

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.

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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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