DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 414, 416, 419, 482, and 485

[CMS-1392-P]

RIN 0938-AO71

Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Medicare and Medicaid Programs: Proposed Changes to Hospital Conditions of Participation; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment

system. These changes would be applicable to services furnished on or after January 1, 2008.

In addition, this proposed rule would update the revised Medicare ambulatory surgical center (ASC) payment system to implement certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). In this proposed rule, we propose the applicable relative payment weights and amounts for services furnished in ASCs, specific HCPCS codes to which the final policies of the ASC payment system would apply, and other pertinent ratesetting information for the CY 2008 ASC payment system. These changes would be applicable to services furnished on or after January 1, 2008.

In this proposed rule, we also are proposing changes to the policies relating to the necessary provider designations of critical access hospitals (CAHs) that are being recertified when a CAH enters into a new co-location arrangement with another hospital or CAH or when the CAH creates or acquires an off-campus location.

Further, we are proposing changes to several of the current conditions of participation that hospitals must meet to participate in the Medicare and Medicaid programs to require the completion and documentation in the medical record of medical histories and physical examinations of patients conducted after admission and prior to surgery or a procedure requiring anesthesia services and for postanesthesia evaluations of patients before discharge or transfer from the postanesthesia recovery area.

DATES: To be assured consideration, comments on all sections of the preamble of this proposed rule must be received at one of the addresses provided in the "ADDRESSES" section no later than 5 p.m. on [**OFR insert 60 days after the date of display].**

ADDRESSES: In commenting, please refer to file code CMS-1392-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. Electronically. You may submit electronic comments on specific issues in this regulation to http://www.cms.hhs.gov/eRulemaking**.** Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. By regular 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-1392-P,

P.O. Box 8011,

Baltimore, MD 21244-1850.

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

3. By express or overnight mail. You may send 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-1392-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. 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:

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, S.W.,

Washington, DC 20201; or

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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.

(Because access to the interior of the Hubert H. Humphrey 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 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.

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

FOR FURTHER INFORMATION CONTACT:

Alberta Dwivedi, (410) 786-0378,	Hospital outpatient prospective payment issues
Dana Burley, (410) 786-0378,	Ambulatory surgical center issues
Suzanne Asplen, (410) 786-4558,	Partial hospitalization and community mental health centers issues
Sheila Blackstock, (410) 786-3502,	Reporting of quality data issues
Mary Collins, (410) 786-3189, and Jeannie Miller, (410) 786-3164,	Necessary provider designations for CAHs issues
Scott Cooper, (410) 786-9465, and Jeannie Miller, (410) 786-3164,	Hospital conditions of participation issues

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. You can assist us by referencing file code CMS-1392-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. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.cms.hhs.gov/eRulemaking. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also 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, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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Alphabetical List of Acronyms Appearing in the Proposed Rule

ACEP	American College of Emergency Physicians
AHA	American Hospital Association
AHIMA	American Health Information Management Association
AMA	American Medical Association
APC	Ambulatory payment classification
AMP	Average manufacturer price
ASC	Ambulatory Surgical Center
ASP	Average sales price
AWP	Average wholesale price
BBA	Balanced Budget Act of 1997, Pub. L. 105-33
BBRA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106-113
BCA	Blue Cross Association
BCBSA	Blue Cross and Blue Shield Association
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106-554
CAH	Critical access hospital
CAP	Competitive Acquisition Program
CBSA	Core-Based Statistical Area

B. Proposed Revisions to Hospital CoPs

(If you choose to comment on the issues in this section, please include the caption "Hospital CoPs" at the beginning of your comment.)

1. Background

On November 27, 2006, we published a final 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" (71 FR 68672). In that final rule (also frequently referred to as the "Carve-out rule"), we finalized changes, which were based on timely public comments submitted on the proposed rule published in the March 25, 2005 **Federal Register** (70 FR 15266), to four of the current requirements (or conditions of participation (CoPs)) that hospitals must meet to participate in the Medicare and Medicaid programs. Specifically, that final rule revised and updated 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 services and the Medical record services CoPs; securing medications in the Pharmaceutical services CoP; and, completion of the postanesthesia evaluation in the Anesthesia services CoP. This action was initiated in response to broad criticism from the medical community that the then-current requirements governing these areas were burdensome and did not reflect current practice.

Since this final rule became effective on January 26, 2007, we have received a great number of comments and questions from providers about the timeframe requirements (for both the initial medical history and physical examination and its update) as well as about the postanesthesia evaluation requirements. In both areas, commenters have sought clarification on the application of these requirements for patients undergoing outpatient surgeries and procedures. While the new requirements contained in the Carve-out rule provide hospitals greater flexibility in ensuring the quality of *inpatient* care, the issues surrounding *outpatient* care in the hospital setting, particularly with regard to outpatient surgeries and procedures, are not clear. After conducting a thorough review of the hospital CoPs and the interpretive guidelines, we have isolated the relevant issues regarding outpatient care and are proposing revisions to the current regulations to address these concerns.

According to the most recent data, 30 million surgical procedures are performed each year in the United States with over 60 percent done as outpatient procedures and another 10 to 15 percent performed on a same-day admission basis. These figures combined translate to approximately 21 million surgical procedures performed each year in the U.S. on patients who are admitted to the hospital on the day of their procedure. A majority of these patients are also discharged from the hospital the same day that they are admitted. It is unclear whether these numbers also include other procedures, such as diagnostic ones, which also require anesthesia services, and which include all of the risks to patient safety inherent in such procedures. In either case, significant numbers of patients undergo surgeries and other procedures each year as either outpatients or same-day admission patients.

The current requirements for the completion of the medical history and physical examination are found in the regulations at §482.22 (Medical staff CoP), §482.24 (Medical record services CoP), and §482.51 (Surgical services CoP). We believe that these requirements do not adequately address the patient who is admitted for outpatient or same-day surgery or a procedure requiring anesthesia services. The standards at §482.22(c), Medical staff bylaws, and §482.24(c), Content of record, both contain requirements for a medical history and physical examination, and an update of the medical history and physical examination documenting any changes in a patient's condition if the medical history and physical examination was completed within 30 days before admission, to be completed and documented within 24 hours after admission. Under the Surgical services CoP at §482.51(b)(1), there is a provision that requires a complete history and physical workup to be in the chart of every patient prior to surgery. However, there is currently no requirement for an updated examination of the patient, including any changes to the patient's condition, to be completed and documented after admission or registration, *and* prior to any surgery or procedure being performed. For patients who are admitted as inpatients for surgery to be performed in the next day or so, this does not pose a problem. These inpatients will be followed while in the hospital with both daily progress and nursing notes made in their medical record. In addition, as required under the current regulations, these patients will also have an updated examination for any changes in their condition within 24 hours after their admission.

As evidenced by the numbers of outpatient and same day admission inpatient procedures discussed above, procedures that were once done only on an inpatient basis are now routinely performed in outpatient settings. Therefore, the patient is not admitted or registered as an outpatient until the day of the procedure. Often this admission or registration is just hours before the procedure is performed. In addition, there are many patients who are admitted as inpatients on the same day that they are scheduled for more complex procedures, which will then require postoperative hospital stays. However, for patients admitted or registered for outpatient procedures as well as for those patients admitted on the same day as their surgery, there is currently no mechanism to ensure that these patients are examined for any changes in their condition prior to undergoing a procedure. Paragraph (b)(1) of §482.51 currently requires that every patient have a complete medical history and physical examination documented in the chart prior to surgery, except in emergencies. However, the timeframe requirements for this medical history and physical examination contained under both §482.22(c)(5) and §482.24(c)(2)(i)(A) allow for a medical history and physical examination that may be as much as 30 days old. Without a requirement that an updated examination be completed after admission and prior to surgery or other procedure, any changes in a patient's condition would most likely be missed by hospital staff. Failing to identify changes in a patient's condition prior to surgery may adversely impact not only the procedure but also consequently, and perhaps more significantly, the outcome of the procedure for the patient.

We are proposing revisions to §§482.22, 482.24, and 482.51 that would require an updated examination, including any changes in a patient's condition, to be completed and documented for each patient after admission or registration and prior to surgery or to a procedure requiring anesthesia services. These revisions would ensure that any changes in the patient's condition are discovered before a procedure is performed. With the most up-to-date information regarding a patient's condition readily available to hospital staff prior to a procedure, the risks to patient safety should be minimized and a poor outcome for the patient would be avoided. However, under these proposed requirements, it is not our intent to include those minor procedures that only require the administration of local anesthetics, as might be the case for procedures such as biopsies of skin lesions or suturing of noncomplex lacerations.

Conversely, the current requirements at §482.52, Anesthesia services, still distinguish between inpatients and outpatients with regard to postanesthesia evaluation, with the requirements for outpatient evaluation actually being less stringent than those for inpatients. When the current hospital regulations were originally written in 1986, these differences in regulatory oversight may have been entirely appropriate. At that time there were still very clear differences between inpatient and outpatient procedures, with inpatient procedures (and the anesthesia services required) considered much more serious and complex in nature. Since that time, there has been a gradual blurring of the distinctions between what were previously termed "inpatient" procedures and those that were classified as "outpatient" procedures. Procedures that were once done only on an inpatient basis are now routinely performed in outpatient settings. While advances in medical technology and surgical technique have allowed for this shift, the complexity and seriousness of these procedures still remain as do the risks to patient health and safety. Along with the increased complexity and types of outpatient procedures being performed today, come the higher levels of sedation and anesthesia required for these procedures. Thus, distinctions between inpatients and outpatients in the requirements for postanesthesia evaluations are less relevant than ever.

In addition, the current language regarding the completion and documentation of an evaluation "within 48 hours after surgery" assumes that all patients receiving anesthesia services have undergone surgery. It also assumes that they have not been discharged from the hospital prior to the end of this 48-hour timeframe and that they are still available for evaluation. Many patients who have received anesthesia services (either general anesthesia or monitored anesthesia care) have undergone diagnostic or therapeutic procedures as opposed to surgical ones and are discharged within hours after such procedures. Diagnostic and therapeutic procedures that require anesthesia services (either general anesthesia or monitored anesthesia care) include esophagogastroduodenoscopy (EGD), colonoscopy, endoscopic retrograde cholangiopancreatography (ERCP), and electroconvulsive therapy (ECT). Furthermore, and as noted above, even those patients who have undergone inpatient surgical procedures are often discharged well before 48 hours after surgery.

Therefore, we are proposing revisions to §482.52(b) that would ensure that all patients who have received anesthesia services, regardless of inpatient or outpatient status, have a postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia before they are discharged or transferred from the postanesthesia recovery area.

Finally, in our review of the CoPs, we discovered a cross-reference under §482.23, Nursing services, that is no longer valid. We are taking the opportunity in this proposed rule to correct this error through a technical amendment.

2. Provisions of the Proposed Regulations

a. Proposed Timeframes for Completion of the Medical History and Physical Examination

The proposed revisions to §482.22(c)(5) would retain the requirement that the medical staff bylaws 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. We are proposing to revise this provision to include the requirement that the completion and documentation of the medical history and physical examination (and the updated examination) would also be required prior to surgery or a procedure requiring anesthesia services.

We also are proposing to retain the current provision that the medical staff bylaws contain a requirement for the completion and documentation of an updated examination within 24 hours after admission (when the medical history and physical examination has been completed within 30 days before admission). However, we are proposing to delete the language regarding the placement of the medical history and physical examination and the updated examination in the medical record within 24 hours after admission because we believe that the proposed language requiring not only the completion, but also the documentation, of both the medical history and physical examination and the updated examination, achieves this purpose. In addition, requirements for the physical placement of the medical history and physical examination and the updated examination in the patient's medical record are currently, and more appropriately, contained under the "Medical record services" CoP at §482.24(c)(2), which we are proposing to retain under this rule.

Further, we are proposing to separate the requirements for the medical history and physical examination and for the updated examination under two provisions at §482.22(c)(5)(i) and §482.22(c)(5)(ii), respectively. At §482.22(c)(5)(i), we are proposing to retain the current requirement that the medical history and physical examination be completed 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. However, we are proposing to add the words "and documented" after "be completed" as well as "licensed" after "qualified" to further clarify this requirement. In addition, we are proposing to revise §482.22(c)(5)(ii) to require that the updated examination of the patient must be completed and documented by the same individuals as proposed above. We also are proposing to add the words "or registration" to follow "after admission" to reflect differences in terminology that may exist with the admission of patients for outpatient procedures. We are proposing this revision here as well as in §482.24 and §482.51, where appropriate.

We are proposing to revise the words "for any changes in the patient's condition" to "including any changes in the patient's condition" at both §482.22(c)(5) and §482.24(c)(2)(i)(B).

Under §482.24(c), Content of record, we are proposing to revise both §482.24(c)(2)(i)(A) and §482.24(c)(2)(i)(B) by adding the language "but prior to surgery or a procedure requiring anesthesia services" with regard to both the completion and the documentation of the medical history and physical examination and the updated examination.

We are proposing to revise the Surgical services CoP at §482.51(b)(1) by deleting the language regarding medical histories and physical examinations that have been dictated but which are not yet recorded in the patient's chart. Our overall intent in this proposed rule is to require that the most current information regarding a patient's condition be available to the hospital staff prior to surgery or a procedure requiring anesthesia services so that risks to patient safety can be minimized and potential adverse outcomes can be avoided.

We are proposing to retain the language regarding the requirement for a medical history and physical examination prior to surgery, except in the case of emergencies, and are proposing to extend this to a requirement for an updated examination. We are proposing to divide the requirements for the medical history physical examination and the updated examination under two separate provisions at §482.51(b)(1)(i) and §482.51(b)(1)(ii) in the Surgical services CoP.

b. Proposed Requirements for Preanesthesia and Postanesthesia Evaluations

At §482.52(b)(1), under the "Delivery of services" standard of the "Anesthesia services" CoP, we are proposing to revise the requirement for a preanesthesia evaluation to include the language "or a procedure requiring anesthesia services" to include the range of procedures that require anesthesia services, but that are not necessarily surgical in nature. We also are proposing to add this language under §482.52(b)(3) for the postanesthesia evaluation requirement.

Further, we are proposing to revise this standard by deleting both the words "with respect to inpatients" at §482.52(b)(3) and the entire provision at §482.52(b)(4), which are the current requirements for postanesthesia evaluations for patients. We are proposing to revise §482.52(b)(3) by requiring that the postanesthesia evaluation be completed and documented before discharge or transfer from the postanesthesia recovery area. As discussed above, the intent of this section of the proposed rule is to eliminate the distinctions currently found in the regulations between inpatients and outpatients with regard to anesthesia services.

c. Proposed Technical Amendment to Nursing Services CoP

We are proposing to revise the cross-reference to §405.1910(c) currently found under the nursing services CoP at §482.23(b)(1) as this citation has been changed and is no longer valid. We are proposing a technical amendment to this provision to correct the cross-reference to §488.54(c).

XIX. Files Available to the Public Via the Internet

A. Information in Addenda Related to the Revised CY 2008 Hospital OPPS

Addenda A and B to this proposed rule provide various data pertaining to the CY 2008 payment for items and services under the OPPS. Addendum A, a complete list of all APCs payable under the OPPS, and Addendum B, a complete list of all active HCPCS codes regardless of their assigned payment status or comment indicators under

(3,500 hospitals x 5 charts per hospital) submitted by the hospitals to CMS for a total burden of 7,000 hours. Therefore, the total burden for all hospitals would be 921,000 hours per year.

§482.22 Condition of participation: Medical staff.

Proposed §482.22(c)(5)(i) would require that a medical history and physical examination be completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, for each patient by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

The burden associated with this proposed requirement is the time and effort it would take for medical staff to document the patient's medical history and the results of a physical examination. While the burden associated with this proposed requirement is subject to the PRA, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Proposed §482.22(c)(5)(ii) would require that an updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination must also be completed and documented by the same individuals as required under proposed §482.22(c)(5)(i).

The burden associated with this proposed requirement is the time and effort it would take for medical staff to document any changes in the patient's condition. While the burden associated with this proposed requirement is subject to the PRA, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

§482.24 Condition of participation: Medical record services.

Proposed §482.24(c)(2)(i) would require evidence of:

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

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

While the burden associated with these two proposed requirements is subject to the PRA, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

§482.51 Condition of participation: Surgical services.

Proposed §482.51(b)(1) would require medical staff, prior to surgery or a procedure requiring anesthesia services, and except in the case of emergencies, to document no more than 30 days before or 24 hours after admission or registration a patient's medical history, the results of the patient's physical examination, and any changes in the patient's condition.

While the burden associated with these proposed requirements is subject to the PRA, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

§482.52 Condition of participation: Anesthesia services.

Proposed §482.52(b)(1) would require a preanesthesia evaluation to be completed and documented by an individual qualified to administer anesthesia, performed within 48 hours prior to surgery or a procedure requiring anesthesia services. Proposed §482.52(b)(3) would require a postanesthesia evaluation to be completed and documented by an individual qualified to administer anesthesia, after surgery or a procedure requiring anesthesia services, but before discharge or transfer from the postanesthesia recovery area.

While the burden associated with these requirements is subject to the PRA, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

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

If you 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,

Division of Regulations Development,

Attn: Melissa Musotto, (CMS-1392-P)**,**

Room C4-26-05, 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-1392-P**,**

carolyn_lovett@omb.eop.gov**.** Fax (202) 395-6974.

XXI. Response to Comments

Because of 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 proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document(s).

XXII. Regulatory Impact Analysis

A. Overall Impact

(If you choose to comment on issues in this section, please include the caption "Impact" at the beginning of your comment.)

We have examined the impacts 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.

1. Executive Order 12866

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 any 1 year).

We estimate that the effects of the OPPS provisions that would be implemented by this proposed rule would result in expenditures exceeding $100 million in any 1 year.

a. In paragraph (d)(1)(i), removing the cross-reference "§412.63(b)" and adding the cross-reference "§412.64(b)" in its place.

b. In paragraph (d)(2)(i), removing the cross-reference "§412.63(b)" and adding the cross-reference "§412.64(b)" in its place.

c. In paragraph (d)(4)(ii), removing the cross-reference "§412.63(b)" and adding the phrase "§412.63(b) or §412.64(b), as applicable," in its place.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

14. The authority citation for Part 482 continues to read as follows:

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

15. 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--

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

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

* * * * *

§482.23 [Amended]

16. In §482.23(b)(1), the cross-reference "§405.1910(c)" is removed and the cross-reference "§488.54(c)" is added in its place.

17. Section 482.24 is amended by revising paragraph (c)(2)(i) to read as follows:

§482.24 Condition of participation: Medical record services.

* * * * *

(c) * * *

(2) * * *

(i) Evidence of--

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

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

* * * * *

18. Section 482.51 is amended by revising paragraph (b)(1) to read as follows:

§482.51 Condition of participation: Surgical services.

* * * * *

(b) * * *

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

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.

(ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.

* * * * *

19. Section 482.52 is amended by--

a. Revising paragraph (b)(1).

b. Revising paragraph (b)(3).

c. Removing paragraph (b)(4).

The revisions read as follows:

§482.52 Condition of participation: Anesthesia services.

* * * * *

(b) * * *

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

* * * * *

(3) A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, after surgery or a procedure requiring anesthesia services, but before discharge or transfer from the postanesthesia recovery area.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

20, The authority citation for Part 485 continues to read as follows:

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

21. Section 485.610 is amended by adding new paragraph (e) to read as follows:

§485.610 Condition of participation: Status and location.