DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C-10-20-ASC

DATE: **May 21, 2010**

TO: State Survey Agency Directors
State Fire Authorities

FROM: Director
Survey and Certification Group

SUBJECT: Ambulatory Surgical Center (ASC) Waiting Area Separation Requirements

Memorandum Summary

- **ASC Waiting Area Requirements:** ASC regulations require these facilities to be distinct entities, solely providing surgical services, and containing separate waiting areas which must meet Life Safety Code (LSC) requirements for Ambulatory Health Care occupancies.
- **Waivers:** Waivers will be considered for existing ASCs that share a waiting area with other building occupants when compliance with the LSC requirements is not currently feasible. Interim separation barrier and signage is required.
- **New ASCs should not be recommended by State Survey Agencies (SAs) or accreditation organizations (AOs) for waiver approval.**

This memorandum clarifies the Centers for Medicare & Medicaid Services' (CMS) requirements for ASC waiting areas, including the prohibition on the sharing of waiting areas with other entities. It also discusses opportunities for existing ASCs that have waiting areas shared with other entities to obtain waivers as part of their Plan of Correction (POC) when violations have been cited, and when it is not feasible for the ASC to correct the deficiencies.

Pertinent Regulatory Requirements

Several provisions of the Medicare ASC regulations, when taken together, require ASCs to have waiting areas separated from other entities.

- **42 CFR 416.2 – Definition of an ASC.** In part, the definition of an ASC states that it is a *distinct* entity that operates *exclusively* for the provision of surgical services. As a result, ***an ASC may not share space with another entity when the ASC is open.***

- **42 CFR 416.44 (a)(2)** requires that an ASC must have a separate waiting area, i.e., a distinct area set aside for patients and families, outside of the areas used to prepare patients for their procedures, perform procedures, or recover from procedures.

- **42 CFR 416.44(b) – Environment CfC - Life Safety Code (LSC) Requirements**
  As part of the ASC, a waiting area must meet the provisions applicable to Ambulatory Health Care, Chapters 20 and 21 in the National Fire Protection Association (NFPA) 101:2000 edition of the LSC. According to sections 20.3.7.1 and 21.3.7.1 of the LSC, an "ambulatory health care facility shall be separated from other tenants and occupancies by walls having not less than a 1-hour fire resistance rating. Such walls shall extend from the floor slab below to the floor or roof slab above. Doors shall be constructed of not less than 1 ¾ inch thick solid-bonded wood core or the equivalent and shall be equipped with positive latches. These doors shall be self closing and shall be kept in the closed position except when in use. Any vision panels shall be of fixed fire window assemblies in accordance with 8.2.3.2.2." This requirement applies regardless of whether or not an ASC is "temporally" distinct, i.e., it shares its space with another occupancy(ies) but does not have concurrent or overlapping hours of operation.

  Although sections 20.1.2.1 and 21.1.2.1 of the LSC allow sections of an ASC to be classified as other occupancy types that are subject to lesser fire protection requirements, ASC waiting areas are not eligible for this allowance. The LSC requires that for a section of the ASC to be considered as an occupancy type other than Ambulatory Health Care it should not be intended to serve occupants for purposes of treatment ***or*** to provide customary access to patients incapable of self-preservation. As patients occupy an ASC waiting area for the purpose of receiving treatment, and not all patients in an ASC waiting area may be capable of evacuating without assistance, CMS considers ASC waiting areas to be Ambulatory Health Care occupancies. Therefore, the requirements of the LSC Chapters 20 or 21 apply to all new and existing ASCs waiting areas, respectively.

Enforcement of Waiting Area Requirements

When an ASC is found to have a waiting area that is not separated appropriately from another entity, this is cited as a violation of both 42 CFR 416.2 and 42 CFR 416.44(b).

Existing ASCs

Despite these longstanding ASC regulatory requirements, some ASCs have misinterpreted the requirement for ASCs to be separated from other tenants and occupancies and may not have walls with the requisite rating of at least 1-hour fire resistance. CMS understands that the clarification provided in the updated ASC interpretive guidelines, issued via S&C-09-37 memorandum dated May 15, 2009, as well as in this memorandum may result in existing ASCs being cited for noncompliance related to non-separated waiting areas. Further, we are aware that in some cases there may be substantial hardship for the ASC to bring its waiting area into compliance with the LSC requirements.

Per 42 CFR 416.44(b)(2), CMS may waive, for periods deemed appropriate, specific provisions of the LSC which, if rigidly applied, would result in unreasonable hardship upon an ASC, but

only if the waiver will not adversely affect the health and safety of the patients. Therefore, CMS will consider issuing waivers to existing ASCs that share a waiting area with other building occupants and have been cited for a lack of adequate separation under LSC. CMS Regional Offices (RO) will require, as a condition of waiver approval, the fire protection measures identified in the following paragraph, as well as any additional measures appropriate for the individual ASC's circumstances.

While operating under an approved waiver, the ASC must assure that fire protection for the waiting area is appropriate for the occupancy to which it was designed. In addition, in order for the ASC to be a distinct entity, the ASC's patients and visitors using the waiting area must be separated from other occupants in a shared waiting area by a temporary partition, unless the ASC is "temporally" distinct from the other occupancy. The partition must not block or obstruct visibility of exits, shall be flame resistant in accordance with NFPA 701, and must be located at least 18 inches below sprinkler deflectors in accordance with NFPA 13. In addition, signage must be posted that clearly identifies the distinct separate ASC waiting area.

Existing ASCs that currently do not have a waiting area shared with other entities are not permitted to modify their current arrangement to introduce a shared waiting area, and will not be eligible for a waiver if they do so.

New ASC Agreements

ASCs applying for a new Medicare agreement (including not only new ASCs but also ASCs that have undergone a change of ownership without assumption of the previous owner's Medicare supplier agreement) should <u>not</u> be recommended for approval of a waiver concerning the separation of the ASC's waiting area from other occupancies.

LSC Waiver Process

The standard process for requesting LSC waivers shall be followed. In brief, this waiver process entails:

1. ASC preparation of a Plan of Correction (POC) for all identified deficiencies.
    - The POC for the lack of a proper separation of the ASC, including its waiting area, from other occupancies shall include the intent to request a waiver.
2. ASC preparation of a written request for a waiver.
    - The waiver request must specify both:
        - Unreasonable hardship (e.g., unreasonable structural change), and
        - Justification (i.e., explanation of hardship and verification that waiver will not result in adverse health and safety impact)
3. ASC submission of the POC and written request for waiver to the State Agency (SA) or Accreditation Organization (AO) that performed the survey.
4. SA or AO review of the POC and waiver request.
5. SA or AO transmittal of the POC and waiver request to the CMS RO, along with the SA's or AO's recommendation on whether the waiver should be approved or denied.

6. CMS RO review of the SA or AO recommendation along with the POC and waiver request, and determination whether or not to approve or deny the waiver.
7. CMS RO notification of both the SA or AO and the ASC of the waiver's approval or denial.

Please note that although a continuing waiver may be granted, it does not eliminate the ASC's responsibility to correct the areas of noncompliance. Once a waiver is approved for an ASC waiting area, the continuing waiver will be part of the POC and will remain in effect until such time that a renovation, alteration, or modernization will allow for the implementation of the LSC requirements. A waiver reapplication must be submitted as part of the POC for each subsequent survey until the non-conformities are corrected.

Questions concerning this memorandum should be directed to Martin Casey Martin.Casey@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: This information should be shared with all appropriate survey and certification staff, surveyors, their managers and state fire authorities and their staff.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management