

the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

(b) *Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines.* A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(1) Meet the requirements of AAMI published in “Reuse of Hemodialyzers,” third edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

(2) Reprocess hemodialyzers and bloodlines—

(i) By following the manufacturer’s recommendations; or

(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as a cleaner in this application), during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.

(c) *Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.* In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following:

(1) Monitor patient reactions during and following dialysis.

(2) When clinically indicated (for example, after adverse patient reactions), the facility must—

(i) Obtain blood and dialysate cultures and endotoxin levels; and

(ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected.

(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.

§ 494.60 Condition: Physical environment.

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

(a) *Standard: Building.* The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.

(b) *Standard: Equipment maintenance.* The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer’s recommendations.

(c) *Standard: Patient care environment.*

(1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

(2) The dialysis facility must:

(i) Maintain a comfortable temperature within the facility; and

(ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.

(3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.

(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).

(d) *Standard: Fire safety.* (1) Except as provided in paragraph (d)(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 Life Safety Code (NFPA 101 and its Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4) applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

(2) Notwithstanding paragraph (d)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008 that require sprinkler systems are those housed in multi-story buildings construction Types II(000), III(200), or V(000), as defined in the Life Safety Code, section 21.1.6.1, which were constructed after January 1, 2008, and those housed in high rise buildings over 75 feet in height, which were constructed after January 1, 2008.

(3) If CMS finds that a fire and safety code imposed by the facility's State law adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.

(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 Health Care Facilities Code (NFPA 99 and its Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6).

(e) *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 Health Care Facilities Code, regardless of the number of patients served.

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

(3) If application of the Health Care Facilities Code 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.

(f) *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 obtain the material from the sources listed below. 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, email fedreg.legal@nara.gov, or go to: www.archives.gov/federal_register/cfr/ibr-locations.html. If any changes in the editions of the Codes 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, 1-617-770-3000.

(i) NFPA 99, Health Care Facilities Code, 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]

[73 FR 20475, Apr. 15, 2008, as amended at 77 FR 29031, May 16, 2012; 81 FR 64042, Sept. 16, 2016; 84 FR 51832, Sept. 30, 2019]

§ 494.62 Condition of participation: Emergency preparedness.

The dialysis facility must comply with all applicable Federal, State, and local emergency preparedness requirements. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The dialysis facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least every 2 years. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the dialysis facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.

(b) *Policies and procedures.* The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of

this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of on-duty staff and sheltered patients in the dialysis facility's care during and after an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the dialysis facility must document the specific name and location of the receiving facility or other location.

(2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.

(3) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to dialysis facility patients.

(7) The role of the dialysis facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(8) How emergency medical system assistance can be obtained when needed.

(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen,