Additionally, EPA is proposing to determine that the BRNA has met the criteria under CAA section 107(d)(3)(E) for redesignation from nonattainment to attainment for the 2008 ozone NAAQS. On this basis, EPA is proposing to approve Louisiana's redesignation request for the BRNA. If finalized, approval of the redesignation request would change the official designation of the portion of BRNA, as found at 40 CFR part 81, from nonattainment to attainment for the 2008 ozone NAAQS.

X. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, these proposed actions merely propose to approve state law as meeting Federal requirements and do not impose additional requirements beyond those imposed by state law. For this reason, these proposed actions:

- Are not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- are not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: October 27, 2016.

Samuel Coleman,

Acting Regional Administrator, Region 6.

[FR Doc. 2016–26584 Filed 11–3–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 494

[CMS–3334–P]

RIN 0938–AS94

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update fire safety standards for Medicare and Medicaid participating ESRD facilities, adopt the 2012 edition of the Life Safety Code and eliminate references in our regulations to all earlier editions of the Life Safety Code and adopt the 2012 edition of the Health Care Facilities Code, with some exceptions.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 3, 2017.

ADDRESSES: In commenting, please refer to file code CMS–3334–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3334–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3334–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey 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.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT: Kristin Shifflett, (410) 786–4133.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Overview

The Life Safety Code (LSC) is a compilation of fire safety requirements for new and existing buildings, and is updated and published every 3 years by the National Fire Protection Association (NFPA), a private, nonprofit organization dedicated to reducing loss of life due to fire. The Medicare and Medicaid regulations have historically incorporated these requirements by reference, along with Secretarial waiver authority. The statutory basis for incorporating NFPA's LSC into the regulations we apply to Medicare and, as applicable, Medicaid providers and suppliers is the Secretary of the Department of Health and Human Services' (the Secretary) authority to stipulate health, safety and other regulations for each type of Medicare and (if applicable) Medicaid-participating facility. Specifically, section 1881(b)(1)(A) of the Social Security Act (the Act) provides for payments for ''providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies . . . . '' Under this statutory authority, the Secretary has set out ''Conditions for Coverage,'' including LSC compliance requirements, at 42 CFR part 494, subpart B. Our current LSC provisions are set out at § 494.60(e).

In implementing the LSC provisions, we have given ourselves the discretion to waive specific provisions of the LSC for facilities if application of our rules would result in unreasonable hardship for the facility, and if the health and safety of its patients would not be compromised by such waiver. For dialysis facilities, that authority is set out at § 494.60(e)(4). In addition, the Secretary may accept a State's fire and safety code instead of the LSC if the Centers for Medicare & Medicaid Services (CMS) determines that the protections of the State's fire and safety code are equivalent to, or more stringent than, the protections offered by the LSC; dialysis facility provisions to that effect are set out at § 494.60(e)(3). These flexibilities mitigate the potential unnecessary burdens of applying the requirements of the LSC to all affected health care facilities.

On May 12, 2012, we published a final rule in the **Federal Register**, entitled ''Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction'' (77 FR 29002). In that final rule, we limited the application of LSC requirements to dialysis facilities either located adjacent to industrial high hazard areas, and those that did not provide one or more exits to the outside at grade level from the patient treatment area level. However, we inadvertently neglected to include updated provisions for dialysis facilities in our proposed update to the Life Safety Code provisions for CMS providers and suppliers, ''Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities; Proposed Rule'' (79 FR 21552, April 16, 2014). Therefore, we are proposing these provisions now, with some modifications to address the unique needs of dialysis facilities. The proposed update would apply only to dialysis facilities that do not provide one or more exits to the outside at grade level from the treatment area level (for instance, in upper floors of a mid-rise or high-rise building). We would not require other dialysis facilities to comply with NFPA 99® 2012 edition of the Health Care Facilities Code (NFPA 99) and NFPA 101® 2012 edition of the Life Safety Code (NFPA 101) because we believe that patients in dialysis facilities are generally capable of unhooking themselves from dialysis machines and self-evacuating without additional assistance in the event of an emergency. We believe that in all facilities with at-grade exits, patients would be able to evacuate the building in a timely fashion. Consequently, we believe that state and local requirements are sufficient to protect these patients and staff in the event of an emergency. In accordance with NFPA 101 sections 20.1.3.7 and 21.1.3.7, we would prohibit Medicare-approved dialysis facilities from being located adjacent to industrial high hazard facilities. ''Adjacent to'' is defined as sharing a wall, ceiling or floor, with a facility.

Defining ''Exit to the Outside at Grade Level From the Patient Treatment Area Level''

The phrase ''exit to the outside at grade level from the patient treatment area level'' applies to dialysis facilities that are on the ground or grade level of a building where patients do not have to traverse up or down stairways within the building to evacuate to the outside. Accessibility ramps in the exit area that provide an ease of access between the patient treatment level and the outside ground level are not considered stairways.

A dialysis facility which provides one or more exits to the outside at grade level from patient treatment level and which has a patient exit path to the outside (which may include an

accessibility ramp that is compliant with NFPA and the Americans with Disabilities Act (ADA)) would be exempt from compliance with the applicable provisions of NFPA 99 and NFPA 101.

II. Provisions of the Proposed Regulations

In this rule, we are proposing to update our requirements for dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level, by incorporating by reference the 2012 edition of NFPA 101 and NFPA 99. These facilities are already required to meet the 2000 edition of the LSC; other provider types affected by the LSC are now required to meet the 2012 edition of the NFPA 101 and the NFPA 99 (LSC final rule published May 4, 2016 at 81 FR 26872). The 2012 edition of the LSC includes new provisions that we believe are vital to the health and safety of all patients and staff. Our intention is to ensure that patients and staff continue to experience the highest degree of fire safety possible.

The NFPA 101 2012 edition of the LSC provides minimum requirements, with due regard to function, for the design, operation and maintenance of buildings and structures for safety to life from fire. Its provisions also aid life safety in similar emergencies.

The NFPA 99 2012 edition of the Health Care Facilities Code provides minimum requirements for health care facilities for the installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment, and appliances.

B. 2012 Edition of the Life Safety Code

The 2012 edition of the LSC includes new provisions that we believe are vital to the health and safety of all patients and staff. Our intention is to ensure that patients and staff continue to experience the highest degree of fire safety possible. We do review each edition of the NFPA 101 and NFPA 99 every 3 years to see if there are any significant provisions that we need to adopt. CMS will continue to review revisions to ensure we meet proper standards for patient safety. We have reviewed the 2015 edition of the NFPA 101 and NFPA 99 and do not believe that there are any significant provisions that need to be addressed at this time. Newer buildings are typically built to comply with the newer versions of the LSC because state and local jurisdictions often adopt and enforce newer versions of the LSC as they become available.

CMS must emphasize that the LSC is not an accessibility code, and compliance with the LSC does not ensure compliance with the requirements of the ADA. State and local government programs and services, including health care facilities, are required to comply with Title II of the ADA. Private entities that operate public accommodations such as nursing homes, hospitals, and social service center establishments are required to comply with Title III of the ADA. Entities that receive federal financial assistance from the Department of Health and Human Services, including Medicare and Medicaid, are also required to comply with section 504 of the Rehabilitation Act of 1973. The same accessibility standards apply regardless of whether health care facilities are covered under Title II or Title III of the ADA or section 504 of the Rehabilitation Act of 1973.[1] For more information about the ADA's requirements, see the Department of Justice's Web site at *http://www.ada.gov* or call 1–800–514–0301 (voice) or 1–800–514–0383 (TTY).

C. Incorporation by Reference

This proposed rule would incorporate by reference the NFPA 101® 2012 edition of the LSC, issued August 11, 2011, and all Tentative Interim Amendments issued prior to April 16, 2014; and the NFPA 99® 2012 edition of the Health Care Facilities Code, issued August 11, 2011, and Tentative Interim Amendments issued prior to April 16, 2014 in § 494.60(g).

These materials have been previously incorporated by reference for other provider types by a final rule titled ''Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities'' published on May 4, 2016 (81 FR 26872).

The materials that are incorporated by reference can be found for interested parties and are available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244, or from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes to this edition of the Code are incorporated by reference, CMS will publish a document in the **Federal Register** to announce those changes.

D. Ambulatory Health Care Occupancies

According to our memorandum, ''Survey & Certification: 13–47–LSC/ESRD,'' issued July 12, 2013, dialysis facilities that are subject to the LSC provisions must meet the requirements of the Ambulatory Health Care Occupancy chapters 20 and 21 of the LSC. Dialysis facilities that are not subject to our LSC regulations must continue to meet State and local fire codes. (See *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-47.pdf.)*

The following are key provisions in the 2012 edition of the LSC from Chapter 20, ''New Ambulatory Health Care Occupancies'' and Chapter 21, ''Existing Ambulatory Health Care Occupancies.'' We have provided the LSC citation and a description of the requirement.

The 2012 edition of the LSC defines an ''Ambulatory Health Care Occupancy'' as a facility capable of treating 4 or more patients simultaneously on an outpatient basis. We believe that dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area should also be required to meet the provisions applicable to Ambulatory Health Care Occupancy Chapters, regardless of the number of patients served, as a matter of health and safety of patients receiving services in these facilities. In the burden reduction final rule, published in the **Federal Register** on May 12, 2012 entitled, ''Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction'' (77 FR 29002), we removed the provision's applicability to dialysis facilities with at-grade exits directly from the treatment area because, in our view, there was, and continues to be, an extremely low risk of fire in dialysis facilities. Medicare-approved dialysis facilities that provide exits to the outside at grade level would continue to be required to follow State and local fire codes, which we believe provide for sufficient patient protection in the event of an emergency. If a facility's exits were located above or below grade, patients would require more time to evacuate. Consequently, we believe that the LSC would still be required due to the additional risk entailed in longer exit times.

[1] Facilities newly constructed or altered after March 15, 2012 must comply with the 2010 Standards for Accessible Design (2010 Standards). Facilities newly constructed or altered between September 15, 2010 and March 15, 2012 had the option of complying with either the 1991 Standards for Accessible Design (1991 Standards) or the 2010 Standards. Facilities newly constructed between January 26, 1993 and September 15, 2010, or altered between January 26, 1992 and September 15, 2010 were required to comply with the 1991 Standards under Title III and either the 1991 Standards or the Uniform Federal Accessibility Standards under Title II.

Sections 20.3.2.1 and 21.3.2.1—Doors

This provision requires all doors to hazardous areas be self-closing or close automatically.

Sections 20.3.2.6 and 21.3.2.6—Alcohol Based Hand Rubs

This provision explicitly allows aerosol dispensers, in addition to gel hand rub dispensers. The aerosol dispensers are subject to limitations on size, quantity, and location, just as gel dispensers are limited. Automatic dispensers are also now permitted in ambulatory care facilities, provided, among other things, that—(1) they do not release contents unless they are activated; (2) the activation occurs only when an object is within 4 inches of the sensing device; (3) any object placed in the activation zone and left in place must not cause more than one activation; (4) the dispenser must not dispense more than the amount required for hand hygiene consistent with the label instructions; (5) the dispenser is designed, constructed and operated in a way to minimize accidental or malicious dispensing; and (6) all dispensers are tested in accordance with the manufacturer's care and use instructions each time a new refill is installed. The provision further defines prior language regarding ''above or adjacent to an ignition source'' as being ''within 1 inch'' of the ignition source.

Sections 20.3.5 and 21.3.5—Extinguishment Requirements

This provision is related to sprinkler system requirements and requires the evacuation of a building or the instituting of an approved fire watch when a sprinkler system is out of service for more than 10 hours in a 24-hour period until the system has been returned to service. A facility must evacuate the building or portion of the building affected by the system outage until the system is back in service, or establish a fire watch until the system is back in service.

E. 2012 Edition of the Health Care Facilities Code

The 2012 edition of the NFPA 99, ''Health Care Facilities Code,'' addresses requirements for both health care occupancies and ambulatory care occupancies, and serves as a resource for those who are responsible for protecting health care facilities from fire and associated hazards. The purpose of this Code is to provide minimum requirements for the installation, inspection, testing, maintenance, performance, and safe practices for health care facility materials, equipment and appliances. This Code is a compilation of documents that have been developed over a 40-year period by NFPA, and is intended to be used by those persons involved in the design, construction, inspection, and operation of health care facilities, and in the design, manufacture, and testing of appliances and equipment used in patient care areas of health care facilities. It provides information on subjects, for example, medical gas and vacuum systems, electrical systems, electrical equipment, and gas equipment. The NFPA 99 applies specific requirements in accordance with the results of a risk-based assessment methodology. A risk-based approach allows for the application of requirements based upon the types of treatment and services being provided to patients or residents rather than the type of facility in which they are being performed. In order to ensure the minimum level of protection afforded by NFPA 99 is applicable to all patient and resident care areas within a health care facility, we are proposing adoption of the 2012 edition of NFPA 99, with the exception of chapters 7—''Information Technology and Communications Systems for Health Care Facilities''; 8—''Plumbing''; 12—''Emergency Management''; and 13—''Security Management''. The first three chapters of the NFPA 99 address the administration of the NFPA 99, the referenced publications, and definitions. Short descriptions of some of the more important provisions of NFPA 99 follow:

Chapter 4—Fundamentals

Chapter 4 provides guidance on how to apply NFPA 99 requirements to health care facilities based upon ''categories'' determined when using a risk-based methodology.

There are four categories utilized in the risk assessment methodology, depending on the types of treatment and services being provided to patients or residents. Section 4.1.1 of NFPA 99 describes Category 1 as, ''Facility systems in which failure of such equipment or system is likely to cause major injury or death of patients or caregivers. . . .'' Section A.4.1.1 provides examples of what a major injury could include, such as amputation or a burn to the eye. Section 4.1.2 describes Category 2 as, ''Facility systems in which failure of such equipment is likely to cause minor injury to patients or caregivers. . . .'' Section A.4.1.2 describes a minor injury as one that is not serious or involving risk of life. Section 4.1.3 describes Category 3 as, ''Facility systems in which failure of such equipment is not likely to cause injury to patients or caregivers, but can cause patient discomfort. . . .'' Section 4.1.4 describes Category 4 as, ''Facility systems in which failure of such equipment would have no impact on patient care. . . .''

Section 4.2 requires that each facility that is a health care or ambulatory occupancy define its risk assessment methodology, implement the methodology, and document the results. We did not propose to require the use of any particular risk assessment procedure. However, if future situations indicate the need to define a particular risk assessment procedure, we would pursue that through a separate notice and comment rulemaking.

Chapter 5—Gas and Vacuum Systems

The hazards addressed in Chapter 5 include the ability of oxygen and nitrous oxide to exacerbate fires, safety concerns from the storage and use of pressurized gas, and the reliance upon medical gas and vacuum systems for patient care. Chapter 5 does not mandate the installation of any systems; rather, if they are installed or are required to be installed, the systems will be required to comply with NFPA 99. Chapter 5 covers the performance, maintenance, installation, and testing of the following:

- Nonflammable medical gas systems with operating pressure below a gauge pressure of 300 psi;
- Vacuum systems in health care facilities;
- Waste anesthetic gas disposal systems (WAGD); and
- Manufactured assemblies that are intended for connection to the medical gas, vacuum, or WAGD systems.

Chapter 6—Electrical Systems

The hazards addressed in Chapter 6 are related to the electrical power distribution systems in health care facilities, and address issues such as electrical shock, power continuity, fire, electrocution, and explosions that might be caused by faults in the electrical system. Chapter 6 also covers the performance, maintenance, and testing of the electrical systems in health care facilities.

Chapter 9—Heating, Ventilation, and Air Conditioning (HVAC)

Chapter 9 requires HVAC systems serving spaces or providing health care functions to be in accordance with the American Society of Heating, Refrigeration and Air-Conditioning Engineers (ASHRAE) Standard 170—Ventilation of Health Care Facilities (2008 edition) (*http://www.ashrae.org*).

Chapter 9 does not apply to existing HVAC systems, but applies to the construction of new health care facilities, and the altered, renovated, or modernized portions of existing systems or individual components. Chapter 9 ensures minimum levels of heating, ventilation and air conditioning performance in patient and resident care areas. Some of the issues discussed in Chapter 9 are as follows:

- HVAC system energy conservation;
- Commissioning;
- Piping;
- Ductwork;
- Acoustics;
- Requirements for the ventilation of medical gas storage and trans-filling areas;
- Waste anesthetic gases;
- Plumes from medical procedures;
- Emergency power system rooms; and
- Ventilation during construction.

Chapter 10—Electrical Equipment

Chapter 10 covers the performance, maintenance, and testing of electrical equipment in health care facilities. Much of this chapter applies to requirements for portable electrical equipment in health care facilities, but there are also requirements for fixed-equipment and information on administrative issues.

Chapter 11—Gas Equipment

The hazards addressed in Chapter 11 relate to general fire, explosions, and mechanical issues associated with gas equipment, including compressed gas cylinders.

Chapter 14—Hyperbaric Facilities

Chapter 14 addresses the hazards associated with hyperbaric facilities in health care facilities, including electrical, explosive, implosive, as well as fire hazards. Chapter 14 sets forth minimum safeguards for the protection of patients and personnel administering hyperbaric therapy and procedures. Chapter 14 contains requirements for hyperbaric chamber manufacturers, hyperbaric facility designers, and personnel operating hyperbaric facilities. It also contains requirements related to construction of the hyperbaric chamber itself and the equipment used for supporting the hyperbaric chamber, as well as administration and maintenance. Many requirements in this chapter are applicable only to new construction and new facilities.

Chapter 15—Features of Fire Protection

Chapter 15 covers the performance, maintenance, and testing of fire protection equipment in health care facilities. Issues addressed in this chapter range from the use of flammable liquids in an operating room to special sprinkler protection. These fire protection requirements are independent of the risk-based approach, as they are applicable to all patient care areas in both new and existing facilities.

Chapter 15 has several sections taken directly from the NFPA 101, including requirements for the following:

- Construction and compartmentalization of health care facilities.
- Laboratories.
- Utilities.
- Heating, ventilation and air conditioning systems.
- Elevators.
- Escalators.
- Conveyors.
- Rubbish Chutes.
- Incinerators.
- Laundry Chutes.
- Fire detection, alarm and communication systems.
- Automatic sprinklers and other extinguishing equipment.
- Compact storage including mobile storage and maintenance.
- Testing of water based fire protection systems.

These sections have requirements for inspection, testing and maintenance which apply to all facilities, as well as specific requirements for existing systems and equipment that also apply to all facilities.

The prospective timeline for applicability of these requirements would be 60 days after the publication of the final rule in the **Federal Register**. We are soliciting comments on the proposal of the adoption of the 2012 NFPA 101 and the 2012 NFPA 99 for dialysis facilities that do not provide one or more exits to the outside at grade level from the treatment area level.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Response to Comments

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

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct 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). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act (the Act) requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis

for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of 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. In 2016, that threshold is approximately $146 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 proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We do not know how many, if any, dialysis facilities would be affected by this adoption of the 2012 editions of the NFPA 101 and NFPA 99. However, we anticipate that the impact of this rule would be less than $1,000 for each facility, and that is if they are not already meeting the requirements of the 2012 editions of the NFPA 101 and NFPA 99. Twenty states have already adopted the 2012 editions, so if there are facilities in those States, they are already following the 2012 requirements. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 494

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

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

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 1. The authority citation for part 494 continues to read as follows:

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

■ 2. Amend § 494.60 by revising paragraphs (e)(1) and (4) and adding paragraphs (e)(5), (f), and (g) to read as follows:

§ 494.60 Condition: Physical environment.

* * * * *

(e) * * *

(1) Except as provided in paragraph (e)(2) of this section, dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level must comply with provisions of the 2012 edition of the Life Safety Code of the National Fire Protection Association (NFPA 101 and Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4 applicable to Ambulatory Health Care Occupancies (which is incorporated by reference in paragraph (g) of this section), regardless of the number of patients served.

* * * * *

(4) In consideration of a recommendation by the State survey agency or at the discretion of the Secretary, the Secretary may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ESRD facility, but only if the waiver will not adversely affect the health and safety of the patients.

(5) No dialysis facility may operate in a building that is adjacent to an industrial high hazard area, as described in sections 20.1.3.7 and 21.1.3.7 of the 2012 edition of the Health Care Facilities Code of the National Fire Protection Association (NFPA 99), incorporated by reference in paragraph (g) of this section.

(f) *Standard: Building safety.* (1) Dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level must meet the applicable provisions of the 2012 edition of the Health Care Facilities Code of the National Fire Protection Association (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6), regardless of the number of patients served.

(2) A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD.

(3) Chapters 7, 8, 12, and 13 of the NFPA 99 2012 Health Care Facilities Code do not apply to a dialysis facility.

(4) If application of the NFPA 99 would result in unreasonable hardship for the dialysis facility, CMS may waive specific provisions of the Health Care Facilities Code for such facility, but only if the waiver does not adversely affect the health and safety of patients.

(g) *Incorporation by reference.* The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the **Federal Register** to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org,* 1–617–7470–3000.

(i) NFPA 99, Standard for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12–2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12–3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12–4 to NFPA 99, issued March 7, 2013.

(v) TIA 12–5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12–6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12–1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12–2 to NFPA 101, issued October 30, 2012.

(x) TIA 12–3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12–4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

Dated: September 7, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: October 17, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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