

Junction, Kentucky northward to its confluence with the Salt River. Otter Creek from Point D (latitude 37°51'31.77" N; longitude 86°00'03.79" W) located approximately 3.4 miles north of Vine Grove, Kentucky to Point E (latitude 37°55'21.95" N; longitude 86°01'47.38" W) located approximately 2.3 miles southwest of Muldraugh.

(b) *The regulation.* All persons, swimmers, vessels and other craft, except those vessels under the supervision or contract to local military or Army authority, vessels of the United States Coast Guard, and federal, local or state law enforcement vessels, are prohibited from entering the danger zones without permission from the Commanding General, U.S. Army Garrison, Fort Knox Military Reservation, Fort Knox, Kentucky or his/her authorized representative.

(c) *Enforcement.* The regulation in this section, promulgated by the United States Army Corps of Engineers, shall be enforced by the Commanding General, U.S. Army Garrison, Fort Knox Military Reservation, Fort Knox, Kentucky and/or other persons or agencies as he/she may designate.

Dated: March 16, 2005.

Michael B. White,

Chief, Operations, Directorate of Civil Works.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS-3145-IFC]

RIN 0938-AN36

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

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period adopts the substance of the April 15, 2004 temporary interim amendment (TIA) 00-1 (101), *Alcohol Based Hand Rub Solutions*, an amendment to the 2000 edition of the Life Safety Code, published by the National Fire Protection Association (NFPA). This amendment will allow certain health care facilities to place

alcohol-based hand rub dispensers in egress corridors under specified conditions. This interim final rule with comment period also requires that nursing facilities install smoke detectors in resident rooms and public areas if they do not have a sprinkler system installed throughout the facility or a hard-wired smoke detection system in those areas.

DATES: *Effective date:* These regulations are effective on May 24, 2005.

Comments date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 24, 2005.

ADDRESSES: In commenting, please refer to file code CMS-3145-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3145-IFC, P.O. Box 8018, Baltimore, MD 21244-8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Danielle Shearer, (410) 786-6617; James Merrill, (410) 786-6998; or Mayer Zimmerman, (410) 786-6839.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-3145-IFC and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786-9994.

I. Background

A. Alcohol-Based Hand Rubs (ABHR)

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

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 governing Medicare and Medicaid health care facilities. The Office of the Federal Register's rules regarding incorporation by reference state that the document so incorporated is the one referred to as it exists on the date of publication of the final rule. Among other things, the 2000 edition of the LSC prohibited the placement of accelerants, including alcohol-based hand rub (ABHR) dispensers, in egress corridors, but allowed their placement in patient rooms and other appropriate areas. We did not receive any public comments contesting this prohibition during the rulemaking process.

[If you choose to comment on issues in this section, please include the caption "ABHR RESEARCH" at the beginning of your comments.]

The ABHRs have become an increasingly common infection control method. The issue of infection control has been a concern identified in numerous research studies and reports. The Centers for Disease Control and Prevention (CDC) reports that there are more than 2 million health care acquired infections per year (http://www.cdc.gov/handhygiene/firesafety/aha_meeting.htm). Many of the microorganisms that cause these infections are transmitted to patients because health care workers do not wash their hands or do so improperly or inadequately. Improving hand hygiene is an important step towards reducing the number of health care acquired infections. In October 2002, the CDC posted hand hygiene guidelines for health care settings on its website (<http://www.cdc.gov/handhygiene/firesafety/default.htm>). The guidelines clearly recommended the use of ABHRs. The CDC stated that—

- Compared with soap and water hand washing, ABHRs are more effective in reducing bacteria on hands, cause less skin irritation/dermatitis, and save personnel time;
- Use of ABHRs has been associated with improved adherence to recommended hand hygiene practices;
- Adherence is directly tied to access. The highest possible adherence to hand hygiene practice is achieved when ABHR dispensers are in readily accessible locations such as the corridor near the patient room entrance and inside patient rooms; and

- Improved hand hygiene practices have been associated with reduced health care-associated infection rates.

Research from a variety of sources confirms the CDC's research and statements about the usefulness and effectiveness of ABHRs in health care

facilities. For example, the study "Improving adherence to hand hygiene practice: A multidisciplinary approach" (Pittet D. *Emerging Infectious Diseases*. 2001 March–April; 7(2):243–40. Review) concludes that, "[a]lcohol-based hand rub, compared with traditional handwashing with unmedicated soap and water or medicated hand antiseptic agents, may be better because it requires less time, acts faster, and irritates hands less often."

The same study goes on to state that, "[t]his method was used in the only program that reported a sustained improvement in hand hygiene compliance with decreased infection rates." The relationship between ABHRs and improved adherence to recommended hand hygiene practices is also found in other studies, including "Availability of an alcohol solution can improve hand disinfection compliance in an intensive care unit" (Maury E, *et al. American Journal of Respiratory and Critical Care Medicine*, 2000; 162:324–327). This study saw compliance with hand hygiene practice rates rise from 42.4 percent before the introduction of ABHRs to 60.9 percent after the introduction of ABHRs. Each category of health care provider, from nurses to physicians, and even patients increased compliance with hand hygiene practices.

Another study, "Effectiveness of a hospital-wide programme to improve compliance with hand hygiene" (Pittet D, Hugonnet S, Harbarth S, *et al. Lancet* 356. 2000; 1307–1312), also demonstrated an increase in compliance with hand hygiene practices that was directly related to the use of ABHRs. In this study, compliance rates rose from 47.6 percent to 66.2 percent over a 3-year period. Handwashing rates remained stable at 30 percent during this period while hand disinfection rates rose from 13.6 percent to 37.0 percent. During this time, the annual amount of ABHR use increased from 3.5L per 1,000 patients to 10.9L per 1,000 patients. The increase in hand disinfection through ABHRs and related increase in compliance with hand hygiene practices are directly tied to the increased availability and use of ABHRs.

An important aspect of getting health care workers and others to use ABHRs is their accessibility. In the study "Handwashing compliance by health care workers: The impact of introducing an accessible, alcohol-based antiseptic" (Bischoff WE, *et al. Archives of Internal Medicine*, 2000; 160: 1017–1021), researchers assessed how the accessibility of ABHRs impacted their use. The researchers found that when

one ABHR dispenser was available for every four patient beds the adherence rate for hand hygiene was 19 percent before patient contact and 41 percent after patient contact. When one ABHR dispenser was available for each bed, the rates rise to 23 percent before patient contact and 48 percent after patient contact. Increased availability of ABHR dispensers resulted in increased hand hygiene rates.

The relationship between increased availability and increased use is likely the result of several factors. An increase in the number of ABHR dispensers acts as a continuous reminder to workers and others that they need to disinfect their hands. For example, each time an individual approaches a patient area, he or she may see, right next to the door, an ABHR dispenser. The dispenser reminds an individual to disinfect his or her hands. In addition to reminding an individual, the location of ABHR dispensers in obvious and highly visible locations serves as a convenient way to disinfect hands. Rather than repeatedly walking to a sink located in another area, a worker can use the ABHR as he or she enters a patient's room as well as while inside the room. Easy and immediate access to ABHR dispensers is a key element in improving adherence to hand hygiene practices.

Improving hand hygiene has a direct effect on the number of health care acquired infections. Following the introduction of ABHRs in one hospital, there was a reduction in the proportion of methicillin-resistant *S. aureus* infections for each of the quarters of 2000–2001, when ABHRs were utilized, compared with 1999–2000, when ABHRs were not utilized. There was also a 17.4 percent reduction in the incidence of *Clostridium difficile*-associated disease from 11.5 cases per 1,000 admissions before the introduction of ABHRs to 9.5 cases per 1000 admissions after the introduction of ABHRs (Gopal Rao G, Jeanes A, Osman M, *et al. Marketing hand hygiene in hospitals: A case study. Journal of Hospital Infection* 2002; 50:42–47).

[If you choose to comment on issues in this section, please include the caption "ABHR SAFETY" at the beginning of your comments.]

The benefits of using ABHRs have been well demonstrated. However, until a short time ago there were concerns about placing ABHR dispensers in egress corridors. The ABHRs are most commonly found in a gel form contained in a single use disposable bag that is inserted into a wall-mounted dispenser, similar in appearance to wall-mounted hand soap dispensers. The dispenser compresses the bag to

dispense the gel. During normal operation and replacement, the dispenser remains a closed system, meaning that vapors are not released into the atmosphere. In addition, refilling is done using single-use disposable bags rather than large bulk containers. The relatively small quantity of gel in each dispenser combined with the absence of vapor release means that these dispensers, when properly installed and used, pose little fire risk in health care facilities.

In July 2003, the American Hospital Association (AHA), in conjunction with the CDC, held a stakeholder meeting with representatives from more than 20 governmental and non-governmental agencies, including CMS, to discuss the issue of the placement and use of ABHRs. During the meeting, the AHA presented a fire modeling study that was conducted by Gage-Babcock & Associates, Inc. on behalf of the AHA's sister organization, the American Society for Healthcare Engineering (ASHE). This study demonstrated that placing ABHR dispensers in egress corridors is safe, provided that certain conditions are met (http://www.hospitalconnect.com/ashe/currentevent/alcohol_based_hand_rub/Final_Report_rev1.2_Part_1_2.pdf).

In February 2004, the ASHE submitted and received approval for temporary interim amendment (TIA) 00-1 (101), *Alcohol-Based Hand Rub Solutions*, to amend the 2003 edition of the LSC. This TIA permitted the placement of ABHR dispensers in egress corridors if certain criteria are met. During a meeting of the NFPA's Standards Council on April 15, 2004, TIA 00-1 (101) was approved for the 2003 edition of the LSC. The TIA was also approved for the 2000 edition of the LSC (the edition CMS adopted). The TIA altered chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC. The change became effective May 5, 2004.

Normally, when the NFPA amends the LSC, it amends the most recently published edition of the code. The most recently published edition is the 2003 edition. However, when the NFPA amended the LSC this time, it retroactively amended the 2000 edition of the LSC in addition to the 2003 edition of the LSC. This is the first time that the NFPA ever retroactively adopted an amendment for an earlier edition of the LSC.

We are adopting the amendment to chapters 18 and 19 of the 2000 edition of the LSC, specifically the changes to chapters 18.3.2.7 and 19.3.2.7. Adopting the amended chapters will allow health

care facilities to place ABHR dispensers in egress corridors. We are not adopting the entire revised 2000 edition of the LSC. Anything in the non-amended version of the 2000 edition of the LSC that is contrary to the amended policy will not apply.

Chapters 18 and 19 will apply to hospitals, long-term care facilities, religious non-medical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, intermediate care facilities for the mentally retarded, and critical access hospitals.

Ambulatory surgical centers (ASC) are not covered under chapters 18 or 19 of the LSC; but are rather covered under chapter 21 of the LSC. Many ASCs are interested in installing ABHR dispensers in corridors. However, chapter 21 of the LSC has not been amended thus far to permit the installation of ABHR dispensers in egress corridors in ASCs. We are allowing ASCs to install ABHR dispensers in egress corridors according to the same conditions identified for other health care facilities.

We consider a health care facility to be in compliance with our requirements if the placement of ABHR dispensers meets the specified conditions listed in section II.A of this interim final rule with comment period. The ABHR dispensers will also be required to meet the following criteria that are listed in chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC:

- Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m).
- The maximum individual dispenser fluid capacity shall be:
 - 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.
 - 0.5 gallons (2.0 liters) for dispensers in suites of rooms.
- The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other.
- Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet.
- Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code*.
- The dispensers shall not be installed over or directly adjacent to an ignition source.
- In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be

permitted only in sprinklered smoke compartments.

After careful and thorough consideration of the numerous studies and recommendations presented above, we believe that placing ABHR dispensers in all appropriate areas, including corridors, is safe and appropriate for patients and providers alike.

B. Smoke Detectors

A recent 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 in 2003 that resulted in 31 resident deaths. The report examined Federal fire safety standards and enforcement procedures, as well as results from fire investigations of these two incidents. The report recommended that fire safety standards for unsprinklered facilities be strengthened. It specifically cited requiring smoke detectors in these facilities as one way to strengthen the requirements.

The fires, in Hartford, Connecticut and Nashville, Tennessee, had several things in common. Each fire began in a resident sleeping room at night, neither of those rooms had a smoke detector, and the majority of victims died from smoke inhalation. The lack of smoke detectors in resident rooms, the report concludes, " * * * may have delayed staff response and activation of the buildings' fire alarms."

Relying on an effective and timely staff response is a crucial aspect of the current facility fire safety requirements. Long-term care facilities are required by the LSC (chapters 18.7.1.1 and 19.7.1.1) to have an emergency plan that will be implemented in the event of a fire at the facility. As part of this plan, staff members at Medicare-approved facilities are typically expected to do things such as close resident room doors, turn off fans and other air circulation devices, and evacuate residents.

However, battery-operated smoke detectors, a basic fire safety device, are only required by the 2000 edition of the Life Safety Code to be installed in existing non-sprinklered resident rooms when those rooms contain furniture that the resident has brought from his or her home. This was not the case in either fire; therefore, smoke detectors were not in the resident sleeping rooms where the fires started and staff members were not aware of the fires until smoke reached the smoke detectors in the

corridors. This delay inhibited timely staff response and may have contributed to resident deaths.

While resident rooms are the leading area of fire origin, fires can and do originate in other areas. For example, a fire could originate in an unoccupied resident activity room. As with resident sleeping rooms, there is a possibility that no one will be aware of this fire until its smoke spread to a corridor where there are smoke detectors. By this time, smoke may have also begun filtering into other areas of the facility such as resident sleeping rooms and public areas that are occupied, thus harming those residents. In order to alert staff and residents in the earliest stages of a fire, we believe that it is necessary to install smoke detectors in resident sleeping rooms and public areas. For these reasons, we are requiring that long-term care facilities that do not have sprinklers must at least install battery-operated smoke detectors in patient rooms and public areas. We have discussed this issue in detail in section II.B of this interim final rule with comment period.

We are specifically soliciting public comment on the placement of smoke detectors in long-term care facilities. Should detectors also be placed in non-public areas such as storage rooms, closets, and offices?

Facilities that choose to install a hard-wired smoke detector system in accordance with NFPA 72, *National Fire Alarm Code*, in patient rooms and public areas within the 1 year phase-in period discussed in section II.B of this interim final rule with comment period will be exempt from this requirement. A hard-wired smoke detector system is a system that is wired to both a facility's electrical and fire alarm systems. The detectors draw their energy from a facility's electrical system and use batteries as back-ups in case of power failure. In addition, the detectors communicate with one another so that an alarm in one room would trigger an alarm in every room. The detectors also communicate with the facility's fire alarm system, thus notifying the fire department of the situation. If a facility chose to install a hard-wired system in resident rooms and public areas, then it will not have to install battery-operated smoke detectors because such a system will exceed the requirements of this interim final rule with comment period. Facilities that have installed sprinkler systems throughout in accordance with NFPA 13, *Automatic Sprinklers*, will also be exempt from the proposed requirement to install smoke detectors, because such a system will exceed this requirement.

C. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. We intend to publish the final rule within the 3-year timeframe established under section 902 of the MMA.

II. Provisions of the Interim Final Rule

A. Alcohol-Based Hand Rubs

[If you choose to comment on issues in this section, please include the caption "PLACEMENT REQUIREMENTS" at the beginning of your comments.]

For the reasons specified in the preamble, in sections I.A. and I.B. above, we are modifying the conditions of participation for the following facilities:

- Religious non-medical health care institutions (RNHCI) (new § 403.744(a)(4)).
- Ambulatory Surgical Services (ASC) (new § 416.44(b)(5)).
- Hospices (new § 418.100(d)(6)).
- Programs of all-inclusive care for the elderly (PACE) (new § 460.72(b)(6)).
- Hospitals (new § 482.41(b)(9)).
- Long-term care (LTC) facilities (new § 483.70(a)(6)).
- Intermediate care facilities for the mentally retarded (ICFs/MR) (revised § 483.470(j)(7)).
- Critical access hospitals (CAHs) (new § 485.623(d)(7)).

The numbering that appears above corresponds to the most recent changes to the Life Safety Code regulations, published in the **Federal Register** as a final rule on August 11, 2004.

Specifically, we are adding a new provision that will allow these facilities to place ABHR dispensers in various locations, including egress corridors, if the facilities met the following conditions:

- The use of ABHR dispensers could not conflict with any State or local codes that prohibit or otherwise restrict the placement of ABHR dispensers in

health care facilities. Allowing ABHR dispensers to be installed in egress corridors will be a significant lessening of restrictions. States and/or local jurisdictions may choose to retain stricter codes that prohibit or otherwise restrict the installation of ABHR dispensers in health care facilities. Facilities will still be required to comply with those stricter State and local codes. Therefore, facilities could only install ABHR dispensers if the dispensers were also permitted by State and local codes.

- The dispensers were installed in a manner that minimized leaks and spills that could lead to falls. Like soap, ABHRs are very slick. As such, it is more likely for someone to slip and fall on a surface that is covered by an ABHR solution than on a surface that is clean.

The increased risk of falls posed by the presence of leaky or spilled ABHR dispensers might be compounded by the medical conditions of patients or residents. While a healthy individual may fall and only suffer a bruise, a frail individual may suffer a broken hip. It is the specific safety needs of the patient populations found in hospitals and other health care facilities that necessitates the requirement that facilities take extra steps to ensure that ABHR dispensers do not leak or spill.

In addition to any extra steps such as additional hardware installation, facilities should follow all manufacturer maintenance recommendations for ABHR dispensers. Regular maintenance of dispensers in accordance with the directions of the manufacturer is a crucial step towards ensuring that the dispensers do not leak or spill.

- The dispensers were installed in a manner that adequately protected against access by vulnerable populations, such as residents in psychiatric units. There are certain patient or resident populations, such as residents of dementia wards, who may misuse ABHR solutions, which are both toxic and flammable. As a toxic substance, ABHR solutions are very dangerous if they are ingested, placed in the eyes, or otherwise misused. As a flammable substance, ABHR solutions could be used to start fires that endanger the lives of patients and destroy property.

Due to disability or disease, some patients are more likely to harm themselves or others by misusing ABHR solutions. In order to avoid any and all dangerous situations, a facility will have to take all appropriate precautions to secure the ABHR dispensers from misuse by these vulnerable populations.

- The dispensers were installed in accordance with chapters 18.3.2.7 and

19.3.2.7 of the 2000 edition of the LSC. The revisions to the chapters were thoroughly examined by the NFPA's fire safety experts and are based on the fire modeling study conducted by Gage-Babcock for the ASHE. As noted above, the study demonstrated that ABHR dispensers installed in egress corridors do not increase the risk of fire in certain conditions, as outlined in chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC, are met. The study also showed that if those conditions are not met, there will be an increase in the risk of fire.

B. Smoke Detectors

[If you choose to comment on issues in this section, please include the caption "LOCATION" at the beginning of your comments.]

We are requiring in § 483.70(a)(7) that long-term care facilities will, at minimum, be required to install battery-operated smoke detectors in resident sleeping rooms and public areas, unless they have a hard-wired smoke detector system in resident rooms and public areas or a sprinkler system throughout the facility. We are also requiring that facilities that install battery-operated smoke detectors have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors. Smoke detectors, when properly installed and maintained in resident sleeping rooms and public areas, are a basic, useful and effective fire safety tool.

We believe that at least installing battery-operated smoke detectors will provide earlier warning for facility residents and staff. Fires that originate in these areas will be detected earlier because the detector will be located closer to the fire's origin than if it were only placed in the corridor. Earlier detection, and thus earlier alarm, will allow residents and staff more time to react to the situation and implement the facility's emergency plan. Implementing the emergency plan typically includes notifying the fire department, and this earlier notification will speed the arrival of help. These factors could help to reduce the loss of life in a nursing facility fire.

[If you choose to comment on issues in this section, please include the caption "MAINTENANCE" at the beginning of your comments.]

As discussed earlier, a facility will be required to have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors. Detectors require maintenance every 6 months to 1 year in order to ensure that the batteries are operating at optimum power. A detector

with a depleted battery provides no protection. Thus, a regular maintenance program for the detectors is crucial to ensuring that residents and staff are indeed protected. Facilities will be expected to add maintenance of smoke detectors to their existing maintenance schedule.

[If you choose to comment on issues in this section, please include the caption "1 YEAR PHASE-IN" at the beginning of your comments.]

We are allowing facilities 1 year to comply with this regulation for two reasons. First, allowing facilities an extra year to comply with this regulation will also give interested facilities additional time to purchase and install a hard-wired smoke detector system or a sprinkler system. Purchasing and installing these systems is more complicated than purchasing and installing battery-operated detectors. Therefore, facilities that wanted to exercise this option would be prohibited from doing so if they were required to comply immediately. The 1-year phase-in will give facilities a chance to purchase and install a more advanced fire and smoke protection system than this regulation requires. We are strongly in favor of facilities taking advantage of this extended compliance period to install more advanced fire protection systems than the battery-operated smoke detectors that are required by this regulation.

Second, some facilities might have difficulty obtaining and installing battery-operated smoke detectors within the typical 60-day period from the date of publication of a final rule to the rule's effective date. Therefore, we are allowing facilities to phase-in smoke detectors over a 1-year period from the effective date of a final regulation. Facilities could use this year to purchase and install battery-operated detectors, or they could do so on an abbreviated schedule. We encourage facilities that choose to install battery-operated smoke detectors to do so as quickly as possible in order to increase fire safety. We believe that this phase-in period will give facilities more flexibility in meeting this requirement.

[If you choose to comment on issues in this section, please include the caption "EXCEPTIONS" at the beginning of your comments.]

The regulation will have two exceptions, one for facilities that have hard-wired smoke detection systems and one for facilities that have sprinkler systems. Hard-wired smoke detector systems installed in resident rooms and public areas will protect the same areas as the battery-operated detectors. Therefore, having both hard-wired and

battery-operated detectors in these areas will be redundant, unnecessary, and overly burdensome. Facilities may still choose to use battery-operated detectors along with hard-wired detectors as an additional layer of fire protection, but we will not require the facilities to do so in this interim final rule with comment period.

Likewise, having both a sprinkler system throughout and battery-operated smoke detectors in resident rooms and public areas will duplicate fire safety efforts.

Sprinklers are considered to be the best way to protect building occupants in fires. Their response time and their ability to extinguish fires before they become a significant hazard will make battery-operated smoke detectors an unnecessary requirement. Facilities may still choose to use detectors as an additional layer of fire protection beyond sprinklers, but they will not be required to do so in this interim final rule with comment period.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We believe that continuing to prohibit the placement of ABHR dispensers in all appropriate areas, including egress corridors, is contrary to the public interest because ABHRs are a safe and effective method for increasing hand hygiene compliance rates, and their use has been shown to help decrease health care-acquired infections. As the studies and recommendations described in section I.A of this document

demonstrate, ABHRs are a safe and effective method for cleansing hands.

Although ABHR dispensers were once considered to be a fire safety risk when placed in egress corridors, they are no longer considered by fire safety experts to pose a significant risk to patient safety. According to the Gage-Babcock study, ABHR dispensers can be safely installed in egress corridors if they meet certain specifications, such as being placed at least 4 feet apart and not being placed over carpet in an unsprinklered smoke compartment. Fire safety experts believe that dispensers of ABHRs, when installed properly in egress corridors, do not decrease fire safety. We agree with this position.

Any fire safety concerns are, we believe, more than offset by the potential for health care facilities to improve their infection control practices. As the availability of ABHRs increases in a facility, so does the rate of hand hygiene compliance. An increase in hand hygiene compliance rates results in a decrease in health care acquired infections. We believe that the public will benefit from more ABHR dispensers being available in more places because the increased availability of ABHR dispensers will likely decrease the number of health care acquired infections, thus improving public health and safety in health care facilities.

We believe that allowing long-term care facilities to continue to care for residents in buildings that have neither sprinklers nor smoke detectors is contrary to the public interest because buildings that do not at least have smoke detectors present a greater risk of death or injury due to fire. In 2003, 31 long-term care facility residents died in two separate fires in buildings that did not have smoke detectors in patient rooms, where both fires started, or in public areas. Smoke detectors are basic and relatively inexpensive fire safety tools that have been proven to be effective at alerting residents and staff to fire, and that have been in use in homes and other buildings across the country for several decades. They provide early warning to occupants and have saved countless lives. Continuing to allow long-term care facilities that care for residents in buildings lacking smoke detectors risks the safety of all residents and staff in these buildings.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We have examined the impact of this interim final rule with comment period, and we have determined that this rule is neither expected to meet the criteria to be considered economically significant, nor do we believe it will meet the criteria for a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. For purposes of the RFA, most entities affected by this interim final rule with comment period are considered small businesses according to the Small Business Administration's size standards, with total revenues of \$29 million or less in any 1 year (for details, see 65 FR 69432). Individuals and States are not included in the definition of a small entity. According to CMS statistics, nursing facilities, which we require to install smoke detectors in resident rooms and public areas, earned a total of \$89.6 billion in 1999 (<http://www.cms.hhs.gov/>

[statistics/nhe/historical/t7.asp](http://www.cms.hhs.gov/statistics/nhe/historical/t7.asp)).

According to the National Nursing Home Survey: 1999 Summary (http://www.cdc.gov/nchs/data/series/sr_13/sr13_152.pdf), there were 18,000 nursing facilities in operation at that time. An average facility at this time thus had revenue of approximately \$4,977,778. A facility with revenue 50 percent below this average still earned \$2,488,889. In the first year, this interim final rule with comment period will cost, on average, approximately \$9,800 per facility. In the following years, this interim final rule with comment period will cost \$2,800 annually for maintenance. This amount will be less than one half of one percent of the total revenue for an average- or below-average-revenue facility. Therefore, we certify that this interim final rule with comment period will not have a significant impact on a substantial number of small entities. We are not considering hospitals or other facilities affected by the alcohol-based hand rub regulation in this regulatory flexibility analysis because we do not require those facilities to take any action. We are requiring that, if those facilities choose to install ABHR dispensers in egress corridors, then they will have to do so in accordance with the regulation.

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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This interim final rule with comment period will not have a significant impact on small rural hospitals because the interim final rule with comment period will not impose requirements on small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This interim final rule with comment period will not have an effect on State, local, or tribal governments, and the private sector costs will not be greater than the \$110 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates an interim final rule with comment period (and subsequent final rule) that imposes substantial direct requirement costs on

State and local governments, preempts State law, or otherwise has Federalism implications. This regulation does not have any Federalism implications.

B. Anticipated Effects

1. Alcohol-Based Hand Rubs

This interim final rule with comment period does not require an affected facility to install ABHR dispensers; thus, the facility will not be mandated with a burden associated with this provision of the regulation.

We, however, will require facilities that choose to install ABHR dispensers to do so in accordance with chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC as amended by the TIA. Facilities will have to install them in accordance with the LSC, and in a way that minimized leaks and spills, and access to the dispensers by vulnerable populations. Installing dispensers according to the specifications of the LSC and this regulation may increase installation costs. Facilities that choose to install dispensers are required by this regulation to take additional steps to minimize dispenser leaks and spills. While this regulation does not require a specific method for minimizing leaks and spills, facilities may decide to install additional hardware to ensure compliance with this regulation. Additional hardware, such as a device below the dispenser to catch drips, could increase purchasing and installation costs. The leak and spill minimization requirement is new, therefore we have no data to estimate the cost of the provision. We believe that any additional costs are small when compared to the costs of caring for a frail patient who fell on a slippery, ABHR covered floor.

In addition, the installation of these dispensers in egress corridors was previously prohibited. The requirements for locating dispensers in other areas will not change. Therefore, a facility will not have to relocate or modify existing dispensers to conform to the specifications.

Facilities that choose to install ABHR dispensers in any area, including corridors and patient rooms, are required by the LSC to store large quantities of ABHR solution in a flammable liquids cabinet. Facilities are required to use these cabinets if they choose to store 5 gallons or more of ABHR solution in a single smoke compartment. This LSC requirement helps ensure that large amounts of ABHR solution do not accelerate health care facility fires.

Most hospitals already have these cabinets to store other alcohol products

or flammables, and would therefore not need to purchase a special storage container for ABHR solutions. Other facilities that may choose to install ABHR dispensers are typically smaller than hospitals and would not need to store more than five gallons of ABHR solution in a single smoke compartment. A facility with 20 rooms per smoke compartment will likely install 10 ABHR dispensers, for a total of three gallons of ABHR solution per smoke compartment. That same facility would be permitted to keep an additional two gallons of ABHR solution for refilling in that same compartment without using a flammable liquids cabinet. Therefore, we do not believe that this LSC provision will pose a significant burden to facilities that choose to install ABHR dispensers.

Facilities that choose to install ABHR dispensers may expect to see a decrease in health care acquired infections due to an increase in hand hygiene practices by clinicians and non-clinicians. While we cannot quantify the potential benefit of this decrease in infections, we do know that decreasing infection rates lead to better patient care outcomes and decrease patient care costs.

2. Smoke Detectors

The July 2004 GAO report estimated that 20 to 30 percent of long-term care facilities do not have sprinklers throughout the facility and will therefore be subject to the provisions of this regulation. We do not have information on the number of facilities that have a hard-wired smoke detector system in resident rooms and public areas. For the purposes of our analysis, we estimated that 25 percent of long-term care facilities, or 4,200, will be subject to the provisions of this regulation. We estimate that an average long-term care facility in a building that does not have sprinklers has 100 residents in 50 two-person resident sleeping rooms, and that each room will require one battery-operated smoke detector. We estimated that each average facility will require 20 additional detectors for public areas, for a total of 70 detectors per facility. We estimated that the cost of each smoke detector and its installation will be approximately \$100. Therefore, an average facility will expect to pay \$7,000 to purchase and install battery-operated smoke detectors in resident sleeping rooms and public areas. The total industry cost for purchasing and installing battery-operated smoke detectors in the specified areas will be \$29,400,000.

Following installation of battery-operated smoke detectors in the specified areas, a long-term care facility

will be required to have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors. We estimate that a facility will conduct monthly tests of each detector by activating the test button. This will take approximately 5 minutes per smoke detector per test, or 1 hour per smoke detector per year.

In addition, we estimate that a facility will clean each detector and change its batteries two times per year. This will take 15 minutes per smoke detector per cleaning and replacement, or 30 minutes per smoke detector per year. We estimate that the total annual maintenance time per detector will be one 1.5 hours, for total of 105 hours per average facility.

We estimate that the cost for this provision for an average long-term care facility with 70 smoke detectors, based on a maintenance person earning \$20 per hour and \$5 for batteries per change, is \$2,800. The annual industry total for this maintenance provision will thus be \$11,760,000.

The total cost for the first year of this regulation, including purchase, installation and maintenance costs, will be \$9,800 per average facility, for a total of \$41,160,000 industry wide. The cost for the following years of maintenance will be \$2,800 per average facility annually, or \$11,760,000 industry wide annually.

C. Alternatives Considered

1. Alcohol-Based Hand Rubs

We considered not adopting chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC as amended by the TIA, thereby continuing to prohibit the placement of ABHR dispensers in egress corridors. However, continuing this prohibition was not acceptable for two reasons. First, we want to improve hand hygiene practices in order to reduce health-care-acquired infections. Hand hygiene levels increase when the availability of hygiene stations, such as ABHR dispensers, increase. It is helpful to have these stations in areas that are highly visible and easily accessed, as they are in corridors. Therefore, the potential to increase hand hygiene and thus decrease health care acquired infections by placing ABHR dispensers in all appropriate locations warranted this regulation.

Second, continuing to prohibit ABHR dispensers in egress corridors is contrary to our goal of increasing provider flexibility. We believe that, wherever possible, providers should be allowed the flexibility to meet the needs of their patients/residents in the manner they see fit. Providers are aware of the

hazards posed by infections and have developed many methods for addressing those hazards. The ABHR dispensers are one method, and we believe that providers should be allowed to utilize the ABHR dispensers to the fullest extent within the context of patient safety.

We also considered adopting chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC without the additional requirements. However, the chapters do not address several important areas of patient safety, and we believe that not addressing these areas may put patient safety at risk. The NFPA is dedicated to reducing loss of life due to fires. As such, it concerned itself solely with the fire safety implications of installing ABHR dispensers in egress corridors. Chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC did not address leaks and spills that will result in people slipping and falling, nor did they address the potential for inappropriate use of ABHRs by vulnerable populations such as patients in ICFs/MR or dementia units. Due to disability or illness, these populations require additional protection from substances that are toxic and/or flammable. The ABHRs are both toxic and flammable. Chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC did not address these non-fire safety issues. Therefore, we believe that it is necessary to add other installation requirements in addition to chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC.

2. Smoke Detectors

We considered not requiring long-term care facilities to install smoke detectors; however, we believe that installation of the smoke detectors will help save lives. The July 2004 GAO report clearly outlined the role that smoke detectors, one of the most basic and effective fire safety devices available, played in the Nashville and Hartford fires. The report also outlined the wider role that detectors can and should play in long-term care facility fire safety. The positive impact of smoke detectors on resident safety, we believe, warrants their installation.

We also considered requiring long-term care facilities to immediately install battery-operated smoke detectors, rather than allowing facilities to phase them in over a 1-year period. We strongly support a facility's choice to install a fire safety system that exceeds the requirements of this regulation. It would have been extremely difficult for facilities that wanted to install hard-wired smoke detector systems or sprinkler systems to complete their tasks in 60 days. The 1-year phase-in

period will allow those facilities more time to complete these systems, which would go beyond what we are requiring in this rule.

In addition, requiring facilities to, at a minimum, install battery-operated smoke detectors in 60 days would have posed a significant time and financial burden to facilities. Had we chosen this option, we would have required facilities to purchase and install a fairly large volume of detectors in a fairly short period of time, 60 days. This may have been very difficult for some facilities due to the initial cost of purchasing and installing the detectors. We estimate that it will cost facilities \$7,000 to purchase and install battery-operated smoke detectors. There may be facilities that do not have the full amount of funds immediately available, and therefore would not be able to comply with this regulation within the standard 60-day time period. The 1-year phase-in period allows these facilities to distribute the cost over 12 months, for an average monthly cost of \$584. Distributing the cost of smoke detectors over a 1-year period ensures that all facilities are able to afford the cost of complying with this rule.

Furthermore, we considered requiring long-term care facilities to install a hard-wired smoke detector system in accordance with NFPA 72, *National Fire Alarm Code*, for hard-wired alternating current smoke detector systems. This option would have posed a significant burden to some long-term care facilities because of the cost and time associated with purchasing and installing these devices. Hard-wired detectors must be wired directly into the facility's electrical and fire alarm system. We believe that the costs associated with purchasing this system and the time required to install it would have placed this option out of reach for some nursing facilities.

Therefore, we are requiring only the less expensive and less time consuming battery-operated detector. Facilities may still choose to install a hard-wired smoke detector system, and we encourage them to do so. Installation of such a system in patient rooms and public areas will exempt a facility from installing battery-operated detectors in those areas.

Finally, we considered requiring long-term care facilities that do not have sprinklers to install them. We are aware that the NFPA and long-term care industry are carefully examining this issue in light of the recent fires. We are also aware that installing sprinklers in existing facilities is an expensive proposition. We believe that this issue warrants further examination, and are

committed to working with NFPA, the long-term care facility industry, and advocates to develop a consensus position. Any new sprinkler requirements would be discussed in a separate regulatory document and would be published in the **Federal Register**. Facilities may still choose to install a sprinkler system throughout the facility in accordance with NFPA 13. Installation of such a system will exempt a facility from installing battery-operated detectors in patient rooms and public areas. We encourage all facilities to fully explore this option, as it provides the highest level of fire protection currently available.

D. Conclusion

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

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

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

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

42 CFR Part 418

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

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

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

42 CFR Part 483

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

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements

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

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 is amended to read as follows:

Authority: 42 U.S.C. 1395b–3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

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

■ 2. Add new paragraphs (a)(3) and (a)(4) to § 403.744 to read as follows:

§ 403.744 Condition of participation: Life safety from fire.

(a) * * *

(3) [Reserved]

(4) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, the RNHCI may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire

Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

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PART 416—AMBULATORY SURGICAL SERVICES

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

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

Subpart C—Specific Conditions for Coverage

■ 4. Add new paragraph (b)(5) to § 416.44 to read as follows:

§ 416.44 Conditions for coverage—Environment.

* * * * *

(b) * * *

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with the following provisions:
(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);
(B) The maximum individual dispenser fluid capacity shall be:
(1) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.
(2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;

(C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;

(D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code*;

(F) The dispensers shall not be installed over or directly adjacent to an ignition source; and

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

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PART 418—HOSPICE CARE

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

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

Subpart E—Conditions of Participation: Other Services

■ 6. Add a new paragraph (d)(6) to § 418.100 to read as follows:

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

* * * * *

(d) * * *

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this

amendment, CMS will publish notice in the **Federal Register** to announce the changes.

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

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

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

Subpart E—PACE Administrative Requirements

■ 8. Add a new paragraph (b)(5) to § 460.72 to read as follows:

§ 460.72 Physical environment.

* * * * *

(b) * * *

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a PACE center may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

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PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

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

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

Subpart C—Basic Hospital Functions

■ 10. Add a new paragraph (b)(9) to § 482.41 to read as follows:

§ 482.41 Condition of participation: Physical environment.

* * * * *

(b) * * *

(9) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

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PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 11. 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

■ 12. In § 483.70, add new paragraphs (a)(6) and (a)(7) to read as follows:

§ 483.70 Physical environment.

(a) * * *

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a long-term care facility may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

(7) A long-term care facility must:

(i) Install battery-operated smoke detectors in resident sleeping rooms and public areas by May 24, 2006.

(ii) Have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors.

(iii) Exception:

(A) The facility has a hard-wired AC smoke detection system in patient rooms and public areas that is installed, tested, and maintained in accordance

with NFPA 72, *National Fire Alarm Code*, for hard-wired AC systems; or

(B) The facility has a sprinkler system throughout that is installed, tested, and maintained in accordance with NFPA 13, *Automatic Sprinklers*.

* * * * *

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

■ 13. Revise paragraph (j)(7) to § 483.470 to read as follows:

§ 483.470 Condition of participation: Physical environment.

* * * * *

(j) * * *

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

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

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

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

(ii) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a facility may install alcohol-based hand rub dispensers if—

(A) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(B) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(C) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(D) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire

Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

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PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

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

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

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

■ 15. Add a new paragraph (d)(7) to § 485.623 to read as follows:

§ 485.623 Condition of participation: Physical plant and environment.

* * * * *

(d) * * *

(7) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any

additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the change.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

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

Dated: September 1, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 7, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–5919 Filed 3–24–05; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AI20

Endangered and Threatened Wildlife and Plants; Final Designation of Critical Habitat for Topeka Shiner

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; correction.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce corrections to the final rule designating critical habitat for the Topeka shiner (*Notropis topeka*), published in the **Federal Register** on July 27, 2004. In the final rule, the map legends incorrectly referred to stream segments as “proposed” critical habitat rather than “designated” critical habitat, and six transcription errors were included in legal descriptions of critical habitat from Unit 1 (Iowa) and Unit 4 (Minnesota). This document corrects these errors.

DATES: Effective August 26, 2004.

FOR FURTHER INFORMATION CONTACT:

Vernon Tabor, Kansas Ecological Services Field Office, 315 Houston Street, Suite E, Manhattan, Kansas 66502 (telephone 785–539–3474; facsimile 785–539–8567). The complete file for this correction document and the rule are available for public inspection, by appointment, during normal business hours at the above address. Copies of the rule, draft economic analysis, and draft environmental assessment are available by writing to the above address or by connecting to the Service