

19 provisions in the ASC regulatory text. Chapter 19 only applies to existing Health Care Facilities (for example, hospitals, nursing homes, etc.). Chapter 21 applies to existing ASCs. The related sections of chapter 21 are not significantly different than what existing ASCs are required to meet currently. For example, building construction type, vertical opening requirements and, fire alarm requirements have not changed from earlier editions of the life safety code.

Comment: Several commenters believed that ASCs should only be classified as Ambulatory Health Care Centers if they serve four or more patients who are rendered incapable of self-preservation. If there are less than four patients, we should not subject the ASC to more stringent requirements when the risk is not severe enough to warrant those restrictions and should be classified under the less stringent Business Occupancy chapter of the 2000 edition of the LSC.

Response: Ambulatory facilities are surgery centers regardless of the number of patients they serve. Under § 416.44, ASCs are required to maintain a fully equipped operating room for the types of surgery the ASC conducts in order for the surgery to be performed in a manner that protects the lives and ensures the physical safety of all individuals in the area. It is imperative that these facilities provide the protection of the Ambulatory Health Care Chapters (chapters 20 and 21) rather than the Business Occupancy chapter of the 2000 edition of the LSC that generally pertains to physician offices or clinics because surgery is being performed.

F. Critical Access Hospitals

Comment: Several commenters asked why Critical Access Hospitals (CAHs) were not included in the October 2001 proposed rule.

Response: We should have included CAHs in the October 2001 proposed rule. We corrected this mistake and added CAHs to the final rule at § 485.623(d). Similar to the other facilities, roller latches under chapter 19–3.6.3.2 (exception No. 2) will not be adopted. Thus, all existing CAHs will no longer be permitted to use roller latches. Through fire investigations, roller latches have proven to be an unreliable door latching mechanism requiring extensive maintenance to operate properly. We realize there is some burden with replacing existing roller latches and will phase in this requirement over a 3-year period beginning March 11, 2003. If a CAH believes that this rule (including the 3-year phase in period for the roller

latches) imposes an unreasonable burden, the facility should contact its State Office to request a waiver. The State Agency will review the request for the waiver and make a recommendation to the appropriate CMS regional office. The CMS regional office will review the waiver and the State Agency's recommendation and make a final decision on the waiver request.

G. Miscellaneous

Comment: Two commenters asked us to define major and minor renovations to a facility.

Response: The difference between major and minor renovations has to do with the size and cost of the upgrade. Obviously, replacing a door would be a minor renovation, but adding a wing to a hospital would be a major renovation. We understand there may be times when it is difficult to determine if the renovation would qualify as a major renovation. These decisions are made on a case-by-case basis rather than a "one size fits all" requirement. If a facility is unsure if the renovation would be considered major or minor, the facility may call the State survey agency for an evaluation and final decision.

Comment: Some commenters requested that we adopt updated versions of the LSC more quickly in the future. One commenter requested that we adopt any updated version of the LSC within 90 days of the LSC publication.

Response: We agree and would like to revise our regulations to update the LSC in a more timely manner. However, we cannot adopt the LSC within 90 days of the LSC publication because under the Administrative Procedure Act (APA), we must give notice to the public that we are proposing to revise a regulation. Once we notify the public of the proposal, the public must have the opportunity to comment on the revisions, and we must answer the comments before the update becomes final and binding.

Comment: Some commenters asked when all health care facilities must be in compliance with this final rule.

Response: The final rule is effective 60 days after publication. However, to relieve some burden for providers, we are delaying enforcement of the 2000 edition of the LSC for six months until September 11, 2003. In addition, as stated earlier, because of the burden that may be imposed by the requirement to replace all existing roller latches we will phase in this requirement over a 3-year period beginning on March 11, 2003. We will also phase in the emergency lighting requirement (19.2.9) over a 3-

year period beginning on March 11, 2003. We have revised the regulations text to reflect the phase-in period.

H. Burden Estimates

Comment: Several commenters stated that our "carve-out" of the roller latch exception would be a cost burden.

Response: Roller latches are one of our top three deficiencies and, based on prior incidents, we are concerned about the possible threats to patient safety. We believe that, in the interest of patient and staff safety, all roller latches must be removed. To help alleviate some of the burden to health care facilities, we will phase in this requirement over 3 years.

Comment: A couple of commenters questioned our cost estimates. The commenters stated that our reliance on the AHCA report only applied to nursing homes and the estimates were outdated.

Response: We agree and we reviewed our cost estimates and revised the cost impact for the final rule. All of the revised cost estimates were gathered using OSCAR data as well as figures sent as comments to the October 2001 proposed rule. The revision of our estimates reflects a significant decrease in the number of facilities using the 1985 edition of the LSC. Many of the older facilities that were originally included in our estimate have upgraded their facility using a more recent edition of the LSC rather than the 1985 edition. The total cost impact we originally estimated has changed because many of the items that need to be updated have already been done because older facilities have been phased out or upgraded. Therefore, the number of facilities we originally determined had to make upgrades has decreased.

We phased in two requirements of the LSC over a 3-year period. The requirements are: Emergency lighting (that is, 19.2.9) and replacing all roller latches (that is, 19.3.6.3.2). We phased in the emergency lighting requirement because it is standard practice to routinely replace emergency lighting system batteries every 3 years. Therefore, our decision to phase in the emergency lighting requirement over 3 years is to match providers' current cycle of replacing the batteries in their emergency lighting systems. We believe by phasing in this requirement, we will not adversely affect the health and safety of the patients or staff.

We also phased in over 3 years our requirement that all providers must replace roller latches. In the October 2001 proposed rule, we did not propose to phase in roller latches because we believed that it was an important issue