



State of Louisiana
Louisiana Department of Health
Health Standards Section

TO: All ESRD Providers (dialysis facilities)

FROM: Cecile Castello, RN, Deputy Assistant Secretary, Health Standards Section

SUBJECT: Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in dialysis facilities (Revised)

DATE: April 1, 2020

The Louisiana Department of Health/Health Standards Section encourages all ESRD providers to monitor the CDC website for updated information and resources and contact the Louisiana Office of Public Health when needed (CDC Resources for Health Care Facilities:

<https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html>).

The following guidance from CMS is being shared with all dialysis facilities.

Facilities should monitor the CDC website for information and resources (links below), and contact their local health department, if needed for local information about COVID-19. Also, facilities should be monitoring the health status of everyone (in-center and home dialysis patients/visitors/staff/etc.) in their facility for signs or symptoms of respiratory infection. Per CDC, prompt detection, triage and isolation of potentially infectious patients are essential to prevent unnecessary exposures among patients, healthcare personnel, and visitors at the facility. Therefore, facilities should continue to be vigilant in identifying any possible exposed or infected individuals.

Facilities should consider frequent monitoring for potential symptoms of respiratory infection as needed throughout the day. Furthermore, we encourage facilities to take advantage of resources that have been made available by CDC and CMS to train and prepare staff to improve infection control and prevention practices. Lastly, facilities should maintain open lines of communication with patients, patient representatives and/or family and other care providers to respond to the individualized needs of each patient.

Facilities experiencing an increased number of respiratory illnesses (regardless of suspected etiology) among patients/visitors or healthcare personnel should immediately contact their local or state health department for further guidance.

In addition to the requirements in the Conditions of Coverage (CFC) and associated guidance, we're providing the following information (Frequently Asked Questions) about some specific areas related to COVID-19:

Guidance for Limiting the Transmission of COVID-19 for Dialysis Facilities

What actions should dialysis facilities implement to promote early recognition and management of patients, staff and visitors?

Facilities should screen patients, staff and visitors and contact home dialysis patients for:

1. Signs or symptoms of a respiratory infection, such as a fever, cough, *or difficulty breathing*.
2. *Contact* with someone with or under investigation for COVID-19 or ill with respiratory illness.
3. International travel within the last 14 days to countries with widespread or ongoing community spread. For updated information on countries visit:
<https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html>
4. *Residence* in a community where community-based spread of COVID-19 is occurring. *For more information on mitigation plans for communities identified to be at risk, visit: <https://www.cdc.gov/coronavirus/2019-ncov/community/index.html>*

To promptly identify and manage patients, staff or visitors with undiagnosed respiratory symptoms, the following actions should be implemented:

- Facilities should identify patients with signs and symptoms of respiratory infections before they enter the treatment area.
 - Patients with symptoms of a respiratory infection should be provided a facemask (i.e., surgical mask) at check-in and required to keep it on until they leave the facility.
 - Staff should ask patients about any fever or respiratory symptoms immediately upon arrival at the facility and should consider checking all patient temperatures.
 - Staff should inform patients (e.g., during appointment reminder calls) they need to call ahead to report fever or respiratory symptoms so the facility can be prepared for their arrival or triage them to a more appropriate setting (e.g., an acute care hospital).
 - Post signs at entrances with instructions to patients with fever or symptoms of respiratory infection to alert staff so appropriate precautions can be implemented.

- Facilities should provide patients and staff with instructions (in appropriate languages) about hand hygiene, respiratory hygiene, and cough etiquette.
 - Instructions should include how to use facemasks or tissues to cover nose and mouth when coughing or sneezing, to dispose of tissues and contaminated items in waste receptacles, and how and when to perform hand hygiene
- Facilities should have the following supplies available to ensure adherence to hand and respiratory hygiene, and cough etiquette. These include tissues and no-touch receptacles for disposal of tissues and hand hygiene supplies (e.g., alcohol-based hand sanitizer)
- Visitors with signs and symptoms of a transmissible infection (e.g., a visitor is febrile and exhibiting signs and symptoms of an influenza-like illness) should defer visitation until he or she is no longer potentially infectious (e.g., 24 hours after resolution of fever without antipyretic medication), *self-quarantine at home and call their doctor if they develop symptoms consistent with COVID-19. For more information on managing visitor access and movement within the dialysis facility, see CDC guidance here: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html#manage_access*

How should facilities monitor or restrict dialysis facility staff?

The same screening performed for visitors should be performed for facility staff (numbers 1 through 4 above).

- Dialysis staff who have signs and symptoms of a respiratory infection should not report to work. Facilities should implement sick leave policies that are non-punitive, flexible and consistent with public health policies that allow ill staff members to stay home.
- Any staff member who develops signs and symptoms of a respiratory infection while on- the-job, should:
 - Immediately stop work, put on a facemask, and self-isolate at home;
 - Inform the facility administrator of sick leave and report information on individuals, equipment, and locations the person came in contact with; and
 - Contact and follow the local health department recommendations for next steps (e.g., testing, locations for treatment).
- Refer to the CDC guidance for *[Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease \(COVID-19\)](#)*
- *[Refer to the CDC guidance for Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19.](#)*

Facilities should contact their local health department for questions, and frequently review the CDC website dedicated to COVID-19 for health care professionals (<https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>).

Where should dialysis facilities place patients with undiagnosed respiratory symptoms and/or suspected or confirmed COVID 19?

Facilities should have space in waiting areas for ill patients to sit separated from other patients by at least 6 feet. Medically-stable patients who do not have other care needs *could be asked to wait* in a personal vehicle or outside the healthcare facility. *When the patient is the next to be seen, staff can contact the patient by mobile phone.* Additional placement considerations include:

- Patients with respiratory symptoms should be *escorted* to a designated treatment area for evaluation as soon as possible in order to minimize time in common waiting areas.
- Facilities should maintain at least 6 feet of separation between masked, symptomatic patients and other patients and stations during dialysis treatment. Ideally, symptomatic patients would be dialyzed in a separate room (if available) with the door closed.
 - Hepatitis B isolation rooms may be used to dialyze patients if:
 - The patient with suspected or confirmed COVID-19 is hepatitis B surface antigen positive or;
 - The facility has no hepatitis B surface antigen positive patients who would require treatment in the isolation room.
 - If a separate room is not available, the patient should be treated at a corner or end-of-row station, away from the main flow of traffic (if available). The patient should be separated by at least 6 feet from the nearest patient stations (in all directions).
- *For more information, see “Patient Placement” section of CDC’s [Interim Additional Guidance for Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed COVID-19 in Outpatient Hemodialysis Facilities](#)*

When transmission in the community is identified, the local medical system’s capacity to accept hemodialysis patients for treatment may be exceeded. Public health authorities and dialysis facilities should refer to pandemic and emergency preparedness plans to help determine alternatives. Alternative options may include the need to continue dialysis in the outpatient hemodialysis setting if the patient’s condition does not require a higher level of care. If a hemodialysis facility is dialyzing more than one patient with suspected or confirmed COVID-19, consideration should be given to cohort these patients and the dialysis staff caring for them together in the unit and/or on the same shift (e.g., consider the last shift of the day).

Additionally, per current CDC guidance, an airborne infection isolation room (AIIR) is not required for the evaluation or care of patients with suspected or

confirmed COVID-19. AIIRs should be prioritized for patients who are critically ill or receiving aerosol-generating procedures.

What type of Personal Protective Equipment (PPE) should be used when caring for patients with undiagnosed respiratory symptoms?

When providing dialysis care, facilities should continue to follow the infection control requirements at 42 CFR §494.30 including requirements for hand hygiene, PPE, isolation and routine cleaning and disinfection procedures.

- In general, dialysis staff caring for patients with undiagnosed respiratory infections should follow Standard, Contact, and Droplet Precautions with eye protection unless the suspected diagnosis requires Airborne Precautions (e.g., tuberculosis). This includes the use of:
 - Isolation gowns
 - The isolation gown should be worn over or instead of the cover gown (i.e., laboratory coat, gown, or apron with incorporate sleeves) that is normally worn by hemodialysis personnel. This is particularly important when initiating and terminating dialysis treatment, manipulating access needles or catheters, helping the patient into and out of the station, and cleaning and disinfection of patient care equipment and the dialysis station.
 - Remove and discard the gown in a dedicated container for waste or linen before leaving the dialysis station. Disposable gowns should be discarded after use. Cloth gowns should be laundered after each use.
 - Gloves
 - Facemask
 - Eye protection (e.g., goggles, a disposable face shield that covers the front and sides of the face). Personal glasses and contact lenses are NOT considered adequate eye protection.
- *If your dialysis facility anticipates having a shortage for any of the PPE necessary for caring for symptomatic patients, or patients confirmed to be COVID-19 positive, you should communicate with your state and local public health official. CDC has also released guidance for [Strategies for Optimizing the Supply of PPE](#).*

How should facilities ensure appropriate cleaning and disinfection of environmental surfaces, medical devices and equipment?

- Facilities should continue to follow the infection control requirements related to cleaning and disinfection at 42 CFR §494.30, which include:
 - Ensuring items taken into the dialysis station either be disposed of;
 - Dedicated for use only on a single patient, or
 - Cleaned and disinfected per manufacturer’s directions for use before being taken to a common clean area or used on another patient.
- *HCP should follow the [Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019](#)*

(COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings. This includes recommendations on PPE. Routine cleaning and disinfection are appropriate for COVID-19 in dialysis settings. Any surface, supplies, or equipment (e.g., dialysis machine) located within 6 feet of symptomatic patients should be disinfected or discarded.

- *Products with EPA-approved emerging viral pathogens claims are recommended for use against COVID-19. Refer to List N on the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program from use against SARS-CoV-2.*
- *Products with EPA-approved emerging viral pathogens claims external icon are expected to be effective against COVID-19 based on data for harder to kill viruses. Follow the manufacturer's instructions for all cleaning and disinfection products (e.g., concentration, application method and contact time, etc.).*
- Facilities should provide additional work supplies to avoid sharing (e.g., pens, pads) and disinfect workplace areas (nurse's stations, phones, internal radios, etc.).

When should the dialysis facility consider transferring a *symptomatic and/or COVID-19 positive* patient to an alternative site for treatment?

- If the facility cannot fully implement the recommended precautions or if the patient's condition requires care that the dialysis facility is unable to provide, the patient should be transferred to another facility that is capable of implementation. Transport personnel and the receiving facility should be notified about the suspected diagnosis prior to transfer.
- While awaiting transfer, the patient should wear a surgical mask and be separated from other patients. If stable, the patient can be asked to wait in their vehicles or return home. If that is not possible, then they should be placed in a separate room with the door closed. Contact with patient should be minimized. Appropriate PPE should be used by healthcare personnel when coming within 6 feet of patients with known or suspected COVID-19.

Are there special considerations for Home Dialysis Patients?

Dialysis facilities should continue to follow the guidelines as required regarding monthly monitoring of home dialysis patients onsite at the facility. While limiting the exposure to the virus that causes COVID-19 is a goal for all dialysis patients, complications of COVID-19 are particularly severe in older persons and those with chronic conditions including ESRD. It is important that the home dialysis patients do not miss their onsite appointments, *when applicable*, to ensure that all dialysis procedures are followed to ensure a safe environment for the patient.

Recommendations for screening that apply to in-center patients and visitors, will also apply to any home dialysis patient that comes into the facility for care. Facilities should be vigilant in monitoring any changes in guidelines as new information is available.

Will dialysis facilities be cited for not having the appropriate supplies?

CMS is aware of that there is a scarcity of some supplies in certain areas of the country. State and Federal surveyors should not cite facilities for not having certain supplies (e.g., PPE such as gowns, N95 respirators, surgical masks and *Alcohol-Based Hand Rub* (ABHR) if they are having difficulty obtaining these supplies for reasons outside of their control. However, CMS does expect facilities to take actions to mitigate any resource shortages and show they are taking all appropriate steps to obtain the necessary supplies as soon as possible. For example, if there is a shortage of ABHR, we expect staff to practice effective hand washing with soap and water. Similarly, if there is a shortage of PPE (e.g., due to supplier(s) shortage which may be a regional or national issue), the facility should contact the local and state public health agency to notify them of the shortage, follow national guidelines for [optimizing their current supply](#), or identify the next best option to care for residents. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the state agency should contact their CMS Location.

Please see <https://www.cms.gov/files/document/qso-20-17-all.pdf> for additional guidance regarding use of industrial masks.

What flexibilities are within the ESRD program to address COVID-19 by isolating patients or developing alternate care models?

Current Medicare law and regulations establishes flexibility for ESRD facilities in best meeting the needs of their patients during this national emergency. There are various types of flexibility in care delivery models using current and new authorities available via the 1135 waiver requests.

- 1. Dialysis facilities already certified for Home Training and Support services may consider providing home dialysis services to residents of Long Term Care (LTC) facilities in agreement with the patient's nephrologist and patient or patient representative. Since facilities are already certified to provide home dialysis services, adding home dialysis in a LTC facility only requires notification to the designated State Agency via the CMS- Form 3427. No additional approval or survey is needed in this instance.*
- 2. Dialysis facilities may choose to add Home Dialysis Training and Support services to an existing Medicare certified facility.*

Facilities who choose to add Home Dialysis Training and Support services will need to complete the following actions:

- Complete the CMS Form 855A-Medicare Enrollment Application*
- Complete the CMS- Form 3427 End Stage Renal Disease (ESRD) Application and Survey and Certification Report and submit to the designated State Agency (SA).*

- *For approval of each home dialysis modality for which a dialysis facility is applying, there must be at least one patient on census who, and/or their caregiver, is in the process of being trained or has been trained by that facility.*
 - *Demonstrate compliance with the ESRD CFCs, validated by an on-site survey conducted by the designated SA or CMS-approved Accreditation Organization.*
3. *Establish a Special Purpose Renal Dialysis Facility – with CMS approval. This designation is permitted under current regulatory authority. Please see Frequently Asked Questions regarding that process below.*
 4. *Seek approval for program waivers through the 1135 waiver that accompanies the Presidential Declaration of Emergency for COVID-19. These requests should be made to the CMS Location Office. See below for additional information.*

Information regarding addition of services and other survey procedures may be found in the State Operations Manual, Chapter 2, section 2278.

Special Purpose Renal Dialysis Facility (SPRDF) FAOs

Question: What is a SPRDF?

Response: *The SPRDF certification is a special certification that dialysis facilities may obtain in certain circumstances. The designation of an SPRDF is divided into two categories. The first category is known as vacation camps, which are intended to serve dialysis patients while in a temporary vacation location or camp site. The second category pertains to facilities that are established to serve dialysis patients under emergency circumstances.*

Question: Does an SPRDF certification require an 1135 waiver?

Response: *No, SPRDF certification does not require an 1135 waiver. The special certification for SPRDF designation is addressed in the End Stage Renal Disease (ESRD) CFCs at 42 CFR 494.120.*

Question: Is there a service limitation related to the SPRDF certification?

Response: *Yes, per the Conditions for Coverage (CFC) at 42 CFR 494.120(b), a SPRDF certification is limited to areas in which there are limited dialysis resources or access-to-care problems due to (1) an emergency circumstance as a result of a natural or man-made disaster or (2) a need for a greater capacity to dialyze patients who may have been evacuated from another location.*

An SPRDF may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

Question: Can dialysis facilities apply for SPRDF certification to address the COVID-19 emergency?

***Response:** Yes, dialysis facilities may apply for SPRDF certification if COVID-19 is identified in the facility's geographic area and presents an access to care issue. SPRDFs may also be requested for situations where a dialysis facility encounters symptomatic patients and in order to limit and contain exposure, must cohort such symptomatic patients.*

An SPRDF certification would not be appropriate for facilities who have not encountered active COVID-19 cases in their immediate geographic service area.

CMS will review SPRDF certification requests and consider the impact of COVID-19 in the facility's geographic area before granting requests for this type of certification.

Question: Is there a time limitation or approval period for SPRDF certification?

***Response:** Yes, the SPRDF certification has a maximum period of certification of 8 months in any 12-month period. Facilities cannot maintain SPRDF certification past the required approval period per 42 CFR 494.120 (a). Once the SPRDF certification expires, facilities must have a plan for the safe and coordinated transfer of its patient(s) to a permanent outpatient dialysis setting.*

Question: What actions are required before a SPRDF can provide dialysis services to patients?

***Response:** In order for a special purpose facility to receive its Medicare-participation and allow for billing of services, the following process must occur:*

- *Facility must complete and submit a Medicare enrollment application (CMS-Form 855A);*
- *Facility must complete and submit an End-Stage Renal Disease certification application (CMS-Form 3427) to the respective CMS Location;*
- *Facility must obtain all State requirements, e.g., State license to operate, certificate of need (if applicable)*
- *Facility must undergo a Federal survey within the approved time period of special purpose designation, typically 8-months. A SPRDF set up for emergency circumstance will be issued a unique CMS Certification Number (CCN).*
 - *Note: Dialysis services may be provided prior to completion of onsite survey. Also, in order for the surveyor to assess a facility's compliance with patient management and coordination of care requirements, a dialysis facility must be providing care to a minimum of one patient for the survey to be conducted.*

Question: Does a SPRDF require a survey?

Response: Yes, a SPRDF will be surveyed within the approval time period to ensure they meet the specified requirements for SPRDF facilities found at 42 CFR 492.120 (c)(1) for vacation camp requirements and (c)(2) for emergency circumstance requirements. Dialysis facilities may provide services to its patients prior to a Federal survey.

Question: Where can a SPRDF be located?

Response: Medicare participating hospitals, long term care facilities and new dialysis facilities not yet certified may apply for SPRDF certification in emergency circumstances.

In the event a new dialysis facility which has not yet been certified is approved as an emergency SPRDF, that facility would need to undergo an initial survey for full certification within the 8 month SPRDF certification period in order to continue service and to expand its census beyond those patients who could not otherwise be served in the geographic locality.

Question: Where can I find the requirements for SPRDFs and the associated guidance?

Response: The requirements for SPRDFs and associated guidance may be found at 42 CFR 494.120. Please refer to the CMS website at:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpbgmguidance.pdf>

Also, additional information regarding SPRDFs may be located in the State Operations Manual, Chapter 2, section 2272 and may be accessed at:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf>

Email address for our Regional Office:

- RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.

CDC Resources:

- CDC Resources for Health Care Facilities:
<https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html>
- CDC Resources for Hemodialysis Facilities:
<https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/dialysis.html>

- CDC Updates: <https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html>
- CDC FAQ for COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/infection-prevention-control-faq.html>
- CDC guidance for Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>
- CDC guidance for dialysis safety including infection prevention tools: <https://www.cdc.gov/dialysis/index.html>
- *Strategies for Optimizing the Supply of N95 Respirators:* https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Frespirator-supply-strategies.html
- Weekly e-mails regarding COVID-19: https://tools.cdc.gov/campaignproxyservice/subscriptions.aspx?topic_id=USCDC_2067

FDA Resources:

- *Emergency Use Authorizations:* <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

CMS Resources:

- Appendix H of the State Operations Manual- Guidance to Surveyors: End-Stage Renal Disease Facilities at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_h_esrd.pdf
- Appendix Z of the State Operations Manual - Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf
- Dialysis resources on the CMS website including interpretative guidance at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis>

Please contact the Health Standards Section with any questions you may have regarding the regulatory responsibilities regarding these guidances. You may call the main desk at 225-342-0138 or email your questions to the applicable program manager for this provider type.

Also, please contact the Office of Public Health should you have any questions regarding the management of COVID-19. That number is 800-256-2748.