

## **PART 494--CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES (ESRDF) – DIALYSIS CENTERS**

38. 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 1395hh).

### **§ 494.60 [Amended]**

39. Amend § 494.60 by removing paragraph (d) and re-designating paragraph (e) as paragraph (d).

40. Add § 494.62 to subpart B to read as follows:

### **§ 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:

***Tip #1 – When developing your emergency response plan, write it as if the target audience knows nothing about your organization, the larger community, or your specific facility. Assume everyone who's familiar with your operations are unavailable and the response actions are handled by others totally unaware of your circumstances.***

- ***Include the name, address, and contact information for all key partners.***
- ***Ensure your local emergency management agency name, address, phone numbers, email address, and GIS coordinates (if you can get them) are included. Include these details for each county your agency operates in.***
- ***Include contact information and other details for your local health & medical lead agency (ESF8) in each county where your agency operates***
- ***Ensure these contact names, addresses and contact information is verified at least annually***
- ***Be as specific as possible with every detail***
- ***Due to the sensitivity of information contained in your disaster plans treating these documents as proprietary is acceptable***
- ***Lastly, gathering the necessary details to fully develop your disaster plan will take time and much effort. We recommend working diligently to fully develop your disaster plan.***

#### **(a) Emergency Plan**

The dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least **annually**. 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, including documentation of the dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. 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.

***Tip #2 – These plans are typically called Comprehensive Emergency Management Plans (CEMP). We recommend ensuring the above elements are included in your existing CEMP. If your Organization already has a disaster plan, there's no need to create a completely new response plan to satisfy these CMS requirements. However, if your Organization does not have a CEMP (or similar) these new CMS Rules will require the development of one.***

***Tip#3 – The Tampa Bay Health & Medical Preparedness Coalition (TBHMPC) already performs a regional hazard vulnerability assessment every year. We recommend using our hazard assessment as a basis for your internal risk assessment. Remember to include specific threats or hazards in close proximity pose to your operations.***

***Tip #4 – TBHMPC requires all “members in good standing” to sign a Memorandum of Agreement (MOA) committing the organization to helping / supporting / assisting other members during disasters. This MOA should be included as a strategy for addressing emergency events. It also means your organization should have a signed MOA on file with TBHMPC. If not, contact us to get that process started.***

***Tip #5 – Your organization’s active participation in the TBHMPC should be mentioned to specifically explain paragraph (4) above. The TBHMPC is established specifically to focus on the areas and functions mentioned above. If you’re agency is not active in the TBHMPC, we strongly recommend getting involved. Visit our website at [www.tampabayhmpc.org](http://www.tampabayhmpc.org) for information on how you can get involved.***

## **(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 annually. 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.

***Tip #6 – A “system to track the location of on-duty staff and sheltered patients” could be as simple as pen and paper, a hand-written form, or a laptop based spreadsheet. The important factor is that you have a reliable and robust process to track the location and assignments of on-duty staff and patients. This process is necessary to ensure the safety and health of ALL patients and staff. It also gives you quick access to this information in case of an unforeseen emergency.***

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

***Tip #7 – If you had to evacuate your facility, how would you ensure patients / clients were sent to the appropriate level of care? Since Dialysis facilities cannot arrange patient transportation, how would you evacuate these patients during an emergency? Who would your agency contact to make those arrangements? If you would contact your local Emergency Operations Center, have you exercised this process with your ESF8 lead agency, emergency management, your local EMS agency, and local ambulance companies? Be very specific about how your organization would address patient evacuation and a detailed list of staff responsibilities or actions. Ensure ALL of these details are included in your CEMP and the full contact information for each outside partner is also included.***

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

***Tip #8 – If your Organization provides food, water, shelter, or other subsistence needs to clients / patients then include extremely specific details in your CEMP on how this process would work during a shelter-in-place event. For example, what steps would your organization take to protect patients and clients if there was a tornado warning in your immediate area? These actions qualify as “shelter-in-place” even if the timeframe is within the normal dialysis process for a specific patient and within the normal work shift of staff members. If your organization does not provide food, water, shelter, or other subsistence needs to client / patients, then fully explain those details in your CEMP to address paragraph (3) above.***

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

***Tip #9 – If your Organization uses electronic medical records, consider how staff would access those medical records if you lost both primary and back-up electrical power (this advice comes from recent real-world experience). Does staff know how to complete paper medical records? Are there emergent procedures in-place to perform manual or paper patient charts? How would you medically transfer clients / patients to another dialysis facility if there were no medical records available to send with them? Include these details in your CEMP to address paragraph (4) above.***

- (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.

***Tip #10 – Does your Organization have the means to provide emergency credentialing to licensed volunteers if your agency needed additional help? Is there a system in-place to provide clinical oversight to these volunteers? How would you ensure during a disaster that someone who presents as an MD or RN actually holds that medical license? Would a Federal or State level disaster declaration change your volunteer credentialing? It's best to have these issues answered in advance, and have them detailed in your CEMP, so your staff isn't faced with addressing these challenges when the stakes are highest.***

- (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.

***Tip #11 – Florida operates a robust Special Needs Sheltering program specifically for vulnerable populations to use during tropical weather events or other emergencies. Special Needs Shelters are specifically designed and organized to support the needs of frail, elderly, or vulnerable populations living within the local community. These programs require pre-registration with the local emergency management agency or health department and have limitations of the level of medical care they can provide. Also, the specifics for this pre-registration are different in each county. ACHA rules require pre-event education to ensure the client, their family members, or legal guardians are fully aware of this pre-registration process and the benefits. One element of this pre-registration process involves ensuring Special Needs clients are dialyzed just prior to entry into a Special Needs Shelter. Close collaboration with local emergency management and the ESF8 lead agency will help Dialysis Centers plan their pre-storm workloads. Full documentation of these details will help ensure compliance with paragraph (6) above.***

- (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.

***Tip #12 – In extreme situations (usually post-disaster), Alternate Care Sites can be established within a community. Leadership at these sites will need information about which Dialysis Centers are operational so they can arrange services for the patient. Close communication and coordination between the Dialysis Centers and the local Emergency Operations Centers (EOCs) is critical to ensure dialysis services are provided. Include specific details in your CEMP on how your organization will communicate your pre- and post-disaster operational status to the ESF8 lead agency at your local EOC. If your agency operates in multiple counties, then include communication details and contact information for each County EOC involved.***

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

***Tip #13 – Include specific criteria and circumstances when Emergency Medical Services (EMS) would be contacted. A detailed listing or protocol is necessary to provide staff with clear directions on when to initiate this process. Also include extremely specific information on the EMS agencies or ambulance services used and contact information for each.***

(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

***Tip #14 – Describe in detail the processes used to ensure critical supplies are available at all times. Also ensure your CEMP includes detailed contact information for the each supplier of these critical items.***

### **(c) Communication Plan**

The dialysis facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

- (1) Names and contact information for the following:
  - (i) Staff.
  - (ii) Entities providing services under arrangement.
  - (iii) Patients' physicians.
  - (iv) Other dialysis facilities.
  - (v) Volunteers.

***Tip #15 – Be specific and include these details in your CEMP. Ensure they are verified and updated at least annually. “Entities providing services” typically means any and all outside vendors that support your internal operations. This includes those providing direct patient care, IT system maintenance and repair vendors, utility service providers, and all others.***

- (2) Contact information for the following:
  - (i) Federal, State, tribal, regional or local emergency preparedness staff.
  - (ii) Other sources of assistance.

***Tip #16 – See Tips #13, 14, and 15 above. Include contact details for emergency management and local health & medical lead agency (usually public health department) in each county where your agency operates. This information must be updated ANNUALLY to ensure accuracy and CMS Emergency Management Rule compliance.***

- (3) Primary and alternate means for communicating with the following:
- (i) Dialysis facility's staff.
  - (ii) Federal, State, tribal, regional, or local emergency management agencies.

***Tip #17 – Telephones and cell phones are probably your primary and back-up communication methods. What if they're not functioning? We recommend a third level of emergent communication capability. If all other options fail, sending a runner is a viable option. Also see Tip #16 above.***

- (4) A method for sharing information and medical documentation for patients under the dialysis facility's care, as necessary, with other health care providers to maintain the continuity of care.

***Tip #18 – See Tip #11 above. Who is authorized to release this information? To whom can it be released? Ensure these details are included in your CEMP and the identified staff are both aware of this authorization and are trained on the process.***

- (5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

***Tip #19 – See Tip #18 above. Be specific about the agencies / entities this information can be shared with to ensure patient privacy and HIPPA compliance.***

- (6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

***Tip #20 – See Tip #18 above. Be specific about the agencies / entities this information can be shared with to ensure patient privacy and HIPPA compliance.***

- (7) A means of providing information about the dialysis facility's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

***Tip #21 – Ensure your CEMP includes contact information and reporting schedules for communication with your local health & medical lead agency (ESF8) at the County Emergency Operations Center. This lead agency is usually the local public health department. If your Organization operates in more than 1 county, you'll need to communicate with each county you're operating in. Active participation in the TBHMPC will give you opportunities to develop the working relationships needed to ensure this communication process is far more effective and efficient for your agency.***

#### **(d) Training, Testing, and Orientation**

The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing, and patient orientation program must be evaluated and updated at least ***annually***.

***Tip #22 – In Florida we refer to “training and testing” as training and exercises or drills. CMS has clearly indicated they want to see robust training and disaster drills of ALL dialysis agency staff. This includes any staff who work nights and weekends. Ensure your organization maintains detailed records on ALL training and testing activities.***

***Tip #23 – Additionally, CMS is also expecting to see healthcare agency executives (CEOs, COOs, CNOs, and other senior leadership) DIRECTLY involved in training and drills. Ensure After Action Reports (AARs) from emergency drills include detailed specifics on any senior executive involvement in that drill.***

***Tip #24 – Ensure ALL real-world emergencies and training drills are documented using the Homeland Security Exercise and Evaluation Program (HSEEP) standards and formats. If your agency is unaware of the HSEEP process contact the TBHMPC for assistance and training on the process. Using the HSEEP processes will show great benefit when CMS, ACHA, or accrediting agencies review your records.***

- (1) **Training program.** The dialysis facility must do all of the following:
- (i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.
  - (ii) Provide emergency preparedness training at least annually. Staff training must:
  - (iii) Demonstrate staff knowledge of emergency procedures, including informing patients of--
    - (A) What to do;
    - (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;
    - (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and
    - (D) How to disconnect themselves from the dialysis machine if an emergency occurs.
  - (iv) Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and
  - (v) Properly train its nursing staff in the use of emergency equipment and emergency drugs.
  - (vi) Maintain documentation of the training.

***Tip #25 – We recommend incorporating the above training into your new-hire and annual training processes for staff. Documentation should include details (by name) of who participated in the training and what they were trained on. The term “demonstrate staff knowledge of emergency procedures” can be accomplished by ensuring 100% of staff are directly involved in emergency drills. To accomplish a 100% participation normally requires holding more than 2 drills per year and performing those drills at different times of the day (for all shifts) and on different days of the week to catch all work schedules.***

***Tip #26 - Don't forget to ensure staff are trained on the requirements addressed in paragraph (d)(1)(iii) above. Documenting when this information was shared with new patients is also recommended. Include these details in your CEMP.***

***Tip #27 – Staff members CPR Training records should also be included in your CEMP. Ensure this training and the associated records are maintained meticulously. Doing so will ensure CMS Rule compliance and assist with accreditation agency reviews.***

- (2) **Testing.** The dialysis facility must conduct exercises to test the emergency plan at least **annually**. The dialysis facility must do all of the following:
- (i) Participate in a full-scale exercise that is community-based or when a community based exercise is not accessible, an individual, facility-based. If the dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ESRD is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.
  - (ii) Conduct an additional exercise that may include, but is not limited to the following:
    - (A) A second full-scale exercise that is community-based or individual, facility based.
    - (B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
  - (iii) Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.

***Tip #28 – While the CMS Emergency Management rules above only require 2 exercises per year (at least 1 must be a community-based full-scale exercise) you may find a need for a more frequent exercise schedule to ensure all staff on all shifts are given an opportunity to demonstrate their emergency duty skills. Also see Tips #22, 23, and 24 above. If your organization needs assistance planning and executing these drills, contact the Tampa Bay Health & Medical Preparedness Coalition for guidance.***

***Tip #29 – Actively seek opportunities to participate in community-wide exercises and drills. These events are typically designed and executed by others, thus saving your agency significant time and money. Plus, they'll involve a much wider range of community partners than a single dialysis agency can recruit. Then, ensure your organization participates in the After Action Report process and obtains a copy of that final report. This documentation will address the expectations spelled out in paragraph (iii) above.***

***Tip #30 – Many dialysis facilities operate emergency generators. The ACHA standards for emergency generators are more stringent than the CMS Rules. We recommend maintaining detailed emergency generator testing and recordkeeping processes within your CEMP, along with contact information for the company that maintains your emergency generator.***



- (3) **Patient orientation:** Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.

***Tip #31 – Detailed protocols addressing emergency preparedness and patient training should be developed. Include these protocols in your CEMP along with references of where records are maintained showing when and who provided this orientation to patients. We recommend periodic refresher training of patients, especially for those receiving long-term services at your facilities.***

### **(e) Integrated healthcare systems**

If a dialysis facility is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the dialysis facility may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

- (1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.
- (2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.
- (3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.
- (4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:
  - (i) A documented community-based risk assessment, utilizing an all-hazards approach.
  - (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.
- (5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

***Tip #32 – If a multi-facility / multi-agency dialysis organization elects use this provision we recommend the following:***

- ***Establish a corporate level emergency preparedness committee chaired by someone from executive leadership and hold meetings at least quarterly***
- ***Ensure active attendance and participation from key staff at all participating healthcare facilities / agencies***
- ***Maintain detailed records of meeting agendas, meeting minutes, and formal presentations of each meeting***
- ***Ensure the specific needs or hazards at each location / agency are addressed by this corporate level committee***