§ 416.47 Condition for coverage—Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) Standard: Organization. The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) Standard: Form and content of record. The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

1. Patient identification.
2. Significant medical history and results of physical examination.
3. Pre-operative diagnostic studies (entered before surgery), if performed.
4. Findings and techniques of the operation, including a pathologist’s report on all tissues removed during surgery, except those exempted by the governing body.
5. Any allergies and abnormal drug reactions.
6. Entries related to anesthesia administration.
7. Documentation of properly executed informed patient consent.
8. Discharge diagnosis.

§ 416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(a) Standard: Administration of drugs. Drugs must be prepared and administered according to established policies and acceptable standards of practice.

1. Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.
2. Blood and blood products must be administered by only physicians or registered nurses.
3. Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(b) [Reserved]