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

Baltimore, Maryland 21244-1850



# Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-04

**DATE:** October 3, 2008

**TO:** State Survey Agency Directors

**FROM:** Director

Survey and Certification Group

**SUBJECT:** Adoption of New Fire Safety Requirements for Long Term Care Facilities,

Mandatory Sprinkler Installation Requirement

# **Memorandum Summary**

- On August 13, 2008, the Centers for Medicare & Medicaid Services (CMS)
  published a final rule entitled "Medicare and Medicaid Programs; Fire Safety
  Requirements for Long Term Care Facilities, Automatic Sprinkler Systems."
- This regulation requires all long term care facilities to be equipped with a supervised automatic sprinkler system by August 13, 2013, installed in accordance with the 1999 edition of the National Fire Protection Association's (NFPA) "Standard for the Installation of Sprinkler Systems" (NFPA 13).
- Facilities with existing sprinkler systems should review their sprinkler systems to determine if they meet the requirements of the 1999 edition of NFPA 13.

The purpose of this memorandum is to notify States and regional offices (ROs) of the publication on August 13, 2008, in the Federal Register (73 FR 47075), of a final rule entitled "Medicare and Medicaid Programs; Fire Safety Requirements for Long Term Care Facilities, Automatic Sprinkler Systems" with an effective date of October 14, 2008. A copy of the regulation is attached.

This regulation requires all long term care facilities (Skilled Nursing Facilities/Nursing Facilities) to be equipped with a supervised automatic sprinkler system by August 13, 2013, installed in accordance with the 1999 edition of the National Fire Protection Association's (NFPA) "Standard for the Installation of Sprinkler Systems" (NFPA 13). The regulation also requires that all long term care facilities inspect, test and maintain all sprinkler systems (both newly installed and existing systems) in accordance with the 1998 edition of NFPA "Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems" (NFPA 25). This regulation is also applicable to distinct part nursing home units located in hospitals.

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Facilities with existing sprinkler systems should review their sprinkler system to determine if they meet the requirements of the 1999 edition of NFPA 13. This includes for example, the requirements for closets, walk in coolers/freezers, overhangs, loading docks and shafts to have sprinkler coverage. They should also review there inspection, testing and maintenance program to determine if it is meeting the requirements found in the 1998 edition of NFPA 25.

Facilities that currently have no sprinkler system or partial sprinkler systems installed, use waivers or the Fire Safety Evaluation System (FSES) to comply with previous sprinkler requirements have until August 13, 2013 to install or upgrade their existing sprinkler system to meet the requirements of the 1999 edition of NFPA 13. All installation work is expected to be complete by August 13, 2013, as there are no provisions in the regulation to extend the timeframe for regulatory compliance beyond August 13, 2013, either through waivers or the use of the FSES.

CMS will continue to document the status of sprinkler installation of a facility as currently is being done by categorizing the amount of sprinkler protection as Fully, Partially, and Nonsprinklered.

Facilities that were required to install battery powered smoke alarms are required to maintain them until such time as a complete automatic sprinkler system has been installed in accordance with NFPA 13.

We will be providing additional information as it becomes available. If you have questions concerning this memorandum, please contact James Merrill (James.Merrill@cms.hhs.gov).

**Effective Date:** All long term care facilities referenced in this rule must comply with the requirements by August 13, 2013.

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

/s/ Thomas E. Hamilton

cc: Survey and Certification Regional Office Management State Fire Authorities

Attachment

Dated: July 31, 2008.

#### Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.439 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

### §180.439 Thifensulfuron methyl; tolerances for residues.

(a) \* \* \*

| Commodity          | Par | ts per millior | า    |
|--------------------|-----|----------------|------|
| * *                | *   | *              | *    |
| Barley, hay        | *   | *              | 0.8  |
| Oat, forage        | *   | *              | 0.2  |
| Oat, hay           | *   | *              | 0.05 |
| Wheat, for-<br>age | *   | *              | 2.5  |
| Wheat, hay         | *   | *              | 0.7  |

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid** Services

42 CFR Part 483

[CMS-3191-F]

RIN 0938-AN79

Medicare and Medicaid Programs; Fire Safety Requirements for Long Term Care Facilities, Automatic Sprinkler **Systems** 

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

**ACTION:** Final rule.

**SUMMARY:** This final rule requires all long term care facilities to be equipped with sprinkler systems by August 13, 2013. Additionally, this final rule

requires affected facilities to maintain their automatic sprinkler systems once they are installed.

**DATES:** These regulations are effective on October 14, 2008. The incorporation by reference listed in the rule is approved by the Director of the Federal Register October 14, 2008.

FOR FURTHER INFORMATION CONTACT: Danielle Shearer, (410) 786-6617; James Merrill, (410) 786-6998; Marcia Newton, (410) 786-5265; or Jeannie Miller, (410) 786-3164.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

A. Overview of the Life Safety Code

The Life Safety Code (LSC), published by the National Fire Protection Association (NFPA), a private, nonprofit organization dedicated to reducing loss of life due to fire, is a compilation of fire safety requirements. The LSC contains fire safety requirements for both new and existing buildings. It is updated through a consensus process and generally published every 3 years. Sections 1819(d)(2)(B) and 1919(d)(2)(B)of the Social Security Act (the Act) require that long term care facilities participating in the Medicare and Medicaid programs generally meet the applicable provisions of the edition of the LSC that is adopted by the Secretary.

Beginning with the adoption of the 1967 edition of the LSC in 1971, Medicare and Medicaid regulations have historically incorporated the LSC requirements by reference for all long term care facilities as well as other providers, while providing the opportunity for a Secretarial waiver of a requirement under certain circumstances. The statutory basis for incorporating NFPA's LSC for our other providers is under the Secretary's general rulemaking authority at sections 1102 and 1871 of the Act, and under provider-specific provisions of title XVIII that permit us to issue regulations to protect the health and safety of participants in Medicare and Medicaid.

We adopted the LSC to ensure that patients and residents are consistently protected from fire, regardless of the location in which they receive care. Since adopting and enforcing the 1967 and subsequent editions of the LSC, there has been a significant decline in the number of multiple death fires, indicating that the LSC has been effective in improving fire safety in health care facilities.

On October 26, 2001, we published a proposed rule (66 FR 54179), and on January 10, 2003, we published a final rule in the Federal Register, entitled "Fire Safety Requirements for Certain

Health Care Facilities" (68 FR 1374). In that final rule, we adopted the 2000 edition of the LSC provisions as the standard governing Medicare and Medicaid health care facilities, including long term care facilities. The final rule required all existing long term care facilities to comply with the 2000 edition of the LSC.

The 2000 edition of the LSC required all newly constructed buildings containing health care facilities to have an automatic sprinkler system installed throughout the building. However, like all previous editions, the LSC did not require existing buildings to install automatic sprinkler systems throughout if they met certain construction standards, ranging from the size of the buildings to the types of material used

in their construction.

In accordance with the 2000 edition of the LSC, an existing building that meets the above-mentioned construction standards must install sprinklers if it undergoes a major renovation. However, in such cases, it is required to install sprinklers only in the renovated section(s). Therefore, a building may have sprinklers only on one floor or in one wing. We did not receive any timely public comments in response to the October 2001 proposed rule that addressed the issue of installing automatic sprinkler systems in buildings not undergoing major renovations. That is to say, no public comments supported, questioned or challenged our proposal to incorporate this LSC provision by reference.

In the 2006 edition of the LSC, the NFPA decided to include an automatic sprinkler system requirement for all long term care facilities. We support the NFPA in its decision. We decided to proceed with this rule, without proposing adoption of the NFPA 2006 edition of the LSC, because we want to avoid further delay in requiring an automatic sprinkler system in long term care facilities. As stated in the October 27, 2006 proposed rule (71 FR 62957, 62960), given the large scope of the LSC, we would not be able to adopt and enforce compliance with the 2006 edition of the LSC until 2009 or 2010. Therefore, we decided at this time to proceed with rulemaking that does not include adoption of the NFPA 2006

We will continue to work with the NFPA to revise and refine each edition of the LSC. We are currently working with the NFPA through its consensus process to revise and refine the 2009 edition of the LSC. Once the 2009 edition is issued, we will review the code in its entirety and explore the possibility of adopting it for all

Medicare and Medicaid-participating health care facilities.

## B. Recent Fire Safety Developments

A Government Accountability Office (GAO) report entitled "Nursing Home Fire Safety: Recent Fires Highlight Weaknesses in Federal Standards and Oversight" (GAO-04-660, July 16, 2004, http://www.gao.gov/new.items/ d04660.pdf) examined two long term care facility fires (Hartford and Nashville) in 2003 that resulted in 31 total resident deaths. The report examined Federal fire safety standards and enforcement procedures, as well as results from the fire investigations of these two incidents. The report recommended that fire safety standards for unsprinklered facilities be strengthened and the report cited the effectiveness of smoke detectors' and sprinklers' fire protection features for long term care facilities.

In response to a recommendation made in the GAO report, on March 25, 2005, we published an interim final rule with comment period in the Federal Register entitled, "Fire Safety Requirements for Certain Health Care Facilities; Amendment" (70 FR 15229). This interim final rule added paragraph (a)(7) to  $\S 483.70$ , to require long term care facilities, at minimum, to install battery-operated smoke detectors in resident sleeping rooms and public areas, unless they had a hard-wired smoke detector system in resident rooms and public areas or a sprinkler system installed throughout the facility. This IFC was finalized September 22, 2006 (71 FR 55326).

Structural fires in long term care facilities are relatively common events. From 1994 to 1999, an average of 2,300 long term care facilities reported a structural fire each year (2004 GAO Report). Although approximately 2,300 facilities per year reported fires, those fires resulted in an average of only 5 fatalities nationwide per year (2004 GAO Report). The likelihood of a fatality occurring due to a long term care facility fire was quite low.

From 1990 to 2002, there were no fires in long term care facilities that resulted in more than one or two fatalities. During that time period there were no fires in long term care facilities that resulted in a loss of life comparable to that of the Hartford and Nashville fires.

We believe the low number of firerelated fatalities each year is attributable, in part, to the increasing use of automatic sprinkler systems in long term care facilities as a fire protection method. State and local jurisdictions often adopt an edition of

the LSC or a comparable fire safety code shortly after it is published. Therefore, a building constructed in the early 1990s likely met the requirements of the 1991 edition of the LSC or another comparable code. Beginning with the 1991 edition of the LSC, all newly built facilities were required to have automatic sprinkler systems. In addition, beginning with the 1991 edition of the LSC, all facilities undergoing major renovations were also required by the LSC to install automatic sprinkler systems at least in those renovated areas. Therefore, as new facilities have replaced old facilities, and as facilities have been renovated, the number of residents protected by automatic sprinkler systems has increased. The increase in the number of automatic sprinkler systems and the number of residents residing in sprinklered buildings has decreased significantly the likelihood of a fatality occurring due to fire.

According to NFPA data cited in the 2004 GAO report, there is an 82 percent reduction in the chance of death occurring in a sprinklered building when compared to the chance of death occurring in an unsprinklered building. In addition, we note that there has never been a multiple death fire in a long term care facility that had an automatic sprinkler system installed throughout the facility.

Automatic sprinkler systems are effective in reducing the risk of fatalities due to fire because they limit the size of a developing fire and prevent the fire from growing and spreading beyond the area where the fire ignited. In addition, impeding the fire's growth gives the facility staff and residents and the local fire department more time to respond to the situation.

Automatic fire suppression through sprinklers also alleviates some of the current heavy reliance on facility staff to implement the facility's emergency plan. Fires often occur at night, as both the Hartford and Tennessee fires did, when staffing levels are lowest. Investigators of the Hartford fire determined that the facility's staff did not fully implement the facility's emergency plan, which may have contributed to the number of fatalities in that fire. The 2004 GAO report concluded that "reliance on staff response as a key component of fire protection may not always be realistic, particularly in an unsprinklered facility." Limiting the area of a building affected by a fire may result in less of a need to evacuate or relocate residents.

The effectiveness of automatic sprinkler systems has prompted some States, including Virginia, Connecticut, and Tennessee, to require that all long term care facilities have sprinklers. The NFPA also requires all long term care facilities to have automatic sprinkler systems as part of the 2006 edition of the LSC

# II. Provisions of the Proposed Regulations

We published a proposed rule in the **Federal Register** on October 27, 2006 (71 FR 62957) that would require all long term care facilities to be equipped with sprinkler systems. That proposed rule also requested public comments on the duration of a phase-in period to allow such facilities to install such systems.

For the reasons described in section I of this preamble, we proposed a rule with three main components. First, the regulation proposed to add a sunset provision to paragraph (a)(7) in § 483.70 that would correspond to the phase-in date of the sprinkler requirement. This sunset provision would provide that, as of the phase-in date, we would no longer enforce the requirement that facilities have and maintain at least battery-operated smoke alarms. We proposed to add the sunset date because the requirements of § 483.70(a)(7) apply only to unsprinklered and partially sprinklered long term care facilities. Once all long term care facilities are fully sprinklered, there would not be any unsprinklered or partially sprinklered facilities to which § 483.70(a)(7) would apply.

Second, we proposed to require every long term care facility to install an approved, supervised automatic sprinkler system in accordance with the 1999 edition of NFPA 13, Standard for the Installation of Sprinkler Systems, throughout the facility if it did not have such a system already. If a long term care facility was part of another building, such as a hospital, then the building would be required to have sprinklers only in the long term care facility section. The NFPA 13 specifies how to properly design and install sprinkler systems using the proper components. The standards of NFPA 13 cover a wide variety of factors that are involved in designing and installing sprinkler systems. The NFPA 13 is divided into 10 main chapters governing the design and installation phases of automatic sprinkler systems, and the October 2006 proposed rule summarized the content of these chapters.

The NFPA 13 is a very detailed document, with a wide variety of standards and exceptions to those standards. The document provides many options for the design and

installation of sprinkler systems so that each system may be tailored to the building in which it is installed.

Third, the regulation proposed to require every long term care facility to test, inspect, and maintain an approved, supervised automatic sprinkler system in accordance with the 1998 edition of NFPA 25, Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems. Proper inspections, tests, and maintenance of sprinkler systems are critical to ensuring that sprinkler systems function properly on a continuous basis. Fires are, by nature, unpredictable, and sprinkler systems must be operable at all times to ensure that buildings are protected whenever and wherever fires occur. NFPA 25 covers a wide variety of testing, inspection, and maintenance requirements for the numerous types of sprinkler systems that facilities may install and the auxiliary equipment that may be necessary for some facilities. We summarized the content of NFPA 25 in the proposed rule.

The proposed requirements of this regulation include three technical terms: "approved," "automatic," and "supervised." These terms are terms of art in the fire safety community and are included in NFPA 101, *Life Safety Code*, with which long term care facilities must already comply. There may be, however, individuals who are not familiar with the terms. Their definitions, as used in the fire safety community, are as follows:

• Approved means acceptable to the authority having jurisdiction (from 2000 edition of NFPA 101, the LSC).

 Automatic means that which provides a function without the necessity of human intervention (from 2000 edition of NFPA 101, the LSC).

• Supervised means that the system and particular components of the system are monitored by a device with auditory and visual signals that are capable of alerting facility staff should the system or one of its components become inoperable for any reason (adapted from 1999 edition of NFPA 13, Standard for the Installation of Sprinkler Systems).

# III. Analysis of and Responses to Public Comments

We received 107 comments from the public on the October 27, 2006 proposed rule. The comments received and our responses to those comments are discussed below.

Comment: The vast majority of commenters strongly supported our intent to require automatic sprinkler systems throughout all long term care facilities. Conversely, a small minority of commenters disagreed with the proposed rule, citing the expense of purchasing and installing sprinklers and the availability of other fire safety features such as water-based fire-proof coatings and fire walls as reasons for not requiring sprinklers in all long term care facilities.

Response: We appreciate the strong support expressed by most commenters. While we agree that there are other methods for improving fire safety in long term care facilities, these other methods do not achieve the same high level of fire safety as automatic sprinkler systems. We are proceeding with this final rule requiring all long term care facilities to install and maintain automatic sprinkler systems because we agree with the GAO that such systems are the single most effective fire safety method currently available and that the presence of such systems will help save lives and property.

Comment: Several commenters submitted comments related to the specific facilities that are, or should be, affected by this final rule. One commenter explicitly supported our decision to apply the proposed sprinkler requirements to all affected long term care facilities, regardless of their size. Some commenters requested that this rule be expanded to apply to any residential facility that cares for individuals on a 24-hour basis. One commenter suggested that the rule should apply to federally operated nursing homes as well, such as those operated by the U.S. Department of Veterans Affairs. Another commenter suggested that the rule should apply to inpatient facilities such as hospitals and critical access hospitals with swing beds. Still other commenters asked whether the requirements of the final rule will affect adult day care centers.

Response: We proposed to require all long term care facilities to install automatic sprinkler systems regardless of their size because their recent fire history and current staffing levels indicated the need for additional fire safety features. We do not believe it is necessary for us to require sprinkler systems in other facility types, such as intermediate care facilities, adult day care facilities, or critical access hospitals at this time because there is no demonstrated need for such regulation. While we agree that it may be appropriate for federally operated nursing homes, such as those operated by the U.S. Department of Veterans Affairs, to install automatic sprinkler systems, we do not have regulatory authority over these facilities. Therefore, we are unable to promulgate a regulation applying to them.

Comment: Numerous commenters discussed the financial impact that the proposed rule will have on long term care facilities, and suggested a variety of methods to offset the expected impact. Of these commenters, several suggested that CMS should support legislation in the Congress that will provide financial incentives for long term care facilities to install sprinkler systems. A few commenters indicated that they are actively working with the Congress to obtain financial assistance for long term care facilities in implementing the requirements of this final rule. Other commenters suggested that CMS should make financial assistance available to facilities, with some suggesting that such assistance should be limited to those facilities with not-for-profit status or those that are not profitable. Still another commenter suggested that CMS should compel State Medicaid programs to increase reimbursement rates to fund capital improvements in long term care facilities.

Response: We recognize that purchasing and installing an automatic sprinkler system throughout a long term care facility requires a substantial capital investment. We defer to the Congress and States to provide financial assistance to long term care facilities to complete the purchase and installation process, whether such assistance comes in the form of loans, grants, tax relief, and/or increased reimbursement rates.

We have included a 5 year phase-in period in this final rule. This phase-in period allows facilities the time and flexibility to install sprinkler systems in a manner that is sensitive to the individual circumstances of each facility. We believe this phase-in period will help mitigate the financial impact of this final rule.

Comment: Numerous commenters stated that this final rule should provide additional discussion of the role that State and locally imposed building and fire safety codes play in protecting long term care facility residents.

Response: We acknowledge that State and local authorities use their authority to require long term care facilities to meet building and fire safety codes independent of the codes applied to facilities through Federal regulations. State and local authorities often adopt more recent editions of such codes than those required by Federal rules. Until 2003, Federal fire safety regulations referenced simultaneously Life Safety Code provisions from several editions including the editions of 1967, 1973, and 1985. However, health care facilities were not being built to these older standards because State and local jurisdictions adopted and enforced far

more recent editions of building and fire safety codes. Such prompt adoption of updated codes by State and local jurisdictions likely has led to the large number of long term care facilities that currently have automatic sprinkler systems throughout their facilities. We continue to support the right of State and local authorities to impose building and fire safety codes independent of these Federal requirements and will continue to monitor all efforts to improve safety for long term care facility residents.

Comment: Some commenters expressed concern that this final rule will preempt State and local fire safety requirements. Of these commenters, a few expressed concern that this Federal rulemaking preempted State and local efforts and did not respond to the unique needs of different localities. Furthermore, some of these commenters requested a more detailed discussion of Executive Order 13132 (Federalism) as it relates to this rulemaking action. Conversely, several commenters indicated that they agreed with our conclusion that this rule is in accordance with the actions of State and local governments, and that it is appropriate for the Federal government to require automatic sprinkler systems in Medicare and Medicaid-participating long term care facilities.

Response: The Federal regulations for long term care facilities are considered to be the minimum standards that a facility must meet in order to participate in the Medicare and Medicaid programs. As such, they will not preempt more stringent State and local requirements. For example, if a State or local authority requires a long term care facility to install an automatic sprinkler system within 3 years after adoption of a law requiring it, then a facility must comply with that shorter time frame, even though this Federal regulation allows a facility up to 5 years to install an automatic sprinkler system. However, if a State or local authority requires a long term care facility to install an automatic sprinkler system only in hazardous areas, then a facility must go beyond the State or local requirement and install an automatic sprinkler system throughout its building in order to participate in Medicare or Medicaid. We believe that all facilities must install an automatic sprinkler system throughout a facility by 2013, regardless of the State or locality where a facility is located. In order to achieve this goal, it is necessary to promulgate a Federal regulation. State and local jurisdictions have always had the authority to require automatic sprinkler systems in existing long term care facilities. However, few States have

taken action to require existing long term care facilities to retrofit their buildings with such systems. Thus, we believe it is necessary to take this Federal action.

In addition, this rule adopts the sprinkler installation and maintenance requirements established by the NFPA. The NFPA is a national standard setting body with representatives from all members of the fire safety community, including State and local jurisdictions. As such, these representatives had active input in the content and framework of the NFPA sprinkler standards. The standards allow flexibility in the design, installation, and maintenance of sprinkler systems to adapt to the needs of individual facilities as well as jurisdictions. Facilities are required by the NFPA standards to submit their design and installation plans to the appropriate authorities having jurisdiction. This allows local and State authorities the opportunity to ensure that such plans meet their individual needs. Since this action does not impinge upon a State or local jurisdiction's authority to impose more stringent fire safety requirements upon long term care facilities in response to the unique needs and concerns of the particular area, and gives State and local authorities the opportunity to provide further input into individual sprinkler planning activities, we do not believe this final rule has Federalism implications as described in Executive Order 13132.

Furthermore, we regularly communicate with State and local officials and with the long term care provider community through Open Door Forums, as well as through responses to letters, informal phone calls, and informal e-mails. Through these communications, as well as through the public comment process for this proposed rule, we believe we have sufficiently consulted with all affected parties, including State and local jurisdictions, as is required by Executive Order 13132.

Comment: Several commenters submitted views regarding the assumptions and estimates we used in the impact analysis for the proposed rule. Commenters questioned our estimates of the cost per square foot, the projected number of facilities affected, and the projected number of lives saved.

Response: We appreciate the suggestions that we received, and we considered them as we revised the impact analysis for this final rule. The final impact analysis reflects an increase in our estimate of the cost per square foot, from a high of \$6.10 to a high of \$7.95, to reflect inflation since the

publication of the proposed rule. The final analysis also revises the number of facilities that are affected by this rule by replacing projections of future sprinkler system installations with the actual number of facilities lacking automatic sprinkler systems as of December 2007. The final impact analysis does not revise the method for estimating future lives saved by this rule. Although a commenter questioned this methodology, the commenter did not offer an alternative methodology that would more accurately estimate this number. Since we are not aware of an alternative method to estimate the number of lives that will be saved, we have retained the method used in the proposed rule.

Comment: Some commenters agreed with our proposal to require automatic sprinkler systems in all facilities, while a small number of commenters requested that certain long term care facilities be exempt from the requirements of this final rule.

Response: Automatic sprinkler systems are generally considered to be the single most effective fire protection feature in a building. As such, we believe all long term care facilities, regardless of their size or location in relationship to another type of health care facility, should be required to have sprinklers. Exempting a particular class of long term care facilities, regardless of the criteria used, will not provide a consistent level of fire safety across the country.

Comment: Several commenters submitted comments regarding CMS enforcement of this final rule. Some of these commenters sought assurance that surveyors would be appropriately trained to enforce the new sprinkler requirement. One commenter suggested that we should survey each facility annually to ensure compliance with this rule. Other commenters asked about the enforcement remedies that would be available if a facility was non-compliant with the requirements of this final rule, going so far as to suggest that noncompliant facilities should receive reduced payments from Medicare and Medicaid. Still other commenters requested that additional information about the sprinkler status of particular facilities and facilities as a whole be included on CMS' Nursing Home Compare Web site.

Response: We agree that it is essential to ensure that surveyors are appropriately trained to survey facilities for compliance with all fire safety requirements, including automatic sprinkler systems. To that end, we conduct annual training sessions for surveyors to educate them on, among

other things, fire safety requirements and appropriate survey procedures. This training ensures surveyor competency in this area. We also agree that frequent surveys of long term care facilities are key to ensuring continued compliance with these requirements. By law, we are required to survey long term care facilities every 15 months to ensure compliance with all health and safety requirements, and we will incorporate this new requirement into the existing survey process. If a facility is found to be non-compliant with the provisions of this final rule, we have the full complement of enforcement remedies available to ensure that a facility comes into compliance. In addition to termination of the provider agreement, available remedies include the following: (1) Temporary management (that is, the temporary appointment by CMS or the State of a temporary director or administrator of a facility); (2) denial of payment, including denial of payment for all individuals, imposed by CMS upon a skilled nursing facility for Medicare payments, by a State for Medicaid payments, or denial of payment for all new admissions; (3) civil money penalties; (4) State monitoring; (5) transfer of residents; or (6) transfer of residents and closure of the facility. CMS currently includes information about a facility's sprinkler status on the Nursing Home Compare Web site to enable consumers to make an informed decision.

Comment: A commenter suggested that installation of sprinkler systems should be limited to pre-approved companies with proven fire safety records. Another commenter suggested that we should create a special task force in each State to visit each facility and examine the information used to design the facility's sprinkler system.

Response: While we agree that long term care facilities should look for qualified contractors to design and install their sprinkler systems, we do not believe it is appropriate to, nor do we have the authority to, select or approve such contractors. In addition, we do not believe it is appropriate for us to develop task forces in each State to review a facility's research and design plan. There are numerous qualified designers who are capable of designing sprinkler systems that fulfill facilityspecific specifications. It is incumbent upon facilities to assure that their automatic sprinkler systems meet their specific facility needs as identified during a thorough review of their current fire and building safety features and various other factors.

Comment: A few commenters submitted additional information on

their own fire safety features and requirements (for example State sprinkler requirements and facilityspecific fire safety plans).

Response: We appreciate the additional information provided by the commenters. It validates our understanding of current fire safety efforts, both on the facility and State levels.

Comment: A commenter suggested that staffing levels may also impact facility fire safety, and that we should require additional staffing during the phase-in period to ensure that facility residents are protected from fire.

Response: We agree that sufficient staffing is necessary to ensure resident health and safety, including fire safety. Ensuring resident health and safety, which is closely tied to facility staffing, is already required in § 483.15, "Quality of life," § 483.30, "Nursing services," and § 483.70, "Physical environment." We believe these regulations ensure sufficient staffing levels in long term care facilities to promote and protect resident health and safety in all circumstances.

Comment: A commenter questioned the conclusions of the GAO report regarding the two multiple death fires in Connecticut and Tennessee. The commenter stated that the GAO report did not demonstrate the superiority of sprinklers over smoke alarms. The commenter also stated that the number of multiple death fires before 1990 was zero, and that the installation of sprinklers in new facilities after 1990 thus had no bearing on the number of fires between 1990 and 1992.

Response: While we recognize that the commenter disagrees with the data analysis of current fire safety levels in long term care facilities presented by the GAO, we continue to support the GAO's data, collection methodology, analytic methodology, and conclusions. We concur with the GAO that smoke alarms are necessary in unsprinklered facilities; we now require unsprinklered facilities to have such alarms in accordance with the requirements of § 483.70(a)(7). We also concur with the GAO that before 1990, multiple death fires occurred on a more frequent basis. As stated in the GAO report, "When the federal government first adopted the NFPA fire safety standards in 1971, the number of multiple-death fires in nursing homes was about 15 to 18 per year. With the adoption and enforcement of these standards, including the requirement for sprinklers in homes that were not highly fire resistant, the number of fire-related nursing home fatalities dropped dramatically." (p. 14; we note that the average annual number of long term

care facility fire fatalities, according to the GAO report, is now 5.) Furthermore, we concur with the GAO that sprinklers improve the level of fire safety beyond that which is provided by smoke alarms, and we are implementing this final rule to require sprinklers in all long term care facilities.

Comment: A commenter suggested that all facilities that currently have automatic sprinkler systems throughout their buildings be required to maintain those systems in accordance with the requirements of NFPA 25.

Response: Long term care facilities are required to meet the standards of the LSC, which requires facilities with existing sprinklers to maintain those sprinklers in accordance with the requirements of NFPA 25. We agree with the commenter and are adopting NFPA 25 by reference at § 483.70(a)(8)(ii).

Comment: A commenter stated that NFPA 101, NFPA 13, and NFPA 25 can all be viewed without charge at http://www.nfpa.org/freecodes/free access document.asp.

Response: We thank the commenter for providing this Web site citation. Unfortunately, the citation provided does not link to the documents that a long term care facility will need to comply with this final rule. Instead, an alternative, free Web site for this information is http://www.nfpa.org/aboutthecodes/

list\_of\_codes\_and\_standards.asp.
Comment: A few commenters
suggested that facilities be permitted to
have a reduced water supply that does
not meet the specifications of the NFPA
requirements for health care facilities
when an adequate level of safety can be
assured with less water.

Response: The NFPA uses a consensus process to establish the requirements of its sprinkler installation and maintenance codes. It would not be in the best interests of long term care facilities and their residents to reduce the NFPA standards. We believe that the NFPA standards represent the absolute minimum standards that long term care facilities must meet, and that lowering the standards below those of the NFPA would jeopardize long term care facility resident and staff safety.

Comment: A commenter requested a 90-day extension of the public comment period.

Response: We do not believe it is necessary to extend the standard comment period. We received 107 unique comments, as well as numerous duplicate comments, from interested parties during the comment period, and we believe these comments adequately reflect public sentiment on this matter.

Comment: A few commenters suggested additional requirements to which long term care facilities should be held. One commenter suggested that, in addition to installing and maintaining automatic sprinkler systems, long term care facilities should be required to install and maintain automatic fire alarm systems incorporating commercial smoke detectors that comply with the audio and visual notification standards of the Americans with Disabilities Act. Another commenter suggested that long term care facilities should be required to have mattresses that comply with certain fire safety standards.

Response: We agree with the commenters that numerous additional options are available to long term care facilities that wish to further enhance their fire safety levels. Long term care facilities may explore these options in addition to meeting all requirements of the LSC and this final rule.

Comment: A small number of commenters submitted comments on the existing provision that a State may apply to CMS to use its own alternative fire safety code imposed by State law if that code adequately protects patients. The commenters inquired as to the status of their own particular applications for a waiver under this provision.

Response: CMS actively considers any application submitted by a State regarding the use of an alternate fire safety code in health care facilities. However, these applications have no bearing on the requirements of this final rule because this final rule requires automatic sprinklers independent of the requirements of the LSC.

Comment: A commenter asked us to present a list of those States in the early 1990s that adopted the 1991 or later edition of the LSC or another code requiring newly constructed long term care facilities to install automatic sprinkler systems.

Response: We do not believe it is necessary to present such a list of information regarding the requirements of individual States. While such a list may provide additional historic background on fire safety requirements in the United States, all unsprinklered long term care facilities must install and maintain automatic sprinkler systems.

Comment: A commenter suggested that, instead of requiring all long term care facilities to install an automatic sprinkler system, we should permit such facilities an exemption if they have all of the following features: Smoke detectors, mattresses that meet certain fire safety requirements, and

upholstered furniture that meets certain fire safety requirements.

Response: The fire safety measures noted above are valuable tools for enhancing fire safety in long term care facilities. However, none of these features serve the same purpose as an automatic sprinkler system, which is to actively suppress a fire once it is ignited. Thus, we do not believe the suggested options achieve the same level of fire safety as automatic sprinklers.

Comment: A commenter suggested that we should include regulatory language that endorses standardization and provides for system interconnectivity.

Response: We are not clear regarding the commenter's suggestion. If the commenter is referring to the standardization of installation and maintenance requirements, we believe that referencing the NFPA installation and maintenance standards does endorse standardization of fire safety across long term care facilities.

Comment: Many commenters submitted comments regarding the placement of smoke alarms in long term care facilities. In September 2006 we published a final rule requiring all unsprinklered long term care facilities to, at minimum, install and maintain battery-operated smoke alarms in all resident rooms and common areas. In the October 2006 proposed sprinkler rule, we proposed to add a sunset date to this smoke alarm requirement. The smoke alarm requirement would, according to our proposal, cease to be effective on the phase-in date of the sprinkler requirement. Many commenters disagreed with our proposal to add a sunset date to the smoke alarm requirement. Furthermore, many of these commenters stated that all long term care facilities should be required to have both automatic sprinkler systems throughout their buildings and smoke alarms in resident rooms and common areas. Conversely, several commenters agreed with our proposal to add a sunset provision to the smoke alarm requirement. Of these commenters, many requested that the sunset date be flexible for individual long term care facilities. These commenters suggested that, rather than having a single sunset date, the final rule should state that a long term care facility is no longer required to meet the smoke alarm provision as soon as it installs and begins using an automatic sprinkler system. Additionally, one commenter sought clarification of the relationship between the CMS smoke alarm requirement and the smoke alarm requirement of the 2000 edition of the

Life Safety Code that long term care facilities are required to meet.

Response: The proposed smoke alarm sunset provision appears to have caused significant confusion and concern, and we thank the commenters for the opportunity to clarify our intent. The smoke alarm requirements of paragraph (a)(7) apply only to unsprinklered or partially sprinklered long term care facilities. This final rule will require all facilities to be fully sprinklered. Thus, there will no longer be any facilities that are unsprinklered or partially sprinklered. Since (a)(7) applies only to unsprinklered or partially sprinklered facilities, it will be a moot requirement. Nonetheless, we believe that it is appropriate to retain the requirements of paragraph (a)(7) until the end of the 5year phase-in period. At the end of this period we will consider proposing a rule which would delete both this provision and reference to the phase-in period.

Moreover, facilities that are required to have smoke alarms or smoke detection systems in accordance with the requirements of the 2000 edition of the LSC as incorporated by reference in paragraph § 483.70(a)(1) must continue to comply with those existing LSC standards.

A significant number of commenters advocated for smoke alarms and/or smoke detection systems in all long term care facilities, even those that have automatic sprinkler systems throughout their buildings. All long term care facilities may consider installing smoke detection systems in their facilities in addition to installing automatic sprinkler systems. We may consider the appropriateness of such a requirement in future rulemaking.

Comment: We received a large number of public comments regarding the appropriate length of a phase-in period for the sprinkler installation requirement. Commenter suggestions for the length of the phase-in period ranged from as little as 18 months to as long as 15 years. The most frequently suggested phase-in period was 3-5 years. Other commenters made more general recommendations such as "the sooner the better" and "sooner rather than later." Additionally, many commenters suggested that nursing homes should be allowed phase-in waivers on a case-bycase basis to provide additional time to those nursing homes who make a good faith effort to comply within the stated timeframe, but who do not do so. One commenter suggested that we include an additional requirement that long term care facility owners file a statement with CMS detailing their intent to

comply with the final rule within 180 days of publication of the final rule.

Response: We agree with commenters that a phase-in period is necessary to allow long term care facilities sufficient time to purchase and install automatic sprinkler systems throughout their buildings. While we recognize that a relatively short phase-in period (such as 18 months-3 years) will rapidly increase the level of fire safety in long term care facilities, we believe such a short time frame will not allow facilities enough time to comply with the provisions of this final rule. Re-allocating and/or securing financial resources, securing the services of a system designer and installation contractor, purchasing system components, securing any necessary permits, completing ancillary projects, and completing the actual installation process can take a substantial amount of time. We do not believe an 18-month to 3-year phase-in period allows enough time for all of these tasks to be completed in all affected facilities. Furthermore, we do not believe it is appropriate to allow waivers of this important requirement. Likewise, we do not believe it will be appropriate to allow long term care facilities 7 or more years to install automatic sprinkler systems, as some commenters suggested. While such a lengthy phase-in period will allow more than ample time for facilities to complete the installation process, it may also unnecessarily encourage facilities to postpone this much-needed fire safety improvement. In light of these considerations, we are finalizing a 5year phase-in period. A long term care facility has 5 years from the date of publication of this final rule to purchase and install a fully-operational automatic sprinkler system throughout its building. A 5-year phase-in period balances our dual goals of improved fire safety and feasibility. It ensures that facilities begin planning for installation within a short period of time from the publication of this final rule and allows sufficient time for all facilities to complete the full installation process.

Comment: Numerous commenters submitted comments regarding the exact fire safety codes that should be used in long term care facilities. Many of these commenters supported our proposal to require facilities to meet the requirements of the 1999 edition of NFPA 13 and the 1998 edition of NFPA 25. Some of the commenters suggested that we require facilities to meet more recent editions of the NFPA standards. Other commenters questioned the role of the building codes issued by the International Code Council (ICC). Of these commenters, some suggested that

we require facilities to meet the ICC codes in place of the NFPA codes. Others suggested that States, local jurisdictions, and/or facilities be given the option to meet either the NFPA or ICC codes.

Response: While we agree that more recent editions of NFPA sprinkler codes or sprinkler codes issued by other codesetting bodies may include appropriate installation and maintenance requirements for automatic sprinkler systems in long term care facilities, we believe it is most appropriate to require long term care facilities to comply with the 1998 and 1999 editions of the NFPA sprinkler codes. If we require facilities to meet more recent editions of the sprinkler codes, we could be placing them out of compliance with the provisions of the 2000 edition of the LSC. Similarly, if we were to require or permit facilities to meet another sprinkler code issued by a separate code-setting body, the standards could be incompatible with the 2000 edition of the LSC. We do not believe this will be in the best interest of facilities and their residents.

Comment: A substantial number of commenters submitted thoughts in response to our discussion of potentially adopting the 2006 edition of the LSC, which requires existing long term care facilities to install automatic sprinkler systems. Commenters were nearly evenly divided in their support of or opposition to adopting the 2006 LSC. The commenters who supported adopting the 2006 LSC stressed that this edition is the most recent version and has the potential to increase fire safety levels in all health care facilities. The commenters who did not support adopting the 2006 LSC cited potential delays in implementing the automatic sprinkler requirement and overall facility burden as key factors in their recommendation.

Response: The 2006 edition of the LSC made numerous changes to the requirements applicable to long term care facilities. The most substantial change in the 2006 LSC is the requirement that all long term care facilities must have automatic sprinkler systems. However, since we are addressing that issue in this rulemaking, we do not believe it should affect our evaluation of the overall merits of the 2006 LSC. We do not believe that the other changes in the 2006 edition of the LSC offers substantial improvements in the level of fire safety in long term care facilities that outweigh the additional burden to facilities of complying with the requirements of a newer edition of the LSC at this time. Therefore, we are not adopting the 2006 edition of the LSC at this time. We will continue to participate in the NFPA consensus process as the NFPA revises and refines subsequent editions of the LSC. Additionally, we will carefully examine the 2009 edition of the LSC when it is published for possible incorporation by reference in our regulations governing long term care facilities and a variety of other health care provider types.

#### IV. Provisions of the Final Regulations

In this final rule we are adopting the provisions as set forth in the October 27, 2006 proposed rule with the following revisions:

- Deleted proposed § 483.70(a)(7)(iv), the sunset provision.
- Added a 5-year phase-in date to § 483.70(2)(8)(i).

# V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements:

In summary, § 483.70(a)(8)(ii) requires that all long term care facilities test, inspect, and maintain an approved, supervised automatic sprinkler system in accordance with the 1998 edition of NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems. This section states that facilities will be required by this proposed rule to comply with all applicable chapters of NFPA 25 once they have installed their sprinkler systems in accordance with the requirements of NFPA 13.

We believe facilities will utilize the services of a contractor for all inspection, testing, and maintenance activities, including documentation of those activities. Therefore, no burden will be associated with the development of the documentation. The burden associated with this requirement, is the time and effort necessary for facilities to maintain documentation of inspections, tests, and maintenance activities in accordance with the standards outlined in the NFPA 25.

The burden associated with these requirements is estimated to be 1 hour per long term care facility. Therefore, we estimate it will take 2,446 total annual hours (1 hour  $\times$  2,446 estimated affected long term care facilities) to satisfy this burden.

These requirements are not effective until they are approved by OMB.

## VI. Regulatory Impact Analysis

#### A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), 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), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

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 this rule, and we have determined that this rule would meet the criteria to be considered economically significant, and it would meet the criteria for a major rule. This determination is based on 2,446 long term care facilities being required to install automatic sprinkler systems at an estimated cost of \$7.95 per square foot, for a total cost of about \$847 million over the 5-year phase-in period. Hence, in any one year costs in excess of \$100 million will be incurred regardless of the decisions of individual facilities as to when to make the investment.

The estimated cost for installing a sprinkler system throughout an existing average size unsprinklered facility (50,000 square feet to be sprinklered at \$7.95 per square foot) will be \$397,500. Because these systems are capital investments, their costs are properly amortized over time in estimating their

impact on facility finances. We believe that a reasonable estimate of the useful life of a sprinkler system is 20 years. The projected installation cost of this requirement will account for approximately one fourth of one percent of an average unsprinklered facility's actual revenue over a 20-year period. The estimated cost for installing a sprinkler system throughout an existing average size partially sprinklered facility (37,125 square feet to be sprinklered at \$7.95 per square foot) will be \$295,143. The projected installation cost of this requirement will account for approximately one fifth of one percent of an average partially sprinklered facility's actual revenue over a 20-year period.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions (including tribal governments). Individuals and States are not included in the definition of a small entity. For purposes of the RFA, most long term care facilities are considered to be small entities, either by virtue of their nonprofit or government status or by having revenues of less than \$12.5 million in any one year. The latest SBA size standards classify a "Nursing Care Facility" under North American Industry Classification System (NAICS) as code 623110, and as "small" if its annual revenues fall below \$12.5 million (for details, see the Small Business Administration's Table of Small Business Size Standards at http://www.sba.gov/idc/groups/public/ documents/sba\_homepage/ serv\_sstd\_tablepdf.pdf.) According to our statistics, long term care facilities, all of which will be required to have sprinkler systems throughout their buildings, received a total of \$124.9 billion in revenue in 2006 (National Health Expenditures Accounts, http:// www.cms.hhs.gov/ NationalHealthExpendData/ 02\_NationalHealth AccountsHistorical.asp). Also according to CMS data, there were 15,941 nursing facilities in operation at that time. The average facility therefore had annual revenue of \$7.8 million and thus fell well below the SBA size threshold. Taking into account both typical revenue, and that non-profit facilities of any size are "small entities" within the meaning of the RFA, we assume for purposes of our analysis that all LTC facilities are "small entities" for

purposes of the RFA. Although the

average LTC facility has revenues well

below the SBA size threshold, we have,

as described in what follows, also analyzed impacts on entities that fall even farther below the size threshold. (Note: In the following paragraphs the terms "average facility" and "smaller facility" are strictly based on a revenue metric, just as are most of the SBA size thresholds, including that for NAICS code 623110. That is, the terms only describe facilities in terms of the amount of annual revenue.)

Long term care facilities vary in a number of ways, ranging from the number of residents to the predominant source of payment for those residences. For the purposes of our analysis, we chose to assess the financial impact of this final rule on a facility with average revenue and a facility with a much smaller revenue (50 percent below the mean). An average facility had approximately \$7,837,714 in revenue in 2006. A facility with revenue 50 percent below this average received \$3,918,857, or less than one third of the amount set by SBA to define "small." Over the 20year amortization period revenues of an average facility will be about \$157 million. The "smaller" facility will have revenues of about \$78 million over the same 20-year amortization period. We calculate that the projected cost of this requirement will account for about one fourth of one percent of an average unsprinklered "smaller" facility's actual revenue over the 20-year period. Taking into account their smaller size and lower investment cost, the projected cost of this requirement will account about one fifth of one percent of a partially sprinklered "smaller" facility's actual revenue over the 20-year period. We are assuming that a smaller facility's square footage and number of beds are 50 percent less than an average facility's square footage because there is a strong correlation between the size of a facility, as reflected by the number of resident beds it has, and the facility's revenue level. According to CMS data from December 2007, there (see Table 3 later in this analysis) the median bed size of LTC facilities is about 100 beds, and there are 433 unsprinklered or partially sprinklered long term care facilities that have fewer than 50 beds and presumably meet our revenue definition of a "smaller facility." Hence, there are relatively few very small ("smaller") facilities that will be affected by this rule. That said, a total of about 2,446 unsprinklered or partially sprinklered facilites will be affected, and the great majority of these (we assume all) are "small entities" under the RFA (again, see Table 3 for the size distribution of affected entities).

As a result of these calculations, and because we normally only regard an

impact that reaches several percent of annual revenue as "significant" under the RFA, we certify that this final rule would not have a significant impact on a substantial number of small entities. However, some facilities may face financing or other problems that concentrate the impact and make its effect proportionally much larger than would otherwise be the case. While we do not believe that there would be a substantial number of facilities in this circumstance, we have prepared a voluntary regulatory flexibility analysis. This Regulatory Impact Analysis section, taken together with the remainder of the preamble, constitutes this analysis.

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 of a metropolitan statistical area and has fewer than 100 beds. We know that 8.41 percent of long term care facilities, 1,332 nationwide, are located in hospitals, but we do not know how many of those hospitals are small rural hospitals. However, it is likely that the affected number is quite small. Applying the same percentages that apply to the long term care universe to the 1,332 long term care facilities located in hospitals, we estimate that 1,125 are fully sprinklered, 176 are partially sprinklered, and only 31 are not sprinklered. Using these estimates and the preceding cost amortization calculations, we have concluded that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals and that a regulatory flexibility analysis is not required. Our voluntary analysis, however, applies equally to facilities regardless of location or affiliation and hence covers hospital-based facilities.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year by either the private sector or by State, local, and tribal governments of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$130 million. This final rule does contain mandates that will impose annual spending costs on private long term care facilities of \$154 million, and on public long term care facilities of \$16 million,

based on an estimated cost of about \$847 million distributed over a 5-year phase-in period, for an average annual cost of about \$170 million for all public and private facilities. Estimated impacts on State, local, and tribal governments are well below the UMRA threshold, since over ninety percent of long term care facilities are privately owned, as shown the Federalism analysis that follows. With respect to private sector facilities, this Regulatory Impact Section, together with the remainder of the preamble, constitutes the analysis required under UMRA.

Note: For a more detailed discussion of the cost estimates, see part B.2 of this section.) In the proposed rule we estimated that this rule would cost \$47.8 to \$69.9 million, \$73.5 to \$107.5 million, and \$107.7 to \$157.6 million annually. These estimates were based on example phase-in periods of 10 years, 7 years, and 5 years, and cost-per-square-foot estimates of \$4.10, \$5.50, and \$6.10, respectively. We sought public comment on the length of an appropriate phase-in period, and received suggestions ranging from 18 months to 15 years. The most frequently suggested phase-in period was 3-5 years. We selected the longer phase-in period, 5 years, to help mitigate the impact of this rule upon long term care facilities. We also increased our cost-per-square-foot estimates to reflect increases in construction costs that have occurred since publication of the proposed

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct compliance costs on State or local governments, preempts State law, or otherwise has Federalism implications. Of the 2,446 facilities that will be affected by this final rule, 216 facilities (8.83 percent of all affected facilities) are owned by State and local governments. The majority of these facilities (188) are already partially sprinklered. Of the 188 partially sprinklered facilities, 31 have less than 50 resident beds, 43 have 50–99 resident beds, 63 have 100-199 resident beds, and 49 have 200 or more resident beds. We estimate that it will cost on average about \$14.24 million annually for 5 years to install sprinklers throughout the unsprinklered portions of these facilities. Of the remaining 30 completely unsprinklered facilities, 13 have less than 50 resident beds, 8 have 50-99 resident beds, 7 have 100-199 resident beds, and 2 have 200 or more resident beds. We estimate that it will cost on average about \$2.12 million annually for 5 years to install sprinklers throughout these unsprinklered facilities. The total of these annual average cost estimates, about \$16 million, is negligible in the context of

overall State and local budgets and as a capital expense can be financed over a period of years by borrowing. Therefore, we believe that this final rule will not impose substantial direct compliance costs on State or local governments, and thus has no Federalism implications.

# B. Anticipated Effects

#### 1. Benefits

a. Decreasing Loss of Life
We believe that installing an
approved, supervised automatic
sprinkler system in accordance with
NFPA 13, Standard for the Installation
of Sprinkler Systems, throughout a long
term care facility will have a positive
impact on resident safety. According to
the July 2004 GAO report discussed
above, installing sprinklers decreases
the chances of fire-related deaths by 82
percent. In unsprinklered facilities,
there are 10.8 deaths per 1,000 fires. In
sprinklered facilities, there are 1.9
deaths per 1,000 fires.

The 2003 fires in Hartford and Nashville resulted in more fire related deaths (31) than there were for several previous years combined. Both of these fires occurred in unsprinklered buildings. If sprinklers had been installed in these facilities, and if they were properly maintained, we estimate that 82 percent of those fire-related deaths may have been prevented, based on an 82 percent reduction in the chances of death occurring in a sprinklered facility. We estimate that, based on this reduction, 25 (82 percent of 31 deaths = 25) lives could have been saved by sprinklers in these two fires, or 13 lives in the Hartford fire and 12 lives in the Nashville fire.

According to the U.S. Census Bureau, in 2006, the average age of a long term care facility resident was 83.2 years. This number reflects the overall demographic trend in long term care facilities toward an older patient population. In 2003 (the most recent year of data available), the average life expectancy for an individual at age 85 was 6.6 years (Older Americans Update 2006: Key Indicators of Well-Being. Federal Interagency Forum on Aging-Related Statistics. http:// www.agingstats.gov/agingstatsdotnet/ Main\_Site/Data/2006\_Documents/ *Health\_Status.pdf*). This means that an 85-year-old long term care facility resident could expect to live an average of 6.6 more years. We acknowledge that the average age of a long term care facility resident (83.2 years) is slightly younger than the 85 year data point used to assess average life expectancy; however, we believe that using the life expectancy of an 85 year old is an

acceptable proxy for the life expectancy of an 83.2 year old.

Based on a life expectancy at age 85 of 6.6 years, we estimate that sprinklers in these two fires would have added 165 life years (25 lives saved  $\times$  6.6 life years per life saved).

While the number of deaths in these two fires is not typical of the number of fire-related deaths in long term care facilities as a whole, we believe that they should still be taken into consideration when discussing the impact on the general long term care facility resident population.

In a typical year from 1994 through 1999, about 2,300 long term care facilities report structural fires (July 2004 GAO report). We estimate that 25 percent (575) of the 2,300 facilities that

reported fires annually during the 1994–1999 time period did not have sprinklers installed throughout their buildings. This estimate is based on the results of the 2004 GAO report and a nationwide survey of long term care facilities conducted by CMS following the results of the GAO report.

Based on the rate of 10.8 deaths per 1,000 unsprinklered facility fires, we estimate that 6 deaths occurred in 575 fires in unsprinklered and partially sprinklered facilities annually. (575 facilities = 57.5 percent of 1,000 facilities; 57.5 percent of 10.8 deaths = 6 deaths). This estimate differs slightly from the average number of deaths (5) that occurred due to long term care facility fires, as presented in the July 2004 GAO report, because this estimate

predicts the number of deaths that statistically would be expected to occur, based on established percentages, rather than the average number of deaths that occurred annually in the past. This estimate is prospective, whereas the 2004 GAO figure is retrospective.

If these unsprinklered or partially sprinklered facilities install sprinklers throughout their buildings and those sprinklers are properly maintained, then we estimate that there will be 1 death (57.5 percent × 1.9 deaths per 1,000 fully sprinklered facility fires according to the 2004 GAO report = 1) in those same 575 facilities. Installing sprinklers in unsprinklered and partially sprinklered buildings would, based on these estimates, save 5 lives annually.

TABLE 1—ESTIMATED ANNUAL FIRE DEATHS

| Number of estimated annual fire-related deaths in unsprinklered long term care facilities | Number of estimated annual fire-related deaths if those facilities were sprinklered | Number of estimated annual lives saved by sprinklers |
|-------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------|
| 6                                                                                         | 1                                                                                   | 5                                                    |

Given the estimate described above that installing and maintaining sprinkler systems in existing long term care facilities will save 5 lives annually, we estimate that sprinklers will save 33 life years annually (5 lives saved  $\times$  6.6 years gained per life).

TABLE 2—LIFE YEARS

| Number of life years gained per life saved | Number of life years gained annually |
|--------------------------------------------|--------------------------------------|
| 6.6                                        | 33                                   |

There are a wide variety of estimates regarding the statistical value of a life or of a quality-adjusted life year. For example, there are numerous studies that attempt to quantify how much individuals and society are willing to pay to gain a single, quality year of life, known as a quality-adjusted life year. These studies, using one or more of four different methodologies, have estimated that individuals and society are willing to pay between \$50,000 and \$450,000 for a quality-adjusted life year (see R.A. Hirth, et al, "Willingness to Pay for Quality-Adjusted Life Year: In Search of a Standard," Medical Decision Making, Volume 20, Number 3, July-Sep. 2000). Due to the fact that there is no widely accepted standard value, we refrained in the proposed rule from estimating the statistical value of each life or life year that will be gained as a result of a final rule requiring sprinklers in all long term care facilities. However, a recent FDA rule used an estimate of \$5 million as

the value of a statistical life and derived from this figure values of between \$213,000 (at a 3 percent discount rate) and \$373,000 (at a 7 percent discount rate) for a quality adjusted life-year (QALY). (See the FDA Final Rule on "Medical Devices: Patient Examination and Surgeon's Gloves; Test Procedures and Acceptance Criteria," December 19, 2006, 71 FR 75865, as corrected January 19, 2007, 72 FR 2436.) These are intended to be rough estimates of societal willingness to pay for saving a "statistical life" (not a particular person) or for adding a year of life that does not involve total disability. It is not a settled issue in the literature of valuation of life as to how well these estimates fit an elderly population, and we use them here only to provide a rough estimate as to one of the major benefits of this final rule in the same dollar metric as costs.

Applying these estimates, the life-saving benefits of this final rule once all facilities are compliant will be approximately \$25 million dollars annually based on a value of \$5 million per statistical life saved. These benefits accrue over the entire 20-year horizon during which automatic sprinkler systems save lives. Hence, undiscounted future benefits from life saving would be as much as \$500 million (\$5 million times 5 lives times 20 years).

There are additional life-year benefits, to the extent that residents who survive a fire are nonetheless physically injured in ways that that greatly reduce their future quality of life. For example, a

person who spends months in the hospital recovering from burn injuries and the remainder of his life partially incapacitated by those injuries, or a person whose lungs are permanently damaged by smoke inhalation, do not have the same good health that they would have enjoyed absent the fire. We do not have at this time any basis for estimating the amount of severe morbidity caused by facility fires that sprinklers can mitigate, but it could be very substantial, likely approaching and perhaps exceeding the number of lifeyears lost to mortality. For purposes of this analysis, we assume that it equals the mortality QALYs, and that total benefits from morbidity reduction range from \$7 to \$10 million a year (33 life years times 20 years time either \$213,000 or \$373,000).

The FDA estimates were based on a "willingness to pay" analysis of wage differentials necessary to attract labor to riskier occupations. Such analyses have shown that people demand significantly higher wages to accept even a small additional risk of death. The estimated value of an additional year of life is based on life expectancy in the FDA analysis. However, there are other ways to create such estimates and many studies have done so. For example, an estimate using data on rural interstate highway driving speeds found that the value of a statistical life could be estimated as between \$1.6 and \$5.9 million (Orley Ashenfelter, "Measuring the Value of a Statistical Life: Problems

and Prospects," Working Paper 11916, National Bureau of Economic Research, January 2006). As another example, a recent study of the willingness to pay for better health care found that a reasonable estimate of the value of a QALY lies between \$183,000 and \$264,000 per life year (R. Scott Braithwaite, et al, "What Does the Value of Modern Medicine Say About the \$50,000 per Quality-Adjusted Life-Year Decision Rule?," Medical Care, Volume 46, Number 4, April 2008). Thus, the estimates used by the FDA, and in this CMS analysis, are broadly consistent with estimates from other sources, such as the Hirth and Braithwaite studies.

The reasonableness of applying such estimates to an elderly population is unclear, particularly when that population is, by definition, at least temporarily unable to live outside an institutional setting. However, the general approach used most often in the literature is to use the same value of a statistical life for persons of all ages. As to value of a life-year, there is considerable evidence in the literature that the kinds of disabilities most commonly found in nursing homes, such as mobility and mental impairments, do not substantially reduce the value of a life-year (see Chaim M. Bell, et al, "An Off-the-Shelf Help List: A comprehensive Catalog of Preference Scores from Published Cost-Utility Analyses," Medical Decision Making, Volume 21, Number 4, July-August 2001). For example, on a scale of zero to 1, where zero is represented by a persistent vegetative state and 1 is best attainable health, this synthesis shows that disability after a hip fracture is rated at .8, and even after major stroke from .2 to .5. Absent a compelling rationale to the contrary, we therefore use the full values of a statistical life and a QALY in our analysis.

A few commenters questioned our methodology for assessing the potential life-saving benefits of installing and maintaining automatic sprinkler systems. However, these commenters did not suggest an alternate method for assessing these potential benefits. Therefore, we reaffirm the methodology and results described above.

# b. Decreasing Loss of Property

As a result of installing and properly maintaining sprinklers, we anticipate that facilities that experience fires would lose less property. While the amount of property damage and loss that would be prevented by installing and maintaining sprinklers is not readily quantifiable from existing data, we believe that the amount of damage prevented will be substantial, and that

this prevention will benefit affected long term care facilities.

Preventing property damage and loss may also reduce the amount of money paid by insurers to cover fire-related losses. Such reductions may help control long term care facility insurance costs and reduce any spill-over effect for other insurance markets. Again, these benefits are not easy to estimate reliably from existing data. However, we believe that they should be considered as part of the overall analysis of the benefits of purchasing, installing, and maintaining automatic sprinkler systems in long term care facilities.

For purposes of estimating overall benefits and costs, we believe that an estimate of about \$26 million a year would not be unreasonable. We base this on the following calculations. First, as previously discussed there are approximately 2,300 structural fires annually in long term care facilities, a rate of about one fire per every seven facilities. However, we estimate that the number of fires in unsprinklered or partially sprinklered facilities is far higher, with these 2,446 facilities accounting for one fourth of all structural fires, or about one fire per every four such facilities (575 fires in 2,446 facilities). Assuming that the rate could be reduced to the 13 percent rate in fully sprinklered facilities (1,725 fires in 13,495 facilities), approximately 260 structural fires a year would be prevented. We have no specific data for estimating the dollar cost of fighting these fires and restoring the properties, but assuming illustratively that the average cost of a structural fire is \$100,000, total annual savings would be on the order of \$26 million a year.

# c. Decreasing Fire Recovery Disruption and Time

In addition to losing less property due to fire, we anticipate that long term care facilities that experience fires will be able to recover more quickly with fewer disturbances to residents. Because sprinkler heads generally activate only in the area immediately near the fire source, the area that will be damaged by a fire will likely be much smaller in a sprinklered building than it would be in a building without sprinklers, thus reducing recovery costs. In addition, by limiting the area affected by the fire, there would be fewer disturbances to residents during the recovery time. In particular, fewer residents would be forced into a change in residence, a disruption that often affects residents' physical and mental well-being severely. Finally, by limiting the affected area and duration of disruption, an affected facility will reduce the

number of paid patient-days that it loses. While we cannot quantify most of these benefits to long term care facilities and their residents, we believe that they are substantial. Assuming illustratively that they equal half the cost of a fire prevented, annual savings would be on the order of \$6.5 million a year.

#### d. Decreasing Legal Liability and Insurance Cost

As a result of installing sprinklers, facilities will greatly reduce their potential exposure to legal costs and legal damages, as well as reduce their costs for liability insurance. Again, we cannot quantify these benefits but they could be very substantial. For example, were a court to find that a facility was negligent either in not installing a stateof-the-art system, or in being unable to save residents who would have been saved had such a system been in place, tort liability could be imposed. Absent any way to predict what might occur (which might depend, for example, not only on specific factual circumstances but also on the tort law in the state in which such a fire might occur), we do not estimate the dollar value of these benefits

#### e. Reducing Major Medical Care Costs

Fires cause morbidity as well as mortality. Not all residents who suffer deadly burns die immediately. Treatment of severely burned persons is among the most expensive kinds of medical care. Other effects of fires that require medical treatment include smoke inhalation and injuries cause by falls when fleeing from rooms affected by fire or smoke. No data are available to us on the extent of these medical costs, and hence on costs prevented by this final rule, but they are likely to be substantial. Assuming illustratively that there are ten expensive medical care cases prevented for each death prevented by this rule, and that such cases average \$100,000, annual benefits would be \$5 million  $(5 \times 10 \times $100,000)$ .

#### 2. Costs

This final rule requires a long term care facility to install an approved, supervised automatic sprinkler system in accordance with NFPA 13, Standard for the Installation of Sprinkler Systems, throughout the building. This final rule also allows long term care facilities to install automatic sprinkler systems over a 5-year phase-in period.

Number and Size of Affected Facilities

Following publication of the GAO report, CMS incorporated a data collection element on the long term care facility survey form. When completing a

survey, a long term care facility surveyor must note whether the facility is fully sprinklered, partially sprinklered, or unsprinklered. Based on data collected during the survey process, we know that 13,391 facilities are fully sprinklered, 2,086 facilities are partially sprinklered, and 360 facilities are unsprinklered. The following table groups the partially and unsprinklered facilities by the number of beds.

# TABLE 3-NUMBER OF AFFECTED FACILITIES BY SIZE

|                       | <50 beds | 50-99 beds | 100-199 beds | 200+ beds |
|-----------------------|----------|------------|--------------|-----------|
| Partially sprinklered | 315      | 675        | 870          | 226       |
|                       | 118      | 128        | 102          | 12        |

The number of resident beds in a facility strongly corresponds to its physical size. Simply put, larger buildings have more resident beds, and smaller buildings have fewer resident beds. Therefore, based on the number of beds in a facility, we are able to estimate the square footage of a long term care facility. For purposes of our analysis, we estimate that a long term care facility has 500 total square feet for each resident bed. This estimate, which includes space for the resident's room, community spaces, and administrative spaces, is based on discussions with architects and engineers who are familiar with the design of older long term care facilities. Therefore, for purposes of our analysis, an average facility with fewer than 50 beds is 24,500 sq ft, 50-99 beds is 37,000 sq ft, 100-199 beds is 74,500 sq ft, and 200+ beds is 99,501 sq ft. When estimating the cost of installing an automatic sprinkler system in an unsprinklered facility, we use these square footage estimates.

However, these estimates do not reflect the area that must still be sprinklered in a partially sprinklered long term care facility. By definition, a partially sprinklered facility already has an automatic sprinkler system in one or more sections of the facility. For purposes of this impact analysis, we assume that a partially sprinklered building is 25 percent sprinklered, leaving 75 percent of the building to be sprinklered in accordance with this final rule. Buildings in this category may have more or less sprinkler coverage than this assumption.

For facilities with fewer than 50 resident beds, we estimate that sprinklers will be installed for 18,375 square feet (75 percent of maximum square footage in this size category). For facilities with 50 to 99 resident beds, we estimate that sprinklers will be installed for 27,750 square feet (75 percent of average square footage in this size category). For facilities with 100 to 199 resident beds, we estimate that sprinklers will be installed for 55,875 square feet (75 percent of average square footage in this size category). For

facilities with more than 199 resident beds, we estimate that sprinklers will be installed for 75,000 square feet (75 percent of minimum square footage in this size category).

# a. Installation Cost per Square Foot

Purchasing and installing a sprinkler system according to the requirements of NFPA 13 encompasses a wide variety of factors, including those briefly described in section II of this final rule. Within the requirements of NFPA 13, there are numerous variables that can impact the purchase and installation costs for a facility. Each facility has different needs that must be addressed when purchasing and installing a sprinkler system, and this cost estimate cannot address each particular need or combination of needs. Therefore, we are basing our cost estimates not on the individual requirements of NFPA 13 for an individual facility, but on a bundled purchase and installation estimate for an average facility, as described below. Individual facilities may have costs above or below those of this average facility due to facility size and facilityspecific sprinkler system needs. Long term care facilities that are based in other health care facilities, such as hospitals, are required by this final rule only to have sprinklers in the long term care facility section of the building. Therefore, we do not believe that facility-based long term care facilities will have different installation costs than freestanding facilities with similar resident bed and square footage

We estimate that it will cost \$7.95 per square foot to purchase and install a sprinkler in an existing facility. According to the Architects, Contractors, Engineers Guide to Construction Costs, 2008 Edition by Design and Construction Resources, purchasing and installing sprinklers in new long term care facilities costs \$2.65 per square foot. This cost estimate incorporates all contractor costs such as labor, materials, and a 20 percent overhead fee; 35 percent taxes and insurance on labor, equipment, and tools; and 5 percent sales tax.

Although we recognize that capital and interest costs may increase the cost of purchasing and installing automatic sprinkler systems in long term care facilities, these costs are not included in our estimates. Due to the individual circumstances of each facility, unknown future interest rates, and various other factors, we are unable to accurately estimate the capital and interest costs of installing sprinkler systems. Therefore, we have chosen to exclude these costs from our estimates while acknowledging that they do exist and will play a role to some degree in the decisions of long term care facilities that will be affected by this final rule. Note, however, that the economic costs of financing this capital investment would not be the gross cost of borrowing, but the much smaller opportunity cost of the capital devoted to sprinklers rather than some other investment. Furthermore, to the potentially substantial extent that facilities gain from this investment (reduced disruption, revenue loss, etc. as previously discussed) the opportunity cost may be very low.

Renovation costs are typically two to three times higher than new construction costs because installing the sprinkler system must be completed in a piecemeal fashion while the building remains occupied. This increases the length of the construction time and, thus, increases its costs. In addition, renovations to add sprinkler systems often require upgrading or adding related building components such as water lines and fire pumps. The upgrades and additions require more capital investment and construction time. Increased investment and construction time also increases costs.

For purposes of this impact analysis, we assume that renovating a typical facility to add sprinklers would cost three times more than purchasing and installing sprinklers in new long term care facilities. In the proposed rule, we presented a range of cost per square foot estimates from two to three times the costs of installation in a new building. Commenters indicated that the lower estimates in this range did not reflect the actual costs incurred by existing

long term care facilities. Therefore, we eliminated the lower range and only use the highest estimate (three times the cost of installing sprinklers in new construction, \$7.95).

#### b. Cost Estimates

The cost estimates for both unsprinklered and partially sprinklered facilities are presented in the following tables. They are based on all of the above-described estimates about the number of facilities that would be affected, the sizes of those facilities, and the installation cost per square foot. We estimate that this final rule will cost \$846,680,105 over the 5-year phase-in period, or an average of \$169,336,021 annually for 5 years for all affected partially sprinklered and unsprinklered long term care facilities.

TABLE 4—ONE-TIME INSTALLATION COST FOR PARTIALLY SPRINKLERED FACILITIES AT \$7.95 PER SQUARE FOOT BY SIZE

|                   | >50 beds            | 50–99 beds          | 100–199 beds        | 200+ beds           |
|-------------------|---------------------|---------------------|---------------------|---------------------|
|                   | (18,375 sq ft to be | (27,750 sq ft to be | (55,875 sq ft to be | (75,000 sq ft to be |
|                   | sprinklered)        | sprinklered)        | sprinklered)        | sprinklered)        |
| Cost per facility | \$146,081           | \$220,613           | \$444,206           | \$596,250           |
|                   | 315                 | 675                 | 870                 | 226                 |
|                   | \$46,015,515        | \$148,913,775       | \$386,459,220       | \$134,752,500       |

# TABLE 5—ONE-TIME COST FOR UNSPRINKLERED FACILITIES AT \$7.95 PER SQUARE FOOT BY SIZE

|                   | >50 beds            | 50–99 beds          | 100–199 beds        | 00+ beds            |
|-------------------|---------------------|---------------------|---------------------|---------------------|
|                   | (24,500 sq ft to be | (37,000 sq ft to be | (74,500 sq ft to be | (99,501 sq ft to be |
|                   | sprinklered)        | sprinklered)        | sprinklered)        | sprinklered)        |
| Cost per facility | \$194,775           | \$294,150           | \$592,275           | \$791,033           |
|                   | 118                 | 128                 | 102                 | 12                  |
|                   | \$22,983,450        | \$37,651,200        | \$60,412,050        | \$9,492,395         |

## TABLE 6—TOTAL ONE-TIME INSTALLATION COST FOR ALL FACILITIES BY SIZE

|                       | >50 beds                   | 50–99 beds                  | 100–199 beds                | 200+ beds                  |
|-----------------------|----------------------------|-----------------------------|-----------------------------|----------------------------|
| Partially sprinklered | \$46,015,515<br>22,983,450 | \$148,913,775<br>37,651,200 | \$386,459,220<br>60,412,050 | \$134,752,500<br>9,492,395 |
| Total                 | 68,998,965                 | 186,564,975                 | 446,871,270                 | 144,244,895                |

We do not expect all affected long term care facilities to have all necessary resources immediately available to purchase and install automatic sprinkler systems. Therefore, we are allowing all facilities up to five years from the date of publication of this final rule to purchase and install sprinklers. While we will encourage all facilities to immediately begin the process of purchasing and installing sprinklers, we understand that some facilities will choose to wait until later in the phasein period to begin this process. Therefore, we expect that the one-time cost of this final rule will be distributed over a period of several years as facilities nationwide will likely stagger their installation schedules to meet their individual needs and circumstances. We estimate that long term care facilities will spend, on average, \$169,336,021 annually for five years to purchase and install automatic sprinkler systems throughout their facilities.

## c. Maintenance

After installing an approved, supervised automatic sprinkler system in accordance with the 1999 edition of NFPA 13 throughout the building, all

long term care facilities must test, inspect, and maintain their sprinkler systems in accordance with the 1998 edition NFPA 25. We estimate that long term care facilities will conduct quarterly inspections of their sprinkler systems and annual trip tests. We assume that each inspection will take 4 hours to complete, at a cost of \$150 per inspection. We also assume that each trip test will take 6 hours, at a cost of \$250. Based on these assumptions, we estimate that long term care facilities will spend \$850 annually to test and inspect their sprinkler systems. In addition, we assume that long term care facilities will spend an additional \$150 annually to perform any necessary maintenance duties.

Individuals who perform these testing, inspection, and maintenance duties will have to be properly trained and, in some States and local jurisdictions, they will have to be licensed. Generally, long term care facilities will not have enough sprinkler system work needs to directly employ someone with the necessary skills, training, and licensure. Therefore, we believe that long term care facilities will

likely contract with another company to meet their testing, inspection, and maintenance needs. However, long term care facilities are not required by this rule to contract for these services. In addition to actually conducting the necessary testing, inspection, and maintenance activities, we believe that a contract will also include a provision that the contractor prepares adequate documentation of the activities conducted. We estimate that the total cost of meeting these requirements will be \$1,000 (\$150  $\times$  4 quarterly inspections = \$600 + \$250 annual trip test + \$150 general maintenance costs = \$1,000). We estimate that the total maintenance cost for all affected facilities will be \$2,446,000. We recognize that some commenters suggested that this estimate is not sufficient to capture the cost of maintaining an automatic sprinkler system. However, the commenters did not suggest a more suitable method for assessing the potential maintenance costs or a more suitable dollar estimate for such costs. Therefore, we reaffirm our original estimates.

In addition, all long term care facilities that will be affected by this final regulation are required to maintain documentation of all inspection, maintenance, and testing activities. The burden associated with these requirements is estimated to be 1 hour per long term care facility. Therefore, we estimate it will take 2,446 total annual hours (1 hour  $\times$  2,446 estimated affected long term care facilities) to meet this requirement. This documentation

maintenance requirement will cost an affected facility \$19 a year, based on an hourly rate of \$19 for an office employee (\$19 per hour  $\times$  1 hour). The total annual cost of this final documentation requirement will be \$46,474 (\$19 per facility  $\times$  2,446 facilities).

3. Summary of Estimated Costs and Benefits

Taking into account all these categories of benefits and costs, and

their timing, we believe that this final rule creates a substantial excess of benefits over costs at a social discount rate of 3 percent and a slight excess of benefits over costs at 7 percent. As shown in the table, costs are heavily concentrated in the first five years (we assume one-fifth is invested in each of the five years allowed for compliance) while benefits accrue over the entire 20-year life of these investments.

TABLE 7—TOTAL FIRE SPRINKLER SYSTEM COSTS AND BENEFITS

|                         |                            |                                                    |                                                    | Ben                                        | Benefits                                      |                                            |                                                    |                                                |                            | Costs                 | ıts                  |                         |
|-------------------------|----------------------------|----------------------------------------------------|----------------------------------------------------|--------------------------------------------|-----------------------------------------------|--------------------------------------------|----------------------------------------------------|------------------------------------------------|----------------------------|-----------------------|----------------------|-------------------------|
| Year                    | Statistical<br>lives saved | Life years<br>saved from<br>mortality<br>reduction | Life years<br>saved from<br>morbidity<br>reduction | Monetized<br>statistical<br>lives<br>(\$M) | Monetized<br>morbidity<br>reduction<br>(\$M)* | Decreasing<br>loss of<br>property<br>(\$M) | Decreasing fire recovery disruption and time (\$M) | Reducing<br>major<br>medical<br>costs<br>(\$M) | Total<br>benefits<br>(\$M) | Installation<br>(\$M) | Maintenance<br>(\$M) | Total<br>costs<br>(\$M) |
| 1                       | -                          | 9.9                                                | 9.9                                                | S                                          | -                                             | 5                                          | 2.6                                                | -                                              | 15.2                       | 169                   | 0.5                  | 169.5                   |
| 2                       | 2                          | 13.2                                               | 13.2                                               | 10                                         | က                                             | 13                                         | 6.5                                                | N                                              | 34.3                       | 169                   | 1.0                  | 170.0                   |
| 3                       | က                          | 19.8                                               | 19.8                                               | 15                                         | 4                                             | 16                                         | 7.8                                                | ო                                              | 45.6                       | 169                   | 1.5                  | 170.5                   |
| 4                       | 4                          |                                                    | 26.4                                               | 20                                         | 9                                             | 21                                         | 10.4                                               | 4                                              | 8.09                       | 169                   | 2.0                  | 171.0                   |
| 5                       | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 2                                              | 76.0                       | 169                   | 2.5                  | 171.5                   |
| 9                       | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 7                       | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 8                       | 5                          |                                                    | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 5                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 6                       | 5                          |                                                    | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 5                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 10                      | 5                          | 33                                                 | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 11                      | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 56                                         | 13                                                 | 2                                              | 16.0                       | 0                     | 2.5                  | 2.5                     |
| 12                      | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 13                      | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 56                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 14                      | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 15                      | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 16                      | ນ                          |                                                    | 33                                                 | 25                                         | 7                                             | 56                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 17                      | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 26                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 18                      | 2                          |                                                    | 33                                                 | 52                                         | 7                                             | 56                                         | 13                                                 | 2                                              | 16.0                       | 0                     | 2.5                  | 2.5                     |
| 19                      | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 56                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| 20                      | 2                          |                                                    | 33                                                 | 25                                         | 7                                             | 56                                         | 13                                                 | 2                                              | 76.0                       | 0                     | 2.5                  | 2.5                     |
| Undiscounted Total      | 06                         |                                                    | 594                                                | 450.0                                      | 126.5                                         | 470.6                                      | 235.3                                              | 0.06                                           | 1,372.4                    | 842.0                 | 42.0                 | 890.0                   |
| Net Present Value at 3% |                            |                                                    |                                                    |                                            | 3%                                            |                                            |                                                    |                                                | 991.4                      |                       |                      | 806.4                   |
| Discount Rate           |                            |                                                    |                                                    |                                            |                                               |                                            |                                                    |                                                |                            |                       |                      |                         |
| Net Present Value at 7% |                            |                                                    |                                                    |                                            |                                               |                                            |                                                    |                                                |                            |                       |                      |                         |
| Discount Rate*          |                            |                                                    |                                                    |                                            | 7%                                            |                                            |                                                    |                                                | 722.4                      |                       |                      | 715.0                   |

\*Estimate at 3% discount rate, shown in table, uses a value of \$213,000 per QALY; estimate at 7% uses a value of \$373,000 per QALY.

The Office of Management and Budget has stated that the value of a statistical life could be put anywhere between \$1 and \$10 million (in practice a number as low as \$1 million is almost never used). Clearly using the lower end of this range would greatly reduce the benefits of this final rule, and using the higher end would greatly increase those benefits. Broad (though not equally broad) ranges of comparisons could be made for most categories of benefits. However, only if the most conservative possible estimates were used for almost every category of benefits would total discounted benefits fall below discounted costs at a discount rate of 3 percent. Therefore, we have chosen not to present a detailed sensitivity analysis.

Our installation cost estimates, in contrast, do not pose remotely as wide a range of possibilities. In our view we have estimated these quite conservatively, and actual costs could easily be ten or twenty percent lower than the estimates we use. For example, the five year compliance horizon we provide means that many facilities will be able to combine sprinkler installation with other major renovations such that the cost of sprinkler installation will be considerably less. In fact, during the next five years it is quite likely that a considerable fraction of long term care providers in the older facilities most affected by this final rule will for unrelated business reasons decide to move to new facilities and dispose of their older facility buildings. We have not attempted to estimate the effects of

such estimate-reducing actions.
Finally, there is an alternative way to estimate and present the effects of this rule. Approaching these estimates from the perspective of cost-effectiveness analysis (CEA), Table 7 shows that we estimate a total of 1,188 undiscounted life years saved from both mortality and morbidity reductions. Subtracting from total monetary costs the monetary benefits from reduced property damage, disruption, and medical costs, the net undiscounted costs are \$94.1 million. Undiscounted, the cost per life-year saved is \$79,000. Discounting both life years and costs to present value, the cost per life-year saved would be \$270,000 at a 3 percent discount rate, and \$553,000 at a 7 percent discount rate. These results are markedly sensitive to the discount rate because the benefits of the rule accrue roughly evenly over time, while the costs are highly concentrated in the early years. Despite the fact that this mostly elderly population has relatively few years of life expectancy compared to an average population, even at a 7 percent discount rate the cost per life-year saved, while higher

than the most widely used values for a QALY, is within the range of accepted "willingness to pay" values (e.g., the Hirsch study published in 2000 presents \$450,000 as an accepted value, which adjusted for inflation roughly equals our estimate of \$553,000).

#### C. Alternatives Considered

# 1. Maintain Current Fire Safety Requirements

We currently require long term care facilities to comply with the fire safety requirements in the LSC. In addition, we currently require long term care facilities that do not have sprinklers installed throughout the building to have and maintain at least battery operated smoke alarms in resident rooms and public areas. We believe that these requirements are a solid foundation for ensuring that all long term care facility residents are protected from the threat of fire.

We also believe that these current measures do not go far enough to protect long term care facility residents. Both the Hartford and Nashville facilities were in substantial compliance with the LSC, yet both facilities experienced severe fires with large numbers of fatalities

The smoke alarm requirement that we published in the **Federal Register** on March 25, 2005 (70 FR 15229) after these fires was a step toward improving fire safety and avoiding another devastating fire. Unfortunately, single station smoke alarms can only warn facility staff and residents of the fire. They cannot suppress a fire or prevent it from spreading to other areas.

Long-term care facility residents often have multiple or severe health problems that complicate the facility's ability to ensure their safety in the event of a fire. For example, frail elderly residents may rely on facility staff to assist them in transferring and otherwise moving about the facility. These types of residents are unable to independently protect themselves from the threat of fire by moving away from the danger. They are dependent on facility staff, who are also responsible for ensuring the safety of dozens of other residents. A rapidly growing fire can overwhelm both the staff and residents, leading to tragic consequences.

However, a properly designed, installed, and maintained sprinkler system effectively prevents a fire from spreading to other areas and overwhelming the staff and residents. Containing a fire reduces the threat to residents in other portions of the building and allows facility staff to focus their energy on the area that is

most affected by the fire, without worry about the fire spreading to other areas and threatening other residents. Sprinkler systems have consistently served this function for many years, and they are commonly recognized as the single most effective fire safety device currently available.

Given the past success of sprinkler systems and their potential for saving lives in the future, we believe that maintaining the existing fire safety requirements without adding sprinkler requirements does not ensure the safety of long term care facility residents to the

greatest extent possible.

In addition, maintaining the existing fire safety requirements will have left decisions regarding more stringent fire safety measures in the hands of State and local governments. State and local governments have, in the past, made very different decisions about fire safety requirements in long-term care facilities. For example, some States, such as Tennessee and Virginia, already require all long-term care facilities to have sprinklers throughout their buildings. In contrast, other States, such as South Dakota, Michigan, and the District of Columbia, do not have such requirements, resulting in almost 50 percent or more of their long-term care facilities lacking sprinklers throughout their buildings. This level of variability is not acceptable because residents of long-term care facilities should be assured the same minimum level of fire safety regardless of what State or locality they reside in. Federal regulation is the most efficient and expedient manner for achieving the goal of uniform nationwide minimum fire safety standards; therefore, we chose to pursue Federal regulation rather than depending on State and local governments.

# 2. Exempt Smaller Facilities

The Medicare Conditions of Participation are the minimum requirements that providers are required to meet in order to be Medicare and Medicaid certified. Many other standards setting organizations have requirements that go beyond what Medicare and Medicaid require. Facilities may choose to strive for these higher standards, although Medicare and Medicaid do not require them to do so.

Exempting any facility from this final minimum requirement will be a disservice to the residents of that facility. Residents deserve to be safe from the threat of fire, whether they reside in a large facility or a smaller one. The final sprinkler requirement will ensure that, regardless of the size or

location of their residence, all residents are protected by the same basic minimum fire safety requirements.

However, we did consider whether there might be some size or other threshold creating a "cut off" point below which some facilities might be exempted on the grounds that the cost of sprinkler installation is prohibitively expensive in relation to the number of residents to be protected. We were unable to identify any such threshold from the GAO study, our own analysis, or the comments we received. To the contrary, it appears that there is a linear or near linear relationship among facility revenue, facility size, number of facility residents, and cost of installing automated sprinkler systems. Nor are there any data suggesting that risk or rates of fire vary with facility size. The one certainty is that automated sprinkler systems are the most certainly effective method of preventing and controlling expansion of fires.

We believe that the 5-year phase-in period will substantially help to mitigate the costs of installing sprinklers for small facilities by providing substantial flexibility to coordinate sprinkler decisions with other business arrangements, including financing and renovation decisions. Therefore, we have no reasonable basis to exempt any particular type of facility, including smaller facilities, from this requirement.

# 3. Require Compliance in Less Than or More Than Five Years

Requiring compliance with this final rule in less than five years would, we believe, be a hardship for affected long term care facilities. Allocating resources, designing a sprinkler system, purchasing it, obtaining necessary permits, installing it, and testing it all require a significant amount of time. In 15 states, 20% or more of all long term care facilities will be required to go through this process, potentially increasing the wait time permit applications and for the availability of qualified system designers and installers. For these reasons, and to provide flexibility to coordinate with other business decisions, we have chosen to allow up to 5 years to complete this process.

Allowing facilities more than 5 years to complete the sprinkler process could encourage facilities to unnecessarily delay the installation process. Such delays could unduly jeopardize resident and staff safety. Therefore, we believe that a phase-in period of more than five years would not be in the best interest of long term care facility resident and staff safety and would not accomplish the goals of this final rule.

## D. Accounting Statement

As Required by OMB Circular A-4 (available at http:// www.whitehouse.gov/omb/circulars/ a004/a-4.pdf), in Table 7 below, we have prepared an accounting statement showing the classification of the costs and benefits associated with the provisions of this final rule. This table is based on our best estimate of the undiscounted total cost of \$845 million, over a five year phase in period, for the 2,446 long term care facilities being required to install automatic sprinkler systems at an estimated cost of \$7.95 per square foot, plus an additional \$45 million undiscounted for maintenance costs of about \$2.5 million annually. After discounting to present value, total costs are estimated to be \$806 million at a 3 percent discount rate, and \$715 million at a 7 percent discount rate. The table also reflects total benefits of \$1,372 million undiscounted, \$991 million discounted to present value at 3 percent, and \$722 million discounted to present value at 7 percent.

TABLE 7—ACCOUNTING STATEMENT

| Category                                                      | Primary<br>estimate<br>(\$M) |
|---------------------------------------------------------------|------------------------------|
| Monetized Costs (\$ Millions):<br>Total Cost Over 20-Year Pe- |                              |
| riod (PV at 0% discount rate)                                 | \$890                        |
| riod (PV at 3% discount rate) Total Cost Over 20-Year Pe-     | 806                          |
| riod (PV at 7% discount rate)                                 | 715                          |
| Total Benefits (PV at 0% discount rate)                       | 1372                         |
| count rate)                                                   | 991                          |
| Total Benefits (PV at 7% discount rate)                       | 722                          |

# E. Conclusion

We estimate that this regulation will result in private sector expenditures of \$846,680,105, over a 5-year phase-in period, or \$169,336,021 annually for 5 years, to purchase and install automatic sprinkler systems throughout affected long-term care facilities. We also estimate that this regulation will result in private sector expenditures of \$2,492,474 (\$2,446,000 for maintenance + \$46,474 for documentation) annually to maintain those automatic sprinkler systems. While the effects of this regulation are substantial, they are necessary to protect the safety of longterm care facility residents and staff.

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

# List of Subjects in 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.

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

# 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. In § 483.70, add new paragraph (a)(8) to read as follows:

#### § 483.70 Physical environment.

(a) \* \* \*

(8) A long term care facility must:

(i) Install an approved, supervised automatic sprinkler system in accordance with the 1999 edition of NFPA 13, Standard for the Installation of Sprinkler Systems, as incorporated by reference, throughout the building by August 13, 2013. The Director of the Office of the Federal Register has approved the NFPA 13 1999 edition of the Standard for the Installation of Sprinkler Systems, issued July 22, 1999 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 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/ federal\_register/ code\_of\_federal\_regulations/ ibr locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.

(ii) Test, inspect, and maintain an approved, supervised automatic sprinkler system in accordance with the 1998 edition of NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire

Protection Systems, as incorporated by reference. The Director of the Office of the Federal Register has approved the NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, 1998 edition, issued January 16, 1998 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 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/ federal\_register/ code\_of\_federal\_regulations/ ibr\_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.

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

Dated: March 6, 2008.

#### Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 6, 2008.

# Michael O. Leavitt,

Secretary.

[FR Doc. E8-18670 Filed 8-8-08; 3:30 pm]

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#### **DEPARTMENT OF THE INTERIOR**

## Fish and Wildlife Service

#### 50 CFR Part 21

[FWS-R9-MB-2007-0012; 91200-1231-9BPP]

RIN 1018-AV35

# Migratory Bird Permits; Revisions to Migratory Bird Import and Export Regulations

AGENCY: Fish and Wildlife Service,

Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, change the regulations governing migratory bird permitting. We amend 50 CFR part 21 to allow the export of lawfully-acquired, captive-bred raptors without obtaining a migratory bird export permit; to resolve problems related to export of species

covered by Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permits or certificates; to allow the importation and possession without an import permit of legally-acquired migratory game birds in the families Anatidae, Columbidae, Gruidae, Rallidae, or Scolopacidae that were lawfully hunted in a foreign country; to extend the maximum time for which an import and export permit is valid from 3 to 5 years; and to reorganize and reword the regulations to make them easier to understand.

**DATES:** This rule is effective on September 12, 2008.

FOR FURTHER INFORMATION CONTACT: Dr. George T. Allen, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 703–358–1825.

#### SUPPLEMENTARY INFORMATION:

#### **Background**

The U.S. Fish and Wildlife Service is the Federal agency that has been delegated the responsibility to carry out the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703 et seq.), which implements conventions with Great Britain (for Canada), Mexico, Japan, and the Soviet Union (Russia). Raptors (birds of prey) are afforded Federal protection by the 1972 amendment to the Convention for the Protection of Migratory Birds and Game Animals, February 7, 1936, United States-Mexico, as amended; the Convention between the United States and Japan for the Protection of Migratory Birds in Danger of Extinction and Their Environment, September 19, 1974; and the Convention Between the United States of America and the Union of Soviet Socialist Republics (Russia) Concerning the Conservation of Migratory Birds and Their Environment, November 26, 1976.

Among other things, we manage the import and export of migratory birds and their parts, eggs, and nests. The regulations at 50 CFR 21.21 set forth the requirements for import and export permits for migratory birds and their parts, eggs, and nests, including requirements for import and export permits, application procedures for these permits, additional permit conditions, and the term for which a permit is valid. These regulations are 18 years old and are, in part, outdated. In particular, these regulations do not mention the requirements associated with CITES, addressed in part 23 of our regulations. In addition, many of the requirements currently set forth at § 21.21 simply reference another part or section of our regulations. They are

therefore difficult to read and understand.

We proposed revisions to the regulations governing import and export of migratory birds on November 19, 2007 (72 FR 64981). Among other things, we wanted to: Address the export of species covered by CITES; allow the export of lawfully-acquired, captive-bred raptors without an export permit; allow the importation and possession without a migratory bird import permit of legally-acquired migratory game birds in the families Anatidae, Columbidae, Gruidae, Rallidae, and Scolopacidae that were lawfully hunted in a foreign country; extend the maximum time for which a migratory bird import and export permit is valid from 3 to 5 years; and reorganize and reword the regulations to make them easier to understand. We revised the proposed regulations to address comments we received, but we made no major changes to the proposed rule.

# **Changes in the Migratory Bird Import and Export Regulations**

General requirements (§ 21.21(a)): Current § 21.21(a) provides the general requirements for import and export permits, as well as the exceptions to these requirements. We reorganize current § 21.21 to separate the general requirements (§ 21.21(a)) from the exceptions to the requirements (§ 21.21(b), (c) and (d)). In § 21.21(a), we acknowledge all of the regulations, including the CITES regulations at 50 CFR part 23, that apply to imports and exports of migratory birds and their parts, eggs, and nests. These revisions will help ensure that importers and exporters of migratory birds or their parts, eggs, or nests understand all the requirements applicable to their imports and exports.

Exceptions for import permits (§ 21.21(b)): Current § 21.21(a)(1) provides the requirements for import permits; it does not provide any exceptions to import permit requirements for migratory birds or their parts, eggs, or nests. Current § 21.21(a)(2) does have one import permit exception for raptors for falconry that will be discussed later in this document. We add, in a new § 21.21(b), a provision to allow the importation and possession without an import permit of migratory game birds in the families Anatidae, Columbidae, Gruidae, Rallidae, and Scolopacidae that were lawfully hunted in a foreign country. The imported specimens can be carcasses, skins, or mounts. They must be accompanied by evidence of lawful export from the country of origin and by any other necessary permits, such as a