establishing quality reporting for ASCs would allow time for ASCs to adjust to the changes in payment and case-mix that are anticipated under the revised payment system. We would also gain experience with quality measurement in the ambulatory setting in order to identify the most appropriate measures for quality reporting in ASCs prior to the introduction of the requirement in ASCs. We intend to implement the provisions of section 109(b) of the MIEA-TRHCA, Pub. L. 109-432, in a future rulemaking.

XVIII. Proposed Changes Affecting Critical Access Hospitals (CAHs) and Hospital Conditions of Participation (CoPs)

A. Proposed Changes Affecting CAHs

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

1. Background

CAHs are subject to different participation requirements than are hospitals. Among other requirements, a CAH must be located in a rural area (or an area treated as rural), and, under §485.610(c), must meet an additional distance-related location requirement. Under this requirement, a CAH must be located at least 35-miles (or, in the case of mountainous terrain or in areas with only secondary roads, 15-miles) from the nearest hospital or other CAH. In addition, CAHs receive payment for services furnished to Medicare beneficiaries differently. CAHs receive cost-based payment for 101 percent of their reasonable costs.

Prior to January 1, 2006, States were permitted to waive the CAH minimum distance eligibility requirement by certifying that a CAH was a necessary provider.

Approximately 850 current CAHs entered the program on the basis of a necessary provider designation. The criteria used to qualify a CAH as a necessary provider were established by each State in its Medicare Rural Hospital Flexibility Program (MRHFP). The State's MRHFP rural health care plan contains the necessary assurances that the plan was developed to further the goals of the statute and regulations to ensure access to essential health care services for rural residents. The statute and regulations give some discretion and flexibility within a Federal framework for a State to designate CAHs. States, in consultation with their hospital associations and Offices of Rural Health, have defined those CAHs that provide necessary services to a particular patient community in the event that the facility did not meet the required 35-mile (or, in the case of mountainous terrain or in areas with only secondary roads, 15-mile) distance requirement from the nearest hospital or CAH. Each State's criteria are different, but the criteria share certain similarities and all define a necessary provider related to the facility location.

However, section 405(h)(1) of Pub. L. 108-173 amended section 1820(c)(2)(B)(i)(II) of the Act by adding language that ended States' authority to waive the location requirement for a CAH by certifying the CAH as a necessary provider, effective January 1, 2006. In addition, section 405(h)(2) of Pub. L. 108-173 amended section 1820(h) of the Act to include a grandfathering provision for CAHs that were certified as necessary providers prior to January 1, 2006. We incorporated these amendments in §485.610(c) of our regulations in the FY 2005 IPPS final rule (69 FR 49220). Because those regulations did not address the situation where the grandfathered CAH is no longer the same facility due to relocation, in the FY 2006 IPPS

final rule (70 FR 47490), we amended §485.610 of our regulations to add a new §485.610(d) that addressed the relocation criteria a necessary provider CAH has to meet to retain its necessary provider designation.

Additional circumstances concerning CAHs with existing necessary provider designations have come to our attention that we believe also need to be addressed. Specifically, we have learned that some CAHs with grandfathered necessary provider designations are co-located with other hospitals, which typically are PPS-excluded inpatient psychiatric facilities or inpatient rehabilitation facilities. We are also aware that there is interest in the creation or acquisition by CAHs with necessary provider designation of off-campus facilities that they do not believe would be subject to CAH location requirements.

For the reasons noted below, we are taking a proactive approach by proposing a change in the regulation to be consistent with our belief that the intent of the CAH program is to maintain hospital-level services in rural communities while ensuring access to care. We believe that this proposed change to the regulations will help to maintain the integrity of the MRHFP within the statutory requirements.

2. Co-Location of Necessary Provider CAHs

Some necessary provider CAHs are co-located with other hospitals, particularly specialty psychiatric and or rehabilitation hospitals. Prior to the enactment of section 405(g) of Pub. L. 108-173, it is understandable that a State MRHFP might have allowed co-location of a CAH with a necessary provider designation with the specialized services of a psychiatric and/or an inpatient rehabilitation hospital. The State may have believed

that beneficiary access to care would be enhanced through the provision of both CAH and these specialized services at the same location, and the CAH itself might have had difficulty in providing such services within its permitted bed limits. However, section 405 of Pub. L. 108-173 included several provisions that permit CAHs themselves to address such access to care issues.

Specifically, section 405(e) of Pub. L. 108-173 amended sections 1820(c)(2)(B)(iii) and 1820(f) of the Act to increase the permitted number of CAH inpatient beds from 15 to 25. In addition, section 405(g) of Pub. L. 108-173 added section 1820(c)(2)(E) to the Act, which permits a CAH to operate distinct part inpatient psychiatric and/or rehabilitation units, each subject to a 10-bed limit that is not included as part of the CAH's 25-bed limit. Therefore, a CAH can operate a 45-bed facility addressing a wide range of needs in the rural community it serves. We believe that CAHs seeking to provide access to specialized services should avail themselves of the statutory provisions governing distinct part units in CAHs rather than making arrangements with other hospital providers to share space at the CAH location.

In light of these changes to the statute, we are proposing to no longer allow a necessary provider CAH to enter into co-location arrangements between CAHs and hospitals unless such arrangements were in effect on or before January 1, 2008 and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change. We believe that this restriction will help to ensure that the current necessary services will remain in the community. Further, we are proposing to clarify that a change of ownership of the CAH, when the new owners assume the original

provider agreement, does not constitute a new co-location arrangement and, thereby, under our proposal, a necessary provider CAH would be permitted to continue under an existing co-location arrangement.

We are concerned that, without this change, there may be situations where more necessary provider CAHs will co-locate with PPS hospitals. Currently, co-location arrangements seem to involve psychiatric or rehabilitation hospitals. We are concerned about co-location by a necessary provider CAHs with a short-term acute care hospital, including a physician-owned specialty hospital. We also cannot rule out a scenario where two necessary provider CAHs could co-locate after relocation. We believe the co-location of a necessary provider CAH with another hospital or necessary provider CAH is not consistent with the CAH statutory framework that establishes requirements for a CAH to be a certain minimum distance from other hospitals or CAHs. We believe that the elimination of States' authority to designate necessary provider CAHs and the ability for CAHs to operate psychiatric and rehabilitation units should provide sufficient flexibility for necessary provider CAHs to operate within the statutory framework without engaging in additional arrangements.

We also are clarifying in this proposed rule that under certain circumstances, a change of ownership of any of the facilities (either the CAH or the existing co-located facility) with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement. If a change of ownership should occur in a CAH with a grandfathered co-location arrangement on or after January 1, 2008, we note the provider agreement is generally automatically assigned to

the new owner, unless the new owner rejects assignment of the provider agreement or assignment of the provider agreement is otherwise not made. If the new owner does not get assignment of the provider agreement, the new owner would have to go through the same enrollment process as any other new provider; that is, enrolling with the fiscal intermediary (or if applicable, the MAC), applying for participation, undergoing the Office of Civil Rights clearance and an initial certification survey that meets all the current Medicare conditions (see State Operations Manual 3210) to obtain CAH status. Thus, grandfathered necessary provider CAH status, including grandfathered co-location arrangements, would not transfer to a new CAH owner who does not assume the provider agreement from the previous owner. To obtain CAH designation, the new provider would have to comply with all the CAH designation requirements, including the location requirements relative to other providers, that is, more than a 35-mile drive (or 15 miles in areas of mountainous terrain or secondary roads).

3. Provider-Based Facilities of CAHs

We have consistently taken the position that the intent of the CAH program is to keep hospital-level services in rural communities, thereby ensuring access to care (FY 2006 IPPS final rule (70 FR 47469)). A CAH is permitted to create or acquire an off-campus location, including a distinct part unit that satisfies the location criteria for a CAH and operates under the CAH's provider agreement under the provider-based rules at 42 CFR 413.65. We note that, under section 1820(c)(2)(B)(i)(II) of the Act, a CAH does not have to meet the distance requirements relative to other hospitals or CAHs if it was certified prior to January 1, 2006, as a necessary provider by the State. We stated in the

FY 2006 IPPS final rule (70 FR 47472), when addressing the relocation criteria for a necessary provider CAH, that the "necessary provider" designation is specific to the physical location(s) of the CAH in existence at the time of the designation. We believe the necessary provider CAH designation cannot be considered to extend to any new facilities not in existence when the CAH received its original necessary provider designation. Accordingly, we believe the creation of any new location that would cause any part of the CAH to be situated at a location not in compliance with the distance requirements at 42 CFR 485.610 would cause the entire CAH to violate the distance requirements.

Of the approximately 1,300 CAHs, 453 CAHs have health clinics, 81 have psychiatric units, and 20 have rehabilitation units. We do not know how many of the existing clinics and distinct part units are at off-site locations. However, we are concerned with CAHs creating or acquiring off-campus locations, including distinct part psychiatric and rehabilitation units, that do not comply with the CAH location requirement relative to other facilities. Therefore, when such off-campus facilities are created by a CAH with a necessary provider designation, there is no reason to assume that the distance exemption given to the CAH should be extended without qualification to any location for that CAH's off-campus facilities. Accordingly, any CAH off-campus locations must satisfy the current statutory CAH distance requirements, without exception and regardless of whether the main provider CAH is a necessary provider CAH.

Therefore, we are proposing to clarify that if a necessary provider CAH, or a CAH that does not have a necessary provider designation, operates a provider-based facility as defined in §413.65(a)(2), or a psychiatric or rehabilitation distinct part unit as defined in §485.647 that was created or acquired on or after January 1, 2008, it must comply with the distance requirement of a 35-mile drive to the nearest hospital or CAH (or 15 miles in the case of mountainous terrain or in areas with only secondary roads).

4. Termination of Provider Agreement

In the event that a CAH with a necessary provider designation enters into a co-location arrangement after January 1, 2008, or acquires or creates an off-campus facility after January 1, 2008, that does not satisfy the CAH distance requirements in §485.610(c), we are proposing to terminate that CAH's provider agreement, in accordance with the provisions of §489.53(a)(3). The necessary provider CAH could avoid termination by converting to a hospital that is paid under the IPPS, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions in 42 CFR Part 482. We also note that if the necessary provider CAH corrects the situation that led to the noncompliance, a termination action will not be triggered. A CAH that is not a necessary provider CAH could not have a co-location situation due to the distance requirements it is required to meet at 485.610 (c).

5. Proposed Regulation Changes

We are proposing to amend §485.610 by adding a new paragraph (e) to address situations under our proposal relating to off-campus and co-location requirements for CAHs with a necessary provider designation.

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