
CMS Manual System

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Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 71

Date: May 13, 2011

SUBJECT: Clarifications to Appendix L, Ambulatory Surgical Center Interpretive Guidelines – Comprehensive Medical History and Physical (H&P) Assessment and Anesthetic Risk and Evaluation.

I. SUMMARY OF CHANGES: The Comprehensive Medical History and Physical Assessment and the Anesthetic Risk and Evaluation sections of the ASC Interpretive Guidelines are being revised to provide clarifying information and more detailed guidance to this section.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: May 13, 2011

IMPLEMENTATION DATE: May 13, 2011

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix L/§416.42(a)/Standard: Anesthetic Risk and Evaluation
R	Appendix L/§416.52(a)(1) & (2)/Standard: Admission and Pre-Surgical Assessment

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

State Operations Manual

Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

Q-0061

(Rev.71, Issued: 05-13-11, Effective: 5-13-11-Implementation: 05-13-11)

§416.42(a) Standard: Anesthetic Risk and Evaluation

(1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

Interpretive Guidelines: §416.42(a)(1)

The purpose of the exam immediately before surgery is to evaluate, based on the patient's current condition, whether the risks associated with the anesthesia that will be administered and with the surgical procedure that will be performed fall within an acceptable range for a patient having that procedure in an ASC, given that the ASC does not provide services to patients requiring hospitalization. The assessment must be specific to each patient; it is not acceptable for an ASC to assume, for example, that coverage of a specific procedure by Medicare or an insurance company in an ASC setting is a sufficient basis to conclude that the risks of the anesthesia and surgery are acceptable generically for every ASC patient. The requirement for a physician to examine the patient immediately before surgery is not to be confused with the separate requirement at 42 CFR 416.52(a)(1) for a history *and* physical assessment performed by a physician, although it is expected that the physician will review the materials from such pre-admission examination as part of the evaluation. *Nevertheless*, this requirement does constitute one component of the requirement at 42 CFR 416.52(a)(2) for a pre-surgical assessment upon admission. *In those cases, however, where the comprehensive history and physical assessment is performed in the ASC on the same day as the surgical procedure, the assessment of the patient's procedure/anesthesia risk must be conducted separately from the history and physical, including any update assessment incorporated into that history and physical.* See the interpretive guidelines for §§416.52(a)(1) & (2).

The ASC must have approved policies and procedures to assure that the assessment of anesthesia-related and procedural risks is completed just prior to every surgical procedure. (Ideally, the ASC would conduct such an assessment prior to the patient's admission as well as immediately prior to surgery, but this is not specifically required by the regulations.)

The ASC's policies must address the basis or criteria used within the ASC in conducting these risk assessments, and must assure consistency among assessments.

The regulations do not specify the content or methodology to be employed in such assessments. As an illustrative example, an ASC might choose to incorporate consideration of a patient's ASA Physical Classification into its criteria. Although the American Society of Anesthesiologists did not create its ASA Physical Status Classification System for the purpose of predicting operative risk, this system has nevertheless been found to be useful in predicting morbidity and mortality in surgical patients¹ and has been used by surgical facilities as a standard tool. This system classifies patients' physical status in 6 levels:

- ASA PS I – Normal healthy patient;
- ASA PS II – Patient with mild systemic disease;
- ASA PS III – Patient with severe systemic disease;
- ASA PS IV – Patient with severe systemic disease that is a constant threat to life;
- ASA PS V – Moribund patient who is not expected to survive without the operation; and
- ASA PS VI – Declared brain-dead patient whose organs are being removed for donor purposes.

As the ASA PS level of a patient increases, the range of acceptable risk associated with a specific procedure or type of anesthesia in an ambulatory setting may narrow. An ASC that employed this classification system in its assessment of its patients might then consider, taking into account the nature of the procedures it performs and the anesthesia used, whether it will accept for admission patients who would have a classification of ASA PS IV or higher. For many patients classified as ASA PS level III, an ASC may also not be an appropriate setting, depending upon the procedure and anesthesia.

If a State establishes licensure limitations on the types of procedures an ASC may perform that are based on patient classifications and would permit ASCs to perform fewer procedures than they would under the CfCs, then the ASC must conform to those State requirements. However, State requirements that would expand the types of procedures an ASC may offer beyond what is permitted under the CfCs are superseded by the Federal CfC requirements.

Endnotes for Standard: Anesthetic Risk and Evaluation

¹P. 636, Davenport et al., "National Surgical Quality Improvement Program Risk Factors Can Be Used to Validate American Society of Anesthesiologists Physical Status Classification Levels," *Annals of Surgery*, Vol. 243, No. 5, May 2006

Survey Procedures: §416.42(a)(1)

- Verify that there is evidence for every medical record in the survey sample of an assessment by a physician of the patient's risk for the planned surgery and anesthesia.
- Ask the ASC to provide you with its policies and procedures for assessment of anesthesia and procedural risk. Check to determine that the policies include the criteria the ASC's physicians are to use in making the assessments.
- Ask the ASC's leadership to demonstrate how they assure a consistent approach in the assessment.
- Ask the ASC's leadership whether they can point to any cases where an assessment resulted in a decision not to proceed with the surgery. If there are no such cases, ask the ASC to explain how its patient selection criteria assure that there is an acceptable level of anesthesia and procedural risk for every patient scheduled for surgery in the ASC – for example, do they use patient admission criteria that exclude higher risk patients? If so, ask to see those criteria.
- The survey sample should include cases where a patient died or needed to be transferred to a hospital; discuss the pre-surgical assessment of the patient in those cases, preferably with the physician who conducted the assessments, to explore the basis on which the patient was found to be suitable for the surgery and anesthesia.

Q-0261

(Rev. 71, Issued: 05-13-11, Effective: 5-13-11-Implementation: 05-13-11)

§416.52(a) Standard: Admission and Pre-surgical Assessment

- (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.**

Interpretive Guidelines §416.52(a)(1)

The purpose of a comprehensive medical history and physical assessment (H&P) is to determine whether there is anything in the patient's overall condition that would affect the planned surgery, such as a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce risk to the patient, or which may even indicate that an ASC setting might not be the appropriate setting for the patient's surgery. The H&P must be comprehensive in order to allow assessment of the patient's readiness for surgery *and is required regardless of the*

type of surgical procedure. The H&P should specifically indicate that the patient is cleared for surgery in an ambulatory setting.

The H&P must be completed and documented for each ASC patient no more than 30 calendar days prior to date the patient is scheduled for surgery in the ASC.

- In cases where the patient is scheduled for two surgeries in the ASC within a short period of time, the same H&P may be used so long as it is completed no more than 30 calendar days before each surgery. For example, if a patient has two surgeries for cataracts scheduled, one eye on May 3rd, and the other eye on May 18th, and H&P performed on April 20th could be used for both surgeries.
- The H&P is still required in those cases where the patient is referred to the ASC for surgery on the same day as the referral and the referring physician has indicated it is medically necessary for the patient to have the surgery on the same date. The H&P may be performed by the referring physician, if the ASC's policies permit this, or qualified personnel in the ASC. If there are elements of the H&P that are essential to the performance of the physician assessment required under §416.42(a) or under this requirement at §416.52(a)(1), based on the type of procedure to be performed as well as applicable State health and safety laws, standards of practice, or ASC policy, and those elements cannot be completed prior to the scheduled time of the surgical procedure, then it is questionable whether the case is suitable for that ASC.
- *The H&P may be performed on the same day as the surgical procedure, and may be performed in the ASC, as long as it is conducted by qualified personnel, is comprehensive, and the results of the H&P are placed in the patient's medical record prior to the surgical procedure (see §416.52(a)(3)). It is not acceptable to conduct the H&P after the patient has been prepped and brought into the operating or procedure room, since the purpose of the H&P is to determine before the surgery whether there is anything in the patient's overall condition that would affect the conduct of the planned procedure, or which may even require cancellation of the procedure.*

The medical history and physical examination must be completed and documented by a physician (as defined in Section 1861(r) of the Act) or other qualified licensed individual practitioner in accordance with State law, generally accepted standards of practice, and ASC policy.

Section 1861(r) defines a physician as a:

- doctor of medicine or osteopathy;
- doctor of dental surgery or of dental medicine;
- doctor of podiatric medicine;
- doctor of optometry; or a

- chiropractor.

In all cases the practitioners included in the definition of a physician must be legally authorized to practice within the State where the ASC is located and providing services within their authorized scope of practice.

Other qualified licensed individuals are those licensed practitioners who are authorized in accordance with their State scope of practice laws or regulations to perform an H&P and who are also formally authorized by the ASC to conduct an H&P. Other qualified licensed practitioners could include nurse practitioners and physician assistants.

More than one qualified practitioner can participate in performing, documenting, and authenticating an H&P for a single patient. When performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents.

In the case of an ASC the H&P is typically completed by the patient's primary care practitioner rather than a member of the ASC's medical staff. The ASC's policy on H&Ps should address submission of an H&P prior to the patient's scheduled surgery date by a physician who is not a member of the ASC's medical staff and should indicate whether it will accept H&Ps performed by a qualified licensed individual who does not practice at the ASC but is acting within his/her scope of practice under State law or regulations.

Survey Procedures: §416.52(a)(1)

- Determine whether the ASC has a policy requiring that an H&P be performed for each patient no more than 30 days before each patient's scheduled surgery by a physician (as defined in Section 1861(r) of the Act), or other qualified licensed individual in accordance with State law and hospital policy.
- Does the ASC's policy address who may perform the H&P? If it permits acceptance of H&Ps by qualified licensed individuals who are not physicians, is it consistent with the State's scope of practice law or regulations?
- Review a sample of open and closed medical records to verify that:
 - There is an H&P that was completed no more than 30 days before the patient's surgery date;
 - *For H&Ps performed in the ASC on the day of the surgery, that the H&P is comprehensive and performed prior to the patient's being moved into the OR or procedure room;* and
 - The H&P was performed by a physician, or other qualified licensed individual authorized in accordance with State law, standards of practice, and ASC policy.

Q-0262

(Rev. 71, Issued: 05-13-11, Effective: 5-13-11-Implementation: 05-13-11)

§416.52(a) Standard: Admission and Pre-surgical Assessment

- (2) Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals.**

Interpretive Guidelines: §416.52(a)(2)

Each ASC patient upon admission to the ASC must have a pre-surgical assessment. The requirement at §416.42(a)(1) for a physician to examine the patient immediately before surgery to evaluate the risk of the anesthesia and of the procedure for that patient is one component of the requirement at 42 CFR 416.52(a)(2). This component must be conducted by a physician, *immediately prior to surgery, and must be performed in a manner consistent with the requirements at §416.42(a)(1).* (See the interpretive guidelines for §416.42(a)(1). Other elements of the assessment may be conducted by a licensed practitioner who is credentialed and privileged by the ASC to perform an H&P. In all cases, the update must take place prior to the surgery.

If the H&P required under §416.52(a)(1) is performed on the day of the surgical procedure in the ASC, some, but not all, elements of the pre-surgical assessment may be incorporated into the H&P. However, the assessment of the patient's risk for the procedure and anesthesia required under §416.42(a)(1) must still be conducted separately, by a physician and immediately prior to surgery.

The patient must be assessed for any changes in his/her condition since the patient's H&P was performed that might be significant for the planned surgery. Patients may have had a change in health status after the H&P, but may not recognize the significance for their planned surgery. Any changes in health and medication can have an impact on the patient's ability to tolerate the surgery or anesthesia, and the post-admission pre-surgical assessment is designed to identify these changes and take appropriate action, up to and including postponing or cancellation of the surgery. In addition, the pre-surgical assessment must identify and document any allergies the patient may have to drugs and biologicals, or indicate that the patient has no known allergies to drugs and biologicals. Further, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P prior to the surgery.

The patient's medical record must include documentation that the patient was examined prior to the commencement of surgery for changes since the H&P. The physician or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned surgery to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient's medical record.

If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed. Likewise, any changes in the patient's condition must be documented by the practitioner in the update note prior to the start of surgery.

Survey Procedures: §416.52(a)(2)

- Determine whether the ASC's policies require a pre-surgical assessment for all patients to update the findings of the H&P performed prior to the date of surgery.
- In the sample of medical records selected for review, verify that an updated medical record entry documenting an examination for any changes in the patient's condition was completed prior to the surgery.
- Verify that a physician performs those components of the pre-surgical assessment related to evaluation of anesthetic risk and procedural risk, as required by §416.42(a)(1).
- Verify that the pre-surgical assessment includes documentation in the medical record of the patient's allergies or lack of known allergies to drugs and biologicals.