Part 488, “Survey Certification, and Enforcement Procedures”). However, 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 (HCFA-3745-P)

In the December 19, 1997 proposed rule, 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 deemed of particular urgency by providers was to finalize or “carve-out” specific CoPs as separate final rules. To date, we have finalized the following hospital CoPs: Organ, Tissue and Eye Procurement CoP (*see* the June 22, 1998 **Federal Register**, 63 FR 33856); Patients’ Rights (*see* the July 2, 1999 **Federal Register**, 64 FR 36069); Anesthesia Services—CRNA supervision (*see* the November 13, 2001 **Federal Register**, 66 FR 56762); Fire Safety Requirements for Certain Health Care Facilities (*see* the January 10, 2003 **Federal Register**, 68 FR 1374); and, Quality Assessment Performance Improvement (*see* the January 24, 2003 **Federal Register**, 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 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 this proposed rule would have been stipulated in a final regulation. However, with the passage of section 902 of the MMA, we believe it is in the spirit of the legislation to publish a new proposed regulation.

II. Provisions of This Proposed Rule

A. Overview

In the interest of public health and safety, we propose changing the current requirements for completion of the initial inpatient medical history and physical examination, authentication of verbal orders, securing of medications, and completion of a postanesthesia evaluation within the hospital CoPs. This proposed rule responds 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 burdens, and ensure patient safety, we are proposing to revise aspects of the current medical staff, nursing services, medical record services, pharmaceutical services, and anesthesia services CoPs.

We have developed this proposed rule taking into consideration comments received in response to the December 19, 1997 proposed rule as well as ongoing concerns expressed by the health care community since 1998 via the following public forums: Physicians' Regulatory Issues Team, (PRIT), our open door forums, written correspondence, and general questions. It is our intent to finalize this proposed rule within the 3-year publication timeframe specified in the MMA.

1. Completion of the Medical History and Physical Examination

The current medical history and physical examination requirement has been an ongoing focus and point of contention for the American Medical Association (AMA) and the American Podiatric Medical Association, Inc. (APMA). The current regulatory requirement states that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law. These professional groups continue to challenge the timeframe for completion of the medical history and physical examination, as well as who is permitted to complete the history and physical examination. Questions have intensified as a result of the JCAHO's revised standard that states a history and physical examination performed within 30 days before admission may be used in the patient's medical record, provided any changes in the patient's condition are documented in the

medical record at the time of admission. We believe that expanding the current requirement for completion of a medical history and physical examination from no more than 7 days before admission to within 30 days before admission supports safe patient care as long as the hospital ensures documentation of the patient's current condition in the medical record within 24 hours after admission.

On January 28, 2002, our Survey and Certification Group issued a memorandum (referenced as S&C-02-15) to the Associate Regional Administrators and State Survey Agency Directors addressing our position on hospital admission and presurgical history and physical examination requirements and the timing of the history and physical examination for hospital admissions. (A copy of the memorandum can be found on our Web site at <http://www.cms.hhs.gov/medicaid/survey-cert/012802.asp>). This proposed rule would codify the guidance provided in the January 28, 2002 memorandum, and published in the June 2003 issue of the Open Door Forum Newsletter.

In addition, we have received communications from the President of APMA and other podiatrists regarding their concerns that doctors of podiatric medicine are currently not permitted to perform a history and physical examination. This proposed rule addresses this concern as well.

We propose 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 propose 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 propose 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.

2. Authentication of Verbal Orders

In the December 19, 1997 proposed rule, we solicited comments on authentication of medical record entries. Many in the hospital industry supported modifying and even eliminating the requirement. Many commenters believed that authentication does not add value to the quality of the medical record, especially after the service has been delivered or after the patient has been discharged. Other commenters believed that the absence of authentication leads to questions of accountability. In a related issue, we also solicited comments on the issue of whether a timeframe should be specified for signing verbal orders. Current requirements at § 482.23(c)(2)(ii) state that verbal orders for the administration of drugs or biologicals must be signed or initialed by the prescribing practitioner as soon as possible.

A key CMS goal is to protect the health and safety of patients. We believe that an authentication requirement is necessary to protect the health and safety of patients. Unless all medical record entries are authenticated, patient safety, quality of care, accountability and integrity of the patient medical record are comprised.

When a medical record entry is authenticated, the person authenticating the entry is assuming accountability for a service provided and verifying that the entry is complete and accurate. The authentication requirements decrease the risk of errors that could jeopardize a patient's health and safety by ensuring that all medical record entries, including verbal orders, are communicated and documented completely and accurately. The current regulations use the terms "telephone orders" and "oral orders." For the purposes of this proposed rule, the term "verbal orders" is used to encompass both telephone and oral orders.

Authentication requirements enhance the accountability of a practitioner for verbal orders. Accountability means that the person who signed the entry is responsible for the care of the patient, and has verified that the order has been recorded completely and accurately. It does not mean that the person who authenticates a verbal order is necessarily the person who gave it. Authentication requirements also protect practitioners carrying out verbal orders by preventing those giving the

orders from later denying that the order was made.

Hospitals and practitioners perceive our current requirement that the prescribing practitioner must authenticate verbal orders as soon as possible as unnecessarily burdensome. We continue to receive questions from hospitals about authentication of verbal orders when the prescribing practitioner is not available (for example, the prescribing practitioner gives a verbal order, and then is "off duty" for a weekend or an extended period of time). The current regulation does not address the ability of a covering practitioner to authenticate a verbal order for the prescribing practitioner.

Based on discussions with the health care community concerning authentication and verbal orders, we are proposing a temporary exception to the authentication requirement, which will provide hospitals with flexibility while still maintaining an appropriate level of accountability.

We propose to retain and revise the current requirement for authentication of medical record entries at § 482.24(c)(1). This proposed provision states that all patient record entries must be legible, complete, dated, timed and authenticated in written or electronic form by whomever is responsible for providing or evaluating a service provided. Additionally, we would retain 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 believe this temporary revision to the authentication requirement will maintain an appropriate level of accountability while providing hospitals with flexibility until the advancement of health information technology is sufficient to allow the originating physician to authenticate his or her own orders in an efficient manner. Prior to the conclusion of the 5-year period, we will reevaluate this requirement, taking into account the advancement of health information technology.

We frequently receive questions about the timeframe for authentication of verbal orders and how we define "as

soon as possible." Some States have laws requiring authentication of verbal orders within 24 to 48 hours. Other State laws, however, do not address timeframes for authentication of verbal orders at all, and they defer to hospital policy. There is no consistency on this issue in the absence of a Federal requirement. Therefore, we propose revising § 482.24(c)(1)(iii) to require that all verbal orders must be authenticated based upon Federal and State law. We further propose that if there is no State law that designates a specific timeframe for authentication of verbal orders, then verbal orders must be authenticated within 48 hours. We invite public comment on this proposed approach to the timeframe for authentication of verbal orders. 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 independently write a specific order would be permitted to authenticate a verbal order, even if the order did not originate with him or her. In the interest of public health and safety, the proposed requirement would also establish a consistent timeframe for the authentication of verbal orders when State law does not specify a timeframe for such orders.

We also propose to revise related nursing service requirements at § 482.23(c)(2) that address documentation of orders for drugs and biologicals. We propose 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 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 in accordance with State law. This proposed requirement would provide hospitals, in conjunction with their medical staff, the ability to determine who may authenticate verbal orders for whom, as well as identify and implement systems and processes that meet the safety needs of their patient population.

As stated earlier, authentication requirements serve to protect practitioners carrying out verbal orders by preventing those giving the orders from later denying that the order was made. However, we are requesting comments on whether there are recurring problems with prescribing practitioners denying that they gave a

verbal order after the verbal order was carried out. We are also requesting public comment on the perceived impact of this proposed rule on this potential issue. We expect that a hospital's governing body and administration would address any issues through the hospital's Quality Assessment and Performance Improvement Program and credentialing process.

We propose retaining the current requirements at § 482.23(c)(2)(iii) that state that verbal orders are to be used infrequently. The use of verbal orders should not be a common practice. Verbal orders should be used only to meet the urgent care needs of the patient when it is not feasible for the ordering practitioner to immediately communicate the order in written or electronic form. Verbal orders are not to be used for the convenience of the ordering practitioner. We also propose retaining the current requirement 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.

3. Securing Medications

We have had ongoing dialogue with the American Society of Anesthesiologists (ASA) and the JCAHO regarding the current requirement that all drugs and biologicals be kept in a locked storage area. The dialogue has centered on locked anesthesia carts in the operative suite. Anesthesiologists take issue with the fact that anesthesia carts containing non-controlled drugs must be kept locked or under constant observation inside a secure operative suite. Anesthesiologists contend that it is standard practice for the anesthesiologist to set up an anesthesia cart in advance preparation for use in the operative suite. They contend that the same is true for epidural carts in a labor and delivery suite. 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.")

We have also had ongoing dialogue with the JCAHO and have received numerous questions from the healthcare community regarding patient self-administration of medications. It is current practice for hospitals to give patients access to urgently needed drugs, such as nitroglycerine tablets and inhalers, at the bedside. It is also current practice to place selected nonprescription medications at the bedside for the patient's use (for example, lotions and creams, rewetting

eye drops.) Hospitals have also developed formalized 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. The current hospital CoPs do not contemplate medications at the patient's bedside as the current requirement mandates that all medications be in locked storage.

Therefore, we propose 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 propose 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 propose that only authorized personnel may have access to locked areas. We believe this addresses the identified issues, affords hospitals flexibility in implementation, and is more patient-focused and outcome oriented than the current requirements.

We do not expect the proposed revision to alter the appropriate safety mechanisms that hospitals use to control medications and ensure the health and safety of its patients. All controlled substances need to be securely locked. These drugs must be tightly controlled and accounted for as required by Federal law and regulations. Non-controlled drugs, however, do not necessarily need to be locked. They may be secured, and locked when appropriate, to prevent diversion or tampering with the medications. 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, medications left in an unlocked drawer in a patient waiting area or patient examination room would not be considered secure. However, 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, procedure room), they are considered secure, even if not locked. 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.

4. Completion of the Postanesthesia Evaluation

The medical community has repeatedly requested that we modify the current hospital anesthesia regulation that requires the individual who administers the anesthesia to write the follow up report. The medical community requested that CMS allow the postanesthesia report to be written by an individual qualified to administer anesthesia. This issue has been identified as particularly important by the PRIT, open door forums participants and through general questions submitted to CMS. Discussions with the health care community continue to indicate that the current postanesthesia evaluation requirement at § 482.52(b)(3) is: (1) Not consistent with the current preanesthesia evaluation requirement; (2) not reflective of current practice; and (3) an unnecessary burden for hospitals and practitioners that provide anesthesia. This requirement has also been a priority issue for the American Medical Association (AMA). These ongoing discussions have served as the impetus for us to propose revisions to this requirement in the current anesthesia services CoP. The proposed revision of this regulation would be consistent with the current regulation at § 482.52(b)(1) addressing preanesthesia reports. This requirement states, "A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery." Implementation of the proposed change allowing the postanesthesia evaluation report to be written by an individual qualified to administer anesthesia would give hospitals greater flexibility in meeting the needs of patients and impose less burden than the current requirement.

B. Summary of the Proposed Rule

Condition of Participation: Medical Staff (§ 482.22)

Section 482.22(c)(5)

This proposed requirement would expand the timeframe for completion of the patient's medical history and physical examination and would expand the number of permissible professional categories of individuals who may perform the medical history and physical examination. It would require that each patient receive a medical history and physical examination, to 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. 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, could complete the medical history and physical examination. In addition, when a medical history and physical examination is completed within the 30 days before admission, the hospital would be required to ensure that an updated medical record entry documenting an examination for any changes in the patient's current condition is completed. This updated examination would be completed and documented in the patient's medical record within 24 hours after admission.

Condition of Participation: Nursing Services (§ 482.23)

Section 482.23(c)(2)

This proposed requirement would clarify 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 would 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 these orders by hospital policy in accordance with State law.

Section 482.23(c)(2)(i) and (c)(2)(ii)

This proposed requirement would reinforce the current regulations that verbal orders are to be used infrequently, and, when used, be accepted only by persons authorized by hospital policy and procedures consistent with Federal and State law.

Condition of Participation: Medical Record Services (§ 482.24)

Section 482.24(c)(1)

This proposed requirement would maintain and reinforce the current regulation for authentication of all medical record entries. It would require that all patient medical record entries be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating a service provided.

Section 482.24(c)(1)(i)

This proposed provision would require that all orders, including verbal orders, be dated, timed, and authenticated promptly by the prescribing practitioner, except as noted in subsection (ii).

Section 482.24(c)(1)(ii)

This proposed provision would permit a temporary exception to the requirement that all orders, including verbal orders, be dated, timed, and authenticated promptly by the prescribing practitioner. For a period of 5 years beginning with the effective date of the final rule, verbal orders would not need to be signed by the prescribing practitioner but could be authenticated by another practitioner responsible for the care of the patient. We believe this requirement would reduce burden and provide flexibility and clarity for hospitals in meeting the requirements for authentication of verbal orders.

Section 482.24(c)(1)(iii)

This proposed provision would specify that all verbal orders be authenticated based on Federal and State law. If there were no State law that designates a specific timeframe for the authentication of verbal orders, then verbal orders would need to be authenticated within 48 hours.

In addition, a consistent timeframe for authentication of verbal orders would be established to ensure patient health and safety when State law does not designate a specific timeframe for the authentication of verbal orders and defers to hospital policy.

Section 482.24(c)(2)(i) and (c)(2)(ii)

The proposed requirements would be revised to be consistent with the changes in the Medical staff CoP. These regulations specify documentation requirements for medical history and physical examinations. The two proposed provisions would require evidence of the following: (1) A medical history and physical examination completed no more than 30 days before or 24 hours after admission. The medical history and physical must be 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 condition when the medical history and physical examination was completed within 30 days before admission. This updated examination would need to be completed and documented in the patient's medical record within 24 hours after admission.

Condition of Participation:
Pharmaceutical Services (§ 482.25)

Section 482.25(b)(2)(i)

This proposed provision would specify that all drugs and biologicals be kept in secure areas, and locked when appropriate.

Section 482.25(b)(2)(ii)

This proposed provision would require 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.

Section 482.25(b)(2)(iii)

This proposed requirement states that only authorized personnel would have access to locked areas.

Condition of Participation: Anesthesia Services (§ 482.52)

Section 482.52(b)(3)

This proposed requirement would permit the postanesthesia evaluation for inpatients to be completed and documented by any individual qualified to administer anesthesia. Implementation of this standard would give hospitals greater flexibility in meeting the needs of patients and decrease hospital and practitioner burden.

III. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-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 fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA 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 comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA.

Condition of Participation: Medical Staff (§ 482.22)

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

The burden associated with these proposed requirements is the time spent by the hospital to revise their bylaws. We believe that this proposed 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.

Condition of Participation: Nursing Services (§ 482.23)

Proposed paragraph (c) of this section would require 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 be documented and signed by a practitioner who is responsible for the care of the patient and authorized to write orders by hospital policy in accordance with State law.

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

Condition of Participation: Medical Record Services (§ 482.24)

Proposed paragraph (c) of this section would require that all patient medical record entries be legible, complete, dated, timed and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided.

All orders, including verbal orders, would have to be dated, timed, and authenticated promptly by the prescribing practitioner, except for a 5-year period of time beginning with the effective date of the final rule. During this 5-year time period, all orders, including verbal orders must be dated, timed and authenticated promptly 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 in accordance with State law. This exception is time limited in anticipation that the advancement of health information technology will facilitate a prescribing practitioner authenticating his or her own orders.

Verbal orders would be required to be authenticated based upon Federal and State law. If there were no State law that designated a specific timeframe for the authentication of verbal orders, then verbal orders would need to 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 after admission. When the medical history and physical examination are completed within 30 days before admission, the hospital must ensure that documentation of an examination of the patient's current condition is placed in the medical record within 24 hours after admission.

The burden associated with these proposed requirements would be 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 section 1320.3(b)(2).

Condition of Participation: Anesthesia Services (§ 482.52)

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

The burden associated with these proposed requirements would be 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 section 1320.3(b)(2).

We have submitted a copy of this proposed rule to OMB for its review of the proposed information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping 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: Jim Wickliffe, CMS-3122-P 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: Christopher Martin, CMS Desk Officer, CMS-3122-P, *Christopher.Martin@omb.eop.gov* Fax (202) 395-6974.

IV. Response to Comments

Based on the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this proposed 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 proposed 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 proposed 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 proposed rule will result in greater efficiencies for hospitals, we do not believe that the proposed 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 proposed 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 proposed rule. We invite public comment on the impact on hospitals and practitioners. 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 proposed rule is such that no additional regulatory burden will be placed upon hospitals. Instead, burden would be decreased for hospitals by this proposed 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 proposed 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 proposed rule on small entities or small rural hospitals. We invite public comment on the impact of this proposed rule on small entities and small rural hospitals. 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

the aggregate, or by the private sector, that exceeds the inflation adjusted threshold of \$110 million. This proposed 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 proposed rule and have determined that it would not have a negative impact on the rights, rules, and responsibilities of State, local or tribal governments.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this proposed 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 proposes to amend 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 revising paragraph (c)(5) to read as follows:

§ 482.22 Condition of participation: Medical staff.

* * * * *

(c) * * *

(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), or other qualified individual who has been granted these privileges by the medical staff in accordance with State law. 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 revising paragraph (c)(2) to read as follows:

§ 482.23 Condition of participation: Nursing services.

* * * * *

(c) * * *

(2) With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under § 482.12(c).

(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. Revising paragraph (c)(1).

B. Revising paragraph (c)(2)(i).

The revisions read as follows:

§ 482.24 Condition of participation: Medical record services.

* * * * *

(c) * * *

(1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

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

(ii) For the period 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 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.

(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, then verbal orders must be authenticated within 48 hours.

(2) * * *

(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 revising paragraph (b)(2) to read as follows:

§ 482.25 Condition of participation: Pharmaceutical services.

* * * * *

(b) * * *

(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 revising paragraph (b)(3) to read as follows:

§ 482.52 Condition of participation: Anesthesia services.

* * * * *

(b) * * *

(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: September 1, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 2, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 05-5916 Filed 3-24-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 222 and 229

[Docket No. FRA-1999-6439, Notice No. 15]

RIN 2130-AA71

Use of Locomotive Horns at Highway-Rail Grade Crossings

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of public conference.

SUMMARY: FRA is issuing notice of a public conference that will be held in Fort Lauderdale, FL to discuss the appropriate excess risk estimate that should be applied to highway-rail grade crossings that are currently subject to FRA Emergency Order 15 ("E.O. 15"). The public conference will provide an opportunity for interested parties to provide information to FRA on the effect of silencing the locomotive horn at highway-rail grade crossings that are currently subject to E.O. 15.

DATES: Public Conference: The public conference will be held on Friday, April 15, 2005, beginning at 9 a.m.

ADDRESSES: The public conference will be held at the Holiday Inn Fort Lauderdale Beach, 999 Fort Lauderdale Beach Blvd., Fort Lauderdale, Florida 33304.

FOR FURTHER INFORMATION CONTACT: Ivornette Lynch, FRA Docket Clerk, Office of Chief Counsel, 1120 Vermont Avenue, NW., Washington, DC 20590 (telephone: 202-493-6030); Ron Ries, Office of Safety, FRA, 1120 Vermont Avenue, NW., Washington, DC 20590 (telephone: 202-493-6299); or Kathy Shelton, Office of Chief Counsel, FRA, 1120 Vermont Avenue, NW., Washington, DC 20590 (telephone: 202-493-6038).

SUPPLEMENTARY INFORMATION: Any person who would like to provide an oral statement at the public conference should notify the FRA Docket Clerk at least 10 calendar days prior to the date of the public conference and provide either a telephone number or e-mail

address at which the person may be contacted. (Please refer to the **FOR FURTHER INFORMATION CONTACT** section for contact information for the FRA Docket Clerk.) Any speaker who will be speaking on behalf of an organization should also provide the name of the organization that he/she will be representing.

FRA will attempt to accommodate all persons who wish to provide an oral statement. However, depending on the number of conference participants, FRA may find it necessary to limit the length of oral statements, in order to accommodate as many people as possible. Conference participants may choose to submit complete written statements for inclusion in the record, while providing an oral summary of their written statements at the conference.

Please note that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment), if submitted on behalf of an association, business, labor union, etc. You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (volume 65, number 70, pages 19477-78) or you may visit <http://dms.dot.gov>.

Background

Effective July 1, 1984, a Florida statute authorized counties and municipalities to restrict the nighttime sounding of the locomotive horn by intrastate railroads at highway-rail grade crossings equipped with flashing lights, bells, crossing gates, and advance warning signs indicating that the locomotive horn would not be sounded at night. However, FRA noted an alarming increase in the number of accidents at highway-rail grade crossings subject to these nighttime whistle bans. Therefore, FRA issued Emergency Order 15 ("E.O. 15") on July 26, 1991, which required the Florida East Coast Railway Company (an intrastate railroad) to sound the locomotive horn when approaching and entering public highway-rail grade crossings. E.O. 15 was later amended to allow communities to establish quiet zones, provided FRA approval was obtained prior to the implementation of sufficient safety measures at every highway-rail grade crossing within the proposed quiet zone to alleviate excess risk resulting from the absence of the warning provided by the locomotive horn.

On November 2, 1994, Congress passed Public Law 103-440 ("Act"), which added § 20153 to title 49 of the

United States Code. This Act required FRA to issue regulations that would require railroads to sound the locomotive horn at public grade crossings, but gave FRA the authority to make reasonable exceptions. After issuing a Notice of Proposed Rulemaking on January 13, 2000 (65 FR 2230), FRA published an Interim Final Rule on the Use of Locomotive Horns at Highway-Rail Grade Crossings on December 18, 2003 (68 FR 70586).

Under the Interim Final Rule, public authorities are authorized to create quiet zones by implementing supplementary safety measures and alternative safety measures to offset the excess risk that results from prohibiting routine use of the locomotive horn at highway-rail grade crossings within the proposed quiet zone. However, the Interim Final Rule provides greater flexibility in the types of safety improvements that can be employed within a proposed quiet zone than E.O. 15. Therefore, FRA stated in the Interim Final Rule that it would re-examine the effect of silencing the locomotive horn at E.O. 15 grade crossings.

The upcoming public conference will provide an opportunity for interested parties to provide information to FRA on the effect of silencing the locomotive horn at highway-rail grade crossings that are currently subject to E.O. 15. In particular, FRA is soliciting comments on whether the national excess risk estimate on the effect of silencing the locomotive horn at highway-rail grade crossings equipped with flashing lights and gates (*i.e.*, 66.8% increase in risk) should be applied to E.O. 15 grade crossings. In that regard, participants are requested to address FRA's findings in the report titled, "Florida's Train Whistle Ban", that accident frequency increased by 195% when train horns were banned at nighttime at crossings later subject to E.O. 15. In the alternative, should a regional excess risk estimate be applied to E.O. 15 grade crossings? Or, would a nighttime-specific excess risk estimate be more appropriate?

Conference participants are asked to review the following documents available in the electronic docket of this rulemaking at <http://dms.dot.gov> prior to the conference: Document no. FRA-1999-6439-16 ("Florida's Train Whistle Ban"); Document no. FRA-1999-6439-2391 ("Analysis of the Safety Impact of Train Horn Bans at Highway-Rail Grade Crossings: An Update Using 1997-2001 Data"); and Document no. FRA-1999-6439-2392 ("Interim Final Rule on the Use of Locomotive Horns at Highway-Rail Grade Crossings").