

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**SELECTED DIALYSIS COMPANIES  
IMPLEMENTED ADDITIONAL  
INFECTION CONTROL POLICIES AND  
PROCEDURES TO PROTECT  
BENEFICIARIES AND EMPLOYEES  
DURING THE COVID-19 PANDEMIC**

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May 2022  
A-05-20-00052

# ***Office of Inspector General***

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## Report in Brief

Date: May 2022

Report No. A-05-20-00052

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

End-stage renal disease (ESRD) is a medical condition in which a person's kidneys permanently cease functioning, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life. The Centers for Disease Control and Prevention (CDC) found that beneficiaries with serious underlying medical conditions, such as ESRD, are at a higher risk for severe illness from COVID-19. Health care personnel are also some of the most at-risk essential workers.

Our objective was to determine whether selected dialysis companies implemented additional infection control policies and procedures in accordance with Centers for Medicare & Medicaid Services (CMS) and certain CDC guidance to protect high-risk ESRD beneficiaries during the COVID-19 pandemic.

### How OIG Did This Audit

Our audit covered 9 dialysis companies that owned 6,451 facilities (83 percent) of the 7,813 ESRD facilities that had a Medicare or Medicaid certification at any point during 2020 in 50 States, the District of Columbia, Guam, and Puerto Rico. Our findings are based on responses to a questionnaire and followup interviews that we conducted with nine dialysis companies.

## Selected Dialysis Companies Implemented Additional Infection Control Policies and Procedures To Protect Beneficiaries and Employees During the COVID-19 Pandemic

### What OIG Found

The nine selected dialysis companies surveyed (representing 83 percent of the ESRD facilities that had a Medicare or Medicaid certification at any point during 2020) implemented additional infection control policies and procedures in accordance with CMS and CDC recommendations to protect high-risk ESRD beneficiaries and employees during the COVID-19 pandemic. We found all nine companies had infection control policies and procedures in place to protect beneficiaries and employees, and when recommended by CMS and CDC, the companies implemented additional policies and procedures. However, while two companies provided education about the importance of hand hygiene, they did not emphasize the importance of hand hygiene immediately before and after any contact with a facemask or cloth face covering, as recommended by CDC.

### What OIG Recommends

Because the nine selected companies implemented additional infection control policies and procedures as recommended by CMS and CDC, this report contains no recommendations.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

End-stage renal disease (ESRD) is a medical condition in which a person's kidneys permanently cease functioning, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life. Infection is a leading cause of hospitalizations and death for nephrology patients.<sup>1</sup> According to the Centers for Disease Control and Prevention's (CDC) website, dialysis patients are at a high risk of infection because of weakened immune systems, coexisting conditions such as diabetes, and treatments requiring frequent use of catheters or insertion of needles to access the bloodstream.<sup>2</sup> CDC also stated that prompt detection, triage, and isolation of potentially infectious patients are essential to prevent unnecessary exposure among patients, health care personnel, and visitors at dialysis facilities.<sup>3</sup> We conducted this audit because ESRD beneficiaries are more likely to have chronic comorbidities associated with COVID-19 complications and hospitalizations, and health care personnel are some of the most at-risk essential workers.

COVID-19 has created extraordinary challenges for the delivery of health care and human services to the American people. As the oversight agency for HHS, the Office of Inspector General (OIG) oversees HHS's COVID-19 response and recovery efforts. This audit is part of OIG's COVID-19 response strategic plan.<sup>4</sup>

### OBJECTIVE

Our objective was to determine whether selected dialysis companies implemented additional infection control policies and procedures in accordance with Centers for Medicare & Medicaid Services (CMS) and certain CDC guidance to protect high-risk ESRD beneficiaries during the COVID-19 pandemic.

### BACKGROUND

#### The End-Stage Renal Disease Program and Dialysis Facilities

The Medicare ESRD program is a national health insurance program for people with ESRD. Title XVIII of the Social Security Act established the Medicare program, which provides health

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<sup>1</sup> Nephrology is the branch of medicine that deals with the physiology and diseases of the kidneys.

<sup>2</sup> CDC found that beneficiaries with serious underlying medical conditions, such as ESRD, are at higher risk for severe illness from COVID-19.

<sup>3</sup> CMS Memorandum QSO-20-19-ESRD – REVISED, issued March 30, 2020.

<sup>4</sup> OIG's COVID-19 response strategic plan and oversight activities can be accessed at [HHS-OIG's Oversight of COVID-19 Response and Recovery | HHS-OIG](#).

insurance to people aged 65 or over, people with disabilities, and people with ESRD. People with ESRD are eligible for all covered services under the Medicare benefit, not only those related to kidney failure.

An ESRD facility is an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. In April 2008, CMS published its final rule entitled *Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities*.<sup>5</sup> The rule established the conditions dialysis facilities must meet to be certified under the Medicare program and updated CMS Conditions for Coverage for delivery of quality care to dialysis patients.<sup>6</sup> The Conditions for Coverage include, but are not limited to, implementing policies and procedures for infection control, patient isolation, cleaning and disinfection of contaminated surfaces, and emergency preparedness. CMS incorporated CDC's 2001 Morbidity and Mortality Weekly Report, volume 50, number RR05, entitled *Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients* (CDC 2001 Transmission Prevention Recommendations for Hemodialysis Patients) into the Conditions for Coverage. Thus, effective October 14, 2008, all ESRD facilities were expected to follow these CDC recommendations to be certified under the Medicare program.<sup>7</sup>

### **COVID-19 and End-Stage Renal Disease Patients**

COVID-19, caused by a highly contagious SARS-CoV-2 virus, produces symptoms that range from mild to very severe, with some demographic groups at heightened risk for more severe disease and death.<sup>8</sup> Common symptoms include fever, fatigue, dry cough, sore throat, and shortness of breath. The World Health Organization (WHO) issued a global health emergency alert on January 30, 2020,<sup>9</sup> and the Department of Health and Human Services (HHS) declared a

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<sup>5</sup> 73 Fed. Reg. 20370 (April 15, 2008)

<sup>6</sup> The Conditions of Coverage focus on the patient and the care provided and are the foundation for ensuring that quality care is provided, and the health and safety of Medicare beneficiaries is protected.

<sup>7</sup> The Survey and Certification Program certifies ESRD facilities for inclusion in the Medicare Program by validating that the care and services of each facility meet specified safety and quality standards. The Survey and Certification Program provides initial certification of each dialysis facility and ongoing monitoring to ensure that these facilities continue to meet these basic requirements.

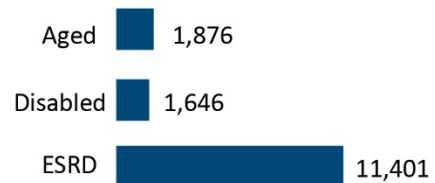
<sup>8</sup> Assessing Risk Factors for Severe COVID-19 Illness. Accessed at <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/assessing-risk-factors.html> on June 21, 2021.

<sup>9</sup> National Public Radio, WHO Declares Coronavirus Outbreak a Global Health Emergency. Accessed at <https://www.npr.org/sections/goatsandsoda/2020/01/30/798894428/who-declares-coronavirus-outbreak-a-global-health-emergency> on July 30, 2021.

public health emergency (PHE) for COVID-19 on January 31, 2020.<sup>10</sup> On March 11, 2020, WHO characterized COVID-19 as a pandemic. As of August 2, 2021, CDC had reported over 35.1 million confirmed cases in the United States and approximately 612,000 deaths.<sup>11</sup>

A CMS analysis of preliminary data on COVID-19 derived from Medicare claims identified ESRD beneficiaries as having the highest COVID-19 hospitalization rates compared with aged and disabled beneficiaries (see Figure).<sup>12</sup> The analysis also indicated that ESRD beneficiaries are more likely than other Medicare beneficiaries to have chronic comorbidities associated with COVID-19 complications and hospitalization.

**Figure: COVID-19 Hospitalizations per 100K by Beneficiary Characteristics**



### CMS and CDC Infection Control Guidance

Since the pandemic began, CMS and CDC have published numerous guidance documents emphasizing existing infection control procedures and recommending new procedures to protect all patients, health care personnel, and visitors in ESRD facilities and other health care facilities.

On March 30, 2020, CMS issued the QSO-20-19-ESRD-REVISED memorandum entitled *Guidance for Infection Prevention and Control of Coronavirus Disease 2019 (COVID-19) in Dialysis Facilities* (CMS Initial ESRD COVID-19 Memo). It provided guidance to dialysis facilities to help them focus their infection prevention and control practices to prevent the transmission of COVID-19. The memorandum referenced the Conditions for Coverage and associated guidance, including the CDC 2001 Transmission Prevention Recommendations for Hemodialysis Patients. The memorandum also asked dialysis facilities to monitor the CDC COVID-19 website, specifically the “Resources for Health Care Facilities” page,<sup>13</sup> for information and resources. It also referenced existing infection prevention and control guidance for dialysis safety, including infection prevention tools on the CDC’s dialysis-specific page,<sup>14</sup> which includes the 2007

<sup>10</sup> HHS, Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus. Accessed at <https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html> on June 30, 2020.

<sup>11</sup> As of February 28, 2022, CDC had reported over 78.7 million confirmed cases in the United States and approximately 944,500 deaths.

<sup>12</sup> Preliminary COVID-19 Data Snapshot, Medicare Claims and Encounter Data: January 1, 2020, to April 24, 2021. Accessed at <https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf> on July 22, 2021.

<sup>13</sup> <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html> accessed July 15, 2020. The page is now entitled “Information for Healthcare Professionals about Coronavirus.”

<sup>14</sup> <https://www.cdc.gov/dialysis/index.html> accessed July 6, 2020.

*Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (2007 Isolation Precautions).<sup>15</sup>

On August 17, 2020, CMS issued memorandum QSO-20-36-ESRD, entitled *Key Components for Continued COVID-19 Management for Dialysis Facilities* (CMS Continued ESRD Guidance Memo). This memorandum provided additional guidance for dialysis facilities to help prevent and minimize the risk of transmission among the dialysis population and reinforced previously released infection control guidance. It also instructed dialysis facilities to continue to monitor the CDC website for critical updates to CDC's infection control guidance for health care personnel during the COVID-19 public health emergency.<sup>16</sup>

We reviewed multiple guidance documents posted on CDC's website for our audit. The two documents most relevant to our audit objective were:

- *Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic* (CDC's COVID-19 Recommendations for Healthcare Personnel)<sup>17</sup> and
- *Interim Additional Guidance for Infection Prevention and Control Recommendations for Patients With Suspected or Confirmed COVID-19 in Outpatient Hemodialysis Facilities* (CDC's COVID-19 Recommendations for Dialysis Patients).<sup>18</sup>

CDC's *COVID-19 Recommendations for Healthcare Personnel* recommended: (1) routine infection prevention and control practices during the COVID-19 pandemic and (2) infection prevention and control practices when caring for a patient with suspected or confirmed COVID-19. CDC's *COVID-19 Recommendations for Dialysis Patients* includes recommendations on: (1) implementing universal mask control measures; (2) screening, triage, and management of individuals with suspected or confirmed COVID-19; (3) placement of patients with suspected or confirmed COVID-19; (4) PPE use when caring for a patient with suspected or confirmed COVID-19; (5) PPE use when caring for patients who are not suspected to have COVID-19; (6) cleaning and disinfection; (7) responding to patients or health care personnel with newly identified COVID-19; and (8) identifying outbreaks of COVID-19 within the dialysis facility.

Appendix B lists Federal regulations, CMS, and CDC guidance documents that were relevant to the objective of this audit.

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<sup>15</sup> <https://www.cdc.gov/dialysis/guidelines/index.html>, accessed February 16, 2021.

<sup>16</sup> <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>, accessed August 14, 2020.

<sup>17</sup> Initially issued July 15, 2020, updated during our fieldwork on December 14, 2020.

<sup>18</sup> Initially issued April 12, 2020, updated during our fieldwork on December 17, 2020.



## HOW WE CONDUCTED THIS AUDIT

For this audit we selected a nonstatistical sample of 9 dialysis companies representing 6,451 facilities (83 percent) of the 7,813 ESRD facilities that had a Medicare or Medicaid certification at any point during 2020.<sup>19</sup> We sought to ensure that our selection included wide coverage and a diverse set of ESRD facilities by selecting companies based on four criteria: (1) Medicare reimbursements in calendar year 2018, (2) business structure (e.g., non- or for-profit), (3) primary location of dialysis treatments (at home or in center), and (4) history of at least one infection-control-related deficiency at one of the company's facilities.

We sent a questionnaire to the nine selected dialysis companies, requested their written procedures, and reviewed their written responses and procedures. We conducted interviews with company officials between October 19 and December 3, 2020, to ask followup questions and request additional documentation (e.g., photos of signage, educational materials for patients and employees, completed infection control audits). We obtained and reviewed the following information:

- policies and procedures related to infection control that dialysis companies had in place before and implemented after the pandemic began;
- information related to infection control that the ESRD Network Organizations provided to the dialysis companies;<sup>20</sup>
- guidance issued by CMS and CDC after the pandemic began and the companies' actions taken because of the guidance; and
- information about dialysis companies' successes, lessons learned, and challenges during the pandemic.

After reviewing responses to the questionnaires, conducting interviews, and reviewing the CMS and CDC guidance documents, we focused on the following 10 infection control topics: universal masking, personal protective equipment (PPE), cleaning and disinfection, hand hygiene, screening, patient placement, cohorting, tracking, communication with nursing homes, and assessing employee competency.

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<sup>19</sup> These facilities had distinct National Provider Identification (NPI) numbers. An NPI number is a unique identification number adopted under the Health Insurance Portability and Accountability Act of 1996 that covered health care providers must use in administrative and financial transactions such as billing.

<sup>20</sup> ESRD Network Organizations act as the administrative governing body to the ESRD Networks and liaisons to the Federal Government. ESRD Networks are defined in 42 CFR § 405 subpart U as all Medicare-approved dialysis facilities in a designated geographic area specified by CMS.

We did not review the dialysis companies' overall internal control structures. Rather, we assessed whether the companies implemented control activities designed to prevent the spread of COVID-19 by obtaining and reviewing their policies and procedures and documentation such as patient and employee education, posters or signs hung in facilities, internal audits, and screenshots of internal websites or applications. This audit is not an assessment of CMS's or CDC's response to the COVID-19 pandemic.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Additional details on our audit scope and methodology appear in Appendix A.

## RESULTS OF AUDIT

We found that for each of the 10 infection control topics reviewed, all 9 companies had policies and procedures in place to protect high-risk ESRD beneficiaries and employees during the COVID-19 pandemic, and when recommended by CMS and CDC, the companies implemented additional policies and procedures. However, while two companies educated patients, employees, and visitors about the importance of hand hygiene, they did not emphasize the importance of hand hygiene immediately before and after any contact with a facemask or cloth face covering, as recommended by CDC.

Details about the 10 infection control topics we reviewed and how the companies addressed them follow.

### UNIVERSAL MASKING

The *CMS Continued ESRD Guidance Memo* states that masks are recommended for everyone (patients, employees, and visitors) in a health care facility (also known as universal source control), even if they do not have symptoms of COVID-19.<sup>21</sup> Specifically, the *CMS Continued ESRD Guidance Memo* states that all patients, regardless of symptoms, should put on a cloth face covering during their transport to and from the facility (if using medical, contracted, or public transportation) or at check-in (if not already wearing) and keep it on until they leave the facility. If a patient does not have a cloth face covering, the facility should offer a facemask or cloth face covering if supplies allow. Patient



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<sup>21</sup> Masks or medical facemasks are used to cover a person's mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing.

education on the importance of covering their mouth and nose with a facemask should be provided and reinforced prior to treatments. *CDC's COVID-19 Recommendations for Healthcare Personnel* states that employees should wear an N95 or equivalent or higher level respirator, instead of a facemask,<sup>22</sup> for certain procedures,<sup>23</sup> and, when not otherwise wearing a respirator, recommended universal use of a facemask. *CDC's COVID-19 Recommendations for Dialysis Patients* were more stringent, stating that health care personnel caring for patients with suspected or confirmed COVID-19 or who have reported close contact with someone with COVID-19 should wear an N95 or equivalent mask or higher level respirator (or medical facemask if a respirator is not available).

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*All nine companies implemented universal masking for patients, visitors, and employees when not otherwise using a respirator or N95 mask.*

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The companies educated patients on the importance of covering their mouth and nose with a facemask (including during transport to and from the facility) verbally or by providing handouts, videos, or online content prior to treatments and reinforced the message by posting signs at entrances and throughout the facilities. The companies provided masks to patients and required employees to wear an N95 mask or equivalent when caring for patients with suspected or confirmed COVID-19 or who had reported close contact with someone with COVID-19.

#### **PERSONAL PROTECTIVE EQUIPMENT**

The *CMS Initial ESRD COVID-19 Memo* states that when providing dialysis care, facilities should continue to follow the infection control requirements at 42 CFR § 494.30, which include CDC recommendations on PPE in *CDC 2001 Transmission Prevention Recommendations for Hemodialysis Patients*.



*CDC's COVID-19 Recommendations for Dialysis Patients* adds that health care personnel caring for patients with suspected or confirmed COVID-19 or who have reported close contact with someone with COVID-19 should use masks (as previously discussed) in addition to isolation gowns, eye protection that covers the front and sides of the face, and gloves. *CDC's COVID-19 Recommendations for Healthcare Personnel* also recommends health

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<sup>22</sup> Facemasks are primarily made to keep particles breathed out by the wearer from contaminating the work environment. Higher level respirators, such as an N95, protect the wearer against potentially hazardous particles present in the work environment.

<sup>23</sup> The procedures for which health care personnel should wear an N95 mask or equivalent or higher are aerosol-generating procedures and surgical procedures that might pose higher risk of transmission if the patient has COVID-19.

care personnel receive training on how to properly don, use, and doff PPE in a manner to prevent self-contamination.

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*All nine companies implemented COVID-19 PPE policies and procedures.*

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All nine companies had the required pre-pandemic PPE policies in place and implemented additional policies to ensure the recommended PPE is worn when caring for patients with suspected or confirmed COVID-19 or who have reported close contact with someone with COVID-19. In addition, all nine companies' health care personnel received training on appropriate PPE use, including donning and doffing PPE in a manner to prevent self-contamination.

### **CLEANING AND DISINFECTION**

The *CMS Continued ESRD Guidance Memo* and *CDC's COVID-19 Recommendations for Healthcare Personnel* states that existing procedures for routine cleaning and disinfection of dialysis stations are appropriate for patients with COVID-19; however, a few additional cleaning and disinfection procedures are necessary as a result of the pandemic. The *CMS Continued ESRD*



*Guidance Memo* states it is important to validate that the product used for surface disinfection is active against the SARS-CoV-2 virus and that any surface, supplies, or equipment (e.g., dialysis machine) located within 6 feet of symptomatic patients should be disinfected or discarded. The memo also states that dedicated medical supplies and equipment should be used when caring for patients with suspected or confirmed COVID-19 unless the item cannot be dedicated to a single patient, in which case it is permissible to clean and disinfect the item with an Environmental Protection Agency (EPA)-approved product per manufacturer's instructions before it is used on another patient. The memo reaffirms that facilities should continue to follow existing procedures in that all non-dedicated, non-disposable medical equipment used for patient care should be cleaned and disinfected according to manufacturers' instructions and facility policies.

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*All nine companies implemented additional cleaning and disinfection policies and procedures in response to the pandemic.*

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In addition to existing requirements for cleaning and disinfection procedures in dialysis facilities, all nine companies had policies in place to disinfect or discard any surface, supplies, or equipment within 6 feet of symptomatic patients, and validate that the product used for disinfection is active against the SARS-CoV-2 virus. The companies also had policies in place to dedicate medical supplies and equipment for use when caring for patients with suspected or confirmed COVID-19.

### **HAND HYGIENE**

The *CMS Continued ESRD Guidance Memo* does not provide new instructions on hand washing; rather, it reiterates infection control guidance based upon current CDC recommendations for dialysis facilities and referenced *CDC's COVID-19 Recommendations for Healthcare Personnel* as a key resource.<sup>24</sup> *CDC's COVID-19 Recommendations for Healthcare Personnel*



emphasizes that dialysis facilities should take steps to ensure that everyone adheres to hand hygiene practices while in the health care facility. *CDC's COVID-19 Recommendations for Healthcare Personnel* also suggests that health care providers take the following additional actions: (1) educate patients, visitors, and employees about the importance of routine hand hygiene, including immediately before and after any contact with their facemask or cloth mask; (2) post signage for patients about how and when to perform hand hygiene; and (3) ensure that hand hygiene supplies are readily available.

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*All nine companies implemented hand hygiene policies and procedures; however, two companies didn't emphasize hand hygiene before and after touching masks.*

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All nine companies took steps to ensure that everyone who entered the facility adhered to hand hygiene practices while in the health care facility, including conducting regular hand hygiene audits. The companies had the recommended hand hygiene policies in place and ensured hand hygiene supplies were readily available. All nine companies also educated patients and visitors about the importance of hand hygiene and posted signage; however, two

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<sup>24</sup> The *CMS Continued ESRD Guidance Memo* refers to hand hygiene, which is a way of cleaning one's hands that substantially reduces potential pathogens on the hands.

companies' policies didn't emphasize the importance of performing hand hygiene before and after touching masks as recommended by CDC.

### SCREENING

The *CMS Initial ESRD COVID-19 Memo* recommends that ESRD facilities screen patients, employees, and visitors for symptoms of COVID-19 or exposure to others with COVID-19; advise patients to call ahead if they have a fever or symptoms of a respiratory illness; provide patients and employees accessible information about hand hygiene, respiratory hygiene, and cough etiquette; and consider active temperature monitoring of patients, employees, and visitors.<sup>25</sup> The *CMS Continued ESRD Guidance Memo* reinforces these recommendations and also recommends that facilities limit and monitor points of entry to the facility and place an employee near all entrances if possible; restrict visitors from entering the facility if they are symptomatic; document the absence of symptoms consistent with COVID-19; and post signs at entrances with instructions for patients to alert staff if they have a fever or symptoms of respiratory infection.



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*All nine companies implemented policies and procedures for screening patients, staff, and visitors.*

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All nine companies implemented procedures for screening patients, employees, and visitors, including but not limited to educating patients to call ahead if symptomatic or exposed; educating patients about hand hygiene, respiratory hygiene, and cough etiquette; implementing active temperature monitoring; limiting and monitoring points of entry; restricting visitors from entering the facility; documenting the absence of symptoms; and posting signs at entrances stating that anyone entering the facility with a fever or symptoms of respiratory infection should alert staff.

### PATIENT PLACEMENT

The *CMS Continued ESRD Guidance Memo* builds upon initial patient placement procedures in *CDC's 2007 Isolation Precautions* to safeguard Medicare beneficiaries. CMS recommends in the *CMS Continued ESRD Guidance Memo* that dialysis facilities set up waiting rooms to allow patients to be at least 6 feet apart; require that patients with respiratory symptoms



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<sup>25</sup> Active temperature monitoring means taking a temperature in-person at the dialysis facility.



be escorted to a designated treatment area for evaluation as soon as possible to minimize their time in common waiting areas; maintain at least 6 feet of separation between patients with suspected or confirmed COVID-19 and other patients during dialysis treatment; dialyze patients with suspected or confirmed COVID-19 in a separate room; and if dialyzing in a separate room is not available, dialyze the patient with suspected or confirmed COVID-19 at a corner or end-of-row station, away from the main flow of traffic.

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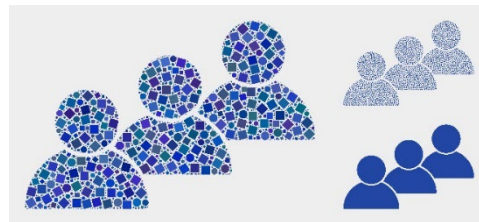
*All nine companies implemented patient placement policies.*

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The companies implemented policies that specified that: (1) waiting rooms, where applicable, should be configured to allow patients to be at least 6 feet apart, and symptomatic patients should be escorted to a designated treatment area for evaluation as soon as possible; (2) at least 6 feet of separation should be maintained between patients with suspected or confirmed COVID-19 and other patients during dialysis treatments; and (3) patients with suspected or confirmed COVID-19 be dialyzed in a separate room, shift, or at a corner or end-of-row station away from the main flow of traffic.

#### **COHORTING**

*CDC's 2007 Isolation Precautions* defines cohorting as the practice of grouping patients infected or colonized with the same infectious agent together to confine their care to one area and prevent contact with susceptible patients. Cohorting is not a new concept for infection control; however, after the pandemic



began, CMS and CDC recommended cohorting patients to help mitigate the risk of transmission of COVID-19 and still be able to provide dialysis treatments. The *CMS Initial ESRD COVID-19 Memo* states that consideration should be given to cohorting suspected or confirmed COVID-19 patients, and the *CMS Continued ESRD Guidance Memo* specifies that patients with different causes of infections should not be mixed (e.g., patients with confirmed influenza and patients with suspected or confirmed COVID-19 should not be placed together).

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*All nine companies had policies and procedures in place for cohorting patients.*

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All nine companies had policies in place for cohorting suspected or confirmed COVID-19 patients and preventing patients with different causes of respiratory symptoms from being cohorted with COVID-19 patients. One company relied on its pre-pandemic policies because

dialysis companies were not required to create new cohorting policies as a result of the pandemic. The other eight companies implemented COVID-specific cohorting policies.

### **TRACKING SUSPECTED OR CONFIRMED CASES**

Conditions for Coverage at 42 CFR § 494.30(c) require that dialysis facilities report incidences of communicable diseases as required by Federal, State, and local regulations.<sup>26</sup> The *CMS Continued ESRD Guidance Memo* states that State and or local public health departments or designees may contact dialysis facilities to obtain information to assist their efforts to perform necessary contact tracing to reduce the risk of community spread of COVID-19. CMS suggested that dialysis facilities implement a process for tracking suspected or confirmed cases to assist State and local public health departments in performing the necessary contact tracing. CMS also requested that the ESRD National Coordinating Center (NCC) coordinate with the Kidney Community Emergency Response (KCER) to produce a COVID-19 Dashboard.<sup>27</sup> To do so, KCER collected data related to suspected or confirmed COVID-19 cases from ESRD Network Organizations and dialysis companies, and the ESRD NCC compiled the data into a single national-level report that included national, State, and county-level aggregate data.



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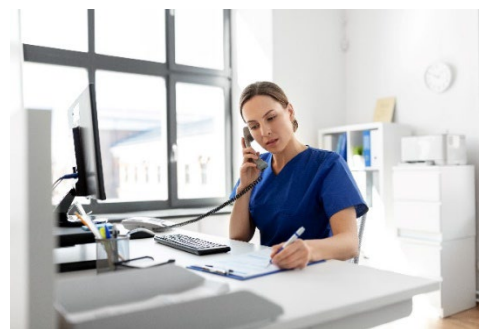
*All nine companies implemented a method for tracking suspected or confirmed COVID-19 cases.*

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All nine companies implemented a method for tracking suspected or confirmed patient and employee COVID-19 cases. All nine companies also reported data to KCER for inclusion in the COVID-19 Dashboard.

### **COMMUNICATION WITH NURSING HOMES**

The *CMS Continued ESRD Guidance Memo* states that to “maintain safe and effective care of dialysis patients, dialysis facilities and nursing homes alike should establish communication and reporting mechanisms which promote situational awareness between both health care facilities.” *CDC’s COVID-19 Recommendations for Healthcare Personnel* also



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<sup>26</sup> In late 2021, CMS issued 86 Fed. Reg. 61555, 61626 (Nov. 5, 2021), which moved this Condition for Coverage to 42 CFR § 494.30(d).

<sup>27</sup> The purpose of the COVID-19 dashboard was to aggregate and display critical COVID-19 related metrics, including COVID-19 positive patients and employees.



recommends facilities communicate information about patients with suspected or confirmed COVID-19 to appropriate personnel before transferring them to other health care facilities.<sup>28</sup>

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*All nine companies implemented a method for communicating with nursing homes regarding suspected or confirmed COVID-19 cases.*

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All nine companies established communication and reporting mechanisms so they can communicate information about nursing home residents with suspected or confirmed COVID-19 to the appropriate personnel before transfer.

### **ASSESSING EMPLOYEE COMPETENCY ON INFECTION CONTROL**

While there were not any new infection control employee competency assessment requirements in response to the pandemic, Conditions for Coverage at 42 CFR § 494.140(e)(3)(vi) state that dialysis technicians must complete a training program that includes infection control. The *CDC 2001 Transmission Prevention Recommendations for Hemodialysis Patients*, which is referenced in 42 CFR



§ 494.30(a)(1)(i), requires infection control training and education as a component of a comprehensive infection control program. Infection control audits performed at dialysis centers are an effective method of assessing employee competency in performing infection control procedures.

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*All nine companies had an infection control program in place that included training and education.*

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All nine companies had an infection control program in place that included training and education. Further, all nine companies performed regular infection control audits that included assessing employee competency on infection control.

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<sup>28</sup> Dialysis patients are occasionally transferred from a hospital or SNF to a dialysis facility for treatment and back again. To safeguard employees and other patients, the appropriate personnel at each facility should be informed if the patient has been exposed to the SARS-CoV-2 virus or is suspected to have or confirmed to have COVID-19.

## CONCLUSION

At the time of our interviews, the nine selected dialysis companies we reviewed had implemented additional infection control policies and procedures in accordance with CMS and CDC recommendations to protect high-risk ESRD beneficiaries and employees during the pandemic. Because the nine selected companies implemented additional infection control policies and procedures as recommended by CMS and CDC, this report contains no recommendations.

We also obtained the selected companies' statements on challenges, successes, and lessons learned during their initial response to the pandemic. Each of the nine companies reported a variety of successes and lessons learned, but most importantly, the companies were able to continue to provide life-saving dialysis treatments despite an unprecedented number and degree of challenges. The companies reported that high-risk Medicare beneficiaries continued to receive the important treatments they needed during the pandemic.

We provided CMS with a draft report for review. CMS elected not to provide formal comments; however, it provided technical comments, which we addressed as appropriate.

## OTHER MATTER

Regulations at 42 CFR § 494.62 require Emergency Preparedness Plans (EP Plans) “[b]e based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.”<sup>29</sup> In February 2019, CMS issued memorandum QSO19-06-ALL that added emerging infectious diseases (EID) to the definition of “all-hazards approach.”<sup>30</sup> CMS determined that it was critical for facilities to include planning for EIDs in their EP Plans and required all facilities to develop an all-hazards emergency preparedness program and plan. We found one dialysis company had not included EIDs within its dialysis facilities' EP Plans at the time of our interviews; however, the company reported successfully containing COVID-19 infections with the additional infection control policies and procedures it implemented.

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<sup>29</sup> An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address a wide spectrum of emergencies or disasters.

<sup>30</sup> CMS Memorandum QSO19-96-ALL, Emergency Preparedness Updates to Appendix Z of the State Operations Manual. Accessed at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-06-ALL.pdf> accessed on April 23, 2020.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered 9 dialysis companies that owned 6,451 facilities (83 percent) of the 7,813 ESRD facilities that had a Medicare or Medicaid certification at any point during 2020 in 50 States, the District of Columbia, Guam, and Puerto Rico. We sought to ensure that our selection included a diverse set of facilities by judgmentally selecting companies based on four criteria: (1) Medicare reimbursements in calendar year 2018, (2) business structure (e.g., non- or for-profit), (3) primary location of dialysis treatments (at home or in center), and (4) history of at least one infection-control-related deficiency at the company's facilities.

We sent a questionnaire to the nine selected dialysis companies and reviewed their written responses, including the policies and procedures requested. We conducted our interviews by telephone with three or more company officials (e.g., the Chief Operating Officer, Chief Compliance Officer, Chief Medical Officer, General Counsel) between October 19 and December 3, 2020.

During each interview, we asked followup questions and requested additional documentation (e.g., educational materials for patients and employees, completed infection control audits, and photos of signage). We obtained and reviewed the following information:

- policies and procedures related to infection control that dialysis companies had in place before and implemented after the pandemic began;
- information related to infection control received from the ESRD Network Organizations;
- guidance issued by CMS and CDC after the pandemic began and the company's actions taken as a result of the guidance; and
- dialysis companies' successes, lessons learned, and challenges as a result of the pandemic.

The information in this report was current when we conducted our interviews but may not reflect all of the specific policy changes that dialysis companies made in response to CMS and CDC guidance. This information may also not represent all the issues that dialysis companies have faced or the actions they have taken to address those issues. Since our interviews, dialysis companies may have implemented additional guidance and identified and addressed new issues. We did not independently verify the information that the companies provided to us beyond reviewing documentation provided.

We did not review the dialysis companies' overall internal control structures. Rather, we assessed whether the companies implemented control activities designed to prevent the

spread of COVID-19 by obtaining and reviewing their policies and procedures and examples of patient and employee education, posters or signs hung in facilities, internal audits, and screenshots of internal websites or applications.

## **METHODOLOGY**

To accomplish our objectives, we:

- reviewed Federal ESRD Conditions for Coverage at 42 CFR part 494 and Federal guidance describing infection control during the COVID-19 pandemic;
- selected a judgmental sample of 9 dialysis companies that managed 6,451 dialysis facilities across 50 States, the District of Columbia, Guam, and Puerto Rico;
- sent questionnaires to the nine selected dialysis companies and requested information and documentation pertaining to infection control and emergency preparedness;
- reviewed company responses, policies and procedures, and other documentation provided;
- interviewed officials at the nine selected dialysis companies; and
- provided a written summary of the selected companies' successes and lessons learned to and discussed the results of our audit with CMS officials.

We provided CMS with a draft report on April 8, 2022, for review. CMS elected not to provide formal comments; however, it provided technical comments, which we addressed as appropriate.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## APPENDIX B: FEDERAL REQUIREMENTS AND GUIDANCE

### FEDERAL REGULATIONS

To qualify for Medicare certification, dialysis facilities must meet the conditions for coverage described in 42 CFR part 494. The Conditions for Coverage include, but are not limited to, implementing policies and procedures for infection control, patient isolation, cleaning and disinfection of contaminated surfaces, and emergency preparedness.

Federal regulations (42 CFR 494.30) state that a dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. The facility must demonstrate that it follows standard infection control precautions, including but not limited to patient isolation procedures to minimize the spread of infectious agents and communicable diseases. Facilities must also maintain procedures in accordance with applicable State and local laws and accepted public health procedures for the handling, storage, and disposal of potentially infectious waste and for the cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

CMS incorporated two of CDC's Morbidity and Mortality Weekly Reports by reference into the Conditions for Coverage. They are volume 50, number RR05, entitled *Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients* and volume 51, number RR10, entitled *Guidelines for Prevention of Intravascular Catheter-Related Infections*. Therefore, all ESRD facilities are expected to follow these CDC recommendations to be certified under the Medicare program.

### CMS GUIDANCE

CMS Memorandum [QSO-20-19-ESRD Revised](#) (March 30, 2020), "Guidance for Infection Control and Prevention of COVID-19 in Dialysis Facilities," provided direction to dialysis facilities to help them focus their infection control and prevention practices to prevent the transmission of COVID-19. This guidance covered, among other things, screening, education, patient placement, personal protective equipment, isolation, cleaning and disinfection, cohorting, and Special Purpose Renal Dialysis Facilities.

CMS Memorandum [QSO-20-36-ESRD](#) (August 17, 2020), "Key Components for Continued COVID-19 Management for Dialysis Facilities," reinforced infection control guidance based upon CDC recommendations for dialysis facilities, which include screening for COVID-19, patient placement, personal protective equipment, isolation, cleaning, and disinfection.

## **CDC GUIDANCE**

CDC guidance is listed below in alphabetical order with the date the webpage or document was last updated during our fieldwork.

[Cleaning and Disinfection for Non-emergency Transport Vehicles](#) (April 14, 2020)

[Considerations for Providing Hemodialysis to Patients With Suspected or Confirmed COVID-19 in Acute Care Settings](#) (July 7, 2020)

[COVID-19 Outpatient Dialysis Facility Preparedness Assessment Tool](#) (April 19, 2020)

[Criteria for Return to Work for Healthcare Personnel With SARS-CoV-2 Infection \(Interim Guidance\)](#) (Aug. 10, 2020)

[Duration of Isolation and Precautions for Adults With COVID](#) (Oct. 19, 2020)

[How Our Facility is Keeping Patients Safe From COVID-19](#) (May 11, 2020)

[Interim Additional Guidance for Infection Prevention and Control Recommendations for Patients With Suspected or Confirmed COVID-19 in Outpatient Hemodialysis Facilities](#) (Dec. 17, 2020)

[Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2](#) (Feb. 16, 2021)

[Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the COVID-19 Pandemic](#) (Dec. 14, 2020)

[Interim SARS-CoV-2 Testing Guidelines for Patients in Outpatient Hemodialysis Facilities](#) (Dec. 21, 2020)

[Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel With Potential Exposure to COVID-19](#) (Dec. 14, 2020)

[Keeping Patients on Dialysis Safe](#) (Aug. 17, 2020)

[Optimizing Supply of PPE and Other Equipment During Shortages](#) (July 16, 2020)

[Preparing Outpatient Hemodialysis Facilities for COVID-19](#) (April 13, 2020)

[Preparing Your Dialysis Facility for COVID-19](#) (May 15, 2020)

[Special Considerations for Patients on Home Dialysis](#) (June 3, 2020)

[Strategies to Mitigate Healthcare Personnel Staffing Shortages](#) (July 17, 2020)

[Using Personal Protective Equipment \(PPE\)](#) (Aug. 19, 2020)