

46162-46195). EPA proposes to allow electronic reporting and electronic recordkeeping under the environmental regulations in Title 40 of the Code of Federal Regulations. It proposes to remove regulatory obstacles to electronic reporting and recordkeeping and sets forth the conditions for the submission of electronic documents or maintenance of electronic records in lieu of paper documents or records. EPA is proposing the rule, in part, under the authority of the Government Paperwork Elimination Act (GPEA) of 1998, Public Law 105-277.

The proposed rule is available electronically on the Internet at <http://www.epa.gov/fedrgstr/EPA-GENERAL/2001/August/Day-31/g21810.htm>. The proposed rule and supporting materials are also available for viewing in the Enforcement and Compliance Docket and Information Center, located at 1200 Pennsylvania Avenue, NW., (Ariel Rios Building), 2nd Floor, Room 2213, Washington, DC 20460. The documents are available for viewing from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling (202) 564-2614 or (202) 564-2119.

Dated: October 18, 2001.

Janette Petersen,

*Acting Director, Collection Services Division,
Office of Information Collection, Office of
Environmental Information.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS-3047-P]

RIN 0938-AK35

Medicare and Medicaid Programs; Fire Safety Requirements for Certain Healthcare Facilities

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

ACTION: Proposed rule.

SUMMARY: This proposed rule replaces the proposed rule of August 1, 1990, on the same subject, which we are withdrawing. This proposed rule would amend the fire safety standards for hospitals, long-term care facilities, intermediate care facilities for the

mentally retarded (ICFs/MR), ambulatory surgery centers (ASCs), hospices which provide in-patient services, religious non-medical health care institutions, and Programs of All-Inclusive Care for the Elderly (PACE) facilities. Further, this proposed rule would adopt the 2000 edition of the Life Safety Code (LSC) and eliminate references in our regulations to all earlier editions.

DATES: In order to ensure that comments will be considered, all comments should be mailed to the appropriate address as provided below, postmarked by December 26, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3047-P, P.O. Box 8018, Baltimore, MD 21244-8010.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses: Hubert H. Humphrey Building, Room 443-G, 200 Independence Avenue, SW, Washington, D.C. 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244.

Because of staffing and resource limitation, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS-3047-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, contact Ms. Freddie Wilder at (410) 786-7195 or (410) 786-0082.

FOR FURTHER INFORMATION CONTACT:

Mayer Zimmerman, 410-786-6839, Jim Merrill, 410-786-6998, or Tamara Syrek, 410-786-3529.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Proposed Rule of August 1, 1990 (55 FR 31196)

On August 1, 1990, we published a proposed rule that would have applied to hospitals, long term care (LTC) facilities, and intermediate care facilities for the mentally retarded (ICFs/MR). It would have eliminated the use of the 1967 and 1973 editions of the Life Safety Code (LSC), which is

updated and published periodically by the National Fire Protection Association (NFPA), a private, non-profit organization created in 1896, dedicated to reducing loss of life and property due to fire. That rule would have required all Medicare and Medicaid participating providers and suppliers subject to the LSC to meet either the 1981 or 1985 edition of the LSC, depending on the date the provider first entered the program. The August 1, 1990 proposed rule did not include references to ambulatory surgery centers (ASCs) or hospices because they were already required to meet either the 1981 or 1985 edition of the LSC. Additionally, no reference was made to Programs of the All-Inclusive Care for the Elderly (PACE) facilities and Religious Non-Medical Health Care Institutions (RNHCIs) because these provider and supplier types did not exist when the August 1, 1990 proposed rule was published. However, in this proposed rule we are proposing PACE and RNHCIs comply with the requirements of the 2000 LSC along with other providers.

We proposed deletion of the 1967 and 1973 editions of the LSC because they relied heavily on "compartmentation," a construction technique that divides buildings into separate compartments or rooms so as to limit the spread of fire and smoke. Moreover, earlier editions of the LSC did not encourage the use of sprinklers. However, subsequent editions of the LSC have encouraged sprinklers and, as a trade-off, less costly construction material may be used if sprinklers are installed. The authors of the newer editions of the LSC no longer believe compartmentation is effective and rely on early detection and extinguishment. Further, every year fewer facilities rely on the concept of compartmentation, and as older, less efficient buildings are upgraded or replaced and newer editions of the LSC are applied, which use early fire detection and extinguishment rather than compartmentation.

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) of the Social Security Act (the Act), and to LTC facilities at sections 1819(d)(2)(B) and 1919(d)(2)(B) of the Act. Currently, the Secretary allows for a waiver to be granted 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. In addition, the Secretary may 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. Application of the FSES for either health care or board and care, as applicable, also mitigated the effects of the proposed rule.

In the August 1, 1990 proposed rule, we relied heavily on our waiver authority, the application of the FSES, and existing regulations "grandfathering" providers that were already in compliance with the 1967 and 1973 editions of the LSC. We asserted that the deletion of the references to the 1967 and 1973 editions of the LSC would not impose an undue burden on most facilities because the 1981 and 1985 LSC updated provisions were minor, and because most facilities would be able to comply with little expense.

B. Analysis of Comments on the August 1, 1990 Proposed Rule

We received 52 timely comments on the August 1, 1990 proposed rule, from nursing homes, State health departments, associations and organizations representing SNFs, NFs, and ICFs/MR. Since we are withdrawing this NPRM, we will not detail each comment and response. We will summarize the major concern those parties raised about the proposed rule and address our approach to meeting this concern in a later section detailing the provisions of this new proposed rule.

A majority of commenters expressed concern regarding the deletion of references to the 1967 and 1973 editions of the LSC, and requested that we codify specific waiver and prior compliance provisions in the regulations to prevent possible arbitrary and inconsistent application of waivers and the FSES. We do not believe it is possible to provide blanket waivers to an entire class of requirements because waivers and the FSES are intended as a response to specific situations and are granted on a case-by-case basis.

C. Decision To Withdraw the August 1, 1990 Proposed Rule

Since the August 1, 1990 proposed rule was published, the 1991, 1994, 1997 and, 2000 editions of the LSC have been published. The 1997 edition has been adopted by the Joint Commission on the Accreditation of Healthcare

Organizations (JCAHO), which accredits over 4,000 hospitals, as well as ASCs, LTC facilities, and hospices that provide inpatient services. In addition, individual States have adopted various editions of the LSC.

The 2000 edition of the LSC includes new provisions that we believe are vital to the health and safety of all beneficiaries. We are not proposing to grandfather any facility under these new provisions because we believe the provisions will not impose an undue burden. This proposed rule is intended to ensure beneficiaries continue to experience the highest degree of fire safety possible.

In addition to developing a notice of proposed rulemaking (NPRM) to adopt the 2000 edition of the LSC, we were intending to propose a more efficient process to allow CMS 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 regulation text and publishing a **Federal Register** notice, instead of a NPRM, each time we planned to adopt the next edition. The **Federal Register** notice would ask for public comment. We worked closely with the Office of Federal Register (OFR) staff and counsel on our draft proposed approach; however, it has become clear that adoption of multiple successive editions of the LSC via reference is not possible. The rationale is that the changes in the future LSCs may be substantial, necessitating that we go through a NPRM and public comment period. Moreover, we can not 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 Office of the Federal Register. Based on this new information we are revising the draft NPRM to propose to adopt the 2000 LSC only.

II. Provisions of the Proposed Regulations

A. General Description

We are proposing to (1) require that all providers and suppliers meet the provisions of the 2000 edition of the LSC with certain exceptions; and (2) delete 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

believe the standards set out in the 2000 edition of the LSC should be met by health care providers, as applicable, depending on provider type.

We are soliciting comments regarding whether to adopt Chapter 5, Performance Based Option, of the LSC. We would like to know (1) are health care facilities using performance based design; and (2) what benefits the facility receives by using performance based design (i.e., better fire safety).

The LSC fire safety goals establish overall outcomes to be achieved with regards to fire safety. These overall outcomes are communicated through specific requirements in the LSC. Performance based design option, Chapter 5, translate 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.

Chapter 19, Existing Health Care Occupancies, Section 19-3.6.3.2 (exception No. 2), roller latches is the only provision of the LSC we propose not to adopt for any provider. 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 number 2, however, allows for the use of roller latches notwithstanding this prohibition, if the latch can withstand a specific level of force applied to it. Nonetheless, we are proposing not to CMS adopt exception No. 2 regarding existing roller latches. Through fire investigations by, roller latches have proven to be an unreliable door latching mechanism requiring extensive maintenance to operate properly. Many roller latches in fire situations failed to provide adequate protection to residents in their rooms during an emergency. The estimated cost to be in compliance with this provision is \$30,754,540 (\$190 per door for 161,866 doors). The cost estimate was derived from information given to us by the American Health Care Association (AHCA).

C. Analysis of Selected New Provisions in the 2000 Edition of the LSC

The following are new provisions in the 2000 edition of the LSC from Chapter 19, "Existing Health Care Occupancies." We are providing the LSC citation, a description of the requirement, an explanation of why we believe it is critical to the safety of beneficiaries to require it, and a brief discussion of our analysis of the burden imposed by the requirement. The cost estimates were derived from information given to us by the American Health Care Association (AHCA).

(1) 19.1.1.4.5—Renovations, Alterations, and Modernization—This provision requires that renovations, alterations, and modernizations must 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 non-sprinklered 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 facilities not undergoing renovations. There is a total of 255 facilities who 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 renovate 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 are phasing in this requirement over a three year period, to allow for the normal replacement cycle of batteries used in emergency lighting systems. We believe this phase-in period will not adversely impact the health and safety of the beneficiaries. The cost to install this equipment is estimated to be \$600 per light. Approximately 790 existing facilities do not have emergency lighting for 1½ hours. To be in compliance we estimate each building will need twelve emergency light units for a total of 9,482

units. This provision will be phased-in over three years. The total amount to implement this provision over a three-year period will be \$5,452,150 or \$1,817,383 annually.

(3) 19.3.1—Protection of vertical openings—Unprotected vertical openings (e.g., 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 will need to be upgraded for compliance. Total cost of compliance of 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/residents. Any delay in the notification of fire or rescue personnel could adversely impact the health and safety of patients/residents and expose them to a fire 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 all areas in non-sprinklered 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 beneficiaries. 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 code. 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/resident-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. The cost to the facility is estimated at \$100 per sleeping room in which patient/resident-owned furniture is located. We estimate approximately 18,498 smoke detectors will need to be installed at a total cost of \$1,849,800.

We are also proposing to retain our existing authority to waive provisions 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. A waiver may be granted for a specific LSC requirement if: (1) We determine that the waiver would not adversely affect patient/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 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. A waiver cannot be granted if patient safety is compromised in any way. A State may request that the State LSC be applicable to all facilities rather than the LSC proposed in this rule. The State must submit the request to the appropriate CMS Regional Office and the Regional Office will forward the request to CMS central office for final determination.

We will also 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 Codes (discussed above) as provided in this proposed regulation.

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

In addition to the proposed changes to the requirements that affect all provider types, as described in sections II. A. and II. B. of this preamble, we propose the following changes which are specific to distinct types of providers:

1. Religious Nonmedical Health Care Institutions: 42 CFR 403.744 Condition of Participation: Life Safety From Fire

We propose to retain the provisions of the existing interim final regulation for Religious Nonmedical Health Care Institutions (RNHCI) published in the **Federal Register** on November 30, 1999 (64 FR 67028), except insofar as they conflict with the 2000 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 of Participation: Environment

For the sake of clarity, we propose to change the terminology in paragraph (b)(1) of 42 CFR 416.44 to reflect that the Life Safety Code refers to ASCs as

Ambulatory Health Care Centers. We propose 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 caring for themselves. We do not believe that the Business Occupancy chapter of the LSC (applied by some authorities having jurisdiction to ASCs treating fewer than 4 patients at a time) affords an adequate level of protection to patients in an ASC.

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

3. Hospices: 42 CFR 418.100(d) Condition of Participation: Hospices That Provide Inpatient Care Directly

We propose 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 propose not to adopt for hospices Chapter 18—Section 3.4.5.3 of the 2000 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 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 detection in new facilities and thus increase the cost of new construction without a parallel increase in safety.

We are also proposing in paragraph (d)(3) to permit a hospice to meet a fire and safety code imposed by the State in lieu of the LSC if we determine that the State code adequately protects patients. We propose 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 propose to delete § 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 Fire Safety Evaluation System (FSES) comparison, which is less stringent than the LSC. We are proposing this for several reasons. This requirement was deleted from the SNF regulations in 1989; however, CMS did not delete it from the parallel hospice regulations. In addition, the provision is redundant since any facility which meets the requirements of the LSC would, by definition, achieve a passing score on the FSES comparison.

4. Programs of All-Inclusive Care for the Elderly: 42 CFR 460.72 Condition of Participation: Physical Environment

We propose to retain most of the provisions of the existing interim final regulation for Programs of All-Inclusive Care for the Elderly (PACE) published in the **Federal Register** on November 24, 1999 (64 FR 66234). PACE providers will continue to be required to meet LSC specifications for the type of facilities in which the programs are located (i.e., hospitals, office buildings, etc.).

We are proposing to require the PACE center to 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.

Moreover, we propose to retain paragraph (b)(2)(i) of 42 CFR 460.72, which permits a PACE center to meet fire and safety requirements imposed by the State in lieu 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 propose to retain paragraph (b)(2)(ii), which allows for the waiver of specific provisions of the LSC which, if rigidly applied, might 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 participants and staff.

5. Hospitals: 42 CFR 482.41 Condition of Participation: Physical Environment

We propose 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 propose not to adopt Chapter 18—Section 3.4.5.3 of the 2000 LSC for long term care (LTC) facilities such as skilled nursing facilities (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 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. Further, 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 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

We propose to retain most of the provisions of the existing regulation for Intermediate Care Facilities for the Mentally Retarded (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 Life Safety Code, as appropriate.

We propose to retain the provision in paragraph (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 propose 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 propose to delete from paragraph (j)(1)(iii) the reference to Appendix F, since 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 propose to delete the reference to facilities of 16 beds or less from this paragraph 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 paragraph (j)(2)(ii), we propose to change "the Secretary" to "CMS" to more accurately reflect the statutory authority (this provision currently appears in paragraph (j)(2)(i)(B)).

We propose in paragraph (j)(3) that waivers of specific provisions 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. Regulatory Impact Statement

This proposed rule, adopting the 2000 edition of the LSC, whose 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 people, both staff and beneficiaries. The 2000 edition of the LSC also protects property and can reduce the dollar loss associated with a fire. For example, this edition of the LSC requires that any new construction must install quick response sprinkler systems increasing the level of protection to our beneficiaries. By

adopting the 2000 edition of the LSC and deleting references to all older editions of the LSC this will decrease confusion. Currently, the provider community must comply with a variety of editions of the LSC. By adopting the 2000 edition of the LSC we will eliminate any 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/additions constructed at different times. Instead of each building complying with different editions of the LSC, the proposed rule will require 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.

We have examined the impact of this proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96-354). This proposed 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. Therefore, an initial regulatory impact analysis is not required.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when 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 annually). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million to \$25 million or less annually (see 65 FR 69432).

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that 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 603 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.

There are several reasons it was determined that this rule will not meet the criteria to be considered economically significant, or the criteria for a major rule. Each new edition of the LSC builds on prior editions, changes from one edition to the next have been relatively minor since 1985. The 1985 Code, for the first time, required newly constructed facilities which met the health care occupancy requirements and which were over 75 feet or higher to be fully equipped with sprinklers. The 1991, 1994, 1997 and 2000 editions require mandatory universal sprinklers in new construction for health care occupancies. While we do not know how many new facilities will be built under this requirement, the provision of sprinkler systems in health care facilities is standard practice today. In addition, for those facilities constructed prior to 1985, the use of the FSES and Secretary approved waivers has enabled older buildings to meet requirements that ensure patient safety from fire without undue cost burdens on providers. The vast majority of facilities that needed to make major physical environment changes to comply with LSC requirements have long since done so or are no longer in service. We estimate the annual regulatory impact of this rule to be approximately \$96,356,599. While \$96 million seems high, this cost does not take into account any waiver the Secretary may grant to waive provisions of the LSC. We are proposing to retain the existing authority of the Secretary to waive provisions 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 which the Secretary determines will not endanger the health and safety of patients. We also note that the 2000 LSC permits the use of the FSES as an alternative approach which may also reduce the cost of compliance significantly. The FSES is an equivalency design 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 this may save a health care facility because each facility must be reviewed individually to determine compliance under the FSES.

Finally, the cost does not estimate any reductions if the Secretary accepts a State's fire and safety code instead of the NFPA's LSC if the State's fire and safety code adequately protects patients. The cost we estimated, \$96 million, for

all health care facilities to come into compliance with the 2000 LSC is the total cost without factoring in any waivers that may be granted which could significantly reduce the total amount to the industry.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year. This rule will not have an effect on the governments mentioned, and the private sector costs will not be greater than the \$100 million threshold.

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

IV. Federalism

Executive Order 13132 establishes requirements an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this final rule and have determined that this final rule will not have a substantial direct impact on the rights, rules and responsibilities of State, local or tribal governments.

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.).

List of Subjects in 42 CFR

Part 403

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

Part 416

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

Part 460

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

Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

For the reasons set forth in the preamble, 42 CFR Chapter IV would be amended as follows:

PART 403—RELIGIOUS NON-MEDICAL HEALTH CARE INSTITUTIONS

A. Part 403 is amended as set forth below:

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 E—Conditions of Participation: Other Services

2. Amend § 403.744 as follows:

- a. The introductory text to paragraph (a) is republished.
- b. Paragraph (a)(1) is revised.

§ 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 new or existing health care occupancies 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, Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish a notice in the **Federal Register** to announce the changes.) The following provisions of the adopted Life Safety Code do not apply to an RNHCI:

- (i) Chapter 5—Performance Based Option.
- (ii) Chapter 19.3.6.3.2, exception number 2.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

B. Part 416 is amended as set forth below:

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. Amend § 416.44 by revising paragraphs (b)(1) and (b)(3) to read as follows:

§ 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 (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter), regardless of the number of patients served. The following provisions of the adopted edition of the LSC do not apply to an ASC:

- (i) Chapter 5—Performance Based Option.
- (ii) Chapter 19.3.6.3.2, exception number 2.

* * * * *

(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.

* * * * *

PART 418—HOSPICE CARE

C. Part 418 is amended as set forth below:

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. Amend § 418.100 as follows:

- a. Paragraphs (d)(1) and (d)(3) are revised.
- b. Paragraph (d)(4) is removed.

§ 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 (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter), regardless of the number of patients served. The following provisions of the adopted edition of the LSC do not apply to a hospice:

(i) Chapter 5—Performance Based Option.

(ii) Chapter 18.3.4.5.3.

(iii) Chapter 19.3.6.3.2, exception number 2.

* * * * *

(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 hospices.

* * * * *

PART 460—PROGRAMS FOR ALL-INCLUSIVE CARE FOR THE ELDERLY

D. Part 460 is amended as set forth below:

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. Revise § 460.72(b)(1) to read as follows:

§ 460.72 Physical Environment.

* * * * *

(b) *Fire safety*—(1) *General rule.* (i) Except as otherwise provided in this section, a PACE center must meet the occupancy provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter) that apply to the type of setting in which the center is located.

(ii) The following provisions of the adopted edition of the LSC do not apply to PACE centers:

(A) Chapter 5—Performance Based Option.

(B) Chapter 19.3.6.3.2, exception number 2.

* * * * *

Subchapter E—Standards and Certification

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

E. Part 482 is amended as set forth below:

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. Amend § 482.41 by revising paragraph (b)(1) to read as follows:

§ 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 (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter).

(i) The following provisions of the adopted edition of the LSC do not apply to hospitals:

(A) Chapter 5—Performance Based Option.

(B) Chapter 19.3.6.3.2, exception number 2.

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PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

F. Part 483 is amended as set forth below:

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. Amend § 483.70 by revising paragraph (a)(1) to read as follows:

§ 483.70 Physical environment.

* * * * *

(a) *Life safety from fire.* (1) 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 (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter). The following provisions of the adopted edition of the LSC do not apply to long term care facilities:

(i) Chapter 5—Performance Based Option.

(ii) Chapter 18.3.4.5.3.

(iii) Chapter 19.3.6.3.2, exception number 2.

* * * * *

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

3. Amend § 483.470 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 (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter).

* * * * *

(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 (FSSES/BC).

(2) *Exceptions for all facilities.* (i) The following provisions of the adopted LSC do not apply to a facility:

(A) Chapter 5—Performance Based Option.

(B) Chapter 19.3.6.3.2, exception number 2.

(ii) If CMS finds that the State has a 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.

(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; and

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

(ii) [Reserved]

* * * * *

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395). (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: September 17, 2001.

Thomas A. Scully,
Administrator, Centers for Medicare &
Medicaid Services.

Dated: October 1, 2001.

Tommy G. Thompson,
Secretary.

[FR Doc. 01-25422 Filed 10-25-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 408

[CMS-4007-P]

RIN 0938-AK42

Medicare Program; Supplementary Medical Insurance Premium Surcharge Agreements

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement legislation contained in section 1839(e) of the Social Security Act, as amended by section 144 of the Social Security Act Amendments of 1994 and section 4582 of the Balanced Budget Act of 1997. That legislation created a new Medicare premium payment arrangement whereby States and local government agencies can enter into an agreement with the Secretary to make periodic lump sum payments for the Supplementary Medical Insurance (SMI) late enrollment premium surcharge amounts due for a designated group of eligible enrollees. Under this proposal, we would define and set out the basic rules for the new SMI premium surcharge billing agreement.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 26, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4007-P, P.O. Box 8013, Baltimore, MD 21244-8013.

If you prefer, you may deliver, by courier, your written comments (one original and three copies) to one of the following addresses:

Hubert H. Humphrey Building, Room 443-G, 200 Independence Avenue, SW, Washington, DC 20201, or

Centers for Medicare and Medicaid Services, C5-14-03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to those addresses designated for courier delivery may be delayed and could be considered late. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Please refer to file code CMS-4007-P on each comment.

Comments received timely will be available for public inspection as they are received, beginning approximately 3 weeks after publication of this document, in room C5-12-08 of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, Monday through Friday of each week from 8:30 a.m. to 5 p.m. Please call (410) 786-7197 to make an appointment to view comments.

FOR FURTHER INFORMATION CONTACT:
Sandy Clarke, (410) 786-7451.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1839(e) of the Social Security Act (the Act), as amended by section 144 of the Social Security Act Amendments of 1994 (Pub. L. 103-432, October 31, 1994), allows States to enter into agreements with us to pay a lump sum for the Part B premium late enrollment surcharge amounts due for a designated group of eligible enrollees. Section 4582 of the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA) amended the Act by adding new language that allows local government agencies to also pay the surcharge. Under section 4582 of the BBA, any appropriate State or local government agency specified by the Secretary may enter into a Supplementary Medical Insurance (SMI) premium surcharge agreement.

This legislation was requested to enable State and local government agencies that are discontinuing to offer a health benefits package to their retirees, and requesting that the retirees utilize Medicare for their health insurance, to pay the ensuing SMI premium surcharge on a lump sum basis.

While covered by the State or local government agency health care plans, some retirees, who believed that these health plans were sufficient to cover their health care needs, chose not to enroll in Medicare when they first became eligible, or enrolled and subsequently canceled their Medicare coverage. When these retirees were notified by their State or local

government agency retirement offices that those agencies would no longer offer a health benefit package (and that it therefore would be necessary for the retirees to enroll or reenroll in Medicare) they learned that they were subject to the late enrollment premium surcharge. State and local government agency retirement offices contacted us and requested either a waiver of the surcharge or establishment of a special enrollment period for the affected retirees. We denied these requests and determined that the affected retirees were subject to the late enrollment premium surcharge. This prompted some State and local government agency retirement offices to offer to pay the surcharge portion of the Supplementary Medical Insurance premium on behalf of their affected retirees. It also prompted a request from a local government agency to enter into a special billing and payment arrangement with us in order periodically to receive a single bill and pay a lump sum for the surcharge amounts due from a specified group of its retirees.

Since there was no law or regulation in place that would have allowed us to send a State or local government agency a single bill to pay a lump sum for the SMI premium surcharge portion for a group of enrollees, we initially denied the request. Subsequently, the Congress enacted legislation that allowed States to pay the Secretary, on a quarterly or other periodic basis, a lump sum for the total amount of the SMI premium surcharges for a group of Medicare enrollees (section 1839(e) of the Act, section 144 of the Social Security Act Amendments (Pub. L. 103-432)). Section 4582 of the BBA subsequently amended section 1839(e) of the Act by adding language that would also allow any appropriate State or local government agency specified by the Secretary to enter into an agreement to pay the SMI premium surcharges on a periodic lump sum basis. Because the CMS third party billing system, which will be used for billing and payment of these surcharge amounts, was developed to accommodate monthly billing and payments, all SMI premium surcharge amounts would be billed and paid on a monthly basis.

The election to make lump sum payments of SMI premium surcharges by a State or local government agency under an SMI premium surcharge agreement would be strictly voluntary and would be provided as a convenience to the State or local government agency.