

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**END-STAGE RENAL DISEASE
NETWORK ORGANIZATIONS' REPORTED
ACTIONS TAKEN IN RESPONSE TO THE
COVID-19 PANDEMIC**

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Office of Inspector General

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Report in Brief

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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. The Centers for Disease Control and Prevention has reported that beneficiaries with serious underlying medical conditions, such as ESRD, are at a higher risk for severe illness from COVID-19.

Our objective was to identify what actions the ESRD Network Organizations (Network Organizations) took during the COVID-19 pandemic to: (1) aid dialysis clinics and patients and (2) keep the Centers for Medicare & Medicaid Services (CMS) informed about quality-of-care issues.

How OIG Did This Audit

Our findings are based on responses to a questionnaire and follow-up interviews with the 18 Network Organizations that represent geographic areas within the ESRD Network program. The questionnaire and interviews focused on Network Organization responsibilities during the COVID-19 pandemic (pandemic). We obtained evidence on Network Organization actions to provide aid and keep CMS informed during the pandemic. We also interviewed officials at CMS ESRD contractors and Federal agencies to gain an understanding of their roles and reviewed Network Organizations' reports submitted to CMS during the pandemic.

End-Stage Renal Disease Network Organizations' Reported Actions Taken in Response to the COVID-19 Pandemic

What OIG Found

The 18 ESRD Network Organizations that we surveyed provided information about the actions they took to aid dialysis clinics and patients and keep CMS informed about quality-of-care issues that arose during the COVID-19 pandemic. Network Organizations also reported to us challenges they encountered in taking those actions during the pandemic.

Despite the unprecedented challenges faced by the Network Organizations during the pandemic, they took actions to ensure continuity of services in a safe manner for high-risk ESRD beneficiaries. Network Organizations served a key role in addressing the additional demands on dialysis clinics during the pandemic through actions such as: (1) disseminating changing guidance, (2) aiding dialysis clinics to address the increased concerns and grievances related to the pandemic, and (3) promoting safe alternative treatment options. Network Organizations also kept CMS informed of quality-of-care issues by communicating through established communication processes and processes modified for better use during the pandemic.

What OIG Recommends

We are providing this information to help CMS identify Network Organizations' actions taken and challenges faced during the COVID-19 pandemic to assist in planning for future public health emergencies; therefore, this report does not contain any 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. Dialysis patients are at a high risk of infection because they have weakened immune systems, are likely to have coexisting conditions such as diabetes, and often need treatments that require the frequent use of catheters or insertion of needles to access the bloodstream. The Centers for Disease Control and Prevention (CDC) reported that beneficiaries with serious underlying medical conditions, such as ESRD, are at higher risk for severe illness from a SARS-CoV-2 infection (COVID-19).

ESRD Networks are groups of Medicare-approved dialysis clinics in geographic areas designated by the Centers for Medicare & Medicaid Services (CMS).¹ ESRD Networks promote systems of effective coordination for patient referral and access to resources. CMS contracts with entities to serve as ESRD Network Organizations (Network Organizations) to support patient care and to engage in quality improvement activities that could be important in protecting ESRD beneficiaries. CMS relies on Network Organizations to develop relationships within the ESRD community to create a collaborative environment that improves patient care. CMS modified its contracts with the Network Organizations at the beginning of the pandemic to focus Network Organization efforts on the response to COVID-19.

COVID-19 has created extraordinary challenges for the delivery of health care and human services to the American people. As the oversight agency for the Department of Health and Human Services (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.²

OBJECTIVE

Our objective was to identify what actions the Network Organizations took during the COVID-19 pandemic to: (1) aid dialysis clinics and patients and (2) keep CMS informed about quality-of-care issues.

¹ 42 CFR § 405.2102.

² 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](#), accessed on February 18, 2022.

BACKGROUND

The End-Stage Renal Disease Program

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

COVID-19 and End-Stage Renal Disease Patients

COVID-19 is caused by a highly contagious SARS-CoV-2 virus.³ Disease severity ranges from mild to very severe, with some demographic groups at heightened risk for more severe disease.⁴ The World Health Organization (WHO) issued a global health emergency alert, and HHS declared a public health emergency for COVID-19 at the end of January 2020.^{5,6} In March 2020, WHO characterized COVID-19 as a pandemic.

CMS confirmed ESRD patients' increased risk from COVID-19 in an analysis of preliminary COVID-19 data derived from Medicare claims, in which CMS identified beneficiaries with ESRD as having the highest COVID-19 hospitalization rates, as well as being more likely to have chronic comorbidities associated with COVID-19 complications and hospitalization.⁷

³ The SARS-CoV-2 virus is a member of a large family of viruses called coronaviruses that can infect people and many animals. The virus spreads when an infected person breathes out droplets, and very small particles contain the virus.

⁴ 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 October 13, 2021.

⁵ National Public Radio, WHO Declares Coronavirus Outbreak a Global Health Emergency on January 30, 2020. Accessed at <https://www.npr.org/sections/goatsandsoda/2020/01/30/798894428/who-declares-coronavirus-outbreak-a-global-health-emergency> on July 30, 2021.

⁶ HHS, Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus on January 31, 2020. 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.

⁷ CMS Article "Trump Administration Issues Call to Action Based on New Data Detailing COVID-19 Impacts on Medicare Beneficiaries," dated 6/22/20. Accessed at <https://www.cms.gov/newsroom/press-releases/trump-administration-issues-call-action-based-new-data-detailing-covid-19-impacts-medicare> on February 4, 2022.

End-Stage Renal Disease Network Organizations

The ESRD Network program was created by statute to ensure the right care for every person with ESRD.⁸ Overarching ESRD Network program goals include improving quality and safety of health care services provided in dialysis clinics and ensuring effective and efficient administration of benefits in accordance with Network Organization responsibilities and functions.

A Network Organization is an ESRD Network's administrative governing body, which performs functions to assist in the delivery of services provided to beneficiaries with ESRD and serves as a liaison to the Federal Government. The 18 ESRD Network regions are each served by their own Network Organization.⁹ Appendix B lists the 18 Network Organizations and the number of dialysis clinics each ESRD Network region covers.

CMS directs the Network Organizations by delineating tasks in the Statement of Work (SOW) that is part of the contracts between CMS and ESRD Network Organizations. These delineated tasks support achieving statutory requirements and CMS goals.¹⁰ CMS modified the SOW in March 2020 to focus efforts on responding to the pandemic (CMS Modified SOW).¹¹ This CMS Modified SOW relaxed certain requirements and added COVID-19-related requirements for Network Organizations, including devoting appropriate staff, resources, and time to provide technical assistance to dialysis clinics and patients in response to the pandemic. See Appendix C for the CMS Modified SOW tasks relevant to the objective of this audit.

HOW WE CONDUCTED THIS AUDIT

We interviewed the 18 Network Organizations that represented 7,625 dialysis clinics across the United States and its territories. Using a questionnaire and follow-up interviews, we obtained and reviewed information from Network Organizations about their actions taken during the pandemic to aid patients, support dialysis clinics in safely continuing services, and keep CMS informed as the COVID-19 pandemic evolved. Our questionnaire was based on Network Organization responsibilities identified in the Act and the CMS Modified SOW. See Appendix D for a list of questions we sent to the Network Organizations.

⁸ The Act §§ 1881(c)(1)(A)(i) and (c)(2).

⁹ For the 5-year period 2016-2020, CMS awarded contracts to 7 entities to serve as the 18 Network Organizations administering the ESRD Program in each of the 18 ESRD Network regions across the United States and its territories.

¹⁰ "CMS goals" refers to specific targets CMS has directed Network Organizations to accomplish as part of their SOW, such as increasing the percentage of telehealth capabilities in dialysis clinics that offer home dialysis and increasing home dialysis as a treatment option.

¹¹ The CMS contract, including the SOW, covering calendar year 2020, was dated December 1, 2019, and the CMS Modified SOW was dated March 25, 2020.

We interviewed officials from the Kidney Community Emergency Response (KCER),¹² the National Coordinating Center,¹³ the Administration for Strategic Preparedness and Response,¹⁴ CMS, and CDC to gain an understanding of their roles and the actions they took during the pandemic and their relationship with the Network Organizations. We also obtained and reviewed the reports the Network Organizations submitted to CMS to gain an understanding of information submitted to keep CMS informed during the pandemic. These reports included KCER's Emergency Situational Status Reporting (Emergency Status) reports, monthly status reports, grievance reports, technical assistance call reports, and KCER incident reports.¹⁵

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

Network Organizations communicated with and assisted the ESRD community during calendar year 2020 to aid dialysis clinics and patients and keep CMS informed about quality-of-care issues that arose during the pandemic by relaying relevant information. Network Organizations reported that in response to the COVID-19 pandemic they aided dialysis clinics, and patients by taking actions to: (1) maintain methods of communication, (2) distribute COVID-19 guidance on

¹² KCER is a CMS ESRD contractor that serves as the leading authority in emergency and disaster response for the ESRD community.

¹³ The National Coordinating Center (also referred to as the NCC) is a CMS ESRD contractor that analyzes and interprets data and functions as a knowledge repository of Network-generated information.

¹⁴ The Administration for Strategic Preparedness and Response (formerly the Office of the Assistant Secretary for Preparedness and Response also referred to as ASPR) serves as the principal advisor to the HHS Secretary on issues related to public health and medical emergency preparedness and response. ASPR has operational responsibilities for the advanced research, development, and stockpiling of medical countermeasures, as well as the coordination of the Federal public health and medical response to emergencies and disasters.

¹⁵ The Emergency Status reports consist of COVID-19 infection data. Monthly status reports include CMS Modified SOW reporting requirements such as CMS goals and emergency preparedness statuses. Grievance reports summarize the cumulative COVID-19-related grievances the Network Organizations report to CMS each week. (ESRD patients may file COVID-19 grievances, for example, if a dialysis clinic is not providing masks for patients.) Technical assistance call reports are summaries of the Network Organizations' technical assistance calls with dialysis clinics that have been targeted with an identified need, such as assistance with infection control to address high COVID-19 infection rates. KCER incident reports are summary reports from the ongoing KCER calls with CMS, Network Organizations, providers, and other Federal entities held to discuss COVID-19 response.

topics such as telehealth and infection control, (3) address dialysis clinic and patient COVID-19-related concerns and grievances, (4) identify and address disparities in patient care, and (5) achieve CMS goals related to home dialysis. Network Organizations reported that they took the following actions to keep CMS informed of quality-of-care issues during the pandemic: (1) conveyed relevant information about the ESRD health care system¹⁶ and how it was impacted by the pandemic, (2) communicated COVID-19 ESRD-related clinic and patient grievances, and (3) developed and implemented procedures for communicating COVID-19 infection data to CMS. Network Organizations also reported to us challenges they encountered in taking actions during the pandemic.

NETWORK ORGANIZATIONS REPORTED ACTIONS THEY TOOK TO AID DIALYSIS CLINICS AND PATIENTS IN RESPONSE TO THE PANDEMIC

Network Organizations reported that in response to the COVID-19 pandemic they aided dialysis clinics and patients by taking actions to: (1) maintain methods of communication, (2) distribute COVID-19 guidance on topics such as telehealth and infection control, (3) address dialysis clinic and patient COVID-19-related concerns and grievances, (4) identify and address disparities in patient care, and (5) achieve CMS goals related to home dialysis. Network Organizations took actions to aid dialysis clinics and patients to ensure continuity of services in a safe manner for high-risk ESRD beneficiaries. Network Organizations also served a key role in addressing additional demands on dialysis clinics during the pandemic.

Network Organizations' Methods of Communication

CMS directed Network Organizations to maintain methods of communication for relaying up-to-date guidance.^{17, 18} A Network Organization role is to provide informational materials, refer people to appropriate sources, and provide assistance to dialysis clinics.¹⁹ Network Organizations reported collaborating with ESRD community partners, using new and existing

¹⁶ The CMS SOW directs the Network Organizations to interpret and convey to CMS information relevant to the ESRD health care system to assist with monitoring and evaluation of policy and program impacts.

¹⁷ CMS Modified SOW, section C.3.13.A.

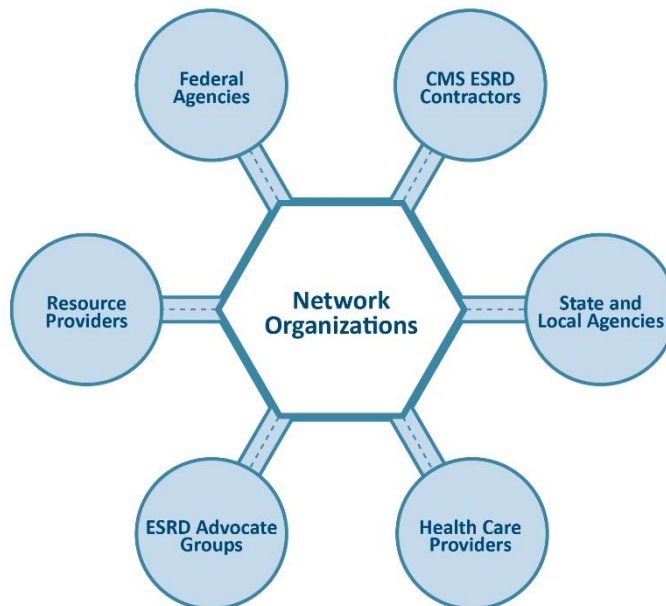
¹⁸ CMS Modified SOW, sections C.3.9.A, C.3.9.B, and C.3.13, specifically identify: (1) KCER for communication during emergencies and disasters, (2) the National Coordinating Center to create an information repository for Network data analysis and interpretation, (3) State Survey Agencies to share issues and findings related to quality and access to care, and (4) Emergency Response Commands for emergency response actions within the Network service area. Emergency Response Commands are entities within the Network service area that define goals and objectives for responding to an incident and processes to manage the emergency response for operations, logistics, planning, and administration.

¹⁹ ESRD Medicare Manual ch. 6, section 10.

methods to relay changing guidance to dialysis clinics and patients, and monitoring and evaluating the effectiveness of those methods.

Network Organizations' Collaboration With End-Stage Renal Disease Community Partners

Network Organizations reported to us that they worked with numerous ESRD Community Partners to leverage available resources and keep up to date on changing guidance. Network Organizations' ESRD community partners included Federal agencies, CMS ESRD contractors, State and local agencies, health care providers, ESRD advocate groups, and resource providers.²⁰ Network Organizations maintained communication with these partners through status meetings to discuss best practices; address challenges that arose; and share COVID-19 infection data and information.²¹ Network Organization reported actions taken in coordination with ESRD Community Partners to address challenges such as increased demands during a time of heightened infection control concerns and limited access to certain resources such as transportation and personal protective equipment (PPE).²²



Network Organizations' Methods for Communicating With Dialysis Clinics and Patients

Network Organizations indicated that they used new and existing methods to relay frequently changing quality-of-care guidance to dialysis clinics and patients. Network Organizations told

²⁰ Federal agencies include CMS, the Administration for Strategic Preparedness and Response, CDC, the Health Resources and Services Administration, and the Veterans Health Administration. CMS ESRD contractors include Network Organizations representing other regions, KCER, and the National Coordinating Center. State and local agencies include State Survey Agencies (which determine ESRD dialysis compliance), Emergency Response Commands (which define goals and objectives for incident and emergency response), and State and county health departments. Health care providers include hospitals, nursing homes, and other health care settings such as dialysis clinics. ESRD advocate groups include health care associations and coalitions advocating for the ESRD community. Resource providers include the entities or individuals that provide dialysis resources to dialysis clinics and patients, such as transportation service providers and PPE suppliers.

²¹ An example of the types of challenges addressed through correspondence with ESRD community partners included problems with accessing transportation to and from the dialysis clinics, which could lead to care access problems.

²² Transportation for dialysis services refers to any method of transportation that patients will use to travel to and from dialysis treatments when they do not have access to personally owned transportation.

us that they established groups composed of Network staff, providers, and patients who meet to discuss, review, and plan the distribution of COVID-19 information (e.g., guidance). Network Organizations also told us about using COVID-19 banners within online and written materials to help identify COVID-19 relevant guidance and information, as well as maintaining contact information and logs for COVID-19 correspondence.

Network Organizations reported to us that to ensure that current reliable COVID-19 information was shared with dialysis clinics and patients, they collaborated and shared information with the ESRD community partners described in the previous section. In addition, Network Organizations joined distribution lists and monitored emails, social media, and public websites of credible sources, such as CMS and CDC, for updated information.

Network Organizations indicated that they ensured broad dissemination of information to dialysis clinics and patients using various communication methods including email, website postings, newsletters, social media, webinars and other educational tools, faxes, mail, phone calls, and text messages. Network Organizations reported that they enlisted the help of dialysis clinics and patient councils in their efforts to reach patients.²³ Network Organizations also reported that they worked with each other, KCER, and the National Coordinating Center to reduce duplication of effort and ensure consistent messaging for dialysis clinics and patients across Networks.

Network Organization Monitoring and Evaluation of Effectiveness of Communication Systems

Network Organizations reported that they relied on their established communication processes to relay current guidance to dialysis clinics and patients, including information on safely continuing dialysis services during the pandemic. Network Organizations told us about actions they took to monitor and evaluate the effectiveness of their communication systems in ensuring that dialysis clinics and patients received the most current information.

Network Organizations reported having controls to monitor the distribution of information, including the review of analytics such as undeliverable email rates and open and click rates for emails, websites, and social media.²⁴ Network Organizations also told us that they tracked the receipt of information by dialysis clinics and ensured that enough copies were distributed to cover all intended recipients, including staff and patients.

Network Organizations indicated that they did not assess the effectiveness of their communications with dialysis clinics as often during the pandemic in an effort not to

²³ Patient councils refer to the Patient Advisory Councils and Patient Representative Groups within the Networks. The Patient Advisory Councils are groups that each Network Organization is required to establish, consisting of ESRD patients, caregivers, or family members who represent the ESRD patients within the Network.

²⁴ An open rate refers to the number of individuals that open an email or website. A click rate refers to actions taken within an email or website, such as clicking on a link or liking a post.

overburden dialysis clinics. However, the Network Organizations also reported to us that they evaluated the effectiveness of their communication systems. To do so, they requested dialysis clinics' and patients' feedback about the quality of communications during individual and group calls. The Network Organizations informed us that they incorporated education and assessment tools into their social media posts and webinars to evaluate dialysis clinic and patient understanding of key information.²⁵

Network Organizations' Distribution of COVID-19 Guidance

During the pandemic, CMS directed Network Organizations to:

- disseminate up-to-date guidance about telehealth and telemedicine (telehealth)²⁶ efforts to dialysis clinics and patients;
- educate dialysis clinics on infection control;²⁷
- identify or develop, in conjunction with other Network Organizations, hand sanitizer and physical environment audit tools²⁸ based on CDC recommendations; and
- educate dialysis clinics and patients on where they can locate credible information (e.g., Network Organizations identified CDC as a credible source of infection control guidance).²⁹

Federal law and regulations mandate that Network Organizations encourage sound medical practice and develop criteria and standards relating to the quality and appropriateness of patient care.³⁰ Network Organizations reported to us that, to meet these requirements, they provided dialysis clinics and patients new guidance on telehealth and infection control, new

²⁵ Education and assessment tools consisted of learning units on social media for patients and webinar assessments. The intention of these tools was to evaluate understanding and reaffirm key points in the information distributed.

²⁶ Telehealth, sometimes called telemedicine, is the use of electronic information and telecommunication technologies to provide care when the patient and the doctor are not in the same location.

²⁷ CMS directed Network Organizations to provide education on infection control topics, including COVID-19 screening and management, and to provide patients and clinic staff with information on preventing transmission of COVID-19 during travel to dialysis and while at home.

²⁸ Physical environment audit tools are tools for observing and analyzing steps for disinfecting surfaces and dialysis stations within dialysis clinics.

²⁹ CMS Modified SOW, section C.3.13.A.

³⁰ The Act § 1881(c)(2)(A) and (B) and 42 CFR §§ 405.2112(b) and (c).

infection control audit tools for hand sanitizer and physical environments in dialysis clinics, and education on sources of credible information.

Network Organizations Distributed a Significant Amount of COVID-19-Related Guidance

Network Organizations reported to us that they disseminated a significant amount of printable guidance and provided numerous educational opportunities through calls, videos, and webinars. All Network Organizations indicated that they disseminated COVID-19 telehealth and infection control guidance to dialysis clinics and patients within the Networks as required by the CMS Modified SOW, and many of the Network Organizations reported disseminating guidance on other pandemic-related topics to dialysis clinics and patients, such as mental health guidance and resources for transplant candidates encountering challenges because of the pandemic.³¹

Network Organizations Distributed Infection Control Audit Tools to Dialysis Clinics

All Network Organizations reported to us that they distributed uniform audit tools for applying hand sanitizer and disinfecting physical environments as required by the CMS Modified SOW using communication methods established with clinics. These audit tools define the individual steps involved in applying hand sanitizer and disinfecting environmental surfaces (e.g., dialysis stations) within the dialysis clinic and assist in evaluating if the steps were performed appropriately. The Network Organizations told us hand sanitizer audit tools were developed in collaboration with the National Coordinating Center and were based on CDC recommendations, and physical environment audit tools were either developed directly by the CDC or were based on CDC recommendations.³²

Network Organizations Educated Dialysis Clinics and Patients on Sources of Credible Information

Network Organizations reported to us that they educated dialysis clinics and patients on sources of credible information during the pandemic. Network Organizations gave dialysis clinics and patients web links and other references to sources they considered credible, such as a link to CDC's website for infection control information. The National Coordinating Center identified tips for searching sites and compiled a reference for general updates from credible sources such as CDC, CMS, KCER, and the American Association of Kidney Patients for kidney disease-related updates.³³ The Network Organizations indicated that they broadly

³¹ The information Network Organizations reported to us varied in form from straightforward narratives to detailed lists of guidance documents with dates, sources, and descriptions.

³² Audit Tool: Hemodialysis station routine disinfection observations. Accessed at <https://www.cdc.gov/dialysis/PDFs/dialysis-Station-Disinfect-Tool-508.pdf> on December 22, 2020.

³³ Where to Find Credible Information About the Coronavirus 2019 (COVID-19). Accessed at <https://www.esrdncc.org/globalassets/covid-19/ncccredibleresources508.pdf> on March 17, 2021.

disseminated this information to dialysis clinics and patients using methods previously discussed.

Network Organizations' Actions To Address COVID-19 Concerns and Grievances

In response to COVID-19, CMS directed Network Organizations to devote appropriate resources to provide technical assistance to dialysis clinics.³⁴ CMS also directs, and Federal law and regulations require, Network Organizations to implement procedures for evaluating and resolving grievances.^{35, 36} Network Organizations have authority to act on all concerns and grievances regarding a clinic or made by a patient.³⁷ In addition, the Network Organizations assume a proactive role in preventing concerns and grievances and for providing dialysis clinical staff and patients with informational material, technical assistance, and referrals to resources to improve quality of care.^{38, 39} Network Organizations reported accomplishing these requirements by addressing COVID-19 concerns and grievances received. Network Organizations also reported using their technical assistance calls to proactively prevent COVID-19 concerns and grievances.

COVID-19-related concerns and grievances spiked at the start of the pandemic. As part of our questionnaire, we inquired about commonly reported concerns and grievances related to the following COVID-19 challenges: (1) limited access to transportation to and from dialysis clinics, (2) limited availability of PPE, (3) difficulties utilizing telehealth or home dialysis services, and (4) difficulties obtaining space for isolation and quarantine purposes. Network Organizations indicated that dialysis clinics reported the concerns and grievances shown in Table 1.

³⁴ CMS Modified SOW, section C.3.13.A.

³⁵ CMS Modified SOW, section C.3.22.A

³⁶ The Act § 1881(c)(2)(D); 42 CFR § 405.2112(g).

³⁷ ESRD Medicare Manual, ch. 7, section 130.3.

³⁸ ESRD Medicare Manual, ch. 6, section 10.

³⁹ A concern is defined as a matter of interest or importance to someone. A grievance is defined as a formal or informal written or verbal complaint that is made to any member of the dialysis or transplant center staff by a patient, or the patient's representative, regarding the patient's care or treatment.

Table 1: Network Organizations Reporting Concerns and Grievances for Commonly Cited COVID-19 Challenges

COVID-19 Challenge	Number of Network Organizations Reporting Concerns or Grievances
Obtaining transportation to and from dialysis clinics	18
Availability of PPE and supply chain challenges	16
Utilizing telehealth or home dialysis	12
Establishing space for isolation and quarantine purposes	11

Network Organizations reported to us many other concerns and grievances they received during the pandemic beyond those we specifically referenced in our questionnaire. Some of these related to mental health and stress due to low staffing levels, patient and dialysis clinic staff resistance to infection control procedures, and concern about the risk of community spread as public places started reopening and lifting restrictions. Network Organizations also informed us about logistical concerns such as planning for the distribution of future vaccines (e.g., advocating prioritization of ESRD population for vaccinations) and waves of infections, managing the supply chain for disinfectants and saline, and overcoming communication challenges such as obtaining COVID-19 statuses for patients coming from nursing homes. Finally, Network Organizations told us about some concerns related to procedural matters such as ensuring that dialysis clinics follow current guidance regarding masking and other infection control procedures, and clearly communicating to families, caregivers, and other health care personnel regarding patients who may be sick or have passed away.

Network Organizations indicated that they helped dialysis clinics and patients address these concerns and grievances by providing Federal- and State-issued guidance and points of contact for various supply, transportation, and quarantine resources. They also told us about working with ESRD community partners to manage resources, assist with infection control procedures during transport, and identify options for overcoming any barriers to accessing resources.

Further, they offered technical assistance calls to dialysis clinics when either they or the communities they were located in experienced increased numbers of COVID-19 cases. The purpose of these technical assistance calls was to mitigate the outbreak by identifying the root cause of the increased number of COVID-19 cases and providing individualized assistance. Network Organizations used data available in the COVID-19 Dashboard as well as other available data on infection rates to select dialysis clinics for technical assistance calls.⁴⁰ In 2020, Network Organizations provided technical assistance calls to 6,596 dialysis clinics.

⁴⁰ KCER and the National Coordinating Center developed the COVID-19 Dashboard to automate the reporting of ESRD infection data in total nationwide by Network Organizations and Large Dialysis Organizations. Data included in the COVID-19 Dashboard is only collected one time and is shared across the Networks.

Network Organizations' Actions To Identify and Address COVID-19-Related Disparities

CMS directs Network Organizations to focus on disparities in patient care (i.e., quality of health care) in conducting all activities.⁴¹ Additionally, Federal law and regulations require Network Organizations to use data to report outcomes and identify dialysis clinics and providers that do not provide appropriate medical care.⁴² Network Organizations reported that they took actions to identify and address disparities in access to testing and care for ESRD patients during the COVID-19 response and also identified disparities in infection rates within the ESRD population. While many Network Organizations told us that they did not have access to specific COVID-19 patient-level data, they took actions to identify disparities using information that was available to them. These actions included:

- reviewing available disparity data obtained from the National Coordinating Center, KCER, CDC, and the State;
- reviewing information from grievances and involuntary discharges from dialysis clinics;
- surveying and communicating with dialysis clinics and other ESRD community partners within the Network to obtain information on disparities;
- reviewing death notices; and
- reviewing publicly available information, such as the news media.

By reviewing available data for disparities in patient care, Network Organizations identified disparities within certain populations. They reported a lack of options in rural areas for ESRD-related health care services and transportation. They also identified challenges for individuals without privately owned transportation in using services such as drive-through testing sites. In addition, Network Organizations indicated that there were increased rates of COVID-19 infection in Hispanic, African American, and senior populations. Network Organizations also told us there were increased rates of COVID-19 for individuals living in multigenerational homes or who were classified as essential workers.

Network Organizations reported to us that they addressed the patient care disparities they identified by disseminating educational resources to patients on staying safe and healthy during the pandemic. Also, Network Organizations tailored guidance for specific populations most impacted by and having higher vulnerability to COVID-19 by adapting the language and format of guidance based on cultural considerations to enhance read rates and comprehension. Other

⁴¹ CMS Modified SOW, section C.2.1.A.

⁴² The Act §§ 1881(c)(2)(F) and (G) and 42 CFR §§ 405.2112 (f)(3) and (j).

actions included: (1) disseminating information about disparities in access to care and infection rates to leadership within the Network, including dialysis clinics and medical review boards; (2) reviewing existing processes to identify areas of improvement and reduce disparities; and (3) developing patient assistance tools and resources aimed at reducing disparities. Some Network Organizations told us that they collaborated with ESRD community partners to identify options for dialysis clinics and patients facing challenges accessing care and COVID-19 testing.

Network Organizations' Actions To Achieve CMS Goals for Home Dialysis

Before COVID-19, CMS directed Network Organizations to increase the number of patients receiving dialysis at home. As part of the pandemic response, CMS suspended that goal but directed Network Organizations to continue promotion efforts to meet the goal.⁴³ CMS also directed Network Organizations to ensure that 70 percent of dialysis clinics that offer home dialysis (called home dialysis clinics) provide their patients access to telehealth. The CMS Modified SOW required Network Organizations to ensure home dialysis clinics had the ability to perform monthly clinical visits in compliance with modified telehealth guidelines issued March 17, 2020.^{44, 45}

Network Organizations' Actions for Promoting Home Dialysis

Network Organizations reported that they promoted home dialysis treatments, as an alternative option to receiving treatment in a dialysis center, to patients during the pandemic by disseminating information about home dialysis, conducting education campaigns targeting dialysis clinics and patients, conducting social media campaigns, and encouraging discussions between patients and dialysis clinic staff by having staff wear stickers promoting home dialysis. Network Organizations also developed resources, such as educational materials, webinars, and mobile applications, to help dialysis clinics promote home dialysis.

Network Organizations told us that they researched other ways to expand the use of home dialysis by reviewing dialysis clinics' educational handouts and discussion of treatment settings to identify emerging practices. Network Organizations also told us about working with ESRD community partners to understand State regulations related to offering home dialysis in nursing homes and barriers that prevent it. Additionally, Network Organizations sought ways to increase the staff available for training home dialysis patients and to identify barriers to staff availability that require Network Organization intervention such as staff education. Despite these barriers and some patients' fear of transitioning their treatments to home dialysis during

⁴³ CMS Modified SOW, section C.4.3.B.

⁴⁴ CMS Modified SOW, section C.3.13.A.

⁴⁵ Expanded telehealth coverage was announced on March 17, 2020. CMS provided a Fact Sheet and Frequently Asked Questions on this announcement, both available at <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>.

the pandemic, all Network Organizations indicated that there were increases in patients dialyzing at home during the COVID-19 pandemic.

Network Organizations' Actions for Monitoring Telehealth Capabilities for Home Dialysis Monthly Clinical Visits

Network Organizations informed us that they monitored the progress of home dialysis clinics with capabilities to perform monthly clinical visits using telehealth, as an alternative option for patients to limit their travel into dialysis clinics and provided updates to CMS. All the Network Organizations indicated that at least 70 percent of home dialysis clinics had the required capability as directed by the CMS Modified SOW at the time of our fieldwork (reported estimates ranged from 74 percent to 100 percent of home dialysis clinics).

While most home dialysis clinics were able to implement the modified telehealth guidelines within a few months of issuance, Network Organizations indicated that home dialysis clinics encountered the following barriers to implementing telehealth: (1) initial setup requirements that came with a learning curve and required dialysis clinic staff and patients to switch the delivery method of health care, (2) the technology involved in using telehealth was not accessible to all patients and raised some privacy considerations, (3) some physicians and patients were not comfortable with telehealth or preferred in-person clinical visits, or (4) regulations in some States did not allow full implementation of the modified telehealth guidelines until necessary State waivers were in place. Network Organizations also reported to us that some smaller clinics with two or fewer patients did not implement telehealth due to size and low exposure risk. At the request of CMS, Network Organizations surveyed home dialysis clinics about the implementation of telehealth capabilities and told us that despite these barriers, home dialysis clinics implemented telehealth quickly.

NETWORK ORGANIZATIONS REPORTED ACTIONS THEY TOOK TO KEEP CMS INFORMED OF QUALITY-OF-CARE ISSUES

Network Organizations reported that they took the following actions to keep CMS informed of quality-of-care issues during the pandemic: (1) conveyed relevant information about the ESRD health care system and how it was impacted by the pandemic, (2) communicated COVID-19 ESRD-related grievances, and (3) communicated COVID-19 infection data. Network Organizations kept CMS informed about quality-of-care issues by communicating through established communication processes and processes modified for better use during the pandemic.

Network Organizations Conveyed Relevant Information About the End-Stage Renal Disease Health Care System to CMS

CMS directed Network Organizations to communicate with and provide reports to CMS in accordance with the CMS Modified SOW, including conveying relevant information to assist

CMS in monitoring and evaluating the policy and program impacts of the pandemic on the ESRD health care system.⁴⁶

In accordance with the CMS Modified SOW, Network Organizations corresponded with CMS during the pandemic about quality-of-care issues through group calls and monthly status reports. Network Organizations also told us that they had ad hoc communication with CMS early in the pandemic to troubleshoot issues that arose and to discuss best practices.

Network Organizations Communicated COVID-19-Related Grievances to CMS

CMS promotes consistency among Network Organizations by making them responsible for coordinating with each other by using standardized procedures for collecting grievances.⁴⁷ The Network Organization may receive grievance from patients, the clinic, or other interested individuals.⁴⁸ The Network is responsible for collecting and appropriately categorizing grievance data.⁴⁹ The ESRD grievance reporting system for formal grievances, known as the Patient Contact Utility (PCU), was modified to identify COVID-19-related grievances.⁵⁰ The Network Organizations use standardized categories for reporting grievances. These categories include Facility Concern, Access to Care, Immediate Advocacy, General Grievance, and Clinical Quality of Care. See Appendix E for definitions of these categories.

Sixteen of the eighteen Network Organizations told us that they had reported COVID-19-related grievances to CMS through the PCU. The remaining two Network Organizations did not report COVID-19-related grievances because they had not received any.

Network Organizations began classifying grievances as COVID-19-related within the PCU on March 21, 2020. From March 21, 2020, through January 1, 2021, Network Organizations reported a total of 1,014 COVID-19-related grievances. As shown in Figure 1, about 50 percent of these grievances were reported during the initial 10 weeks.

⁴⁶ CMS Modified SOW, section C.2.2.A, C.3.7, C.3.8 and CMS Schedule of Deliverables.

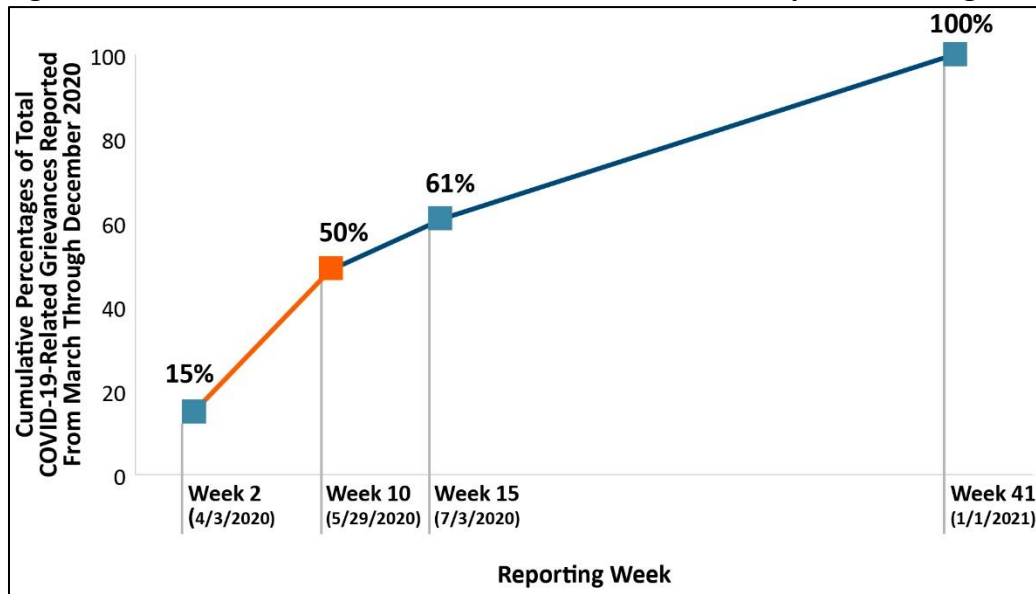
⁴⁷ CMS Modified SOW, section C.2.2.A.

⁴⁸ ESRD Medicare Manual, ch. 7, section 130.4.

⁴⁹ ESRD Medicare Manual, ch. 6, section 40.

⁵⁰ The National Coordinating Center, as part of its contract with CMS, modified the PCU to identify grievances related to COVID-19.

Figure 1: Distribution of COVID-19 Classified Grievances Reported During 2020



The majority of COVID-19-related grievances were categorized as facility concerns (e.g., patients not adhering to COVID-19 guidance).⁵¹ Overall, grievances were categorized as follows:

- facility concerns – 551,
- access to care – 187,
- immediate advocacy – 178,
- general grievance – 57, and
- clinical quality of care – 41.

Network Organizations Communicated COVID-19 Infection Data to CMS

CMS directs Network Organizations to use the Emergency Status report to provide KCER with complete information regarding dialysis clinic operational status, as part of their emergency and disaster responsibilities, as often as KCER or CMS request it, but not less than daily.⁵² Examples of emergencies and disasters for dialysis clinics include severe weather that could displace patients or emergency situations that affect the well-being of patients. In addition,

⁵¹ Examples of facility concerns reported by Network Organizations included concerns from dialysis clinics about general procedures for PPE, hand sanitizer, and patient isolation, and about patients not adhering to COVID-19 guidance.

⁵² CMS Modified SOW, section C.3.13.

one of the Network Organizations' strategic goals is improving the collection, reliability, timeliness, and use of data.⁵³

Network Organizations report COVID-19 infection data to CMS through an official reporting process that includes validating data prior to submission. Following are descriptions of the efforts Network Organizations relayed to us for reporting COVID-19 infection data and validating the data.

Network Organizations' Reporting of COVID-19 Infection Data

Traditionally, Emergency Status reports have been used to report dialysis clinics' operational statuses (i.e., impaired, closed, open) in emergency situations. The Network Organizations and KCER were able to modify the Emergency Status report to collect and report COVID-19 infection data for patients and staff. Network Organizations began reporting COVID-19 infection data to KCER on March 10, 2020. Network Organizations were responsible for collecting and completing Emergency Status reports for independent dialysis clinics (which represent between 8 percent and 51 percent of total dialysis clinics within each of the 18 Network regions).⁵⁴ Large Dialysis Organizations (LDO) reported their data directly to KCER.^{55, 56} Network Organizations informed us about problems with collection, validation, and use that limited Network Organizations' ability to appropriately respond to quality-of-care issues (discussed later in this report in Network Organizations' observations). Initially they reported this data daily in Emergency Status reports but, at CMS's direction, began reporting it weekly in June 2020. KCER consolidated and reported information from both Network Organizations and LDO clinics to CMS.

Data reported on the Emergency Status reports are cumulative. Emergency Status reports provided counts for the COVID-19 infection and treatment status of both patients and staff, including the number of people who tested positive or negative for COVID-19, numbers of patients in treatment settings (i.e., hospital, dialysis clinic, or at home), the number of individuals exposed or showing symptoms, the number of recoveries, and the number of COVID-19-related deaths.

⁵³ ESRD Medicare Manual, ch. 1, section 50.

⁵⁴ We identified independent clinics using CMS's Performance Score Summary Report for the 2021 payment year.

⁵⁰ LDO clinics refer to the largest dialysis providers. Independent clinics represent the smaller dialysis providers.

⁵⁶ Network Organizations and LDO clinics began reporting COVID-19 infection data through the National Healthcare Safety Network in Fall 2020. CMS informed Network Organizations that the reporting of COVID-19 infection data in CDC's National Healthcare Safety Network would be required for all dialysis clinics in early 2021.

Network Organizations' Data Validation

Network Organizations reported to us that they reviewed and validated COVID-19 infection data from independent clinics prior to submitting Emergency Status reports to KCER. Network Organizations indicated that to do so, they reviewed trends in patient counts and identified outliers, suspicious spikes, and duplications within the reported data. Network Organizations informed us that they also discussed clinic-submitted data during follow-up and technical assistance calls with dialysis clinics and compared Emergency Status report data with other available data such as death and recovery totals, State and national COVID-19 infection data for the entire population, and End Stage Renal Disease Quality Reporting System data.⁵⁷ Some Network Organizations indicated that they used an electronic survey form with built-in validation to help staff enter information correctly, which helped ensure the accuracy of data.

Observations About ESRD COVID-19 Infection Data and Reporting Process During the Pandemic

CMS directs Network Organizations, as part of their emergency and disaster responsibilities, to provide KCER with complete information regarding dialysis clinics' operational status.⁵⁸ Network Organizations are also responsible for collecting, validating, and using data in reporting.⁵⁹ COVID-19 brought unprecedented challenges, and to keep CMS informed of clinic operational statuses, Network Organizations reported information to CMS through a reporting tool that evolved during the pandemic to track COVID-19 infection data. In reviewing COVID-19 infection data that Network Organizations reported to CMS, we made observations, and, as part of our questionnaire, we requested Network Organizations' observations regarding the reporting process during the pandemic, which also included responses regarding COVID-19 infection data. We found that Emergency Status Reports contained incomplete and inaccurate information, and Network Organizations reported on aspects of reporting, validation, and use of COVID-19 infection data that worked well and others that could be improved.

Emergency Status Report Contained Incomplete and Inaccurate Information

In our review of the calendar year 2020 totals reported on the January 6, 2021, Emergency Status report, we determined that the report did not contain complete information about the numbers of COVID-19 positive patients within each of the treatment settings and the current

⁵⁷ End Stage Renal Disease Quality Reporting System (formerly known as CROWNWeb) is a software program designed and implemented by CMS to function as the National ESRD Registry, the centralized database that tracks all Medicare ESRD patients.

⁵⁸ CMS Modified SOW, section C.3.13.

⁵⁹ ESRD Medicare Manual, ch. 4, section 20.

statuses of patients and staff who had tested positive for COVID-19.⁶⁰ This Emergency Status report showed that in calendar year 2020, 74,683 ESRD patients and 7,849 staff tested positive for COVID-19. As shown in Table 2, of the 74,683 patients who tested positive for COVID-19, 16,231 were admitted to the hospital to receive treatment, 37,681 received treatment in outpatient dialysis clinics, and 4,746 self-monitored and continued therapies at home. The Emergency Status report did not include the treatment setting for 16,025 of the patients who had tested positive. Network Organizations and dialysis clinics did not report the statuses of these patients and may not be tracking that information. Reporting for the statuses of all of these patients would show whether all of the ESRD patients who tested positive for COVID-19 are receiving or had received treatments.

Table 2: Treatment Settings for Dialysis Patients Who Tested Positive for COVID-19 in 2020

COVID-19 Positive Emergency Status Report Category	Network Organization for Independent Clinics Reporting	Dialysis Clinics Direct Reporting ⁶¹	Total Emergency Status Reporting
Number of positive patients	11,932	62,751	74,683
Positive patients receiving treatment in hospitals	4,364	11,867	16,231
Positive patients receiving treatment in outpatient dialysis clinics	5,773	31,908	37,681
Positive home patients self-monitoring and continuing home therapy	790	3,956	4,746
Positive patients for whom treatment setting data was not provided			16,025

As shown in Table 3 below, of the 74,683 patients and 7,849 staff who tested positive for COVID-19, 52,912 patients and 6,621 staff recovered, while 8,883 patients and 37 staff died. The Emergency Status report did not provide information on the recovery status of 12,888 patients and 1,191 staff. Reporting for all patient and staff recovery statuses ensures everyone is getting the aid they need and assists Network Organizations with planning. One of the reasons the recovery statuses for these patients and staff were not identified may have been that there is no category for patients and staff who had tested positive and were receiving treatment as of the reporting date but who had not yet either recovered or died.

⁶⁰ The January 6, 2021, report was the first Emergency Status report in 2021, representing cumulative values from March 10, 2020, through January 6, 2021. For the purposes of our audit, we considered the January 6, 2021, Emergency Status report as representative of calendar year 2020 ESRD infection data.

⁶¹ LDO clinics report Emergency Status data directly to KCER.

Table 3: Statuses of Patient and Staff Who Tested Positive for COVID-19 in 2020

COVID-19 Positive Emergency Status Report Category	Network Organization for Independent Clinics Reporting	Dialysis Clinics Direct Reporting	Total Emergency Status Reporting
Number of positive patients	11,932	62,751	74,683
Positive patients who recovered	8,109	44,803	52,912
Positive patients who died	3,183	5,700	8,883
Positive patients with unknown recovery status			12,888
Number of positive staff	2,195	5,654	7,849
Positive staff who recovered	1,981	4,640	6,621
Positive staff who died	31	6	37
Positive staff with unknown recovery status			1,191

In response to questions about inaccuracies and incomplete information we found in the Emergency Status reports, CMS and KCER stated that they do not recommend using Emergency Status report data for drawing conclusions about ESRD COVID-19 infection data because of the variation in data reported among dialysis clinics. Despite steps KCER and Network Organizations took to validate data, data from the Emergency Status report may be inaccurate due to differences in how each dialysis clinic reported the requested information for their clinic. CMS further stated that dialysis clinics did not have the ability to track status such as hospitalizations or home monitoring, making those data points unreliable. Inaccuracies and incomplete COVID-19 infection data reported on the Emergency Status reports could limit decision makers’ ability to use the information. CMS stated that it primarily relied on Emergency Status report information to identify trends in COVID-19 cases and to target locations within ESRD Networks that needed additional assistance.

Network Organizations’ Observations About Reporting, Validation, and Use of COVID-19 Infection Data

We asked Network Organizations about their processes for reporting, validating, and using information during the pandemic. Some Network Organizations told us about aspects of the efforts that worked well and others that could be improved.

Network Organizations told us about the following efforts to collect, validate, and use COVID-19 infection data that worked well during the pandemic:

- Using electronic survey tools, dialysis clinic staff report requested information, which validates COVID-19 case numbers collected from independent clinics to ensure accurate and timely data.

- Using the National Coordinating Center compiled statistics on COVID-19 infection data was helpful to Network Organizations' ability to see local and national trends.
- The transition of the repository of COVID-19 data from KCER to the National Healthcare Safety Network allowed dialysis clinic personnel to enter COVID-19 data and other reportable infection control data into the same system.⁶²
- Requesting data from dialysis clinics ahead of the reporting deadline allowed time for data validation.
- Working with LDO clinics to address reporting issues and to identify high-infection areas and dialysis clinics that needed additional support.

Network Organizations also told us about problems with data collection, validation, and use that limited Network Organizations' ability to appropriately respond to quality-of-care issues:

- Changing instructions about what to report and the required use of a reporting tool that was difficult to use led to inaccurate reporting.
- Network Organizations did not have access to COVID-19 infection data that LDOs reported directly to KCER.
- Challenges in obtaining consistent data were due to: (1) differences in provider compliance with data reporting requirements, (2) potential inconsistencies in how COVID-19 deaths were reported, and (3) the accuracy of information reported for patients receiving services from a cohort clinic that is not their home clinic.⁶³

CONCLUSION

The COVID-19 pandemic created unprecedented challenges for the delivery of health care to the American people, particularly those with ESRD. According to CDC, beneficiaries with serious underlying medical conditions, such as ESRD, are at higher risk for severe illness from COVID-19. CMS relies on Network Organizations to develop relationships within the ESRD community to create a collaborative environment that improves care.

Network Organizations reported to us challenges they encountered in taking action during the pandemic, including: (1) a need to provide increased support for dialysis clinics and patients

⁶² The transition of reporting COVID-19 infection data to CDC's Network Healthcare Safety Network started in the fall of 2020, starting out as an option and becoming a requirement for all dialysis clinics starting in early 2021.

⁶³ Cohorting is the practice of grouping together patients who are infected with the same organism to confine their care to one area (e.g., a separate dialysis clinic) and prevent contact with other patients. Cohort clinics are created based on clinical diagnosis, microbiologic confirmation when available, epidemiology, and mode of transmission of the infectious agent.

trying to access essential resources that were limited because of the pandemic, and promoting alternative safe options for dialysis services; (2) not having full access to patient-level data to identify COVID-19-related disparities and COVID-19 infection data for informed decision making; and (3) inaccurate COVID-19 infection data gathered from the dialysis clinics that limited the usefulness of the data.

Despite the unprecedented challenges faced by the Network Organizations during the pandemic, they took actions to aid dialysis clinics and patients to ensure continuity of services in a safe manner for high-risk ESRD beneficiaries. Network Organizations served a key role in addressing the additional demands on dialysis clinics during the pandemic through actions such as: (1) maintaining methods of communication with ESRD Community Partners, dialysis clinics, and patients, (2) disseminating changing guidance, (3) aiding dialysis clinics to address the increased concerns and grievances related to the pandemic, (4) identifying and addressing COVID-19-related disparities in access to testing and care, and (5) promoting safe alternative treatment options through cohorting, telehealth, and home dialysis.

Network Organizations also kept CMS informed about quality-of-care issues by communicating: (1) relevant information about the ESRD Health Care System, (2) COVID-19-related grievances reported within the Network, and (3) COVID-19 infection data.

We are providing this information to help CMS identify Network Organizations' actions taken and challenges faced during the COVID-19 pandemic to assist in planning for future public health emergencies; therefore, this report does not contain any recommendations.

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.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

To conduct our fieldwork, we interviewed 18 Network Organizations that represented 7,625 dialysis clinics across the United States and its territories.⁶⁴ We sent a questionnaire to the 18 Network Organizations and received responses from all 18. We conducted interviews by telephone with two or more executives and administrative officials (e.g., the executive director, quality improvement coordinator, or patient services director) from each Network Organization between September 15 and October 15, 2020. We interviewed CMS ESRD contractors and relevant Federal agencies including CMS, CDC, and the Administration for Strategic Preparedness and Response. We also reviewed reports that Network Organizations submitted to CMS during the pandemic.

During each interview, we obtained information on actions the Network Organization took during the pandemic to aid patients, support dialysis clinics in safely continuing services, and keep CMS informed as the situation evolved. In addition, we obtained information about the roles of the CMS ESRD contractor and Federal agencies during the pandemic and their relationships with the Network Organizations.

The information in this report was current when we conducted our interviews but may not represent all the actions taken and challenges faced by Network Organizations in response to the pandemic. We did not independently verify the information that Network Organizations provided to us beyond reviewing documentation provided.

We did not review the Network Organizations' overall internal control structures. Rather, we assessed whether the Network Organizations took actions to aid dialysis clinics and patients and keep CMS informed about quality-of-care issues. We reviewed information provided in response to our questions and pandemic-related information reported to CMS regarding the ESRD health care system, grievances, and infection data. We conducted our audit from July 2020 through August 2022.

METHODOLOGY

To accomplish our objectives, we:

- reviewed Federal regulations and guidance to identify Network Organizations' responsibilities related to aiding dialysis clinics and patients and keeping CMS informed of quality-of-care issues;

⁶⁴ The dialysis clinic count is based on CMS's Performance Score Summary Report for the 2021 payment year. The Performance Score Summary Report is a yearly report CMS posts containing performance values of each dialysis clinic for a given payment year as part of Medicare requirements for CMS and dialysis clinics to inform beneficiaries about performance.

- interviewed the KCER, the National Coordinating Center, the Administration for Strategic Preparedness and Response, CMS, and CDC to gain an understanding of their roles during the pandemic and their relationships with the Network Organizations;
- obtained and reviewed the Network Organizations' reports submitted to CMS including KCER's Emergency Status reports, monthly status reports, tracking of reported grievances reports, technical assistance call reports, and KCER incident reports;
- developed a survey questionnaire and sent it to executive directors for each Network Organization;
- reviewed and compiled Network Organizations' responses and information obtained from interviews and our review of reports submitted to CMS; and
- discussed the results of our audit with CMS officials.

We provided CMS with a draft report on August 22, 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: NETWORK ORGANIZATION ENTITIES AND COVERAGE

Network	Entity	Geographic Area	Number of Dialysis Clinics
1	IPRO ⁶⁵	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	198
2	IPRO	New York	326
3	Quality Insights	New Jersey, Puerto Rico, and Virgin Islands	247
4	Quality Insights	Delaware and Pennsylvania	358
5	Quality Insights	Washington, D.C., Maryland, Virginia, and West Virginia	450
6	IPRO	Georgia, North Carolina, and South Carolina	774
7	HSAG ⁶⁶	Florida	498
8	Alliant Health	Alabama, Mississippi, Tennessee	480
9	IPRO	Indiana, Kentucky, and Ohio	649
10	Qsource	Illinois	343
11	Midwest Kidney Network	Michigan, Minnesota, North Dakota, South Dakota, and Wisconsin	509
12	Qsource	Iowa, Kansas, Missouri, and Nebraska	338
13	HSAG	Arkansas, Louisiana, and Oklahoma	349
14	Alliant Health	Texas	749
15	HSAG	Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming	376
16	Comagine Health	Alaska, Idaho, Montana, Oregon, and Washington	226
17	HSAG	American Samoa, Guam, Hawaii, Northern Mariana Islands, and Northern California	317
18	Comagine Health	Southern California	438
Total Dialysis Clinics			7,625

⁶⁵ The name of the entity is Island Peer Review Organization, with a doing-business-as certificate for IPRO.

⁶⁶ Health Services Advisory Group (HSAG).

APPENDIX C: FEDERAL REGULATIONS AND GUIDANCE

SOCIAL SECURITY ACT AND CODE OF FEDERAL REGULATIONS

The Act identifies responsibilities for ESRD Network Organizations (the Act § 1881(c)(2)), and the corresponding regulation is codified under 42 CFR § 405.2112. The Network Organizations' responsibilities include, but are not limited to:

- encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation;
- developing criteria and standards relating to the quality and appropriateness of patient care;
- implementing a procedure for evaluating and resolving patient grievances;
- collecting, validating, and analyzing such data as necessary to prepare required reports; and
- identifying dialysis clinics and providers that are not cooperating to meet Network goals and assisting such dialysis clinics and providers in developing appropriate plans for correction and reporting to the Secretary on dialysis clinics and providers that are not providing appropriate medical care.

CENTERS FOR MEDICARE & MEDICAID SERVICES GUIDANCE

Centers for Medicare & Medicaid Services Guidelines

At the time of our review, CMS provided guidelines for Network Organizations in the *Medicare ESRD Network Organizations Manual, Pub. No. 100-14* (ESRD Medicare Manual).⁶⁷ The chapters of the ESRD Medicare Manual relevant to this audit were: chapter 1, *Background and Responsibilities* (revised 12-14-07); chapter 4, *Information Management* (revised 5-17-19); and chapter 6, *Community Information and Resources* (revised 3-12-04).

Network responsibilities for roles include: (1) assuming a proactive role in the prevention, facilitation, and resolution of complaints and grievances, including implementing educational programs that will assist dialysis clinic staff in handling difficult situations; and (2) providing informational material, technical assistance and guidance, and referring appropriate resources to the dialysis clinics/providers and patients with ESRD to improve the quality of care and the quality of their lives (ESRD Medicare Manual, ch. 6, section 10).

⁶⁷ CMS updated the ESRD Medicare Manual through the scope of our audit but subsequently removed it from the CMS website. According to CMS, relevant information not found within Federal statutes was incorporated into the CMS contract with Network Organizations.

In terms of grievances, the Network is responsible for mitigating difficult patient and dialysis clinic situations and collecting and appropriately categorizing inquiries, complaints, and grievances (ESRD Medicare Manual, ch. 6, section 40). The Network has the authority under §1881(c)(2)(D) of the Act to act on all complaints/grievances regarding a Medicare certified facility or made by a Medicare beneficiary alleging a facility's failure to provide care and services to which beneficiaries are entitled (ESRD Medicare Manual, ch. 7, section 130.3). The Network may receive a written or verbal inquiry, complaint, or grievance from an ESRD patient, a personal representative, a family member, a friend, a facility employee, a physician, a Federal or State agency, a patient advocate, or a concerned individual. In addition, other sources, such as the media, may make the Network aware of quality of ESRD care issues that should prompt an investigation. The Network may be requested to investigate certain cases. The Network may also receive referrals of complaints affecting or made by ESRD patients from Quality Improvement Organizations, State Survey Agencies, other ESRD Networks, the Medicare 1-800 Hotline, Medicare fiscal intermediaries, and CMS Central Office (ESRD Medicare Manual, ch. 7, section 130.4).

In terms of data collection, Network Organizations' strategic goals include improving collection, reliability, timeliness, and use of data to measure processes of care and outcomes, to maintain a patient registry, and to support the goals of the ESRD Network Program (ESRD Medicare Manual, ch. 1, section 50). In addition, Network responsibilities for data processing, information management, and reporting include effectively managing the collection, validation, storage and use of data, including data provided by CMS, for review, profiling, pattern analysis, and sharing appropriate data (ESRD Medicare Manual, ch. 4, section 20).

CMS Contract With Network Organizations

CMS directs the Network Organizations by delineating tasks in the SOW that are part of the contracts between CMS and ESRD Network Organizations. The CMS SOW covering calendar year 2020 was dated December 1, 2019, with a modified version dated March 25, 2020 (CMS Modified SOW).

The CMS SOW requires Network Organizations to collaborate with various entities, specifically identifying collaboration with the National Coordinating Center (CMS Modified SOW, section C.3.9.A), State Survey Agency/Agencies (CMS Modified SOW, section C.3.9.B), CMS components (CMS Modified SOW, section C.3.9.C), and the KCER (CMS Modified SOW, section C.3.13). Additionally, CMS requires the Network Organizations to ensure awareness of and maintain communication with emergency response commands in their Network service areas and KCER as arranged by mutual agreement during the pandemic (CMS Modified SOW, section C.3.13.A).

CMS requires that Network Organizations work with patients and providers in their service area to improve the quality of care and quality of life of ESRD patients by providing informational material and technical assistance on ESRD-related issues (CMS Modified SOW, section C.3.4). They are also required to incorporate a focus on disparities in conducting all activities outlined

in the SOW (CMS Modified SOW, section C.2.1.A). As part of additional pandemic requirements in section C.3.13.A of the CMS Modified SOW, Network Organizations were directed to:

- devote appropriate staff, resources, and time to provide technical assistance to dialysis clinics and patients;
- identify and maintain methods of communication and fact finding to stay abreast of changing guidance as the situation unfolds and relay those changes to dialysis clinics;
- disseminate up-to-date guidelines on telehealth and telemedicine efforts for dialysis provider and patient use;
- provide education to all dialysis clinics in the Network service area on information for screening and management of COVID-19;
- using available CDC resources, provide patients and dialysis clinic staff with information on how to prevent transmission of COVID-19 during travel to dialysis and while at home;
- educate dialysis clinics and patients on sources and locations of credible information and education during the pandemic; and
- if not available from CDC, develop hand sanitizer audits and physical environment audits in conjunction with other Networks for consistent messaging using CDC recommendations for COVID-19 as available.

CMS supports the promotion of home dialysis as an option through goals for increasing rates of patients dialyzing at home. While CMS provided leniencies during the pandemic for home dialysis rates and reporting, Networks were still required to provide educational materials to the patients and dialysis clinic staff and maintain established communication relationships, as possible, to increase patients dialyzing at home (CMS Modified SOW, section C.4.3.B). The Network Organizations were also required during the pandemic to ensure that by June 30, 2020, 70 percent of home dialysis clinics have the capability to perform monthly clinical visits through the modified telemedicine guidelines issued March 17, 2020 (CMS Modified SOW, section C.3.13.A).

CMS requires Network Organizations to interpret and convey to CMS or its designee information relevant to the ESRD health care system to assist in the monitoring and evaluation of policy and program impacts (CMS Modified SOW, section C.2.2.A). Specific reporting requirements include meeting minutes for tasks identified in the SOW and schedule of deliverables upon request, monthly progress and status reports of the previous month's activities and data, and use of CMS-approved templates, if provided, for reporting deliverables outlined in the schedule of deliverables (CMS Modified SOW, section C.3.7).

CMS directs Network Organizations to coordinate and share information across 18 Networks using standardized procedures to collect data and address grievances to promote consistency (CMS Modified SOW, section C.2.2.A). The Network's case review responsibilities shall include taking all necessary steps to evaluate and resolve grievances filed by, or on behalf of, one or more ESRD patients. A grievance is defined as a formal or informal written or verbal complaint that is made to any member of the dialysis or transplant center staff by a patient, or the patient's representative, regarding the patient's care of treatment (CMS Modified SOW, section C.3.22.A).

CMS requires Network Organizations to report on emergency statuses to KCER, the national presence for ESRD-related emergency and disaster response, using the KCER Emergency Status report (CMS Modified SOW, section C.3.13).

APPENDIX D: FORMAL SURVEY QUESTIONNAIRE SENT TO NETWORK ORGANIZATIONS

Interview Question	Network Organization Reported Action Taken		
	Action Reported	No Action Reported	Action Reported Percentage
1. What communication has been maintained and what reports have been provided to the following entities as part of the Network’s COVID-19 emergency response?			
a. Administration for Strategic Preparedness and Response	18	0	100%
b. CMS	18	0	100%
c. Kidney Community Emergency Response (KCER)	18	0	100%
d. National Coordinating Center	18	0	100%
e. State Survey Agency/Agencies	18	0	100%
f. Emergency Response Commands in the Network, please identify	18	0	100%
g. Other Entities, please identify (Optional)	14	4	78%
2. What is the process you use to communicate information and/or guidance to facilities and patients?	18	0	100%
3. What controls are in place to ensure dialysis facilities and patients receive communicated information and/or guidance regarding COVID-19 in a timely manner?	18	0	100%
4. Does the Network Organization assess the effectiveness of this communication system(s)? If yes, please describe the Network Organization’s process of assessing the effectiveness of the communication system(s).	18	0	100%
5. What information and/or guidance did the Network Organization disseminate to its dialysis facilities in response to COVID-19 for items listed below? Please provide dissemination dates and a copy of all the information and/or guidance that the Network Organization disseminated.			
a. Telemedicine and telehealth	18	0	100%
b. Information for screening and management of COVID-19	18	0	100%
c. Other significant guidance for COVID-19 (Optional)	17	1	94%
6. What information and/or guidance has the Network Organization disseminated to its dialysis and transplant patients in response to COVID-19 for items listed below? Please provide dates and a copy of all the information and/or guidance that the Network Organization disseminated.			
a. Telemedicine and telehealth	18	0	100%
b. Prevention of COVID-19 during travel to dialysis and at home	18	0	100%
c. Other significant guidance for COVID-19 (Optional)	16	2	89%
7. What procedures have been followed within the Network for hand sanitizer and physical environment audits? How have guidelines for hand sanitizer and physician environment audits been developed? To what extent were CDC procedures available?	18	0	100%

Interview Question	Network Organization Reported Action Taken		
	Action Reported	No Action Reported	Action Reported Percentage
8. What information and/or guidance did the Network Organization disseminate to its dialysis facilities in response to COVID-19 for distribution of information on location of credible information on COVID-19?	18	0	100%
9. What information and/or guidance has the Network Organization disseminated to its dialysis and transplant patients in response to COVID-19 for distribution of information on location of credible information on COVID-19?	18	0	100%
10. Have dialysis facilities expressed concerns or grievances for the below item in response to COVID-19? How did the Network Organization address these concerns? *			
a. Obtaining personal protective equipment	16	2	89%
b. Space for isolation/quarantine purposes	11	7	61%
c. Transportation to and from dialysis facilities	18	0	100%
d. Utilizing telehealth, telemedicine or home dialysis	12	6	67%
e. Other matters of concern related to COVID-19	18	0	100%
11. What analysis of data has been done to identify disparities in patient care in response to COVID-19, such as access to care? What actions have been taken for any of these disparities identified?	18	0	100%
12. How many home dialysis clinics have the capability to perform monthly clinical visits through the modified telemedicine guidelines issued March 17, 2020? What percentage was this of total home dialysis clinics?	18	0	100%
13. How have you continued to promote patients dialyzing at home? Has there been an increase as a result of the response to COVID-19?	18	0	100%
14. How have concerns discussed above and in general been categorized for grievance reporting to CMS? **	16	2	89%
15. How is COVID-19 related data and information validated prior to use for items such as supporting the ESRD Dashboard and monthly progress and status reports?	18	0	100%
16. Have you identified any process or practices in reporting COVID-19 quality of care issues that are working well or could be improved? If yes, please explain. ***	N/A	N/A	N/A

* The number in the “no action reported” column for this question shows the number of Network Organizations that reported not receiving these types of concerns or grievances.

** The number in the “no action reported” column for this question reflects Network Organizations that did not report COVID-19.

*** This was an open-ended question that did not inquire about specific action from the Network Organizations.

APPENDIX E: PATIENT CONTACT UTILITY SYSTEM GRIEVANCE CATEGORIES AND EXAMPLES

Grievance Report Category	Description	Example
Facility Concern	Concerns related to the dialysis clinic	Dialysis clinic personnel stating they are concerned about general procedures for PPE, hand sanitizer, and patient isolation, and about patients not adhering to COVID-19 guidance.
Access to Care	Concerns that could include behaviors, medical needs, or dialysis clinic refusal	Patients stating that they are being denied placement due to their COVID-19 status or failure to comply with COVID-19 protocols and not being permitted back in dialysis clinics.
Immediate Advocacy	Anonymous or confidential concerns that are less complex	Patient reporting something that can be resolved quickly, such as stating dialysis clinic is not enforcing COVID-19 policies and procedures among clinic personnel and patients equally, or not enough supplies such as masks or hand sanitizer.
General Grievance	Services that did not meet expectation with respect to safety, civility, patient rights, or clinical standards of care	Patient stating dialysis clinic is not providing masks for the patients upon arrival, temperatures are not being taken, or a home dialysis patient is not being offered telehealth as an option for monthly meetings.
Clinical Quality of Care	The rights of two or more ESRD patients have been violated or that services provided to beneficiaries with ESRD from a Medicare-certified dialysis clinic provided did not meet professionally recognized standards of clinical care or professional conduct and that the failure to meet recognized standards potentially resulted in an adverse clinical outcome for more than one patient.	Patient stating a staff member was not wearing a mask and coughed, staff and patients only permitted one surgical mask per week, or COVID-19 positive patient receiving services in the same space as non-positive patients.