Restricted area	Inspection description	Frequency
Building 39	Inspect to ensure that use does not allow residential, daycare or school (children under 18 years old), hotel, motel, community center (children under 18 years old), and/or recreational uses or activities uses.	Annually in June.
Buildings 131, 117, & 313–S	Inspect area to ensure no excavation, drilling or otherwise disturbance of the building foundations and slabs that would likely result in human contact with underlying soils have occurred.	Annually in June.

The second five-year review, completed in March 2006, concluded that the remedy at OU1 (the only site where hazardous materials remain on-site) is protective of human health and the environment in the short-term because there is no evidence of exposure. However, there was concern that some bank erosion occurred along the Charles River adjacent to Charles River Park (in areas where the Army was not required to remediate). In order for the remedy to remain protective in the long term, the Army must stabilize the riverbank adjacent to Areas P and Q before the next five-year review. While the integrity of the two-foot soil coverage required by the ROD and ESD remains intact along the riverbanks, the Army will undertake preventive measures to ensure long-term site integrity. This work began in September 2006 and is expected to be completed before the end of the year.

Community Involvement

In addition to the regular community meetings discussed below, community relations activities for the Army Materials Testing Laboratory NPL Site have included the following: development of a community relations plan, public meetings and site tours during the RI and remedy selection process, public comment periods on proposed plans, and publication and distribution of fact sheets updating the status of site cleanup.

In 1989, the Army established a Technical Review Committee (TRC) to enhance community involvement. In 1993 the TRC transitioned into a Restoration Advisory Board (RAB). The purpose of the TRC and RAB was to serve as a forum where representatives of the community, regulators, and the Army could discuss and exchange information on environmental cleanup issues and progress at the Site. The TRC and RAB provided an opportunity for stakeholders to participate in the decision-making process by reviewing and commenting on documents and proposed remedial actions. Through the TRC and RAB, cleanup decisions were discussed and approved.

During fiscal year 2006, a fact sheet that discussed the intention to delete the site from the NPL was distributed to the RAB. EPA will also announce the deletion of the Site from the NPL once the deletion has been completed with fact sheet and public notice.

V. Deletion Action

EPA, with concurrence from the Commonwealth of Massachusetts, has determined that all appropriate responses under CERCLA have been completed, and that no further response actions under CERCLA are necessary. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be non-controversial and routine, EPA is taking it without earlier publication of a notice of intent to delete. This action will become effective November 21, 2006 unless EPA receives adverse comments by October 23, 2006 or a parallel notice of intent to delete is published in the Proposed Rule section of today's **Federal Register**. If adverse comments are received, EPA will withdraw this direct final notice of deletion before the effective date of the deletion and it will not take effect. EPA will respond to comments, as appropriate, and continue with the traditional deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment. If EPA receives no adverse comment(s), this deletion will become effective November 21, 2006.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: September 12, 2006.

Robert W. Varney,

Regional Administrator, U.S. EPA—New England.

■ For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp.; p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

■ 2. Table 2 of Appendix B to part 300 is amended by removing the entry for ''Materials Technology Laboratory (US ARMY), Watertown, MA.''

[FR Doc. 06–7966 Filed 9–21–06; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS–3145–F]

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: Final rule.

SUMMARY: This final rule adopts the substance of the April 15, 2004 tentative 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 allows certain health care facilities to place alcohol-based hand rub dispensers in egress corridors under specified conditions. This final rule also requires that nursing facilities at least install battery-operated single station smoke alarms in resident rooms and common areas if they are not fully sprinklered or they do not have system-based smoke detectors in those areas. Finally, this final rule confirms as final the provisions of the March 25, 2005 interim final rule with changes and responds to public comments on that rule.

DATES: *Effective Date:* These regulations are effective on October 23, 2006. The incorporation by reference of certain

publications listed in the rule is approved by the Director of the Federal Register as of October 23, 2006.

FOR FURTHER INFORMATION CONTACT: Danielle Shearer, (410) 786–6617; James Merrill, (410) 786–6998; Jeannie Miller, (410) 786–3164; or Mayer Zimmerman, (410) 786–6839.

SUPPLEMENTARY INFORMATION:

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 general 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.

On April 15, 2004 the NFPA adopted a tentative interim amendment (TIA) 001 (101), Alcohol Based Hand Rub Solutions, to the 2000 edition of the LSC. This amendment allows certain health care facilities to install alcohol-based hand rub (ABHR) dispensers in egress corridors under certain specified conditions.

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). In that interim final rule, we adopted the substance of the April 15, 2004 TIA.

As stated in the preamble to the March 2005 interim final rule, ABHRs have become an increasingly common infection control method. Effective 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 Web site (*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 afterwards. Each category of health care employer, 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 healthcare-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).

The benefits of using ABHRs have been well demonstrated. However, there have been previous 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 tentative 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. At the April 15, 2004 meeting of the NFPA's Standards Council, 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 at that time was 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.

Chapters 18 and 19 of the Life Safety Code 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 (ASCs) are not covered under chapters 18 or 19 of the LSC; but are rather covered under chapters 20 (new construction) and 21 (existing construction) of the LSC. Many ASCs are interested in installing ABHR dispensers in corridors. However, chapters 20 and 21 of the 2000 edition of the LSC have 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 final rule. 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 as amended:

- 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 Alarms

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.

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). In that interim final rule, we required that long term care facilities at least install battery operated smoke detectors in resident rooms and public areas if they did not have sprinklers installed throughout or they did not have a hard-wired smoke detection system in the specified areas. This interim final regulation implemented the smoke detector recommendation made by the GAO in the 2004 report. As we will discuss in section III.B, Analysis of and Responses to Public Comments, Smoke Alarms, of this document, we are altering the terminology used to describe the smoke detector requirement. From this point forward, we will refer to the following terms in the manner specified below unless otherwise noted:

- ''Smoke detectors'' are now ''smoke alarms'';
- ''Public areas'' are now ''common areas'';
- Having ''sprinklers installed throughout'' is now ''fully sprinklered''; and
- ''A hard-wired smoke detection system'' is now ''system-based smoke detectors''.

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 alarm, and the majority of victims died from smoke inhalation. The lack of smoke alarms 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 was, and still is, a crucial aspect of facility fire safety requirements. Long-term care facilities are required by the 2000 edition of 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 alarms, a basic fire safety device, are only required by the 2000 edition of the Life Safety Code (which refers to them as smoke detectors) 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 alarms were not in the resident sleeping rooms where the fires started.

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. There is a possibility that no one will be aware of this fire until smoke spreads to a corridor where there are smoke alarms. By this time, smoke may have also begun filtering into other areas of the facility such as resident sleeping rooms and common 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 alarms in resident sleeping rooms and common areas. For these reasons, we are requiring that long-term care facilities that do not have sprinklers must at least install battery-operated single station smoke alarms in resident rooms and common areas. We have discussed this issue in detail in section II.B of this final rule.

This rule requires facilities to at least install battery-operated single station smoke alarms in the identified areas. We encourage facilities to go beyond this minimum requirement by installing multiple station smoke alarms that can be interconnected to other smoke alarms so that the activation of one alarm causes the alarm signal in all interconnected smoke alarms to sound. Installing and maintaining these more advanced smoke alarms would meet and exceed the minimum requirements of this regulation.

Facilities that chose to install system-based smoke detectors in accordance with NFPA 72, *National Fire Alarm Code,* in resident rooms and common areas would be deemed to have met this requirement. System-based smoke detectors are connected to a building's general fire alarm system and are designed to activate that system, thus alerting the occupants of the entire building and notifying the fire department. If a facility chose to install system-based smoke detectors in resident rooms and common areas, then it does not have to install battery-operated single station smoke alarms because such a system exceeds the requirements of this final rule.

Facilities that are fully sprinklered in accordance with NFPA 13, *Standard for the Installation of Sprinkler Systems,* would also be considered to meet the requirement and would not have to install smoke alarms, because such a system exceeds this requirement.

II. Provisions of the Proposed Regulations

A. Alcohol-Based Hand Rubs

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)(5)).
- 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)).

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 meet the following conditions:

- The use of ABHR dispensers does 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 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 are 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 necessitate the requirement that facilities take extra steps to ensure that ABHR dispensers do not leak or spill.

• The dispensers are installed in a manner that adequately protects against inappropriate access. 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 inappropriately using 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 inappropriate access.

This may mean that facilities could choose to not install ABHR dispensers in corridors in or near dementia or psychiatric units. It may also mean that facilities could choose to install ABHR dispensers only in areas that can be easily and frequently monitored, such as in view of a nursing station or a continuously monitored security camera. These are just a few of the many options that facilities may choose to utilize in securing ABHR dispensers against inappropriate access.

• The dispensers are installed in accordance with chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC as amended. 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 if 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 dispensers are maintained in accordance with dispenser manufacturer guidelines. 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. Having a maintenance program will help ensure that the dispensers are functioning properly and that any malfunctions are addressed in a timely manner. Following manufacturer guidelines will help ensure that maintenance is properly performed and assure properly functioning dispensers.

B. Smoke Alarms

We are requiring in § 483.70(a)(7) that long-term care facilities will, at minimum, be required to install battery-operated single station smoke alarms in resident sleeping rooms and common areas, unless they have system-based smoke detectors in those areas or they are a fully sprinklered facility. Facilities may choose to use more advanced smoke alarms such as dual sensor alarms or AC-powered alarms. These devices are at least equivalent to battery-powered single station smoke alarms and can be used in place of or in conjunction with each other. We are also requiring that facilities that install battery-operated single station smoke alarms have their own program for inspection, testing, maintenance, and battery replacement that verifies correct operation of the battery-operated single station smoke alarms. Facilities should ensure that their testing, maintenance, and battery replacement programs conform with manufacturer recommendations. Battery-operated single station smoke alarms, when properly installed and maintained in resident sleeping rooms and common areas, are a basic, useful, and effective fire safety tool.

We believe that at least installing battery-operated single station smoke alarms will provide earlier warning for facility residents and staff. Fires that originate in these areas will be detected earlier because the alarm will be located closer to the fire's origin. 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 would help to reduce the loss of life in a nursing facility fire.

As discussed earlier, a facility will be required to have a program for inspection, testing, maintenance, and battery replacement to ensure the correct operation of the battery-operated single station smoke alarms.

Battery-operated single station smoke alarms with standard batteries require maintenance every 6 months to 1 year in order to ensure that the batteries are operating at optimum power. We understand that there are battery-operated single station smoke alarms that use longer-lasting batteries. If a facility chooses to use such longer life batteries, we would continue to expect that the maintenance plan would reflect manufacturer recommendations. An alarm with a depleted battery provides no protection. Thus, a regular maintenance program for the alarms is crucial to ensuring that residents and staff are indeed protected. Facilities will be expected to add maintenance of smoke alarms that conforms to manufacturer recommendations to their existing maintenance schedule.

The regulation has two exceptions, one for facilities that have system-based smoke detectors in accordance with NFPA 72, *National Fire Alarm Code*, and one for facilities that are fully sprinklered in accordance with the requirements of NFPA 13, *Standard for the Installation of Sprinkler Systems*. System-based smoke detectors installed in resident rooms and common areas will protect the same areas as the battery-operated alarms. Therefore, having both system-based smoke detectors and battery-operated alarms in these areas will be redundant, unnecessary, and overly burdensome. Facilities may still choose to use battery-operated single station alarms along with system-based smoke detectors as an additional layer of fire protection, but we are not requiring the facilities to do so in this final rule.

Likewise, having both a fully sprinklered facility and battery-operated smoke alarms in resident rooms and common 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 alarms an unnecessary requirement. Facilities may still choose to use smoke alarms as an additional layer of fire protection beyond sprinklers, but they will not be required to do so in this final rule.

III. Analysis of and Responses to Public Comments

We received 11 timely public comments in response to the March 2005 publication of the interim final rule with comment period. We received comments from Federal government officials, State government officials, health care providers and provider organizations, other national organizations, and private industry. A summary of the comments and our responses follows.

A. Alcohol-Based Hand Rubs

Comment: One commenter stated that chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC refer to rooftop heliports.

Response: The Tentative Interim Amendment (TIA) 00–1 (101) amended the 2000 edition of the LSC. One result of this amendment was that chapters 18 and 19 of the 2000 edition of the LSC were slightly renumbered. Under the new numbering scheme, chapters

18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC now refer to the placement of ABHRs in egress corridors.

Comment: Several commenters stated their support for CMS' adoption of the TIA permitting ABHR dispensers to be installed in egress corridors as a means of decreasing the risk of transmission of health care associated infections, while one commenter disagreed with CMS' decision. The commenter who disagreed considers ABHR dispensers to potentially be a significant fire risk and stated that adopting the TIA sets a dangerous precedent for allowing other flammable solutions to be placed in exit corridors.

Response: We appreciate the support that we have received regarding the placement of ABHR dispensers in egress corridors. We believe that ABHRs are an important tool that health care facilities should have at their disposal to help minimize the risk of the transmission of health care associated infections. We agree that making ABHR dispensers available in highly visible and convenient locations such as corridors will likely increase their rate of usage.

At the same time, we understand that there are concerns regarding the safety of placing ABHR dispensers in egress corridors. The fire modeling study conducted by Gage-Babcock & Associates, Inc. demonstrated that installing ABHR dispensers in egress corridors can be done in a way that does not dramatically increase the threat of fire in these areas. The manner in which the dispensers are installed (that is, in a 6-feet-wide corridor and at least 4 feet apart) minimizes the potential fire safety risk associated with the dispensers. We adopted all of the technical installation requirements recommended by the NFPA, and we added other installation requirements related to other non-fire safety risks. We believe that all of these requirements will provide for a safe patient care environment while allowing health care providers the flexibility to address infection control concerns in a manner they see fit.

Any lingering fire safety concerns are, we believe, outweighed by the strong body of evidence that demonstrates that ABHRs are an effective hand hygiene tool and that their use has a positive impact on infection control practices. Healthcare-associated infections pose an imminent threat to patient health and safety, and we believe that all steps should be taken to prevent and control such infections.

Comment: A few commenters expressed their concern with the LSC TIA language which states that, ''The dispensers shall not be installed over or directly adjacent to an ignition source.'' The commenters requested that we define the term ''adjacent to'' and that we describe the ''adjacent to'' relationship between ABHR dispensers and palm readers and time clocks.

Response: The NFPA does not define a specific distance for the term ''directly adjacent to'' when discussing flammable substances and potential ignition sources. If the NFPA were to define this term at a later date, we would consider using their definition. In the absence of a clear definition from the NFPA, we believe that the term ''directly adjacent to'' means that ABHR dispensers should not be placed in close proximity to an electrical source. We would expect that facilities would not install dispensers next to or directly over electrical outlets or equipment. Rather than installing dispensers next to an electrical device such as an employee palm reader or time punch clock in order to encourage the use of ABHRs before or after touching these devices, facilities may choose to install them on other walls, near doorways, or other appropriate areas as permitted by this rule.

Comment: Several commenters stated that CMS should not defer to State or local codes that prohibit or otherwise restrict the placement of ABHR dispensers in health care facilities. One commenter agreed that State and local jurisdictions have the right to retain stricter codes. The commenters who disagreed with the deferral to State and local codes indicated that the potential infection control benefits of ABHRs should take precedence over any State or local codes that would prohibit or restrict ABHR dispenser placement.

Response: Health care facilities that participate in the Medicare and Medicaid programs are required to comply with Federal, State, and local laws, regulations, and codes. For some facility types, this requirement is explicitly stated in the applicable Conditions of Participation. For other facility types, this requirement stems from the requirement that facilities must be licensed by the State in which they function if the State has such licensure requirements.

In this particular situation, we believe that whichever code is the most stringent (with respect to fire protection) is the one that facilities should be required to meet. States and local jurisdictions are the most attuned to the particular needs of their populations and have the right to decide how to best meet those needs. If State or local jurisdictions have chosen to use codes that are more restrictive in regards to the placement of ABHR dispensers, then facilities must meet those codes.

Comment: One commenter stated that TIA stands for Tentative Interim Amendment rather than Temporary Interim Amendment.

Response: We appreciate the correction and have adjusted our terminology as needed throughout the preamble and regulation.

Comment: One commenter noted that ambulatory surgical centers (ASCs) are covered under both chapters 20 and 21 of the LSC, rather than only under chapter 21 as stated in the preamble of the interim final rule. The same commenter also questioned whether or not ASCs are, like other health care providers, required to have at least 6-feet-wide corridors in order to install ABHR dispensers in those corridors.

Response: We appreciate the correction and have adjusted the preamble discussion to reflect the fact that Chapter 20 applies to newly constructed ASCs while Chapter 21 applies to existing ASCs.

In the interim final rule, we permitted ASCs to install ABHR dispensers in egress corridors in accordance with the technical specification of the TIA, even though the LSC chapters for ASCs were not amended. We did this because the evidence supporting the safety and effectiveness of ABHRs in corridors equally supports their installation in health care occupancies and ASCs.

We understand that ASCs may not be able to meet all of the technical specifications for installing ABHR dispensers in egress corridors, particularly the requirement that corridors must be at least 6 feet wide. However, the 6-feet-wide minimum corridor requirement is considered to be an essential fire safety precaution. Narrowing the corridor requirement would, according to the fire modeling study evidence presented by Gage-Babcock, likely increase the fire-related risk of these dispensers. Chapters 20 and 21 of the 2006 edition of the LSC allow ABHR dispensers in egress corridors, provided that those dispensers and corridors meet the same technical specifications as for health care occupancies, including having minimum 6-feet-wide corridors.

Comment: A few commenters commended CMS for addressing the potential ''slip/fall'' and misuse hazard potentials of ABHRs. These commenters agreed that these hazard potentials are legitimate concerns that CMS should address since they were not the focus of the TIA.

However, one commenter stated that, while addressing a necessary component of safety, CMS should delete the requirement that facilities must install ABHR dispensers in a manner

that minimizes leaks and spills that could lead to falls. The commenter stated that this requirement goes beyond the requirements of the LSC amendment and that installation would not necessarily ''prevent leaks and spills.'' The commenter went on to state that long term care facilities are already required in regulation to maintain an environment that is as free of accident hazards as is possible. The commenter did not cite similar regulations for other provider types.

Response: We agree that addressing all aspects of ABHR dispenser placement is a necessary component of ensuring that patients and residents receive care in a safe environment. As stated in the preamble of the interim final rule, we believe that steps can and should be taken during the installation process to minimize leaks and spills that could lead to falls. Facilities may choose a variety of installation options such as drip cups or other devices and techniques to address this area of concern. We understand that taking the necessary steps to minimize leaks and spills, as required by the interim final rule, does not necessarily mean that ABHR-related falls will be completely prevented.

We acknowledge that long term care facilities are already required in the Conditions of Participation to address accident hazards. Addressing leak and spill possibilities during the installation process should help these facilities meet the existing requirement that they maintain environments that are as free of accident hazards as is possible.

Comment: One commenter questioned whether facilities that had already installed nonconforming ABHR dispensers in egress corridors would be allowed to keep those dispensers in place.

Response: ABHR dispensers installed in corridors must be installed in accordance with the technical specifications of chapters 18.3.2.7 and 19.3.2.7 as well as the additional specifications included in this final rule. If a facility were to have ABHR dispensers in its corridors that did not meet our specifications, then that facility would be out of compliance with the applicable fire safety standard. Such a facility would be expected to remove and/or relocate the improperly installed ABHR dispensers. The facility could choose to have ABHR dispensers in areas other than corridors or the facility could choose to re-install their dispensers in corridors in accordance with this rule. However, we do not anticipate that any Medicare or Medicaid participating facility will face this situation. Until March 25, 2005 when the interim final rule was published, all Medicare and Medicaid participating facilities were prohibited from installing ABHR dispensers in egress corridors under any circumstances. Therefore, we would not expect that there would be many instances of facilities installing ABHR dispensers that were out of compliance with our rules.

Comment: One commenter observed that the requirement that facilities install ABHR dispensers in a manner that adequately protects against access by vulnerable populations lacks specificity. The commenter suggested that language be added to the regulation stating that vulnerable populations are determined by the facility's clinical staff.

Response: We agree that the term ''vulnerable populations'' is too general. We have removed this term. However, we continue to believe that protecting against inappropriate access to minimize the potential for misuse of ABHRs is an appropriate goal of the Conditions of Participation. Therefore, we have revised the regulatory text to read, ''The dispensers are installed in a manner that adequately protects against inappropriate access.''

Comment: One commenter noted that CMS did not require facilities to maintain their ABHR dispensers and noted that, without such maintenance, the devices may pose an increased risk.

Response: We agree that proper maintenance of ABHR dispensers is an essential step toward ensuring that ABHR dispensers are, and continue to be, safe. To that end, we have added a new requirement at § 403.744(a)(4)(v), § 416.44(b)(5)(v), § 418.100(d)(6)(v), § 460.72(b)(5)(v), § 482.41(b)(9)(v), § 483.70(a)(6)(v), § 483.470(j)(7)(ii)(E), and § 485.623(d)(7)(v) that facilities that choose to install ABHR dispensers must maintain those dispensers in accordance with dispenser manufacturer guidelines. If there were no manufacturer guidelines, we would expect facilities to have their own ABHR dispenser maintenance policies and procedures.

Comment: One commenter noted that there are other products available that fulfill the same purpose as ABHRs, but do not pose the flammability risk that ABHRs do. The commenter contended that the availability of these other products makes the TIA unnecessary.

Response: We support allowing health care facilities a wide variety of safe options to use in their efforts to improve infection control practices. Facilities can choose to use hand hygiene products based on their unique characteristics, and those products may or may not contain flammable substances like alcohol. Facilities are encouraged to examine all of the infection control options that are available to them. We believe that, as long as hand hygiene products like ABHRs can be safely used under certain specified conditions, the Conditions of Participation for Medicare and Medicaid providers should not unnecessarily impede their use.

B. Smoke Alarms

Comment: Many commenters noted that the proper term for the device that we described in the preamble is ''single station smoke alarm'' rather than ''smoke detector.'' One commenter went on to note that the proper term for the smoke detection system that we described in exception one is ''system-based smoke detectors'' rather than ''hardwired smoke detection system.''

Response: We agree with this comment that the proper terms are ''single station smoke alarm'' and ''system-based smoke detectors,'' and we have made the appropriate changes in both the preamble of this document and in the regulations text located at § 483.70(a)(7).

Comment: Several commenters expressed concern regarding the extent of the inspection, testing, and maintenance program that is expected. The commenters suggested that it may be difficult for CMS to judge compliance with this standard without further guidance. The commenters requested that CMS reference a specific edition of NFPA 72, *National Fire Alarm Code*, as the standard for installing, testing, and maintaining battery-operated single station smoke alarms and smoke detection systems in long term care facilities as discussed in § 483.70(a)(7). The commenters suggested that NFPA 72 would establish the extent and frequency of the necessary inspection, testing, and maintenance activities for smoke alarms.

Response: National Fire Protection Association publication 72, *National Fire Alarm Code*, has extensive installation, inspection, testing, and maintenance requirements for a variety of facility and system types. We agree that it is a very useful resource that facilities should consult when installing, inspecting, testing, and maintaining their smoke alarms.

However, we do not believe that requiring facilities to comply with the many standards within NFPA 72 is appropriate in this regulation. The NFPA standards require significant amounts of documentation that may not all be necessary for this minimum requirement. In addition, NFPA 72 has very specific qualifications for those

individuals who are eligible to inspect, test, and maintain smoke alarms in health care facilities. General facility maintenance personnel may not meet these high qualifications, which may force such facilities to hire or contract with additional personnel. This would unnecessarily increase the burden of this minimum provision.

Therefore, we will not require long term care facilities to comply with NFPA 72. At the same time, we encourage facilities to refer to NFPA 72 for technical guidance when establishing their own policies and procedures for inspecting, testing, and maintaining battery-operated single station smoke alarms. We believe that NFPA 72 can be used in conjunction with manufacturer recommendations to develop a comprehensive, facility-specific maintenance program.

Comment: A few commenters questioned the role that AC powered single station smoke alarms may play in long term care facilities. Specifically, the commenters wanted CMS to clarify that AC powered (also known as hard-wired) single station smoke alarms are acceptable in place of battery-operated smoke alarms. One commenter also wanted CMS to add a specific exception for facilities that have AC powered single station smoke alarms in resident rooms and common areas, similar to the exceptions for fully sprinklered buildings and buildings with system-based smoke detectors.

Response: Battery-operated single station smoke alarms are, according to this regulation, the minimum fire safety devices that a facility must install in resident rooms and common areas. Facilities may choose to go beyond this minimum requirement by installing AC powered single station smoke alarms in the specified areas. We do not believe that it is necessary to add a specific exception for facilities that choose AC powered single station smoke alarms, because we state that battery-operated single station smoke alarms are the minimum requirement. Since AC powered single station smoke alarms are equivalent to, if not superior to, battery-operated single station smoke alarms, they would meet the minimum requirement.

If facilities choose to go beyond the minimum requirement by installing AC single station smoke alarms, they may choose to install AC powered single station smoke alarms in all areas, or they may choose to use a combination of AC powered and battery-operated single station smoke alarms. For example, a facility may have system based smoke detectors in corridors, AC single station smoke alarms in other common areas such as activity rooms and battery-operated single station smoke alarms in resident rooms. This combination of alarms and detectors is acceptable because all three fire safety device types meet the minimum requirement of at least having battery-operated single station smoke alarms in all common areas and resident rooms.

Regardless of the type of alarm or combination thereof that a facility chooses to use, the facility will still be required to ensure that at least battery-operated single station smoke alarms are installed in all resident rooms and common areas.

Comment: One commenter stated that battery-operated smoke alarms with 10-year batteries would not require the annual battery replacement schedule that we described in the regulatory impact statement section of the interim final rule. Another commenter stated that the bi-annual or annual battery replacement schedule that we described should be mandatory for all facilities.

Response: In the interim final rule, § 483.70(a)(7)(ii) requires facilities to have a program for testing, maintenance and battery replacement. In the preamble to this final rule, we state that this program should be in accordance with manufacturer recommendations. We expect that this program would be included in the facility's own policies and procedures. Also in the preamble, we estimate that an average facility's program would provide for annual battery replacement.

However, as one commenter suggested, facilities may choose to use long life batteries. In that case, we would expect that the facility's program for testing, maintenance, and battery replacement would be in accordance with the smoke alarm manufacturer and battery manufacturer recommendations for testing, maintenance, and battery replacement of long life batteries. If the program's replacement schedule, as described in the facility's own policies and procedures, was longer than our estimate of annual replacement because the manufacturers' recommendations were longer, then the longer battery replacement schedule would be acceptable.

Due to the variability of battery life and smoke alarm life, we believe that requiring facilities to conform their maintenance schedules to manufacturer recommendations rather than to imposed timeframes is the most effective and flexible regulatory option at this time.

Comment: In response to our request for public comment, a few commenters recommended that long term care facilities not be required to install smoke alarms in areas other than resident rooms and common areas. The commenters cited two reasons for not installing smoke alarms in other areas such as storage rooms, closets and office spaces. Those reasons are:

- No other national consensus codes or standards require smoke alarms in these areas; and
- Since 1972 there has never been a multiple death fire that originated in one of these other areas.

Another commenter, however, recommended that smoke alarms should be required in non-public areas as well as common areas and resident rooms.

Response: For the reasons cited by the commenters, we agree that installing moke alarms in other areas such as closets and offices in long term care facilities is not necessary. Therefore, we are not requiring facilities to install smoke alarms beyond resident rooms and common areas. However, if a long term care facility chose to install smoke alarms in these additional areas, there is nothing in this regulation to prohibit this practice.

Comment: One commenter contested a statement in the preamble to the interim final rule that said, ''The lack of smoke detectors in resident rooms, the report concludes, '* * * may have delayed staff response and activation of the building's fire alarms.' '' The commenter stated that there was no evidence of a delayed staff response in the Hartford fire and that the resident accused of setting the fire summoned the nurse to the room of origin before smoke reached the corridor.

Response: We appreciate the information provided by the commenter. However, the information that we cited on both the Hartford and Nashville fires came directly from the 2004 GAO report. The report states that, ''In the Hartford fire, it is unclear whether the alarm was first activated by the corridor smoke detector or manually by the staff member who first attempted to extinguish the fire. According to the Hartford fire department, the absence of smoke detectors in resident rooms contributed to a delay of up to 5 minutes or more.''

We understand that there has been some disagreement regarding the exact timeline of events in the Hartford fire. None of this disagreement negates the fact that smoke alarms would have likely been helpful in both the Hartford and Nashville fires.

Comment: A few commenters suggested that CMS either remove or define the term ''public areas'' in relationship to the requirement that long term care facilities must install smoke alarms in ''public areas.'' Suggested

definitions included areas such as cafeterias, waiting rooms, lobby areas, treatment rooms, activity rooms, and other meeting rooms. One commenter suggested that the need to place smoke alarms in ''public areas'' be addressed in the interpretive guidelines rather than in the regulations. In addition, a few commenters suggested that CMS use the term ''common areas,'' the term used in a Survey & Certification letter (S&C–05–25) that further elaborated on this requirement, rather than ''public areas'' to describe these spaces.

Response: We believe that installing, at a minimum, single station battery-operated smoke alarms in areas other than resident rooms is a good idea. As stated in the preamble, fires can and do develop in other areas. Having the minimum smoke alarms in these areas would provide facility staff and residents earlier notice about the existence of the fire, thus giving them more time to respond to the situation and enabling earlier notification of local fire responders.

At the same time, we agree that the term ''common areas'' is a more appropriate term for resident gathering areas as used in this regulation, and we have made the appropriate changes throughout this document.

We also agree that it would be helpful to include a definition of this term in the definitions section of the long term care regulations. Therefore, in the definitions section at § 483.5, we have added the following definition, ''*Common area.* Common areas are dining rooms, activity rooms, meeting rooms where residents are located on a regular basis, and other areas in the facility where residents may gather together with other residents, visitors, and staff.'' This definition is in accordance with the description of ''common areas'' in the Survey & Certification letter cited above.

Comment: A few commenters suggested that CMS should require facilities to install system-based smoke detectors in corridors that directly serve resident sleeping and treatment rooms and one commenter suggested that system-based smoke detectors should be installed in resident rooms as well. The commenters indicated that it was important that an alarm in one area of the building should notify staff at the nursing station.

Response: The Medicare and Medicaid Conditions of Participation are the minimum standards that providers must meet in order to participate in the Medicare and Medicaid programs. We added the single station battery-operated smoke alarm requirement on top of the requirements of the 2000 edition of the Life Safety Code because we believe that these smoke alarms are necessary in order to achieve an acceptable level of fire safety. We specifically required smoke alarm installation in resident rooms and common areas because these areas can be closed off, thus impeding the ability of other residents or facility staff to detect a fire situation. Behind closed doors fires can grow undetected. Corridors, however, are highly trafficked areas that are open to other areas and do not pose the same risk of undetected fire development and growth. In addition, corridors are already protected by having smoke detectors at smoke barriers to control the doors and activate a facility's alarm system. Requiring facilities to secure additional funds and undergo the construction process to install system-based smoke detectors in corridors without the benefit of any significant fire safety gains is, we believe, not the best option for long term care facilities or their residents.

While we are not requiring facilities to do so, they are encouraged to go beyond the minimum requirements of this rule by installing system-based smoke detectors in resident rooms and common areas, either as a stand-alone fire safety feature or in combination with battery-operated single station smoke alarms. However, due to concerns about the increased cost and time associated with installing system-based smoke detectors in resident rooms and common areas, we are not, at this time, requiring facilities to install system-based smoke detectors in any section of their building.

Comment: One commenter stated that CMS incorrectly described the way that system-based smoke detectors function. The commenter stated that system-based smoke detectors, rather that causing each other to sound, cause the facility's general building fire alarm system to sound. The commenter also stated that the detectors themselves are not equipped with a battery to use as a back-up power supply. Rather, the detectors are connected to the fire alarm control panel, which has a back-up power supply.

Response: We appreciate this clarification of the mechanics of system-based smoke detectors and have clarified our description of their function in the preamble of this rule.

Comment: One commenter suggested that CMS clarify in the preamble text that, in order to be exempt from installing, at a minimum, battery-operated single station smoke alarms, a facility's sprinkler system must meet the requirements of the publication NFPA 13, *Standard for the Installation of Sprinkler Systems*.

Response: We agree that the preamble should be clear that in order for a facility to qualify for an exception to this rule it must be fully sprinklered in accordance with NFPA 13, as stated in the regulation. We thank the commenter for suggesting this area for further clarification of our intent.

Comment: A few commenters expressed support for installing smoke alarms in resident rooms and common areas and one commenter indicated that long term care facilities required financial assistance from CMS in order to install these minimum devices.

Response: We appreciate the commenters' support of these minimum fire safety requirements and understand that there is a cost associated with installing smoke alarms. We estimated in the interim final rule that an average size facility would spend $7,000 to purchase and install battery-operated single station smoke alarms in resident rooms and common areas. This is less than one half of one percent of the total revenue for an average or small facility. In light of this information, we believe that purchasing and installing battery-operated single station smoke alarms is of minimal cost to affected facilities.

To mitigate even this minimal cost, we also allowed affected facilities one year from the effective date of the interim final rule to comply with the installation requirement. We believe that these two factors make it unnecessary for us to provide financial assistance to aid in the purchase and installation of smoke alarms in affected facilities.

Comment: A few commenters stated that the one year phase-in period for installing at least battery-operated single station smoke alarms was unnecessarily long. The commenter suggested that a 90-day phase-in period would be a more appropriate length of time due to low purchase costs and easy installation. Another commenter requested that CMS allow long term care facilities an additional 180 days to comply with the smoke alarm requirement if they have signed contracts and funding in place to fully sprinkler their buildings in accordance with NFPA 13.

Response: We agree that facilities that choose to comply with the minimum requirement, which is installing battery-operated single station smoke alarms, should be able to purchase and install the alarms in less that one year's time. These devices increase the level of fire safety above what is required in the 2000 edition of the LSC. Alarms can be a primary fire safety goal or they can be an interim part of a facility's long term

plan to upgrade to sprinklers. That is, facilities that anticipate that fully upgrading to a more sophisticated fire protection system such as sprinklers would take more than one year would use smoke alarms during the installation period as an immediate fire safety improvement. Since we have already provided for a one year phase-in period, extending this phase-in period for an additional 180 days does not seem prudent.

Comment: One commenter requested that CMS choose either the term ''fully sprinklered'' or the term ''sprinklered throughout the facility'' to describe the type of facility that is exempt from having to install at least battery operated single station smoke alarms in resident rooms and common areas. The commenter also requested that CMS define whichever term we choose to use in the regulation.

Response: We agree that a single term should be used to describe a facility's sprinkler status. Therefore, we are using the term ''fully sprinklered'' from the Survey & Certification memo discussed above (S&C–05–25). In addition, we have added the definition of ''fully sprinklered'' from the memo to the definitions section on the long term care regulations at new § 483.5(e). The definition is, ''*Fully sprinklered.* A fully sprinklered long term care facility is one that has all areas sprinklered in accordance with National Fire Protection Association 13 'Standard for the Installation of Sprinkler Systems' without the use of waivers or the Fire Safety Evaluation System.''

Comment: One commenter recommended that facilities should be encouraged or required to use dual sensor smoke alarms that can quickly detect slow burning smoldering fires as well as fast burning flaming fires. The commenter stated that these detectors would enhance fire safety with only a small increase in cost.

Response: The Medicare and Medicaid Conditions of Participation are the minimum standards that providers must meet in order to participate in the Medicare and Medicaid programs. We added the single station battery-operated smoke alarm requirement on top of the requirements of the 2000 edition of the Life Safety Code because we believe that these smoke alarms are necessary in order to achieve an acceptable level of fire safety. Therefore, we have decided not to require dual sensor alarms in this rule, but would consider requiring them in the future.

However, facilities are free to go beyond the minimum requirements of this rule by installing dual sensor alarms. We agree that these alarms would enhance fire safety, potentially saving lives and reducing the loss of property by notifying staff and residents of a fire situation at the earliest possible time.

Comment: A few commenters stated that CMS should require long term care facilities to have both smoke alarms and sprinklers. The commenters indicated that smoke alarms and sprinklers serve different fire safety functions, and that smoke alarms respond sooner than sprinklers. However, another commenter suggested that CMS should insert language into the regulation that would explicitly allow the removal of smoke alarms in long term care facilities once those facilities are fully sprinklered.

Response: Facilities that are fully sprinklered would qualify for exception from this rule; fully sprinklered facilities may forgo having and maintaining battery-operated single station smoke alarms. This means that once a facility becomes fully sprinklered in accordance with NFPA 13, it is no longer required by this regulation to keep its smoke alarms.

The 2004 GAO report only indicated that we should strengthen the fire safety requirements for long term care facilities that do not have sprinklers. The purpose of this rule is to implement this GAO recommendation.

C. Other Areas of Comment

Comment: A few commenters expressed support for CMS requiring all long term care facilities to be fully sprinklered with an appropriate (3- to 5-year) phase-in period. One commenter indicated that the 2006 edition of the LSC is slated to require the installation of automatic sprinkler systems in all existing nursing homes. According to the commenters, major constituency groups such as the American Healthcare Association, the National Citizens' Coalition for Nursing Home Reform, and the International Fire Marshals Association are supporting this change.

Response: We appreciate the support and the information that the commenter provided. We are carefully examining the sprinkler requirement and phase-in period issues and expect to issue a proposed rule in the near future.

Comment: One commenter suggested that CMS should incorporate the International Fire Code, published by the International Code Council, into the long term care facility regulations.

Response: We continue to specifically cite the LSC because under sections 1819(d)(2)(B) and 1919(d)(2)(B) of the Social Security Act, nursing homes must meet the provisions of ''such edition (as specified by the Secretary in regulation) of the Life Safety Code of the National Fire Protection Association * * *.'' However, if a State's own fire and safety code would ''adequately protect patients'' and the State code is imposed by State law, the State may submit a request in writing to substitute its fire safety code for the LSC to its CMS regional office. The CMS regional office will forward the request to CMS central office. The CMS central office will make a final decision on whether the State code may be used in place of the LSC.

IV. Provisions of the Final Regulations

For the most part, this final rule confirms the provisions of the March 25, 2005 interim final rule. Those provisions of this final rule that differ from the interim final rule are as follows:

A. Alcohol-Based Hand Rubs

1. In response to public comments, we are revising the third requirement in the list of specifications that a facility must meet in order to install ABHR dispensers in egress corridors. In the interim final rule we required, ''The dispensers are installed in a manner that adequately protects against access by vulnerable populations.'' In this final rule, we require ''The dispensers are installed in a manner that adequately protects against inappropriate access.'' The revised requirement eliminates the unclear term ''vulnerable populations'' while achieving the same goal of ensuring that ABHRs are not misused in a manner that may cause harm to individuals or property.

2. Also in response to public comments, we are adding a requirement that ''The dispensers are maintained in accordance with dispenser manufacturer guidelines.'' If there were no manufacturer guidelines, we expect facilities to have their own ABHR dispenser maintenance policies and procedures. Regular maintenance is a crucial step towards ensuring that the dispensers do not leak or spill. Having a maintenance program will help ensure that the dispensers are functioning properly and that any malfunctions are addressed in a timely manner. Following manufacturer guidelines will help ensure that maintenance is properly performed in a manner that will help, rather than hinder, the facility's goal of having properly functioning dispensers.

3. We have removed the statement ''If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes'' because we believe that this

statement is not necessary. The term ''notice'' refers to the notice-and-comment rulemaking process that CMS undergoes to amend the conditions of participation for health care providers. Any substantive changes to the conditions of participation are already required to go through the normal notice-and-comment rulemaking procedures. Since notice-and-comment rulemaking is the standard procedure for amending regulations, we do not believe that this statement is needed.

B. Smoke Alarms

1. We are altering the terminology used to describe the smoke detector requirement. Throughout this document, we are referring to the following terms in the manner specified below unless otherwise noted:

- ''Smoke detectors'' are now ''smoke alarms'';
- ''Public areas'' are now ''common areas'';
- Having ''sprinklers installed throughout'' is now ''fully sprinklered''; and
- ''A hard-wired smoke detection system'' is now ''system-based smoke detectors.''

All of these terminology changes were made in response to public comments.

2. In addition to altering the terminology used to describe the smoke alarm requirement, we are adding definitions for the terms ''common areas'' and ''fully sprinklered'' to the definitions section of the regulation. New § 483.5(d) and (e) will provide facilities with more explicit guidance about where smoke alarms must be installed and about what requirements their buildings must meet in order to qualify for exception B of the smoke alarm requirement.

3. In the interim final rule, in § 483.70(a)(7)(ii), we required facilities to have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke alarms. We are modifying this requirement to be more specific about the contents of the inspection, testing, maintenance, and battery replacement program. The revised requirement states that facilities must ''[h]ave a program for inspection, testing, maintenance, and battery replacement that conforms to the manufacturer's recommendations and that verifies correct operation of the smoke alarms.'' Conforming to manufacturer guidelines, coupled with our strong recommendation that facilities should also incorporate, to the extent possible, the requirements of NFPA 72, should help ensure that smoke alarms are consistently functioning in top working order. We expect that this program would be included in the facility's own policies and procedures.

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 final rule, and we have determined that this rule is neither expected to meet the criteria to be considered economically significant, nor do we believe it will meet the criteria for a major rule.

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 final rule 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 at least battery-operated single station smoke alarms in resident rooms and common areas, earned a total of $89.6 billion in 1999 (*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. This final rule 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. There is no installation cost associated with this final rule because, upon its effective date, facilities will have already installed their smoke alarms in accordance with the interim final rule. Therefore, we certify that this final rule 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 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. This final rule will not have a significant impact on small rural hospitals because the final rule 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 whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a 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 final rule 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 inappropriate access. 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. Therefore, no facility should have improperly installed ABHR dispensers in a manner that conflicts with the provisions of this final rule. 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 5 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 3 gallons of ABHR solution per smoke compartment. That same facility would be permitted to keep an additional 2 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 decreased patient care costs.

2. Smoke Alarms

As discussed in section VI.A of this section, Overall Impact, affected facilities were required by the interim final rule to install, at a minimum, battery-operated single station smoke alarms in resident rooms and common areas by May 24, 2006. Since this date is close to the date of publication of this rule, there is not an installation burden associated with this final rule. There is, however, a maintenance burden associated with this final rule. That burden is described below.

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 system-based smoke detectors in resident rooms and common 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, based on data from our Online Survey Certification and Reporting System. In addition, we estimate that each room will require one battery-operated single station smoke alarm. We estimate that each average facility requires 20 additional alarms for common areas, for a total of 70 alarms per facility.

TABLE 1.—NUMBER OF SMOKE ALARMS

	Number of alarms
Per Facility	70
Nationwide	378,000

Formulas:

- 50 alarms in resident rooms + 20 alarms in common areas = 70 total alarms per average facility × 4,200 affected facilities = 378,000 total alarms nationwide

Following installation of battery-operated single station smoke alarms in the specified areas, a long-term care facility will be required to have a program that conforms to manufacturer recommendations for testing, maintenance, and battery replacement that verifies the correct operation of the smoke alarms. We estimate that a facility will conduct monthly tests of each smoke alarm by activating the test button. This will take approximately 5 minutes per smoke alarm per test, or 1 hour per smoke alarm per year.

In addition, we estimate that a facility will clean each smoke alarm and change its batteries two times per year. Based on the time necessary to remove dust and debris from the smoke alarm, as well as the time necessary to remove old batteries and properly insert new ones, we estimate that this maintenance task will take 15 minutes per smoke alarm per cleaning and replacement, or 30 minutes per smoke alarm per year. We estimate that the total annual maintenance time per smoke alarm will be 1.5 hours, for a 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 alarms, based on a maintenance person earning $20 per hour (salary from May 2003 National Occupational Employment and Wage Estimates, *http://www.bls.gov/oes/2003/may/oes_37Bu.htm* plus 30 percent fringe benefits) and $5 for batteries per change, is $2,800. The annual industry total for this maintenance provision will thus be $11,760,000.

TABLE 2.—SMOKE ALARM MAINTENANCE TIME AND COSTS

	Time (hours)	Cost
Maintenance per detector	1.5	$40
Maintenance per facility	105	2,800
Maintenance nationwide	441,000	11,760,000

Formulas:

• 5 minutes per test per alarm × 12 tests per year per alarm = 1 hour per year per alarm for testing × 70 alarms per facility = 70 hours per year per facility for tests × 4,200 affected facilities = 294,000 hours per year nationwide for tests

• 15 minutes per cleaning and battery change per alarm × 2 cleanings and battery changes per year = 30 minutes per alarm for cleaning and battery changes × 70 alarms = 35 hours per facility for cleaning and battery changes × 4,200 affected facilities = 147,000 hours nationwide for cleaning and battery changes

• 1 hour per year per alarm for testing + 30 minutes per alarm for cleaning and battery changes (sum of the two 15-minute cleaning and battery changes described above) = 1.5 hours per year per detector for maintenance and testing × 70 detectors per facility = 105 hours per year per facility for maintenance and testing × 4,200 affected facilities = 441,000 hours nationwide for maintenance and testing

• 1.5 hours per year per detector for maintenance and testing × $20 per hour = $30 per alarm + $10 for battery replacement = $40 per alarm for maintenance, testing and battery replacement per alarm × 70 alarms per facility = $2,800 per facility for maintenance, testing and battery replacement of alarms × 4,200 affected facilities = $11,760,000 nationwide for maintenance, testing and battery replacement of alarms

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 increases, including stations that dispense ABHRs. 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 that meets the facility's needs. 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 such as the potential for slips and falls on slippery, ABHR-coated floors and the potential for the misuse of ABHR solutions. 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. Due to disability or illness, certain populations require additional protection from substances that are toxic and 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 Alarms

We considered not requiring long-term care facilities to install smoke alarms, thus maintaining the existing fire safety regulations that required facilities to only meet the standards of the 2000 edition of the Life Safety Code. Maintaining the existing requirements would 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 Arkansas and Nebraska, do not have such requirements, resulting in 25 percent or more of their long-term care facilities completely lacking sprinklers. The same State-to-State variability that is seen in sprinkler requirements would likely be seen in smoke alarm requirements. This level of variability is not acceptable to us because we believe that 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.

In addition to pursuing Federal regulation in this area, we chose to require smoke alarms because we believe that their installation will help save lives. The July 2004 GAO report clearly outlined the role that smoke alarms, one of the most basic and effective fire safety devices available, did or did not play in the Nashville and Hartford fires. The report also outlined the wider role that alarms can and should play in long-term care facility fire safety. The positive impact of smoke alarms on resident safety, we believe, warrants their installation.

We also considered requiring long-term care facilities to install system-based smoke detectors in accordance with NFPA 72, *National Fire Alarm Code,* for system-based smoke detectors. System-based detectors must be wired directly into the facility's electrical and fire alarm system. This option would have likely required a longer phase-in period to accommodate the increased

time and cost associated with installing this type of system. A longer phase-in period would have delayed our ability to quickly increase the level of fire safety in long term care facilities.

Therefore, in order to quickly increase the level of fire safety in long term care facilities, we are requiring only the less expensive and less time consuming battery-operated single station smoke alarm. Facilities may still choose to install system-based smoke detectors, and we encourage them to do so. Installation of such a system in resident rooms and common areas will exempt a facility from installing battery-operated single station smoke alarms 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 are currently examining this issue. We are committed to working with NFPA, the long-term care facility industry, and advocates to develop a consensus position. Facilities may still choose to become fully sprinklered in accordance with NFPA 13. Installation of sprinklers will exempt a facility from installing battery-operated single station smoke alarms in resident rooms and common 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, Incorporation by reference, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

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

42 CFR Part 418

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

42 CFR Part 460

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

42 CFR Part 482

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

42 CFR Part 483

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

42 CFR Part 485

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

■ For the reasons set forth in the preamble, the interim final rule amending 42 CFR parts 403, 416, 418, 460, 482, 483, and 485, which was published on March 25, 2005 (70 FR 15229) is adopted as final with the following changes:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues 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. Section 403.744 is amended as follows:

■ A. Paragraph (a)(4)(iii) is revised.

■ B. Paragraph (a)(4)(iv) is amended by removing the last sentence.

■ C. Paragraph (a)(4)(iv) is further amended by removing the period at the end of the paragraph and adding in its place ''; and''.

■ D. New paragraph (a)(4)(v) is added.

The revisions read as follows:

§ 403.744 Condition of participation: Life safety from fire.

(a) * * *

(4) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

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. Section 416.44 is amended as follows:

■ A. Paragraph (b)(5)(iii) is revised.

■ B. Paragraphs (b)(5)(iv)(F) and (G) are revised.

■ C. Paragraph (b)(5)(v) is added.

The revisions read as follows:

§ 416.44 Conditions for coverage-Environment.

* * * * *

(b) * * *

(5) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) * * *

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

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

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

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. Section 418.100 is amended as follows:

■ A. Paragraph (d)(6)(iii) is revised.

■ B. Paragraph (d)(6)(iv) is amended by removing the last sentence.

■ C. Paragraph (d)(6)(iv) is further amended by removing the period at the end of the paragraph and adding in its place ''; and''.

■ D. Paragraph (d)(6)(v) is added.
The revisions read as follows:

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

* * * * *

(d) * * *

(6) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

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. Section 460.72 is amended as follows:

■ A. Paragraph (b)(5)(iii) is revised.

■ B. Paragraph (b)(5)(iv) is amended by removing the last sentence.

■ C. Paragraph (b)(5)(iv) is further amended by removing the period at the end of the paragraph and adding in its place ''; and''.

■ D. Paragraph (b)(5)(v) is added.
The revisions read as follows:

§ 460.72 Physical environment.

* * * * *

(b) * * *

(5) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

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. Section 482.41 is amended as follows:

■ A. Paragraph (b)(9)(iii) is revised.

■ B. Paragraph (b)(9)(iv) is amended by removing the last sentence.

■ C. Paragraph (b)(9)(iv) is further amended by removing the period at the end of the paragraph and adding in its place ''; and''.

■ D. Paragraph (b)(9)(v) is added.
The revisions read as follows:

§ 482.41 Condition of participation: Physical environment.

* * * * *

(b) * * *

(9) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

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 § 483.5, add new paragraphs (d) and (e) to read as follows:

§ 483.5 Definitions.

* * * * *

(d) *Common area.* Common areas are dining rooms, activity rooms, meeting rooms where residents are located on a regular basis, and other areas in the facility where residents may gather together with other residents, visitors, and staff.

(e) *Fully sprinklered.* A fully sprinklered long term care facility is one that has all areas sprinklered in accordance with National Fire Protection Association 13 ''Standard for the Installation of Sprinkler Systems'' without the use of waivers or the Fire Safety Evaluation System.

■ 13. Section 483.70 is amended as follows:

■ A. Paragraph (a)(6)(iii) is revised.

■ B. Paragraph (a)(6)(iv) is amended by removing the last sentence.

■ C. Paragraph (a)(6)(iv) is further amended by removing the period at the end of the paragraph and adding in its place ''; and''.

■ D. Paragraph (a)(6)(v) is added.

■ E. Paragraph (a)(7) is revised.
The revisions read as follows:

§ 483.70 Physical environment.

(a) * * *

(6) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(7) A long term care facility must:

(i) Install, at least, battery-operated single station smoke alarms in accordance with the manufacturer's recommendations in resident sleeping rooms and common areas.

(ii) Have a program for inspection, testing, maintenance, and battery replacement that conforms to the manufacturer's recommendations and that verifies correct operation of the smoke alarms.

(iii) Exception:

(A) The facility has system-based smoke detectors in patient rooms and common areas that are installed, tested, and maintained in accordance with NFPA 72, *National Fire Alarm Code*, for system-based smoke detectors; or

(B) The facility is fully sprinklered in accordance with NFPA 13, *Standard for the Installation of Sprinkler Systems*.

* * * * *

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

■ 14. Section 483.470 is amended as follows:

■ A. Paragraph (j)(7)(ii)(C) is revised.

■ B. Paragraph (j)(7)(ii)(D) is amended by removing the last sentence.

■ C. Paragraph (j)(7)(ii)(D) is further amended by removing the period at the end of the paragraph and adding in its place ''; and''.

■ D. Paragraph (j)(7)(ii)(E) is added.
The revisions read as follows:

§ 483.470 Condition of participation: Physical environment.

* * * * *

(j) * * *

(7) * * *

(ii) * * *

(C) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(E) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 15. 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)

■ 16. Section 485.623 is amended as follows:

■ A. Paragraph (d)(7)(iii) is revised.

■ B. Paragraph (d)(7)(iv) is amended by removing the last sentence.

■ C. Paragraph (d)(7)(iv) is further amended by removing the period at the end of the paragraph and adding in its place ''; and''.

■ D. Paragraph (d)(7)(v) is added.

The revisions read as follows:

§ 485.623 Condition of participation: Physical plant and environment.

* * * * *

(d) * * *

(7) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(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: February 8, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: May 31, 2006.

Michael O. Leavitt,

Secretary.

[FR Doc. 06–7885 Filed 9–21–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 491

[CMS–1910–IFC]

RIN 0938–AJ17

Medicare Program; Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program; Suspension of Effectiveness

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

ACTION: Interim final rule with comment period; partial suspension of effectiveness.

SUMMARY: This interim final rule with comment period revises the rural health clinic (RHC) regulations to revert to those provisions set forth in regulations before publication of the December 24, 2003 RHC final rule. That final rule implemented certain provisions of the Balanced Budget Act (BBA) of 1997 to establish a process and criteria for disqualifying from the RHC program clinics that no longer meet basic location requirements (rural and medically underserved), and to require RHCs to establish quality assessment and performance improvement programs. That rule also prohibited ''commingling'' (the use of the space, professional staff, equipment, and other resources) of an RHC with another entity. [In addition, it addressed comments on the February 28, 2000 proposed rule. Since the publication of the RHC final rule exceeded the 3-year timeline for finalizing proposed rules set by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, we are suspending the effectiveness of the current provisions by removing the RHC provisions set forth in the December 2003 final rule and reverting to those RHC provisions previously in effect.] We intend to reissue new proposed and final RHC rules to reinstate the current provisions. However, these revisions do not impact the effectiveness of the self-implementing provisions of the BBA or any provisions we had previously implemented or enforced through program memoranda.

DATES: *Effective date:* These regulations are effective on September 22, 2006.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 21, 2006.

ADDRESSES: In commenting, please refer to file code CMS–1910–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular 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–1910–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send 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–1910–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *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) 786–7195 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