
CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 215

Date: July 21, 2023

SUBJECT: Revisions to the State Operations Manual (SOM) Appendix L - Ambulatory Surgical Centers.

I. SUMMARY OF CHANGES: This Transmittal includes revisions to one tag to fix a website that was broken and has since been changed by CMS. No other edits were made to this tag.

**NEW/REVISED MATERIAL - EFFECTIVE DATE: July 21, 2023
IMPLEMENTATION DATE: July 21, 2023**

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	Appendix L/Q-0221/§416.50(a) Standard: Notice of Rights
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III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2023 operating budgets.

IV. ATTACHMENTS:

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

State Operations Manual

Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

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(Rev. 215; Issued: 07-21-23)

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Q-0221

(Rev. 215; Issued: 07-21-23; Effective: 07-21-23; Implementation: 07-21-23)

§416.50(a) Standard: Notice of Rights

An ASC must, prior to the start of the surgical procedure, provide the patient, the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

Interpretive Guidelines: §416.50(a)

The ASC must inform each patient, the patient's representative, or surrogate of the patient's rights. This notice must be provided both verbally and in writing prior to the start of the surgical procedure, i.e., prior to the patient's movement out of the preoperative area, and, if applicable, before the patient is medicated with a drug(s) that suppresses the patient's consciousness. It is not acceptable for the ASC to provide the notice when the patient has already been moved into the operating room (including procedure room) or has been medicated in such a manner that he or she is not able to follow or remember the provision of notice.

This regulation does not require that in every instance notice be delivered just prior to the start of the surgical procedure. Instead, the regulation indicates the latest acceptable time for delivery of the notice. It would be acceptable for the ASC to mail or e-mail the notice of patient rights in advance of the date of the scheduled procedure, or at the time the patient appears in the registration area on the date of the procedure. CMS recommends that ASCs provide patients notice of their rights as soon as possible after the procedure is scheduled, but so long as notice is provided prior to the start of the surgical procedure, the ASC is in compliance with the regulation.

Notice must be provided regardless of the type of procedure scheduled to be performed. The regulation does not require a specific form or wording for the written notice, so it is acceptable for the ASC to develop a generic, pre-printed notice for use with all of its patients, as long as the notice includes all of the patient rights established under the regulation.

The notice must include the address and telephone number of the appropriate State agency to which patients may report complaints about the ASC. If available, an e-mail or web address for submission of complaints to the State agency should also be provided. The notice must also include, with respect to ASC patients who are Medicare beneficiaries, the Web site for the Office of the Medicare Beneficiary Ombudsman: <https://www.cms.gov/center/special-topic/ombudsman/medicare-beneficiary-ombudsman-home>

Patients who are Medicare beneficiaries, or their representative or surrogates, should be informed that the role of the Medicare Beneficiary Ombudsman is to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their Medicare rights and protections. These Medicare rights are in addition to the rights available to all ASC patients under this CfC.

The notice must:

- Address all of the patient’s rights under this Condition.
- Be provided and explained in a language and manner that the patient or the patient’s representative or surrogate understands, including patients who do not speak English or with limited communication skills. The patient has the choice of using an interpreter of his or her own, or one supplied by the ASC.

A professional interpreter is not considered to be a patient’s representative or surrogate. Rather, it is the professional interpreter’s role to pass information from the ASC to the patient. In following translation practices, CMS recommends, but does not require, that a written translation be provided in languages that non-English speaking patients can read, particularly for languages that are most commonly used by non-English-speaking patients of the ASC. We note that there are many hundreds of languages (not all written) that are used by one or more residents of the United State, but that in most geographic areas the most common non-English language generally is Spanish. We note there are other applicable legal requirements, most notably, those under title VI of the Civil Rights Act of 1964. The Department of Health and Human Services’ (HHS) guidance related to Title VI of the Civil Rights Act of 1964, “Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons” (68 FR 47311, Aug. 8, 2003) applies to those entities that receive federal financial assistance from HHS, including ASCs. This guidance may assist ASCs in ensuring that patient rights information is provided in a language and manner the patient understands. The regulation at §416.50(a) is compatible with guidance on Title VI.

Survey Procedures: §416.50(a)

- Determine what the ASC’s policy and procedures are for providing all patients and/or their representatives or surrogates notice of their rights prior to the start of the surgical procedure. Are the policies and procedures consistent with the regulatory requirements?
- Determine whether the information provided in the written notice to the patients and/or their representatives or surrogates by the ASC is complete and accurate:
 - o Does the notice address all of the patients’ rights listed in this Condition?
 - o Does the notice provide the required information about where to file complaints or how to contact the Medicare Ombudsman?

- Is the staff who are responsible for advising patients of their rights aware of the ASC's policies and procedures for providing such notice, including to those patients with special communication needs?
- Review records, interview staff, and observe staff/patient interaction to examine how the ASC communicates information about patient rights to diverse patients, including patients who need assistive devices or translation services.
- Does the ASC provide all patients with verbal and written notice of their rights prior to the start of the surgical procedure?
- Does the ASC have a significant number of patients with limited English proficiency? If so, are there written notice materials available for patients who have a primary language other than English? If not, does the ASC have translators available to provide verbal notice of their rights to ASC patients?
- Ask patients to tell you how, when and what the ASC has told them about their rights.