

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-24

DATE: February 11, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Implementation of the Life Safety Code (LSC) Component for the New End Stage Renal Disease (ESRD) Conditions for Coverage

Memorandum Summary

- **The major portions of the new ESRD Conditions for Coverage became effective on October 14, 2008. The Life Safety Code (LSC) components of these regulations became effective on February 9, 2009.**
- **The LSC component** for dialysis facilities includes Chapters 20 and 21 of the 2000 Edition of the National Fire Protection Association's (NFPA) 101 LSC.
- **The ESRD regulation provides certain exceptions** to the LSC provisions, including sprinkler systems, Essential Electrical Systems (EES), and fire drills. The regulation also provides for specific LSC waivers.

Background

In this memorandum, we describe the procedures we are implementing for the LSC provisions of the new ESRD Conditions for Coverage. While major portions of the ESRD regulation became effective on October 14, 2008, the LSC component became effective on February 9, 2009. The ESRD regulation provides certain exceptions to the LSC provisions, including sprinkler systems, Essential Electrical Systems (EES), and fire drills. The regulation also provides for specific LSC waivers based upon an “unreasonable hardship.”

Compliance with LSC Provisions for ESRD Facilities

Dialysis facilities must comply with Chapter 20 (for “new” dialysis facilities) or Chapter 21 (for “existing” dialysis facilities) of the 2000 edition of the Life Safety Code (LSC) for Ambulatory Health Care Occupancies of the National Fire Protection Association (NFPA), titled *NFPA 101 Life Safety Code (LSC), 2000 Edition*.

Definitions:

- A “new” dialysis facility is defined as a facility that has not received approval of all of its building permits (or alternatively, completed all of its plan reviews in jurisdictions that do not require building permits) on or after February 9, 2009. A facility that is relocating on or after February 9, 2009, or a facility that is undergoing “major renovations” on or after February 9, 2009, is also classified as a “new” facility.
- A “major renovation” is classified as a renovation that involves more than 50 percent or more than 4,500 square feet of the smoke compartment of the facility. Cosmetic changes, such as painting or floor replacement, are not considered “major renovations” regardless of the size of the area involved.
- An “existing” facility is defined as a facility that has received approval of all of the required building permits (or alternatively, plan reviews in jurisdictions that do not require building permits) prior to February 9, 2009.

With regard to LSC, States may request permission to use a State fire and safety code (State Code) in lieu of the LSC for Federal certification but only if the State Code applies to all provider/supplier types for which there are Medicare-certified providers or suppliers in the State. Currently, no State is approved to use its State Code in lieu of the Federal certification for LSC. If the State Code is approved by CMS as adequately protecting residents and patients, then the National Fire Protection Association’s (NFPA’s) 2000 edition of the LSC for Ambulatory Health Care Occupancies (Chapters 20 and 21) will not apply to dialysis facilities. The State application process is detailed in a Survey and Certification Letter dated September 5, 2008 (S&C-08-34).

Performance-Based Options for LSC

Chapter 5 of the *LSC, 2000* allows a dialysis facility a performance-based option for meeting the LSC occupant protection, structural integrity, and systems effectiveness goals and objectives. This chapter allows the design of a LSC-compliant dialysis facility building, using a performance-based template that employs a computer-based methodology.

The *NFPA 101A, Guide on Alternative Approaches to Life Safety, 2001 Edition* discusses an alternative Fire Safety Evaluation Survey (FSES), which is also a performance-based option. However, this is not an alternative option for dialysis facilities because a FSES is not available for the ambulatory health care occupancies of the LSC.

Application of LSC Provisions

Compliance with the LSC provisions for dialysis facilities is required for both owned and leased space. Home training facilities, whether integrated into the dialysis facility or detached from the dialysis facility, must meet the LSC, without regard to the number of patients served.

If a dialysis facility is located within a hospital, the dialysis facility must either meet the hospital chapters or the dialysis facility must be separated from the hospital by two-hour fire-wall construction, and be surveyed under chapters 18 and 19 of the LSC. An outpatient dialysis facility must meet the hospital chapters of the LSC if the dialysis facility provides acute services for hospitalized patients. If the dialysis facility is located in a mixed-use building, the dialysis facility must be separated from other tenants by a fire separation of at least one-hour duration. The fire-separation hourly ratings are dependent upon the height of the building and the combustibility of the building materials as explained by the LSC.

When a portion of a dialysis facility is used intermittently by another health-care entity, e.g., an exam room used for a nephrology practice, that portion does not need to be separated from the dialysis facility by fire-wall construction as long as the shared mixed-use space complies with the LSC.

Sprinkler Systems: Exception to the LSC, 2000

The *LSC, 2000* requires buildings with certain structural configurations to have sprinkler systems. Specifically, the 2000 Edition at section 21.1.6.3 requires buildings of two or more stories in height with the following construction types be protected by an approved, supervised, automatic sprinkler system: Type II (000), Type III (200), and Type V (000).

CMS rules apply the sprinkler provisions of the LSC only to dialysis facilities classified as “new” facilities. The CMS final rule states that “existing” dialysis facilities which are participating are exempt from the requirement for a sprinkler system if the facility is located in a building that was “constructed” before January 1, 2008, and if State law permits. For the purposes of implementing these new requirements, we are including facilities that were operational or had a valid certificate of occupancy before October 14, 2008, in our definition of “existing” facilities.

Essential Electrical Systems (EES): Exception to the LSC, 2000:

Dialysis facilities are not required to meet the parts of sections 20.2.9.2 and 21.2.9.2 of the *LSC, 2000* that require the facility to provide an “essential electrical system” (EES) in accordance with *NFPA 99, 1999*. Generators would be required if there was an ongoing need for “general anesthesia or life support equipment.” “Life support equipment” is defined as electrically-powered equipment whose continuous operation is necessary to maintain a patient’s life. An EES is not required in a dialysis facility because dialysis machines are not considered life support equipment. Continuous operation of a dialysis machine is not required to maintain life.

Physical Removal of Patients for Fire Drills: Exception to the LSC, 2000

Sections 20.7.1.2 and 21.7.1.2 of *LSC, 2000* state “infirm or bedridden patients shall not be required to be moved during drills.” CMS does not require that any dialysis patient be physically moved during a fire drill. Fire drills may be conducted using simulated patients or empty wheelchairs or by talking patients through the actions to be taken in the event of a fire.

Waivers for Unreasonable Hardship

A facility may apply for a time-limited waiver for one or more specific provision(s) of the *LSC, 2000*, for appropriate periods, if the application of the provisions of the LSC would result in an “unreasonable hardship” for a dialysis facility. A time-limited waiver will only be granted if it is determined that the waiver will not adversely affect the health and safety of the dialysis facility’s patients.

A “new” or “existing” facility may request a waiver for a specific provision of the LSC:

- An “existing” facility may request a LSC waiver through the State Survey Agency following the citation of a LSC deficiency on form CMS-2567, the Summary Statement of Deficiencies. If the facility requests a waiver, the facility uses the right side of CMS-2567 to specify the waiver request, to describe the “unreasonable hardship,” and to document the lack of an “adverse effect” to facility patients’ health and safety as a result of the waiver. The waiver statement is filed on the CMS-2567 in lieu of a Plan of Correction.
- A “new” facility may request a LSC waiver through the State Survey Agency at any point during the design or construction of the facility. If the facility requests a waiver, the facility needs to specify the waiver request, to describe the “unreasonable hardship,” and to document the lack of an “adverse effect” to facility patients’ health and safety as a result of the waiver.

CMS’ approval of a facility’s waiver request is not open-ended. CMS continues to have the goal of protecting the health and safety of patients, and any exception will be time-limited and valid only so long as the facility continues to offer safe and effective care to its patients. CMS may at any time, based upon evidence that a facility does not adequately protect patients, rescind a prior approval for a waiver or exception.

The application process for an ESRD waiver for a LSC requirement is detailed in Survey and Certification Letter dated November 21, 2008 (S&C-09-13).

The Survey Process for NFPA 2000 (LSC)

The LSC surveys generally will be conducted separately from the basic portion of the ESRD facility survey. The LSC surveys will be conducted by a LSC specialist who is hired by or contracted by the State Survey Agency. A LSC specialist is an individual who has completed online LSC courses in Principles of Documentation and LSC; attended a Basic LSC course; and observed a LSC survey.

CMS-2786U, the Fire Safety Report Form, will be completed by the LSC surveyors. Upon completion of the Fire Safety Report Form, K tags will be cited in the ASPEN survey data system. Although CMS does not require that LSC deficiencies (i.e., K tags) be cited with the ESRD survey deficiencies (i.e. V tags), some States do require that the K tags be cited with the V tags. If your State requires that K tags be cited with V tags, use V417 for the K tag citations.

It is CMS' intention that all initial ESRD surveys and a sampling of ESRD recertification surveys will be accompanied by LSC surveys of the ESRD facilities. The sampling level of ESRD recertification surveys will depend upon an ongoing review and assessment of the results of the LSC surveys. Each year, the level of sampling will be communicated in the Mission and Priority Document (MPD).

The ASPEN survey data system for LSC in ESRD facilities (i.e., future ASPEN version 9.5) will not be ready until the summer of 2009. For this reason, we are applying the following schedule:

- **Complaint Surveys:** Complaint surveys which involve a LSC issue in ESRD facilities must be handled following the time frame used generically for complaint surveys. Surveyors will use form CMS-2786U for the survey and manually enter the survey report into the ASPEN system, using V417 for citing LSC deficiencies.
- **Initial Facility Surveys:** The LSC component of the ESRD Initial Survey will be performed in the same manner as the complaint surveys, using CMS-2786U for the survey and manually entering the survey report into the ASPEN system, using V417 for citing LSC deficiencies.
- **Recertification Surveys:** Until the ASPEN data system is updated to version 9.5, surveyors will use the current automated ESRD V tags related to emergency preparedness (i.e., V408 through V416 of ASPEN version 9.2.1), including the tags on fire response and evacuation plans, as required by section 494.60(d) of the new Conditions for Coverage. Once the ASPEN data system is updated to version 9.5, surveyors will use the automated LSC K tags.

We will notify States, with adequate lead time, when the LSC component of the ESRD survey (i.e., ASPEN version 9.5) is complete.

Effective Date: Immediately. Please ensure that all appropriate staff is fully informed within 30 days of the date of this memorandum.

If you have additional questions or concerns regarding the integration of the LSC survey with the ESRD survey, please contact Judith Kari at judith.kari@cms.hhs.gov. For questions or concerns regarding specific aspects of the LSC survey, please contact James Merrill at james.merrill@cms.hhs.gov.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management