DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 460, 482, 483, and 485

[CMS–3047–F]

RIN 0938–AK35

Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the fire safety standards for hospitals, long-term care facilities, intermediate care facilities for the mentally retarded, ambulatory surgery centers, hospices that provide inpatient services, religious nonmedical health care institutions, critical access hospitals, and Programs of All-Inclusive Care for the Elderly facilities. Further, this final rule adopts the 2000 edition of the Life Safety Code and eliminates references in our regulations to all earlier editions.

DATES: *Effective Date:* These regulations are effective on March 11, 2003. The incorporation by reference of certain publications in this rule is approved by the Director of the Federal Register as of March 11, 2003.

Compliance Dates: All health care facilities referenced in this rule must comply with the requirements of this final rule on September 11, 2003, except that compliance with § 403.744(c), § 416.44(b)(4), § 418.100(d)(4), § 460.72(b)(3), § 482.41(b)(1)(iv), § 483.70(a)(4), § 483.470(j)(2)(iii), and § 485.623(d)(5) is not required until March 13, 2006.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Life Safety Code

The Life Safety Code (LSC) is a compilation of fire safety requirements for new and existing buildings and is updated and published every 3 years by the National Fire Protection Association (NFPA), a private, nonprofit organization dedicated to reducing loss of life due to fire. The Medicare and Medicaid regulations have historically incorporated by reference these requirements along with Secretarial waiver authority. The statutory basis for incorporating NFPA's LSC for our providers is under the Secretary's general rulemaking authority at sections 1102 and 1871 of the Social Security Act.

We have not updated the LSC regulations for several years. We published a proposed rule in the **Federal Register** on August 1, 1990 (55 FR 31196) proposing to eliminate the use of the 1967 and 1973 editions of the LSC. In the August 1990 proposed rule, hospitals, nursing homes, and intermediate care facilities for the mentally retarded (ICFs/MR) would be required to comply with either the 1981 or 1985 editions of the LSC, depending on the date the provider entered the program. The proposed rule did not include ambulatory surgery centers (ASCs), hospices, or end-stage renal disease (ESRD) facilities. The August 1990 proposed rule also made no reference to the Program of the All-Inclusive Care for the Elderly (PACE) facilities, Critical Access Hospitals, and religious nonmedical health care institutions (RNHCIs) because these provider and supplier types did not exist when we published the August 1990 proposed rule.

On October 26, 2001, we published a proposed rule proposing to withdraw the August 1, 1990 proposed rule because the NFPA published four new editions of the LSC since the publication of our August 1990 proposed rule. Some accrediting organizations had adopted the 1997 edition of the LSC. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) which accredits over 4,000 hospitals, as well as ASCs, long-term care (LTC) facilities, and hospices that provide inpatient services has adopted the 1997 edition of the LSC. We had to update our requirements to a more recent edition of the LSC because the 1985 edition of the LSC had been superseded by later editions which incorporated the latest technology in fire protection.

B. The Proposed Rule of October 26, 2001 (66 FR 54179)

The 2000 edition of the LSC includes new provisions that we believe are vital to the health and safety of all patients and staff. The term ''patient'' represents the population in each of the provider-types discussed in this rule. We proposed not to grandfather any facility under these new provisions because the provisions would not impose an undue burden. Our intention is to ensure that patients and staff continue to experience the highest degree of fire safety possible.

In the past, our authority to grant waivers was critical to our ability to continuously improve fire safety in the Medicare and Medicaid programs and not impose an undue burden on providers. The Secretary has broad authority to grant waivers to hospitals under section 1861(e)(9)(C) of the Act, and to LTC facilities under sections 1819(d)(2)(B) and 1919(d)(2)(B) of the Act. For all other providers we have authority under the Secretary's general rulemaking authority to establish specific health and safety standards as well as under section 1871 of the Act. The proposed rule allows the Secretary to grant waivers on a case-by-case basis if specific provisions of the LSC would result in unreasonable hardship on the provider, and if the safety of patients would not be compromised. The Secretary may also accept a State's fire and safety code instead of the LSC if the State's fire and safety code adequately protects patients. Further, the NFPA's Fire Safety Evaluation System (FSES), an equivalency system, provides alternatives to meeting various provisions of the LSC, thereby achieving the same level of fire protection as the LSC.

In addition to the development of a proposed rule to adopt the 2000 edition of the LSC, we planned to propose a more efficient process that allows us to adopt future editions of the LSC in a more timely manner. We explored incorporating, by reference, the NFPA LSC without specific dates in the regulations text and publishing a **Federal Register** notice, instead of a proposed rule. We worked closely with the Office of the **Federal Register** (OFR) staff on our draft proposed approach; however, it has become clear that adoption of multiple successive editions of the LSC via reference is not possible. Changes in future editions of the LSC may be substantial, necessitating that we go through a proposed rule and public comment period. Moreover, we cannot automatically incorporate successive versions of the LSC because of the statutory restrictions of 5 U.S.C. section 552(a) and accompanying regulations at 1 CFR part 51. All LSC editions we adopt must include a specific edition and a copy of the edition cited must be on file at the OFR.

II. Provisions of the Proposed Regulations

A. General Description

In the October 26, 2001 proposed rule, we proposed to (1) require that all

providers and suppliers meet the provisions of the 2000 edition of the LSC with certain exceptions; and (2) remove references to all previous editions of the LSC.

B. The 2000 Edition of the Life Safety Code

Some requirements in the 2000 edition of the LSC are substantially different than earlier LSC editions. We solicited public comments regarding whether to adopt Chapter 5, ''Performance Based Option,'' of the LSC. Specifically, we wanted to know (1) whether health care facilities are using performance based design; and (2) what benefits the facility receives by using performance based design.

The LSC fire safety goals establish outcomes to be achieved with regard to fire safety. These overall outcomes are communicated through specific requirements in the LSC. The performance based design option translates fire safety goals into performance objectives and performance criteria. Performance based design establishes broad goals and objectives with a team effort. The performance based design is applied to make the building safe as well as functional. The design is specific to the building. Computer fire models and other calculation methods are used in combination with the building design specifications, specified fire scenarios and assumptions to calculate the overall performance criteria and whether it meets the fire life safety goals and is in compliance with the intent of the LSC.

In the October 2001 proposed rule, we proposed not to adopt the roller latch provision in chapter 19, ''Existing Health Care Occupancies,'' section 19.3.6.3.2 (exception No. 2), of the LSC for any facility. A roller latch is a type of door latching mechanism to keep a door closed. The 2000 edition of the LSC prohibits the use of roller latches on corridor doors in buildings not fully protected by an approved sprinkler system. Exception No. 2, however, allows for the use of roller latches under this prohibition, if the latch can withstand a specific level of force applied to it. We proposed not to adopt exception No. 2 regarding existing roller latches.

Through fire investigations, roller latches have proven to be an unreliable door latching mechanism requiring extensive on-going maintenance to operate properly. Many roller latches in fire situations failed to provide adequate protection to residents in their rooms during an emergency. Roller latches that are not properly maintained may be a danger to the health and safety of patients and staff. In addition, we have found through our online survey, certification, and reporting (OSCAR) system data report that doors that include roller latches are consistently one of our most cited deficiencies. In fact, in skilled nursing facilities roller latches in corridor doors are consistently the number one cited deficiency under the life safety requirements.

The estimated cost to remove roller latches on existing doors is $30,754,540 ($190 per door for 161,866 doors). We derived the cost estimate from information the American Health Care Association (AHCA) gave to us.

C. Analysis of Selected New Provisions in the 2000 Edition of the Life Safety Code

In the October 2001 proposed rule, we provided the LSC citation, a description of the requirement, an explanation of why we believe the requirement is critical to the safety of beneficiaries and a brief discussion of our analysis of the burden imposed by the requirement. We derived the cost estimates from information the AHCA gave to us. The following are new provisions in the 2000 edition of the LSC from chapter 19, ''Existing Health Care Occupancies.''

(1) 19.1.1.4.5—Renovations, Alterations, and Modernization—This provision requires that renovations, alterations, and modernizations comply with standards applicable to new construction when possible. Existing facilities that are extensively renovated must meet the requirements of a newly constructed facility, including the installation of sprinkler systems in nonsprinklered buildings. The Fire Analysis & Research Division of the NFPA has shown that sprinklers have been the most important life safety system installed in health care facilities. The LSC generally requires sprinkler systems in renovations, regardless of construction. The estimated cost of installing sprinkler systems in buildings that presently do not have them is $2.50 per square foot, or approximately $125,000 for a 50,000 square foot building. This requirement is not imposed on facilities not undergoing renovations. Approximately 2,550 facilities currently do not have sprinkler systems. Because a facility does not have to comply with this provision unless the facility chooses to renovate an existing building, we estimate approximately 128 facilities may be renovated in a year. The total amount to implement this provision would be $16,000,000 annually.

(2) 19.2.9—Emergency Lighting—This provision requires emergency lighting for a period of 1½ hours in health care facilities, enabling those inside to move about safely in an emergency. We proposed to phase in this requirement over a 3-year period, to allow for the normal replacement cycle of batteries used in emergency lighting systems. We believe this phase-in period would not adversely impact the health and safety of the beneficiaries. We estimate the cost to install this equipment will be $600 per light. Approximately 790 existing facilities do not have emergency lighting for 1½ hours. To be in compliance, we estimated that each building would need 12 emergency light units for a total of 9,482 units. The total amount to implement this provision over a 3-year period would be $5,452,150 or $1,817,383 annually.

(3) 19.3.1—Protection of Vertical Openings—Unprotected vertical openings (for example, open stairwells) permit fire and toxic gases to spread from one level to another in a building, making evacuation difficult, if not impossible. The estimated cost of compliance with this requirement is $2,938 per vertical opening. Approximately 9,877 vertical openings in 1,976 facilities would need to be upgraded for compliance. Total cost of compliance with this provision is $29,018,626.

(4) 19.3.4.3.2—Emergency Forces Notification—This provision requires the fire alarm system to provide automatic notification of a fire to emergency forces. This is of great importance to the protection of all patients. Any delay in the notification of fire or rescue personnel could adversely impact the health and safety of patients and expose them to a fire, smoke or toxic gases created by the fire. Approximately 2,750 buildings at $900 per facility would need to be connected to a fire alarm retransmission system. The cost is estimated to be a total of $2,475,000.

(5) 19.3.6.1—Corridors—This provision requires that all areas in nonsprinklered buildings be separated from the corridor by corridor walls that are fire-rated. This requirement, which provides a protected passageway for movement during an emergency, is necessary to increase the safety of the patients. The cost to upgrade a facility to meet this requirement is estimated to be approximately $7,124 for 1,976 buildings that currently meet the 1967 LSC and approximately $5,735 for 46 buildings meeting the 1973 LSC. The total estimated cost for compliance is $14,341,000.

(6) 19.7.5.2 & 19.7.5.3—Upholstered Furniture—These provisions allow patient-owned furniture to be brought

into the facility without meeting the requirements of 10.3.2(2) and 10.3.3 (regarding fire resistant furniture) if a single station smoke detector is placed in the sleeping room where the furniture is located. The cost to the facility is estimated at $100 per sleeping room where patient-owned furniture is located. We estimate approximately 18,498 smoke detectors would need to be installed at a total cost of $1,849,800.

In the October 2001 proposed rule, we proposed to retain our existing authority to waive provisions of the 2000 edition of the LSC, on a case-by-case basis, and thereby reduce the exposure to additional cost and burden for those facilities with unique situations that may justify the application of waivers. We may grant a waiver for a specific LSC requirement if (1) We determine that the waiver would not adversely affect patient and staff health and safety; and (2) we determine that it would impose an unreasonable hardship on the facility to meet a specific LSC requirement. Generally, a provider may request a waiver from its State agency. The State agency will review the request and make a recommendation to our appropriate regional office. Our regional office will review the waiver request and the State agency's recommendation and make a final decision. We cannot grant a waiver if patient safety is compromised in any way. A State may also request that the State fire and safety code be applied to all its facilities rather than the 2000 edition of the LSC we proposed in the October 2001 proposed rule. State law must impose the State fire and safety code. The State must submit the request to our appropriate regional office. The regional office will forward the request to our central office for a final determination.

We proposed to retain our authority to apply the Fire Safety Evaluation System (FSES) as an alternative approach to meeting the requirements of the LSC, as well as accept alternative State fire and safety codes as we discussed in section I.B in the October 2001 proposed rule.

D. Discussion of Fire Safety Requirements for Individual Providers and Suppliers

In the October 2001 proposed rule, we proposed changes to the requirements that affect all provider types, as described in sections II.A and II.B of this preamble. We proposed changes for distinct types of providers that include the following:

1. *Religious Nonmedical Health Care Institutions—Benefits, Conditions of Participation, and Payment:* 42 CFR 403.744 Condition of participation: Life safety from fire.

We proposed to retain the provisions of the existing interim final regulation for RNHCIs published in the **Federal Register** on November 30, 1999 (64 FR 67028), except as they conflict with the 2000 edition of the LSC and are not within the exceptions detailed in section II.B of this preamble (regarding our exceptions to the LSC).

2. *Ambulatory Surgery Centers:* 42 CFR 416.44 Condition for coverage: Environment.

We proposed to change the terminology in § 416.44 (b)(1) to reflect that the LSC refers to ASCs as Ambulatory Health Care Centers. We proposed that all ASCs meet the provisions applicable to Ambulatory Health Care Centers in the 2000 edition of the LSC, except as detailed in section II.B of this preamble, regardless of the number of patients the facility serves.

We believe the protection provided in the Ambulatory Health Care Centers chapter is necessary to protect the health and safety of patients who are incapable of taking action of self-preservation. We do not believe that the Business Occupancy chapter of the LSC (applied by some authorities having jurisdiction to ASCs treating fewer than four patients at a time) affords an adequate level of protection to patients in an ASC.

We also proposed to retain the discretion to accept compliance with fire and safety codes imposed by a State, if we determine that the State's fire and safety code will adequately protect patients in ASCs. We have included this provision in § 416.44 (b)(3).

3. *Hospice Care:* 42 CFR 418.100(d) Condition of participation: Hospices that provide inpatient care directly.

In the October 2001 proposed rule, we proposed that all inpatient hospices meet the provisions applicable to nursing homes in the 2000 edition of the LSC, with the exceptions discussed in section II.B of this preamble, regardless of the number of patients they serve. This is not a change in requirements, but merely a clarification that, for LSC purposes, an inpatient hospice is considered a nursing home, and not another type of occupancy.

We also proposed not to adopt for hospices chapter 18—section 3.4.5.3 of the 2000 edition of the LSC. This section requires new nursing homes to be equipped with corridor smoke detection systems. We believe there is no technical justification for this requirement because the 2000 edition of the LSC requires that newly constructed patient sleeping zones be provided with quick-response sprinklers. Quick-response sprinklers activate quickly enough to serve a detection function, thus making corridor smoke detection unnecessary. The 1991 and 1994 editions of the LSC required quick-response sprinklers in new nursing homes but did not require smoke detection. Therefore, we see no technical reason to require corridor smoke detection in new facilities and thus increase the cost of new construction without a parallel increase in safety.

We also proposed, in § 418.100(d)(3), to permit a hospice to meet a fire and safety code imposed by the State in lieu of the 2000 edition of the LSC if we determine that the State code adequately protects patients. We proposed to do this for two reasons: (1) To afford hospices the benefit of meeting a State code in lieu of the Federal requirements where the State code offers adequate protection; and (2) because we recognize that hospices are often located within buildings containing other providers already subject to this provision. For example, a hospice may be located entirely within a skilled nursing facility (SNF). If the SNF is exempt from the LSC by virtue of meeting a State code, other participating providers within the same building should also be afforded this exception.

We also proposed to remove § 418.100(d)(4), the requirement that blind and nonambulatory patients may not be housed above the street level floor unless the building is fully sprinklered or has achieved a passing score on the FSES comparison, which is less stringent than the LSC. The provision is redundant since any facility that meets the requirements of the 2000 edition of the LSC would, by definition, achieve a passing score on the FSES comparison. In addition, this requirement was removed from the SNF regulations in 1989; however, we did not remove it from the parallel hospice regulations.

4. *Programs of All-Inclusive Care for the Elderly (PACE):* 42 CFR 460.72 Physical environment.

In the October 2001 proposed rule, we proposed to retain most of the provisions of the existing interim final regulation for PACE that we published in the **Federal Register** on November 24, 1999 (64 FR 66234). PACE centers will continue to be required to meet the LSC specifications for the type of facilities in which the programs are located (that is, hospitals, office buildings, etc.).

We also proposed to require that a PACE center meet the requirements for use of fire alarm systems in accordance with the occupancy section of the LSC that applies to its building. Each occupancy section of the LSC also

requires evacuation plans, fire exit drills, and fire procedures, and these will be applicable to the PACE program.

We also proposed to retain § 460.72(b)(2)(i), which permits a PACE center to meet fire and safety requirements imposed by the State in lieu of the 2000 edition of the LSC if we determine that the State code adequately protects patients. We have done this for two reasons: (1) To afford a PACE center the benefit of meeting a State code in lieu of the Federal requirements where the State code offers adequate protection; and (2) because we recognize that PACE centers are often located within buildings containing other providers already subject to this provision. For example, a PACE center may be located within a hospital. If the hospital is exempt from the LSC by virtue of meeting a State code, other participating providers within the same building should also be afforded this exemption.

Further, in some buildings it may be impractical or impossible to provide a specific feature due to the construction of the building. Therefore, we proposed to retain § 460.72(b)(2)(ii), which allows for the waiver of specific provisions of the 2000 edition of the LSC that, if rigidly applied, would result in unreasonable hardship on the organization. We may waive specific provisions only if the waiver does not adversely affect the health and safety of the patients and staff.

5. *Conditions of Participation For Hospitals:* 42 CFR 482.41 Condition of participation: Physical environment.

In the October 2001 proposed rule, we proposed only the changes to this section described in sections II.A and II.B of this preamble, for the reasons described therein.

6. *Long-Term Care Facilities:* 42 CFR 483.70 Condition of participation: Physical environment.

As with hospices, we proposed not to adopt chapter 18-section 3.4.5.3 of the 2000 edition of the LSC for LTC facilities such as SNFs. This section requires new nursing homes to have corridor smoke detection systems. We believe there is no technical justification for this new requirement because the 2000 edition of the LSC requires that new construction patient sleeping zones be provided with quick-response sprinklers. We believe that quick-response sprinklers activate quickly enough to serve a detection function, thus making corridor smoke detection unnecessary. The 1991, 1994, and 1997 editions of the LSC required quick-response sprinklers in new nursing homes, but did not require smoke detection. Therefore, we do not see any technical reason to require smoke detection in new facilities and thus increase the cost of new construction without a parallel increase in safety.

7. *Intermediate Care Facilities for the Mentally Retarded:* 42 CFR 483.470 *Condition of participation:* Physical environment.

In the October 2001 proposed rule, we proposed to retain most of the provisions of the existing regulation for ICFs/MR. ICFs/MR will continue to be permitted to meet either the Residential Board and Care Occupancies chapter or the Health Care Occupancy chapter of the 2000 edition of the LSC, as appropriate.

We also proposed to retain the provision in § 483.470(j)(1)(ii) that allows the State survey agency to apply different chapters of the LSC to different buildings or parts of buildings so as not to place an undue burden on providers to have an entire building comply with the more stringent provisions of the Health Care chapter when they could instead meet the Board and Care for part of their facility, when appropriate.

We also proposed that, for ICFs/MR under Board and Care, the Evacuation Difficulty Index (EDI) must be determined by use of the Fire Safety Evaluation System for Board and Care Facilities (FSES/BC). In referring to the EDI, we proposed to remove the reference to Appendix F in § 483.470(j)(1)(iii). The FSES/BC is no longer an appendix of the LSC, but appears as its own NFPA document in the NFPA 101A Guide on Alternative Approaches to Life Safety. Additionally, we proposed to remove the reference to facilities of 16 beds or less from § 483.470(j)(1)(iii) to clarify that a larger facility could be subject to the Board and Care Chapter, and that its EDI would have to be calculated based on the FSES/BC. Again, this provision would allow certain ICFs/MR to meet the less restrictive Board and Care Chapter rather than the health care chapter.

In § 483.470(j)(2)(ii), we proposed to change ''the Secretary'' to ''CMS'' to more accurately reflect the statutory authority (this provision currently appears in § 483.470(j)(2)(i)(B)).

We also proposed in § 483.470(j)(3) that waivers of specific provisions of the 2000 edition of the LSC apply only to facilities that meet the LSC definition of a Health Care occupancy. There are no waivers for facilities under Board and Care, since the FSES/BC affords the flexibility of alternative arrangements for compliance.

III. Analysis of and Responses to Public Comments

We received approximately 160 timely public comments in response to the October 26, 2001 proposed rule. We received letters from State government officials, county government organizations, health care providers and provider organizations, and private citizens. We reviewed each comment and grouped like or related comments. The comments and our responses are summarized below.

A. General Comments

Comment: The majority of commenters expressed support of our adoption of the 2000 edition of the National Fire Protection Association (NFPA) Life Safety Code (LSC).

Response: We appreciate the support. Our current regulations allow health care providers to meet different editions of the LSC (that is, providers may meet the 1967, 1973 and 1985 editions of the LSC). These earlier editions are outdated and create confusion in the industry. The updated LSC includes new provisions vital to the health and safety of all our beneficiaries. This rule is intended to ensure that beneficiaries continue to experience the highest degree of fire safety possible.

B. Exceptions

Comment: Several commenters, while supporting the adoption of the LSC, urged us to adopt the LSC as written, with no exceptions. The commenters argued that by allowing exceptions to the NFPA LSC, we are violating the National Technology Transfer and Advancement Act (Pub. L. 104–113).

Response: Section 12 of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) codified an existing Office of Management and Budget (OMB) circular (OMB Circular A–119). Section 12 directs Federal agencies to use, to the extent not inconsistent with applicable law or otherwise impractical, technical standards that are developed or adopted by voluntary consensus standards organizations.

The National Technology Transfer and Advancement Act does not mandate that we use an entire code without exceptions if we determine it is impractical. We did not adopt the entire LSC as written because through our surveys, comments, and experience, we have determined that for the health and safety of patients and staff we could not adopt the LSC in its entirety.

We have ''carved-out'' two provisions from the LSC. These provisions are: (1) Roller latches; and (2) ambulatory facilities serving under four patients.

We are not allowing any exceptions for roller latches because roller latches are one of our top three deficiencies for life safety. Roller latches that are not properly maintained may be a danger to the health and safety of patients and staff. We have found through our OSCAR data report that doors that include roller latches are consistently one of our most cited deficiencies. In fact, in skilled nursing facilities, roller latches in corridor doors are consistently the number one cited deficiency under our life safety requirements.

We also define all ambulatory facilities as 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 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 chapter (chapters 20 and 21) rather than the Business Occupancy chapter of the 2000 edition of the LSC that pertains to physician offices or clinics because surgery is being performed in these facilities.

Comment: Several commenters opposed the October 2001 proposed rule's carve-out of the roller latch exception provision in the LSC (chapter 19–3.6.3.2 (exception No. 2)). The commenters claimed there is no evidence supporting our carve-out of the roller latch exception.

Response: As described above, roller latches that are not properly maintained may be a danger to the health and safety of patients and staff and are consistently one of our most cited deficiencies.

One of the most tragic examples of roller latch failure occurred in the fall of 1989 where a fire claimed 12 lives in a nursing home. In all the rooms where the door was closed and remained closed through out the fire, the patients lived. In the rooms where the door was open or originally closed but bounced open, the patients died. During our investigation, we tested the doors on the floor above the fire origin. We discovered the majority of the doors tested failed to stay closed because of the roller latches. In fact, as a result of the failure of the roller latches in this facility, the 1991 edition of the NFPA LSC prohibited the use of roller latches in new buildings.

Therefore, in this final rule, we are prohibiting the use of roller latches in existing and new buildings except for ASCs under Chapter 20 and Chapter 21. We understand the burden that may be caused to replace all existing roller latches and will phase-in this requirement over a 3-year period beginning March 11, 2003.

Comment: Many commenters supported the proposed rule's carve-out of the roller latch exception in the LSC (chapter 19–3.6.3.2).

Response: We appreciate the support. We believe, as discussed in our response to the previous comment, that prohibiting use of roller latches will allow patients and staff to experience the highest degree of fire safety possible.

Comment: Several commenters opposed the proposed exception to delete the smoke detector requirement for hospices and nursing facilities. Many believed smoke detectors are an inexpensive requirement for new facilities that provides an extra layer of protection.

Response: We agree with these comments and have changed the regulations text to no longer exempt new nursing homes or inpatient hospices from Chapter 18–3.4.5.3 of the LSC. Please note that this requirement does not apply to existing facilities, but only to new nursing homes or inpatient hospices.

C. Chapter 5—Performance Based Option

Comment: In the October 2001 proposed rule, we solicited comments on whether to adopt chapter 5, the performance based option of the LSC. Most of the comments we received specifically on chapter 5, the performance based option, stated that they had little experience with this option.

The performance based design option in chapter 5 of the LSC translates fire safety goals into performance objectives and performance criteria. Performance based design establishes broad goals and objectives with a team effort. The performance based design is applied to make the building safe as well as functional. The design is specific to the building. Computer fire models and other calculation methods are used in combination with the building design specifications, specified fire scenarios and assumptions to calculate the overall performance criteria and whether it meets the fire life safety goals and is in compliance with the intent of the code.

Response: We have decided to include chapter 5, the performance based option provision. We do not expect many providers to choose this option. However, we would like all providers to have the alternative to use the performance based option if the provider believes it would be beneficial for it to comply with the LSC.

Please note that the final rule will also continue to allow two other options besides the prescriptive requirements of the LSC. Health care facilities may choose the FSES, and a facility may apply for a waiver of specific provision of the LSC if it is unable to meet a specific requirement. We may grant a waiver for a specific LSC requirement if (1) we determine that the waiver would not adversely affect patient and staff health and safety; and (2) we determine that it would impose an unreasonable hardship on the facility to meet a specific LSC requirement. A provider may request a waiver from its State agency. The State agency will review the request and make a recommendation to our appropriate regional office. Our regional office will review the waiver request and the State agency's recommendation and make a final decision on the waiver request. We cannot grant a waiver if patient safety is compromised in any way.

D. State Codes

Comment: One commenter opposes the LSC because it would preempt State or local decision-making authority and create an unfunded mandate.

Response: If a State or local authority would rather use its State fire and safety code, this is an allowable option as long as the State fire and safety code is imposed by State law and adequately protects the life and safety of the patients. To request this option, the State must forward the request to its CMS regional office. The CMS regional office will forward the request to the CMS central office where a final determination will be made as to whether the State fire and safety code may be used in place of the NFPA LSC.

We also have retained our authority to waive provisions of the LSC, on a case-by-case basis. We may grant a waiver for a specific LSC requirement if we determine that the waiver would not adversely affect the patient or staff health and safety and it would impose an unreasonable hardship on the facility to meet a specific LSC requirement. If a health care facility would like a waiver for a specific provision in the LSC, the facility must forward the request to their State survey agency. The State agency will review the request, make a recommendation and forward the request to the appropriate CMS regional office. The CMS regional office will review the State agency's recommendation and make a final decision.

Comment: Several commenters requested that the October 2001 proposed rule be revised to allow health care facilities to choose other codes that

are nationally recognized, such as the International Building Code and International Fire Code. Referencing only the NFPA's LSC in the final rule creates conflict for many jurisdictions that enforce other equivalent or more stringent fire and life safety requirements. By not referencing other applicable codes, CMS favors one code to the detriment of other codes.

Response: We continue to specifically cite the LSC because under sections 1819(d)(2)(B) and 1919(d)(2)(B) of the Act, nursing homes must meet the provisions of ''such edition (as specified by the Secretary in regulation) of the Life Safety Code of the National Fire Protection Association * * *.'' To avoid confusion and to be consistent for all provider types we require the LSC for all inpatient facilities. This is especially applicable for facilities with mixed occupancies. For example, a health care facility's west wing could be a nursing home while the rest of the facility is a hospital. It would be impractical as well as burdensome for the facility to follow the LSC for the nursing home and another health and safety code for the hospital. The regulation reflects this by requiring a single code for all inpatient health care facilities.

However, if a State's own fire and safety code would ''adequately protect patients'' and the State code is imposed by State law, the State may submit a request in writing to its CMS regional office. The CMS regional office will forward the request to the CMS central office. The CMS central office will make a final decision on whether the State code may be used in place of the NFPA LSC.

Comment: Several commenters support CMS's authority to ''accept a State's fire and safety code instead of the LSC if the State's fire and safety code adequately protects patients.'' However, these same commenters stated that the CMS must have a system in place to evaluate any State code to determine that the requirement provides adequate protection for patients and staff.

Response: We appreciate the support for accepting State fire and safety codes in addition to the LSC. If a State chooses to use its fire and safety code rather than the LSC, it must be imposed by State law and adequately protect patients and staff. Any State that chooses this option should send the request to its CMS regional office. The regional office will forward the request to the CMS central office. The central office will make the final determination and respond in writing as to whether the State fire and safety code adequately protects patients and staff.

E. Ambulatory Surgical Centers (ASCs)

Comment: Some commenters believe that we should allow grandfathering for Ambulatory Surgical Centers (ASCs) that meet previous editions of the LSC. Some commenters stated that, at the very least, we should permit ASCs to postpone compliance with the 2000 edition of the LSC until the ASC undertakes a major renovation. The commenters stated that compliance with the 2000 edition of the LSC, especially for smaller ASCs would impose a financial burden. One commenter asked us to phase-in the requirements because it would be a financial hardship for most ASCs to comply with the 2000 edition of the LSC. The commenter suggested that we consider a couple of approaches for phasing in the 2000 edition of the LSC. For ASCs already Medicare-certified, the 2000 edition of the LSC would only need to be met if the ASC underwent a major renovation, or we could implement a timeline for full compliance to the 2000 edition of the LSC (for example, 5 years).

Response: It is not our intent to impose a retroactive requirement for ASCs. For existing ASCs, most provisions in the 2000 edition of the LSC are similar to past editions. Furthermore, existing facilities in compliance with early editions of the LSC are not required to upgrade to a later edition of the LSC for certain provisions. For example, an existing ASC is not required to upgrade its Type I Essential Electrical System (EES). Chapter 21–2.9.2 references NFPA 99, Standard for Health Care Facilities. This provision states that ASCs ''shall be provided with an EES in accordance with NFPA 99, Standard for Health Care Facilities.'' Under NFPA 99 existing ASCs are able to continue to use existing electrical and medical gas systems that are in compliance with the earlier editions of the LSC provided the ASC continues to meet the edition of the LSC requirements when it was constructed. The referencing to the NFPA 99 for certain provisions (that is, EES, and medical gas) should relieve some burden for ASCs.

In addition, an ASC may also request a waiver for a specific provision of the LSC further reducing the exposure to additional cost and burden for ASCs with unique situations that can justify the application of waivers and will not endanger the health and safety of patients. A waiver may be granted for a specific LSC requirement if (1) we determine that the waiver would not adversely affect patient and staff health and safety; and (2) we determine that it would impose an unreasonable hardship on the facility to meet a specific LSC requirement. All waivers are determined on a case-by-case basis. An ASC may request a waiver from its State Agency. The State Agency will review the request and make a recommendation to the appropriate CMS regional office. The CMS regional office will review the waiver request and the State agency's recommendation and make a final decision on the waiver request. A waiver cannot be granted if patient safety is compromised in any way.

Comment: A few commenters objected to the requirements in the 2000 edition of the LSC that ASCs must have a Type I Essential System (EES) and upgrade their medical gas capabilities. Most of the ASCs, especially smaller ASCs, do not have a Type I EES or meet the medical gas requirement in the 2000 edition of the LSC. The commenters stated that the change to a Type I EES and to upgrade their medical gas capabilities will be a financial hardship on the ASCs.

Response: Only new facilities will be required to have a Type I EES or upgrade its medical gas capabilities. Existing ASC facilities in compliance with early editions of the LSC for EES and medical gas requirements are not required to upgrade to the 2000 edition of the LSC. Per chapter 21–2.9.2 and chapter 21–3.2.2, an ASC facility shall be in compliance with ''NFPA 99, Standard for Health Care Facilities.'' Under NFPA 99 existing ASCs may continue to use existing electrical and medical gas systems that are in compliance with earlier editions of the LSC provided the ASC continues to meet the earlier edition of the LSC requirements when it was constructed. If the ASC fails to meet the earlier LSC requirements, the ASC must upgrade to the 2000 edition of the LSC. An ASC must also meet the 2000 edition of the LSC if its EES or medical gas system undergo alteration, modernization, or renovation.

Comment: Three commenters requested that ASCs be exempt from the fire-rated wall standards in Chapter 19–3.6.1 and the vertical opening standard in Chapter 19–3.1 of the 2000 edition of the LSC. The commenters explained that ASCs would be unable to comply with these requirements because most ASCs do not control spaces outside of their leased area.

Response: The commenters may have misunderstood which chapters apply to ASCs. Chapters 20 and 21 apply to ASCs, not chapter 19. This confusion may have been caused because we improperly cited chapter 19 in the ASC regulatory text. We deleted all chapter

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

of ensuring fire safety for patients and staff. However, we received a large number of comments regarding the amount of time and the cost required to replace the roller latches. While we still believe that replacing roller latches is an important fire safety issue, we realize we have to balance the burden to providers with the impact this change will have. To alleviate some of the burden of the roller latch requirement, we are phasing in the requirement over 3 years. During this 3-year phase in period, we will continue to monitor, through our existing survey process, a facility's maintenance of its existing roller latches to ensure that they are maintained and operating properly. We believe that this will help ensure fire safety for patients and staff.

We did not phase in any other of the LSC requirements because we believe updating the other requirements is an important safeguard for ensuring fire safety to all patients and staff of each facility.

Below we outlined all the major changes a health care facility would have to undergo if the health care facility has not upgraded its facility since meeting earlier editions of the LSC. As in the October 26, 2001 proposed rule, below we have provided the LSC citation, a description of the requirement, an explanation of why we believe it is critical to the safety of patients to require it, and a brief discussion of our analysis of the burden imposed by the requirement. The following are new provisions in the 2000 edition of the LSC from chapter 19, ''Existing Health Care Occupancies.''

Please note that we did not include chapter 19, section 1.1.4.5 (Renovations, Alterations, and Modernization) in our total estimate. This provision is not a requirement of the final rule. This provision only applies if a health care facility chooses to extensively renovate its facility or build a new facility. Existing facilities that are extensively renovated must meet the requirements of a newly constructed facility, including the installation of sprinkler systems in nonsprinklered buildings. The Fire Analysis & Research Division of the NFPA has shown that sprinklers have been the most important life safety system installed in health care facilities. The LSC generally requires sprinkler systems in renovations, regardless of construction techniques or materials used in constructing the facility. The estimated cost of installing sprinkler systems in buildings that presently do not have them is $2.50 per square foot, or approximately $125,000 for a 50,000 square foot building. This requirement is not imposed on existing facilities. In the proposed rule we stated there were 255 facilities that do not have sprinkler systems. This was a typographical error. There are approximately 2,550 facilities that do not currently have sprinkler systems. Again, none of these facilities are required to install sprinkler systems under this final rule.

(1) 19.2.9—Emergency Lighting—This provision requires emergency lighting for a period of 1½ hours in health care facilities, enabling those inside to move about safely in an emergency. We proposed to phase-in this requirement over a 3-year period, to allow for the normal replacement cycle of batteries used in emergency lighting systems. We believe this phase in period would not adversely impact the health and safety of the patient. In the October 2001 proposed rule, we estimated that 790 existing facilities do not have emergency lighting for 1½ hours. Approximately 12 emergency light units would be needed for each facility. We estimated that the cost to be in compliance with this provision was $7,200 per facility. In the proposed rule we estimated that the total cost for all facilities to be upgraded under this provision would be $5,452,150.

Approximately 642 existing facilities do not have emergency lighting for 1½ hours. We estimate each facility would need approximately 12 emergency light units at a cost of $750 per light. We estimate it will cost each facility $9,000 to upgrade its emergency lighting. The total amount to implement this requirement for all facilities will be $1,926,000 for the first year. Because we are phasing in this requirement over 3 years, we estimate that it will be approximately $1,926,000 for each of the next 2 years.

(2) 19.3.1—Protection of Vertical Openings—Unprotected vertical openings (for example, open stairwells) permit fire, smoke, and toxic gases to spread from one level to another in a building, making evacuation difficult, if not impossible. In the October 2001 proposed rule, we estimated that to upgrade the vertical openings would be $2,938 per vertical opening. We estimated that 9,877 vertical openings in 1,976 facilities needed to be upgraded for a total cost of $29,018,626 or an average of $14,690 per facility.

We revised this figure estimating that 5,573 vertical openings in 1,115 facilities would be affected because many facilities have already upgraded their buildings to meet this requirement. Each vertical opening costs approximately $3,819. We estimate the facilities that need to be upgraded will need to install an average of five vertical openings. The total estimated cost is $21,283,687 for all facilities to be upgraded or an average of $19,095 per facility.

(3) 19.3.4.3.2—Emergency Forces Notification—This provision requires the fire alarm system to provide automatic notification of a fire to emergency forces. This is of great importance to the protection of all patients. Any delay in the notification of fire or rescue personnel could adversely impact the health and safety of patients and expose them to a fire, smoke, or toxic gases created by the fire. In the October 2001 proposed rule, we estimated that approximately 2,750 buildings at $900 per facility would need to be connected to a fire alarm retransmission system for a total estimated cost of $2,475,000.

We revised our cost estimates because the October 2001 proposed rule was incorrect. The proposed rule estimate did not account for installation. The one time cost to install a fire department or central monitoring station connection is $1,707 per facility. In addition, we estimate that there is a $97.50 monthly fee for the monitoring stations and telephone costs.

We determined that 2,358 buildings at $2,877 (installation fee + monthly fee for one year) per facility would need to be connected to a fire alarm retransmission system. We estimate that to be in compliance with this provision the total cost is approximately $6,783,966.

(4) 19.3.6.1—Corridors—This provision requires that all areas in nonsprinklered buildings must be separated from the corridor by corridor walls that are fire-rated. This requirement, which provides a protected passageway for movement during an emergency, is necessary to increase the safety of the patients. In the October 2001 proposed rule, we estimated that the cost to upgrade a facility to meet this requirement was $7,124 for 1,976 buildings that currently meet the 1967 LSC and approximately $5,735 for 46 buildings meeting the 1973 LSC.

We revised the proposed rule estimates and approximately 1,606 buildings currently meet the 1967 LSC and will need to be upgraded. We estimate that to upgrade facilities that currently meet the 1967 LSC is $14,871,560 or approximately $9,260 per facility.

We also calculated that 39 buildings currently meet the 1973 LSC. The estimated cost to upgrade the 39 buildings is $290,745, approximately $7,455 per facility.

The revised total cost estimate for all facilities to meet this requirement is $15,162,305.

(5) 19.7.5.2 & 19.7.5.3—Upholstered Furniture—These provisions allow patient-owned furniture to be brought into the facility without meeting the requirements of 10.3.2(2) and 10.3.3 (regarding fire resistant furniture) if a single station smoke detector is placed in the sleeping room where the furniture is located. This gives the facility a more home-like atmosphere. In the October 2001 proposed rule, we estimated that 18,498 smoke detectors would need to be installed at approximately $100 per smoke detector. We estimated in the proposed rule that the total cost to be in compliance with this provision was $1,849,800.

We revised this cost estimate because we believe 19,262 smoke detectors need to be installed rather than the 18,498 we estimated in the October 2001 proposed rule. We did not change our estimate of the cost of the smoke detector (that is, $100 per smoke detector). The total amount to be in compliance with this provision is $1,926,200.

(6) 19.3.6.3.2—Roller Latches—We ''carved out'' the exception the LSC allowed for roller latches in existing buildings. In the October 2001 proposed rule we estimated the total cost for all facilities to remove exiting roller latches was $30,754,540 ($190 per door for 161,866).

We revised the estimate and 190,303 roller latches must be replaced at a cost of $250 per roller latch, for a total cost estimate of $47,575,750. We are phasing in this requirement over 3 years. Thus, we estimate that it will cost $15,858,583 for the first year and $15,858,583 for each of the next 2 years.

In the October 2001 proposed rule, we proposed to retain our existing authority to waive provisions of the 2000 edition of the LSC, on a case-by-case basis, further reducing the exposure to additional cost and burden for facilities with unique situations that can justify the application of waivers, which we determine will not endanger the health and safety of patients.

We proposed to retain our authority to apply the FSES as an alternative approach to meeting the requirements of the LSC, as well as accept alternative State fire and safety codes discussed in section I.B in the October 2001 proposed rule.

IV. Provisions of the Final Regulations

For the most part, this final rule adopts the provisions of the October 26, 2001 proposed rule. Those provisions of this final rule that differ from the October 2001 proposed rule follow. In response to comments, we are revising § 485.623(d) to require all critical access hospitals (CAHs) to meet the applicable provisions of the 2000 edition of the LSC. The provision of the adopted 2000 edition of the LSC that does not apply to a CAH is chapter 19, ''Existing Health Care Occupancies,'' section 19.3.6.3.2 (exception No. 2), roller latches.

We deleted the reference to chapter 19 (that is, 19.3.6.3.2) under the ASC regulatory text because it was improperly cited for ASCs. We cited chapter 19.3.6.3.2 because all roller latches must be replaced in existing health care occupancies. However, Chapter 19 does not apply to ASCs. ASCs are under chapter 20 (that is, new ASCs) and chapter 21 (that is, existing ASCs).

We also decided to include chapter 5, the performance based option provision. We do not expect many providers to choose this option. However, we would like all providers to have the alternative to use the performance based option if the provider believes it would be useful for it to comply with the LSC. In addition, we have provided for a 3-year phase in period for the requirements regarding roller latches and emergency lighting.

The final rule will continue to allow other options besides the prescriptive requirements of the LSC. Health care facilities may choose the FSES, and a facility may apply for a waiver of a specific provision of the LSC if it is unable to meet a specific requirement. We may grant a waiver for a specific LSC requirement if (1) we determine that the waiver would not adversely affect patient and staff health and safety; and (2) we determine that it would impose an unreasonable hardship on the facility to meet a specific LSC requirement. A provider may request a waiver from its State agency. The State agency will review the request and make a recommendation to the appropriate CMS regional office. The CMS regional office will review the waiver request and the State agency's recommendation and make a final decision on the waiver request. We cannot grant a waiver if patient safety is compromised in any way.

A State may also choose to use its fire and safety code rather than the LSC if the State fire and safety code is imposed by State law and adequately protect patients. Any State that chooses this option must send the request to its CMS regional office. The regional office will forward the request to the CMS central office. The central office will make the final determination and respond in writing as to whether the State fire and safety code adequately protects patients and staff. Lastly, we no longer exempt new nursing homes or new hospices providing inpatient care from chapter 18.3.4.5.3 of the LSC. Several commenters opposed the proposed exception to remove the smoke detector requirement for hospices and nursing facilities. Many commenters believe smoke detectors are an inexpensive requirement for new facilities and they provide an extra layer of protection. We agree and removed the exception from the regulations text in hospices at § 418.100(d) and nursing facilities at § 483.70(a).

V. Collection of Information Requirements

This rule does not impose any information collection and record keeping requirements that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Statement

A. Introduction

This final rule adopts the 2000 edition of the LSC. The objective is to provide safety to life during fires and other emergencies. Adoption and use of the 2000 edition of the LSC will bring us up-to-date in requiring the latest and best technology in fire protection for our beneficiaries. These requirements are designed to protect all patients and staff. The 2000 edition of the LSC also protects property and can reduce the dollar loss associated with a fire. For example, the 2000 edition of the LSC requires that any new construction install quick-response sprinkler systems increasing the level of protection to our beneficiaries. Adopting the 2000 edition of the LSC and removing references to all older editions of the LSC will eliminate confusion as to which edition a health care facility must follow. This is particularly important when a facility has multiple buildings constructed at differing times or a single building with multiple wings or additions constructed at different times. Instead of each building complying with different editions of the LSC, this final rule requires all the buildings to comply with the same edition of the LSC. The use of a single edition of the code should also contribute to lowering the cost of complying with the requirements for testing and maintenance of fire protection systems.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and

the Regulatory Flexibility Act (RFA) (September 16, 1980 Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have examined the impact of this final rule and we have determined that this rule is neither expected to meet the criteria to be considered economically significant, nor do we believe it will meet the criteria for a major rule. All entities affected by this rule are considered small entities. Therefore, a final regulatory impact analysis is not required for the same reasons explained in section VI.C of this rule.

We revised our estimate of the regulatory impact of this final rule from $96,356,599 to $63 million for the first year and $17.5 million for each of the next 2 years. The estimate appears lower than the estimate in the October 2001 proposed rule because unlike the October 2001 proposed rule, we are phasing in the requirement to replace all existing roller latches over 3 years. Thus, the cost estimate to replace the roller latches is reduced from approximately $48 million for the first year to approximately $16 million per year for 3 years. For a detailed description of our estimates for each provider, section II.C of this final rule outlines our cost estimates in the 2001 proposed rule, and section III.H of this final rule outlines our revised cost estimates for this rule as well as why we revised the estimates.

C. Impact on Small Entities and Rural Hospitals

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 to $29 million in any one year (for details, see the Small Business Administration's regulation that sets forth size standards for health care industries at 65 FR 69432). For purposes of the RFA, all health care facilities affected by this regulation are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

Based on the Small Business Administration (SBA) and CMS data (these data can be found in the April 2002 CMS Statistics Publication No. 03437 or *www.cms.hhs.gov*), approximately 4,593 out of 6,650 hospitals are considered to be small businesses or nonprofit hospitals. We do not consider this rule to significantly impact these hospitals because the cost of this rule is less than 1 percent of the total costs for hospitals. According to the CMS 2002 national expenditure data, the total national costs for hospitals in 2002 was $412.1 billion. We estimate this rule will cost hospitals, including CAHs, approximately $8,263,848 for the first year and $4,131,924 for each of the next 2 years due to the phase in of emergency lighting and the replacement of all roller latches.

Based on the SBA and CMS data, approximately 3,064 out of 3,474 ASCs are considered to be small businesses or nonprofit providers. However, we do not consider this rule to significantly impact the ASCs because the cost of this rule is less than 1 percent of the total costs for ASCs. According to the CMS 2002 national expenditure data, the total national cost for ASCs in 2002 was $286.4 billion. We estimate that it will cost ASCs approximately $2,511,667 for the first year and $1,255,833 for each of the next 2 years due to the phase in of emergency lighting and the replacement of all roller latches.

Based on the SBA and CMS data, approximately 17,901 out of 23,500 LTC providers, inpatient hospices, and ICF/MR facilities are considered to be small businesses or nonprofit providers. We do not consider this rule to significantly impact the LTC providers, inpatient hospices, or ICF/MR facilities because the cost of this rule is less than 1 percent of the total costs for these providers. According to the CMS 2002 national expenditure data, the total national costs for LTC providers, inpatient hospices, and ICF/MR facilities in 2002 were $89.3 billion. Our cost estimate for compliance with this rule for LTC providers, inpatient hospices, and ICF/MR facilities is approximately $59,195,736 for the first year and $5,788,375 for each of the next 2 years due to the phase in of emergency lighting and the replacement of all roller latches. We combined the estimates of LTC facilities, inpatient hospices, and ICF/MR facilities because of the similarities in how the provider types are surveyed for compliance with the LSC and the items that must be upgraded to meet the 2000 edition of the LSC. In addition, most ICF/MR facilities will not be impacted by this rule because the majority of these facilities are fairly new and are considered a residential occupancy rather than the more stringent health care occupancy type. However, there are ICF/MR facilities that care for the more severely impaired. These ICF/MR facilities are similar to an LTC facility and will be impacted by the 2000 edition of the LSC.

Lastly, we do not believe this rule will affect PACE centers or RNHCI facilities because PACE and RNHCI are new programs and they already meet the 1997 edition of the LSC. The changes from the 1997 edition of the LSC to the 2000 edition of the LSC are negligible. For example, PACE centers and RNHCI facilities have 1.5-hour emergency lighting, no vertical opening problems, and do not have any roller latches. Moreover, because both of these providers are new programs, the SBA does not have an estimate as to how many are considered small businesses. We consider all RNHCIs to be nonprofit entities.

Please note we also provided a cost estimate for each of the provisions with respect to which we believe that each facility will need to upgrade to be in compliance with this final rule in section III.H.

The cost estimate does not take into account any waivers that may be granted. We will retain the existing authority to waive specific provisions of the 2000 edition of the LSC, further reducing the exposure to additional cost and burden for facilities with unique situations that can justify the application of waivers, and that we determine will not endanger the health and safety of patients.

The cost estimate does not factor in any cost reduction if we accept a State's fire and safety code instead of the NFPA's 2000 edition of the LSC. We have the authority to accept a State fire and safety code in lieu of the NFPA LSC if the State code is imposed by State law, and adequately protects patients.

We also note that the 2000 LSC permits the use of the FSES as an alternative approach that may also reduce the cost of compliance significantly. The FSES is an equivalency system. The FSES may allow a facility to comply with the LSC without having to make changes to the facility due to other offsetting or compensating fire protection features that exist in the facility.

We do not know the amount that any of the above waivers or alternatives may save a health care facility because each facility must be reviewed on a case-by-case basis to determine whether the facility will be granted a waiver for a specific provision of the LSC or use its State fire and safety code or if the facility chooses to use the FSES.

While we expect a revised edition of the LSC to be published in 2003, we believe it is imperative to publish this final rule, which incorporates the 2000 edition of the LSC in response to the needs of the providers, States, accrediting organizations, and the public for clarity and consistency with the current regulatory and accreditation setting. The 2000 edition of the LSC includes new provisions that we believe are vital to the health and safety of all patients and staff. This final rule is intended to ensure that beneficiaries continue to experience the highest degree of fire safety possible. We believe by adopting the 2000 edition of the LSC now instead of waiting for the release of the 2003 edition will (1) minimize the burden on health care providers because the standards we currently require most of the providers to follow are at least 15-years old and (2) increase the level of safety for patients and staff. Once the NFPA adopts the 2003 edition of the LSC, we will quickly begin the process of reviewing the revised edition with the intent to publish a proposed rule to set forth requirements we think would be beneficial to the providers, States, accrediting organizations, and the public. Providers, States, accrediting organizations, and the public are requesting that we publish this rule now rather than wait because many of the providers can only comply with our regulations by using older fire safety techniques.

D. The Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule will not have an effect on the governments mentioned, and the private sector costs will not be greater than the $110 million threshold. We discuss specific private sector costs in section VI.C of this rule.

E. Federalism

Executive Order 13132 establishes requirements that an agency must meet when it publishes a final rule that imposes substantial direct requirement costs on State, local, or tribal governments, preempts State law, or otherwise has Federalism implications.

We have examined this final rule and have determined that this rule will not have a substantial effect on State, local, or tribal governments.

F. Anticipated Effects

While all health care facilities are affected by this regulation, most health care facilities will be affected minimally. Most changes that would occur would be minor and should not adversely impact patients. Each new edition of the LSC builds on prior editions; changes from one edition to the next have been relatively minor since 1985. Many health care providers have updated their facilities since 1985 and already meet most of the provisions in the 2000 edition of the LSC. In fact, most health care providers stated that they are exposed to additional work and expense without any gain in fire safety by continuing to abide by the 1985 edition of the Life Safety Code. For example, the JCAHO requires all its accredited facilities to meet the 1997 edition of the LSC, while Medicare requires all facilities to meet an earlier edition of the LSC. This has caused confusion, as well as additional burden to the health care facility in requesting waivers or changing some of the renovations to meet both editions of the LSC. Updating the LSC will not only relieve burden for health care providers but also assist in ensuring the health and safety of patients and staff.

By adopting the 2000 edition of the LSC, we will eliminate confusion as to which edition a health care facility must follow. The use of a single edition of the code should also contribute to lowering the cost of complying with the requirements for testing and maintenance of fire protection systems under multiple editions of the LSC.

1. Effects on Specific Entities

This rule will affect hospitals, LTC facilities, ICFs/MR, ASCs, hospices that provide inpatient services, RNHCIs, CAHs, and PACE Centers.

2. Effects on Other Providers

We do not expect this regulation to affect any other providers.

3. Effects on the Medicare and Medicaid Programs

If facilities decide to use the performance-based option to meet the requirements of the LSC, we estimate that it could cost approximately $3.5 million in the aggregate for States to survey facility plans using the performance-based option. We estimate that 25 states will be affected by the use of the performance-based option. Our estimate is based on the hiring of one fire protection engineer at an average of $60,000 annual salary and one engineer technician at an average $40,000 annual salary plus minimal travel and training expenses. We expect that we would have to additionally fund the States in order for them to be able to have the expertise to survey any facility using the performance-based option.

G. Alternatives Considered

The statutory basis for incorporating the NFPA's code for nursing homes is specific authority in the Act at sections 1819(d)(2) and 1919(d)(2). For hospitals, the statutory authority to adopt fire safety provisions is section 1861(e)(9) of the Act. To be consistent and to avoid confusion among health care providers, we incorporated the NFPA's 2000 edition of the LSC for all Medicare inpatient facilities under the Secretary's general rulemaking authority.

Alternatively, we could have chosen not to update the fire safety code. This is not an acceptable alternative because many health care facilities are exposed to additional work and expense without any gain in fire safety by continuing to abide by the 1985 edition of the Life Safety Code. For example, the JCAHO requires all its accredited facilities to meet the 1997 edition of the LSC, while Medicare requires all facilities to meet an earlier edition of the LSC. This has caused confusion, as well as additional burden to the health care facility in requesting waivers or changing some of the renovations to meet both editions of the LSC. Updating the LSC will not only relieve burden for health care providers but also assist in ensuring the health and safety of patients and staff.

Please note that while we incorporate the NFPA's 2000 edition of the LSC, all health care providers have other options besides the prescriptive requirements of the LSC. Health care facilities may choose the Fire Safety Evaluation System (FSES) and a facility may apply for a waiver of a specific provision of the LSC if it is unable to meet a specific

requirement. A waiver may be granted for a specific LSC requirement if (1) we determine that the waiver would not adversely affect patient and staff health and safety; and (2) we determine that it would impose an unreasonable hardship on the facility to meet a specific LSC requirement. A provider may request a waiver from its State Agency. The State Agency will review the request and make a recommendation to the appropriate CMS regional office. The CMS regional office will review the waiver request and the State agency's recommendation and make a final decision on the waiver request. A waiver cannot be granted if patient safety is compromised in any way.

H. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this final rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Health insurance, Hospitals, Incorporation by reference, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health, Incorporation by reference, Medicare, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Incorporation by reference, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs—health, Health facilities, Incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as follows:

PART 403—SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for part 403 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart G—Religious Nonmedical Health Care Institutions—Benefits, Conditions of Participation, and Payment

2. Section 403.744 is amended as follows:

a. The introductory text to paragraph (a) is republished.

b. Paragraph (a)(1) is revised.

c. Paragraph (c) is added.

§ 403.744 Condition of participation: Life safety from fire.

(a) *General.* An RNHCI must meet the following conditions:

(1) Except as otherwise provided in this section, the RNHCI must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes. Chapter 19.3.6.3.2, exception number 2 of the adopted Life Safety Code does not apply to an RNHCI.

* * * * *

(c) *Phase-in period.* An RNHCI must be in compliance with the following provisions beginning on March 13, 2006:

(1) Chapter 19.3.6.3.2, exception number 2.

(2) Chapter 19.2.9, Emergency Lighting.

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Specific Conditions for Coverage

2. Section 416.44 is amended as follows:

a. Paragraph (b)(1) is revised.

b. Paragraph (b)(3) is revised.

c. Paragraph (b)(4) is added.

§ 416.44 Condition for coverage—Environment.

* * * * *

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

* * * * *

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

* * * * *

PART 418—HOSPICE CARE

1. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart E—Conditions of Participation: Other Services

2. Section 418.100 is amended as follows:

a. Paragraph (d)(1) is revised.

b. Paragraph (d)(3) is revised.

c. Paragraph (d)(4) is revised.

§ 418.100 Condition of participation: Hospices that provide inpatient care directly.

* * * * *

(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section, the hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes. Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to a hospice.

* * * * *

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.

(4) A hospice must be in compliance with the following provisions beginning on March 13, 2006:

(i) Chapter 19.3.6.3.2, exception number 2.

(ii) Chapter 19.2.9, Emergency Lighting.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

1. The authority citation for part 460 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395).

Subpart E—PACE Administrative Requirements

2. Section 460.72 is amended as follows:

a. Paragraph (b)(1) is revised.

b. Paragraph (b)(3) is added.

§ 460.72 Physical environment.

* * * * *

(b) *Fire safety—(1) General rule.* (i) Except as otherwise provided in this section, a PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association that apply to the type of setting in which the center is located. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to PACE centers.

* * * * *

(3) *Phase-in period:* A PACE center must be in compliance with the following provisions beginning on March 13, 2006:

(i) Chapter 19.3.6.3.2, exception number 2.

(ii) Chapter 19.2.9, Emergency Lighting.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Basic Hospital Functions

2. Section 482.41 is amended as follows:

a. Paragraph (b)(1) introductory text is revised.

b. Paragraph (b)(1)(i) is revised.

c. Paragraph (b)(1)(iv) is added.

§ 482.41 Condition of participation: Physical environment.

* * * * *

(b) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section, the hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

(i) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

* * * * *

(iv) A hospital must be in compliance with the following provisions beginning on March 13, 2006:

(A) Chapter 19.3.6.3.2, exception number 2.

(B) Chapter 19.2.9, Emergency Lighting.

* * * * *

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

1. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Requirements for Long Term Care Facilities

2. Section 483.70 is amended as follows:

a. Paragraph (a) introductory text is revised.

b. Paragraph (a)(4) is added.

§ 483.70 Physical environment.

* * * * *

(a) *Life safety from fire.* Except as otherwise provided in this section, the facility must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes. Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to long-term care facilities.

* * * * *

(4) A long-term care facility must be in compliance with the following provisions beginning on March 13, 2006:

(i) Chapter 19.3.6.3.2, exception number 2.

(ii) Chapter 19.2.9, Emergency Lighting.

* * * * *

Subpart I—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

3. Section 483.470 is amended as follows:

a. Paragraph (j)(1)(i) is revised.

b. Paragraph (j)(1)(iii) is revised.

c. Paragraph (j)(2) is revised.

d. Paragraph (j)(3) is added.

§ 483.470 Condition of participation: Physical environment.

* * * * *

(j) *Standard: Fire protection*—(1) *General.* (i) Except as otherwise provided in this section, the facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

* * * * *

(iii) A facility that meets the LSC definition of a residential board and care occupancy must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the Fire Safety Evaluation System for Board and Care facilities (FSES/BC).

(2) *Exceptions for all facilities.* (i) Chapter 19.3.6.3.2, exception number 2 of the adopted LSC does not apply to a facility.

(ii) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects a facility's clients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(iii) The facility must be in compliance with the following provisions beginning on March 13, 2006:

(A) Chapter 19.3.6.3.2, exception number 2.

(B) Chapter 19.2.9, Emergency Lighting.

(3) *Facilities that meet the LSC definition of a health care occupancy.*

(i) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:

(A) The waiver would not adversely affect the health and safety of the clients.

(B) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(ii) [Reserved]

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

1. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

2. Section 485.623 is amended as follows:

a. Paragraph (d)(1) is revised.

b. Paragraph (d)(2) is revised.

c. Paragraph (d)(5) is added.

§ 485.623 Condition of participation: Physical plant and environment.

* * * * *

(d) *Standard: Life safety from fire*—(1) Except as otherwise provided in this section, the CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes. Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

* * * * *

(5) A critical access hospital must be in compliance with the following provisions beginning on March 13, 2006:

(i) Chapter 19.3.6.3.2, exception number 2.

(ii) Chapter 19.2.9, Emergency Lighting.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance Program)

Dated: May 9, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 26, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–273 Filed 1–9–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AI33

Migratory Bird Hunting; Approval of Tungsten-Iron-Nickel-Tin Shot as Nontoxic for Hunting Waterfowl and Coots

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We approve shot formulated of 65% tungsten, 10.4% iron, 2.8% nickel, and 21.8% tin as nontoxic for hunting waterfowl and coots. We assessed possible effects of the tungsten-iron-nickel-tin (TINT) shot, and we believe that it does not present a significant toxicity threat to wildlife or their habitats and that further testing of the shot is not necessary. Approval of this shot provides another nontoxic option for hunters.

DATES: This rule takes effect on January 10, 2003.

ADDRESSES: Copies of the Environmental Assessment are available from the Chief of the Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 634, Arlington, Virginia 22203–1610.

FOR FURTHER INFORMATION CONTACT: Bob Blohm, Acting Chief, or John J. Kreilich, Jr., Division of Migratory Bird Management, 703–358–1714.

SUPPLEMENTARY INFORMATION: The Migratory Bird Treaty Act of 1918 (Act) (16 U.S.C. 703B–712 and 16 U.S.C. 742 a–j) implements migratory bird treaties between the United States and Great Britain for Canada (1916 and 1996 as amended), Mexico (1936 and 1972 as amended), Japan (1972 and 1974 as amended), and Russia (then the Soviet Union, 1978). These treaties protect certain migratory birds from take, except as permitted under the Act. The Act authorizes the Secretary of the Interior to regulate take of migratory birds in the United States. Under this authority, the Fish and Wildlife Service controls the hunting of migratory game birds through regulations in 50 CFR part 20.

Since the mid-1970s, we have sought to identify shot that is not significantly toxic to migratory birds or other wildlife. Compliance with the use of nontoxic shot has increased over the last few years (Anderson *et al.* 2000), and we believe that it will continue to increase with the approval and availability of other nontoxic shot types. Currently, steel, bismuth-tin, tungsten-iron, tungsten-polymer, tungsten-matrix, and tungsten-nickel-iron shot are approved as nontoxic.

The purpose of this rule is to approve the use of TINT shot in the tested formulation (65% tungsten, 10.4% iron, 2.8% nickel, and 21.8% tin by weight) for waterfowl and coot hunting. This rule amends 50 CFR 20.21(j), which describes prohibited types of shot for waterfowl and coot hunting, to allow the use of this shot.

Background

On October 12, 2001, we received an application (Tier 1) under 50 CFR 20.134 from ENVIRON-Metal, Inc. for approval of HEVI-SHOT™ brand of Soft Shot in a 65% tungsten, 10.4% iron, 2.8% nickel, and 21.8% tin formulation. The application included information on chemical characterization, production variability, use volume, toxicological effects, environmental fate and transport, and evaluation. In accordance with our regulation, on May 10, 2002, we published in the **Federal Register** a proposed rule indicating our intention to approve TINT shot. We have reviewed the Tier 1 application, the supporting data, and the public comment, and the Director, U.S. Fish and Wildlife Service, has concluded that this shot does not impose a significant danger to migratory birds and other wildlife or their habitats.

In addition, since the 2000–2001 hunting season is completed, tin (99.9 percent tin with 1 percent residual lead) shot is no longer authorized for use and therefore the reference to it in 50 CFR 20.21(j) is deleted.

Toxicity Information

Tungsten may be substituted for molybdenum in enzymes in mammals. Ingested tungsten salts reduce growth and can cause diarrhea, coma, and death in mammals (Bursian *et al.* 1996, Cohen *et al.* 1973, Karantassis 1924, Kinard and Van de Erve 1941, National Research Council 1980, Pham-Huu-Chanh 1965), but elemental tungsten is virtually insoluble and therefore essentially nontoxic. A dietary concentration of 94 parts-per-million (ppm) did not reduce weight gain in growing rats (Wei *et al.* 1987). Lifetime exposure to 5 ppm tungsten as sodium tungstate in drinking water produced no discernible adverse effects in rats (Schroeder and Mitchener 1975). At 100 ppm tungsten as sodium tungstate in drinking water, rats had decreased enzyme activity after 21 days (Cohen *et al.* 1973).

Chickens given a complete diet showed no adverse effects of 250 ppm sodium tungstate administered for 10 days in the diet. However, 500 ppm in the diet had detrimental effects on day-old chicks (Teekell and Watts 1959). Adult hens had reduced egg production and egg weight on a diet containing 1,000 ppm tungsten (Nell *et al.* 1981a). EPT (1999) concluded that 250 ppm in the diet would produce no observable adverse effects. Kelly *et al.* (1998) demonstrated no adverse effects on mallards dosed with tungsten-iron or tungsten-polymer shot according to nontoxic shot test protocols.

Most toxicity tests reviewed were based on soluble tungsten compounds rather than elemental tungsten. As we found in our reviews of other tungsten shot types, we have no basis for concern about the toxicity of the tungsten in TINT shot to fish, mammals, or birds.

Nickel is a dietary requirement of mammals, with necessary consumption set at 50 to 80 parts per billion for the rat and chick (Nielsen and Sandstead 1974). Though it is necessary for some enzymes, nickel can compete with calcium, magnesium, and zinc for binding sites on many enzymes. Water-soluble nickel salts are poorly absorbed if ingested by rats (Nieboer *et al.* 1988). Nickel carbonate caused no treatment effects in rats fed 1,000 ppm for 3 to 4 months (Phatak and Patwardhan 1950). Rats fed 1,000 ppm nickel sulfate for 2 years showed reduced body and liver weights, an increase in the number of stillborn pups, and decrease in weanling weights through three generations (Ambrose *et al.* 1976). Nickel chloride was even more toxic; 1,000 ppm fed to young rats caused weight loss in 13 days (Schnegg and Kirchgessner 1976).

Soluble nickel salts are toxic to mammals, with an oral LD_{50} (lethal dose) of 136 mg/kg in mice, and 350 mg/kg in rats (Fairchild *et al.* 1977). Nickel catalyst (finely divided nickel in vegetable oil) fed to young rats at 250 ppm for 16 months, however, produced no detrimental effects (Phatak and Patwardhan 1950).

In chicks from hatching to 4 weeks of age, 300 ppm nickel as nickel carbonate or nickel acetate in the diet produced no observed adverse effects. However, concentrations of 500 ppm or more